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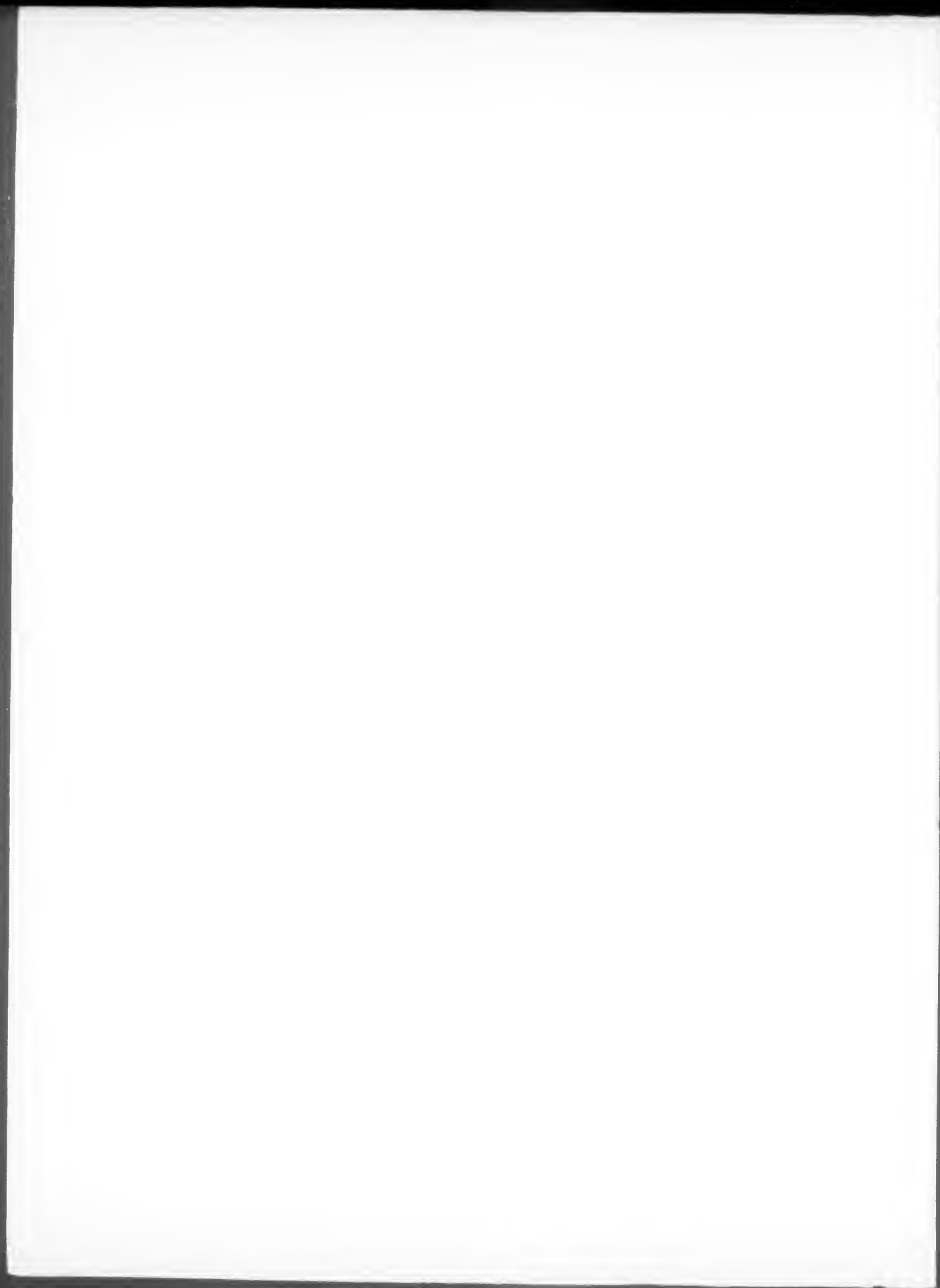
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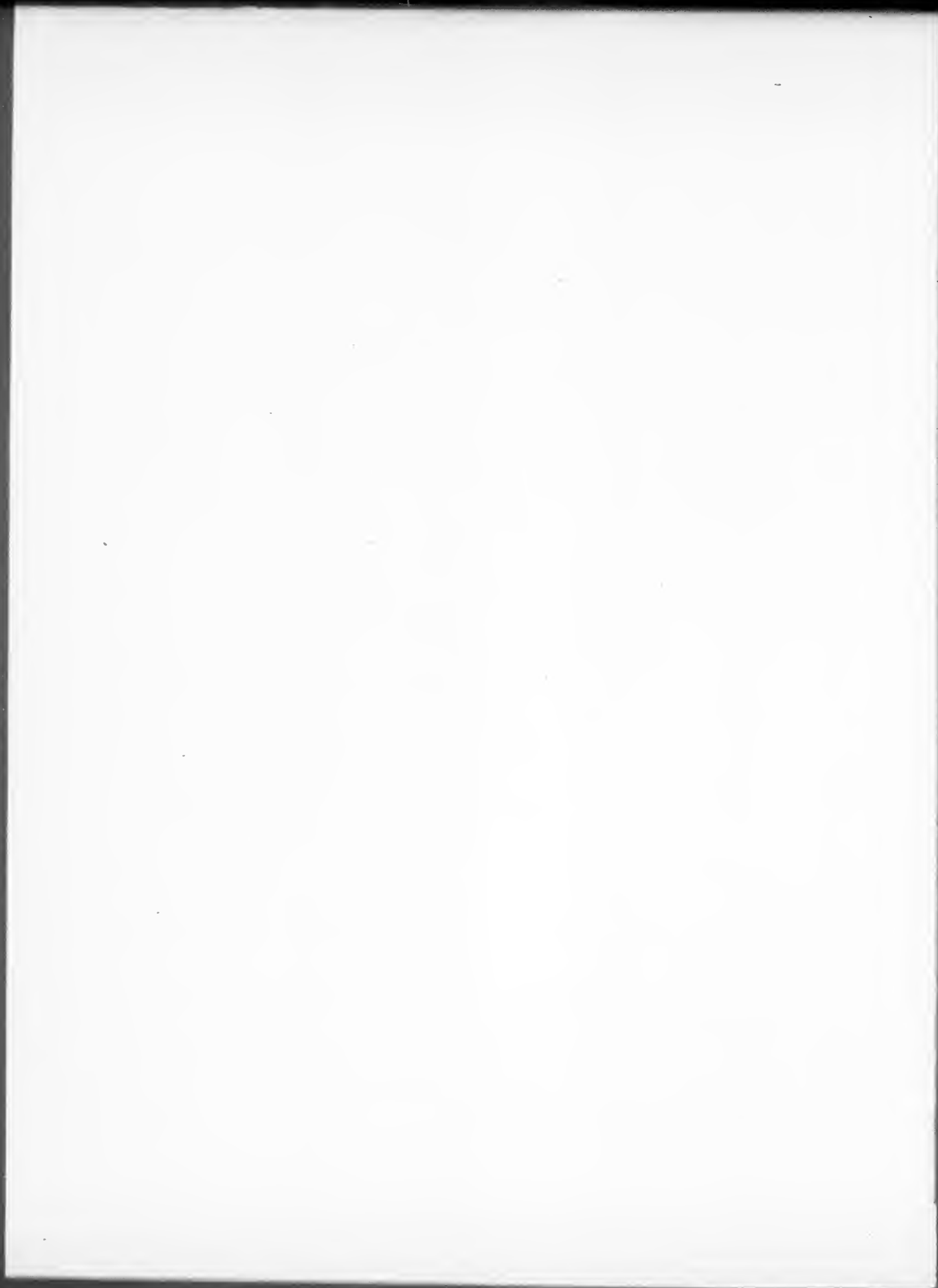
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The President

Delegation of Certain Congressional Reporting Functions

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. The functions of the President of submitting certain recurring reports to the Congress are assigned as follows:

(a) The Secretary of State shall submit the following reports:

1. Report on Kosovo Peacekeeping, consistent with section 1213 of Public Law 106-398;
2. Report on Bosnia and U.S. Forces in NATO-Led Stabilization Force (SFOR), consistent with section 7(b) of Public Law 105-174 and section 1203(a) of Public Law 105-261;
3. Report on Partnership for Peace Developments, consistent with section 514 of Public Law 103-236 (22 U.S.C. 1928 note);
4. Report on U.S. Military Personnel and U.S. Civilian Contractors in Colombia, consistent with section 3204(f) of Public Law 106-246;
5. Report on Nuclear Nonproliferation, consistent with section 601(a) of Public Law 95-242, as amended by Public Law 103-236 (22 U.S.C. 3281(a));
6. Report on Resolution of the Cyprus Dispute, consistent with section 620C(c) of Public Law 87-195, as amended by Public Law 95-384 (22 U.S.C. 2373(c));
7. Report on Peacekeeping, consistent with section 4 of Public Law 79-264, as amended (22 U.S.C. 287b);
8. Report on Proposed Refugee Admissions, consistent with section 207(d)(1) of Public Law 96-212 (8 U.S.C. 1157(d)(1));
9. Report on Continued Compliance With the Provisions of the Jackson-Vanik Amendment, consistent with sections 402(b) and 409(b) of Public Law 93-618, as amended (19 U.S.C. 2432(b), 2439(b));
10. Report Regarding Conditions in Burma and U.S. Policy Toward Burma, consistent with section 570(d) of Public Law 104-208;
11. Report on Tibet Negotiations, consistent with section 613(b) of Public Law 107-228 (22 U.S.C. 6901 note);
12. Report on Strategy for Meeting Security Needs of Afghanistan, consistent with section 206(c)(2) of Public Law 107-327 (22 U.S.C. 7536(c)(2));
13. Report on Proliferation of Missiles and Essential Components of Nuclear, Biological, Chemical, and Radiological Weapons, consistent with section 1308(a) of Public Law 107-228 (50 U.S.C. 2368(a));
14. Report on the National Emergency With Respect to Proliferation of Weapons of Mass Destruction, Executive Order 12938, consistent with section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c), and section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c);
15. Report on Adherence to and Compliance With Arms Control Agreements and Nonproliferation Agreements and Commitments, consistent with section 403 of Public Law 87-297, as amended (22 U.S.C. 2593a);

16. Report on Chemical Weapons Convention Inspections, consistent with section 309 of the Chemical Weapons Convention Implementation Act of 1998 (22 U.S.C. 6728);

17. Report on U.S. Participation in the United Nations, consistent with section 4 of Public Law 79-264, as amended (22 U.S.C. 287b); and

18. Report on Russian Proliferation to Iran and Other Countries of Proliferation Concern, consistent with section 1206 of Public Law 107-314 (22 U.S.C. 5952 note).

(b) The Secretary of the Treasury shall submit the following reports:

1. Report on the National Emergency With Respect to Libya, Executive Order 12543, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

2. Report on the National Emergency With Respect to the Western Balkans, Executive Order 13219, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

3. Report on the National Emergency With Respect to the Risk of Nuclear Proliferation Relating to the Disposition of Highly Enriched Uranium Extracted from Nuclear Weapons of the Government of the Russian Federation, Executive Order 13159, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

4. Report on the National Emergency With Respect to Burma, Executive Order 13047, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

5. Report on the National Emergency With Respect to Middle East Terrorism, Executive Order 12947, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

6. Report on the National Emergency With Respect to the 1979 Iranian Emergency and Assets Blocking, Executive Order 12170, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

7. Report on the National Emergency With Respect to Iranian Petroleum Resources, Executive Order 12957, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

8. Report on the National Emergency With Respect to Significant Narcotics Traffickers Centered in Colombia, Executive Order 12978, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

9. Report on the National Emergency With Respect to Persons Who Commit, Threaten to Commit, or Support Terrorism, Executive Order 13224, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

10. Report on the National Emergency With Respect to Sierra Leone and Liberia, Executive Order 13194, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

11. Report on the National Emergency With Respect to Sudan, Executive Order 13067, consistent with section 401(c) of the National Emergencies

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12. Report on the National Emergency With Respect to Iraq, Executive Order 12722, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

13. Report on the National Emergency With Respect to the Development Fund for Iraq, Executive Order 13303, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c);

14. Classified Report on the Status of Sanctions Imposed on Significant Foreign Narcotics Traffickers, consistent with section 804(d) of Public Law 106-120 (21 U.S.C. 1903(d));

15. Report on Telecommunications Payments Made to Cuba Pursuant to Department of the Treasury Specific Licenses, consistent with section 1705(e)(6) of Public Law 102-484, as amended by Public Law 104-114 (22 U.S.C. 6004(e)(6));

16. Report on the National Emergency With Respect to Persons Undermining Democratic Processes or Institutions in Zimbabwe, Executive Order 13288, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c); and

17. Report on International Debt Relief, consistent with section 1000(a)(5) of Public Law 106-113.

(c) The Secretary of Defense shall submit the following reports:

1. Report on Kosovo Benchmarks, consistent with section 1212(c) of Public Law 106-398; and

2. Report on the National Emergency With Respect to Terrorist Attacks on the United States, Proclamation 7463 of September 14, 2001, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c).

(d) The Secretary of Commerce shall submit the Report on the National Emergency Caused by the Lapse of the Export Administration Act of 1979, Executive Order 13222, consistent with section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c).

(e) The Director of Central Intelligence shall submit the following reports:

1. Report on Foreign Economic Collection and Industrial Espionage, consistent with section 809(b) of Public Law 103-359 (50 U.S.C. App. 2170(b)); and

2. Reports on Commerce With, and Assistance to, Cuba from Other Foreign Countries, consistent with section 108(a) of Public Law 104-114 (22 U.S.C. 6038(a)).

(f) The Director of National Drug Control Policy shall submit the Report on Support for Plan Colombia, consistent with section 3204(e) of Public Law 106-246.

Sec. 2. Reports to the Congress described in certain Senate resolutions shall be submitted as follows:

(a) The Secretary of State shall submit the following reports:

1. Report on the Inter-American Convention Against Corruption, consistent with the Resolution of Advice and Consent to Ratification of the Inter-American Convention Against Corruption adopted by the Senate on July 27, 2000;

2. Report on Compliance With the Treaty on Conventional Armed Forces in Europe, consistent with Condition 5(C) of the Resolution of Advice and

Consent to Ratification of the Document Agreed Among the States Parties to the Treaty on Conventional Armed Forces in Europe of November 19, 1990;

3. Report on Chemical Weapons Convention Compliance, consistent with Condition 10(C) of the Resolution of Advice and Consent to the Chemical Weapons Convention adopted by the Senate on April 24, 1997; and

4. Report on Moscow Treaty Implementation, consistent with section 2(2) of the Resolution of Advice and Consent to Ratification of the Treaty on Strategic Offensive Reductions of May 24, 2002.

(b) The Secretary of Commerce shall submit the Report on the Status of the World Intellectual Property Organization Copyright Treaty and the Performance and Phonograms Treaty, consistent with the Senate's resolution of ratification of October 21, 1998.

(c) The Secretary of Defense shall submit the Report on Moscow Treaty Implementation, consistent with section 2(1) of the Resolution of Advice and Consent to Ratification of the Treaty on Strategic Offensive Reductions of May 24, 2002.

Sec. 3. In carrying out sections 1 and 2 of this order, officers of the United States shall ensure that all actions taken by them are consistent with the President's constitutional authority to: (a) conduct the foreign affairs of the United States; (b) withhold information the disclosure of which could impair the foreign relations, the national security, the deliberative processes of the Executive, or the performance of the Executive's constitutional duties; (c) recommend for congressional consideration such measures as the President may judge necessary and expedient; and (d) supervise the unitary executive branch.

Sec. 4. Nothing in this order shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

Sec. 5. This order is intended only to improve the internal management of the executive branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.



THE WHITE HOUSE,
July 31, 2003.

Rules and Regulations

Federal Register

Vol. 68, No. 150

Tuesday, August 5, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1778

[0572-AB90]

Emergency and Imminent Community Water Assistance Grants

AGENCY: Rural Utilities Service, USDA.
ACTION: Direct final rule.

SUMMARY: The Rural Utilities Service (RUS) is amending its regulation governing Emergency Community Water Assistance Grants (ECWAG). This action is needed to comply with requirements set forth in the 2002 Farm Bill. The intended effect is to amend the regulation so that it allows eligibility for the program to be extended to situations where an emergency is considered imminent.

DATES: This rule will become effective September 19, 2003, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before September 4, 2003. If we receive such comments or notice, we will publish a timely document in the *Federal Register* withdrawing the rule. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time.

ADDRESSES: Submit adverse written comments or notice of intent to submit adverse comments to F. Lamont Heppe, Jr., Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., STOP 1522, Room 5168, South Building, Washington, DC 20250, telephone number (202) 720-9550 or via facsimile transmission to (202) 720-4120. RUS requires a signed original and three copies of all comments (7 CFR Part 1700). All comments received will be

made available for inspection in room 4034, South Building, Washington, DC, between 8 a.m. and 4 p.m. (7 CFR part 1.27(b)). Comments regarding the information and recordkeeping requirement must be received by October 6, 2003.

FOR FURTHER INFORMATION CONTACT: Robin Pulkkinen, Loan Specialist, Water and Environmental Programs, Rural Utilities Service, Room 2229 South Building, Stop 1570, 1400 Independence Ave. SW., Washington, DC 20250-1570. Telephone: (202) 720-9636, FAX: (202) 690-0649, E-mail: rpulkkin@rus.usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This proposed rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. RUS has determined that this proposed rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all State and local laws and regulations that are in conflict with this rule will be pre-empted; no retroactive effect will be given to the rule; and in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (5 U.S.C. sec. 6912(e)), appeal procedures must be exhausted before an action against the Department or its agencies may be initiated.

Regulatory Flexibility Act Certification

RUS has determined that this rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The amendments reflect changes needed to comply with requirements set forth in the Farm Security and Rural Investment Act of 2002.

Information Collection and Record Keeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), RUS invites comments on this information collection for which

RUS intends to request approval from the Office of Management and Budget (OMB). These requirements have been approved by emergency clearance under OMB Control Number 0572-0110.

Comments on this notice must be received by October 6, 2003.

Comments are invited on (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumption used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to F. Lamont Heppe, Jr., Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Stop 1522, Room 4034 South Building, Washington, DC 20250-1522.

Title: Emergency and Imminent Community Water Assistance Grants.

Type of Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1.6 hours per response.

Respondents: Not-for-profit institutions; State, Local or Tribal Government.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondent: 2.5.

Estimated Total Annual Burden on Respondents: 400 hours.

Copies of this information collection can be obtained from Michele Brooks, Program Development and Regulatory Analysis, at (202) 690-1078.

All responses to this information collection and recordkeeping notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

National Environmental Policy Act Certification

The Administrator of RUS has determined that this proposed rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The program described by this proposed rule is listed in the Catalog of Federal Domestic Assistance Programs under number 10.763—Emergency Community Water Assistance Grants. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC, 20402-9325, telephone number (202) 512-1800. This program is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Unfunded Mandates

This rule contains no Federal mandates (under the regulatory provision of title II of the Unfunded Mandates Reform Act of 1995) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of section 202 and 205 of the Unfunded Mandates Reform Act.

Background

This action amends the existing regulation for the Emergency Community Water Assistance Grant Program to allow grants to be made before an emergency has actually occurred.

The ECWAG program was authorized by the Rural Development Act of 1972. The grants are made to public bodies, nonprofit corporations, and Indian tribes for the purpose of improving rural living standards and for other purposes that create safe and affordable drinking water in rural areas or towns with a population not exceeding 10,000 inhabitants.

These grants can be made to construct or improve drinking water facilities serving the most financially needy communities. This revision is undertaken specifically to respond to requirements of Section 6009 of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171). (2002 Farm Bill)

Under the revised regulation, grants may be made for situations where an emergency is imminent, but has not yet

occurred. Applicants will be expected to furnish evidence that an emergency is expected to occur. The 2002 Farm Bill also increased the limit for the category of projects covering repairs and significant maintenance to \$150,000.

List of Subjects in 7 CFR Part 1778

Community development, Community facilities, Grant programs—housing and community development, Loan program—housing and community development, Reporting and recordkeeping requirements, Rural areas, Waste treatment and disposal, Water supply, Watersheds.

■ Therefore, the Rural Utilities Service revises 7 CFR part 1778 to read as follows:

PART 1778—EMERGENCY AND IMMINENT COMMUNITY WATER ASSISTANCE GRANTS

- Sec.
- 1778.1 General.
 - 1778.2 [Reserved]
 - 1778.3 Objective.
 - 1778.4 Definitions.
 - 1778.5 [Reserved]
 - 1778.6 Eligibility.
 - 1778.7 Project priority.
 - 1778.8 [Reserved]
 - 1778.9 Uses.
 - 1778.10 Restrictions.
 - 1778.11 Maximum grants.
 - 1778.12 [Reserved]
 - 1778.13 Set-aside.
 - 1778.14 Other considerations.
 - 1778.15–1778.20 [Reserved]
 - 1778.21 Application processing.
 - 1778.22 Planning development and procurement.
 - 1778.23 Grant closing and disbursement of funds.
 - 1778.24–1778.30 [Reserved]
 - 1778.31 Performing development.
 - 1778.32 [Reserved]
 - 1778.33 [Reserved]
 - 1778.34 Grant servicing.
 - 1778.35 Subsequent grants.
 - 1778.36 [Reserved]
 - 1778.37 Forms, Instructions and Bulletins.
 - 1778.38–1778.99 [Reserved]
 - 1778.100 OMB control number.

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 16 U.S.C. 1005.

§ 1778.1 General.

(a) This part outlines policies and procedures for making Emergency Community Water Assistance Grants (ECWAG) authorized under Section 306A of the Consolidated Farm and Rural Development Act, (7 U.S.C. 1926(a)), as amended. Any processing or servicing activity conducted pursuant to this part involving authorized assistance to Agency employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of

part 1900 of this title. Applicants for this assistance are required to identify any known relationship or association with an Agency employee.

(b) Agency officials will maintain liaison with officials of other Federal, State, regional and local development agencies to coordinate related programs to achieve rural development objectives.

(c) Agency officials shall cooperate with appropriate State agencies in making grants that support State strategies for rural area development.

(d) Funds allocated for use in accordance with this part are also to be considered for use by Indian tribes within the State regardless of whether State development strategies include Indian reservations within the State's boundaries. Indians residing on such reservations must have an equal opportunity along with other rural residents to participate in the benefits of this program. This includes equal application of outreach activities of Field Offices.

(e) Federal statutes provide for extending the Agency financial programs without regard to race, color, religion, sex, national origin, marital status, age, or physical/mental handicap (provided the participant possesses the capacity to enter into legal contracts).

§ 1778.2 [Reserved]

§ 1778.3 Objective.

The objective of the ECWAG Program is to assist the residents of rural areas that have experienced a significant decline in quantity or quality of water, or in which such a decline is considered imminent, to obtain or maintain adequate quantities of water that meets the standards set by the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*) (SDWA).

§ 1778.4 Definitions.

Acute shortage. An acute shortage is a situation in which the system either cannot deliver water at all through its distribution system or can only deliver water on a sporadic basis.

Emergency. Occurrence of an incident such as, but not limited to, a drought; earthquake; flood; tornado; hurricane; disease outbreak; or chemical spill, leakage, or seepage.

Rural areas. Includes any area not in a city or town with a population in excess of 10,000 inhabitants, according to the latest decennial census of the United States, located in any of the fifty States, the Commonwealth of Puerto Rico, the Western Pacific Territories, Marshall Islands, Federated States of Micronesia, Republic of Palau, and the U.S. Virgin Islands.

Significant decline in quality. A significant decline in quality of potable water occurs when the present community source or delivery system does not meet, as a result of an emergency, the current SDWA requirements. For a private source or delivery system a significant decline in quality occurs when the water is no longer potable as a result of an emergency. As used in this Subpart, the term significant decline in quality may also include a situation where a significant decline is likely to occur within one year from the date of the filing of an application.

Significant decline in quantity. A significant decline in the quantity is caused by a disruption of the potable water supply by an emergency. The disruption in quantity of water prevents the present source or delivery system from supplying potable water needs to rural residents. This would not include a decline in excess water capacity. As used in this Subpart, the term significant decline in quantity may also include a situation where a significant decline is likely to occur within one year from the date of the filing of an application.

§ 1778.5 [Reserved]

§ 1778.6 Eligibility.

(a) Grants may be made to public bodies and private nonprofit corporations serving rural areas. Public bodies include counties, cities, townships, incorporated towns and villages, boroughs, authorities, districts, and other political subdivisions of a State. Public bodies also include Indian tribes on Federal and State reservations and other Federally recognized Indian Tribal groups in rural areas.

(b) In the case of grants made to alleviate a significant decline in quantity or quality of water available from the water supplies of rural residents, the applicant must demonstrate that the decline occurred within two years of the date the application was filed with the Agency. This would not apply to grants made for repairs, partial replacement, or significant maintenance on an established water system. In situations involving imminent decline, evidence must be presented to demonstrate that the decline is likely to occur within one year of the date the application is filed with the Agency.

§ 1778.7 Project priority.

Paragraph (d) of this section indicates items and conditions which must be considered in selecting applications for further development. When ranking

eligible applications for consideration for limited funds, Agency officials must consider the priority items met by each application and the degree to which those priorities are met.

(a) **Applications.** The application and supporting information submitted with it will be used to determine the proposed project's priority for available funds.

(b) **State Office review.** All applications will be reviewed and scored for funding priority using RUS Bulletin 1778-1. Eligible applicants that cannot be funded should be advised that funds are not available.

(c) **National Office review.** Each year all funding requests will be reviewed by the National Office beginning 30 days after funds from the annual appropriation are made available to the Agency. Reviews will continue throughout the fiscal year as long as funds are available. Projects selected for funding will be considered based on the priority criteria and available funds. Projects must compete on a national basis for available funds, and the National Office will allocate funds to State offices on a project by project basis.

(d) **Selection priorities.** The priorities described below will be used by the State Program Official to rate applications and by the Assistant Administrator of Water and Environmental Programs to select projects for funding. Points will be distributed as indicated in paragraphs (d)(1) through (d)(5) of this section and will be considered in selecting projects for funding. A copy of RUS Bulletins 1778-1 and 1778-2 used to rate applications, should be placed in the case file for future reference.

(1) **Population.** The proposed project will serve an area with a rural population:

- (i) Not in excess of 1,500—30 points.
- (ii) More than 1,500 and not in excess of 3,000—20 points.
- (iii) More than 3,000 and not in excess of 5,000—15 points.
- (iv) Over 5,000—0 points.

(2) **Income.** The median household income of population to be served by the proposed project is:

- (i) Not in excess of 70% of the statewide nonmetropolitan median household income—30 points.
- (ii) More than 70% and not in excess of 80% of the statewide nonmetropolitan median household income—20 points.
- (iii) More than 80% and not in excess of 90% of the statewide nonmetropolitan median household income—10 points.

(iv) Over 90% of the statewide nonmetropolitan median household income—0 points.

(3) **Significant decline.** Points will be assigned for only one of the following paragraphs when the primary purpose of the proposed project is to correct a significant decline that has occurred in the:

(i) Quantity of water available from private individually owned wells or other individual sources of water—30 points; or

(ii) Quantity of water available from an established system's source of water—20 points; or

(iii) Quality of water available from private individually owned wells or other individual sources of water—30 points; or

(iv) Quality of water available from an established system's source of water—20 points.

(4) **Imminent decline.** The proposed project will attempt to avert an imminent decline expected to occur during the one-year period following the filing of an application—10 points.

(Note: If points were assigned above for a significant decline, no points will be awarded for imminent decline.)

(5) **Acute shortage.** Grants made in accordance with § 1778.11(b) of this part to assist an established water system remedy an acute shortage of quality water or correct a significant decline in the quantity or quality of water that is available—10 points.

(6) **Discretionary.** In certain cases the Administrator may assign up to 30 points for items such as geographic distribution of funds, rural residents hauling water, severe contamination levels, etc.

§ 1778.8 [Reserved]

§ 1778.9 Uses.

Grant funds may be used for the following purposes:

- (a) Waterline extensions from existing systems.
- (b) Construction of new waterlines.
- (c) Repairs to an existing system.
- (d) Significant maintenance to an existing system.
- (e) Construction of new wells, reservoirs, transmission lines, treatment plants, and other sources of water.
- (f) Equipment replacement.
- (g) Connection and/or tap fees.
- (h) Pay costs that were incurred within six months of the date an application was filed with the Agency to correct an emergency situation that would have been eligible for funding under this part.
- (i) Any other appropriate purpose such as legal fees, engineering fees,

recording costs, environmental impact analyses, archaeological surveys, possible salvage or other mitigation measures, planning, establishing or acquiring rights associated with developing sources of, treating, storing, or distributing water.

(j) Assist rural water systems to comply with the requirements of the Federal Water Pollution Control Act (33 U.S.C. 1251 *et seq.*) (FWPCA) or the SDWA when such failure to comply is directly related to a recent decline in quality of potable water. This would not apply to changes in the requirements of FWPCA or SDWA.

(k) Provide potable water to communities through means other than those covered above for not to exceed 120 days when a more permanent solution is not feasible in a shorter time frame.

§ 1778.10 Restrictions.

(a) Grant funds may not be used to:

(1) Assist any city or town with a population in excess of 10,000 inhabitants according to the most recent decennial census of the United States. Facilities financed by RUS may be located in non-rural areas. However, loan and grant funds may be used to finance only that portion of the facility serving rural areas, regardless of facility location.

(2) Assist a rural area that has a median household income in excess of the statewide nonmetropolitan median household income according to the most recent decennial census of the United States.

(3) Finance facilities which are not modest in size, design, cost, and are not directly related to correcting the potable water quantity or quality problem.

(4) Pay loan or grant finder's fees.

(5) Pay any annual recurring costs that are considered to be operational expenses.

(6) Pay rental for the use of equipment or machinery owned by the rural community.

(7) Purchase existing systems.

(8) Refinance existing indebtedness, except for short-term debt incurred in accordance with § 1778.9(h).

(9) Make reimbursement for projects developed with other grant funds.

(10) Finance facilities that are not for public use.

(b) Nothing in paragraph (a)(1) of this section shall preclude rural areas from submitting joint proposals for assistance under this part. Each entity applying for financial assistance under this part to fund their share of a joint project will be considered individually.

§ 1778.11 Maximum grants.

(a) Grants not to exceed \$500,000 may be made to alleviate a significant decline in quantity or quality of water available to a rural area that occurred within two years of filing an application with the Agency, or to attempt to avoid a significant decline that is expected to occur during the twelve month period following the filing of an application.

(b) Grants made for repairs, partial replacement, or significant maintenance on an established system to remedy an acute shortage or significant decline in the quality or quantity of potable water, or an anticipated acute shortage or significant decline, cannot exceed \$150,000.

(c) Grants under this part, subject to paragraphs (a) and (b) of this section, shall be made for 100 percent of eligible project costs.

§ 1778.12 [Reserved]

§ 1778.13 Set-aside.

(a) At least 70 percent of all grants made under this grant program shall be for projects funded in accordance with § 1778.11(a).

(b) At least 50 percent of the funds appropriated for this grant program shall be allocated to rural areas with populations not in excess of 3,000 inhabitants according to the most recent decennial census of the United States.

§ 1778.14 Other considerations.

(a) *Civil rights compliance requirements.* All grants made under this part are subject to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) as outlined in subpart E of part 1901 of this title.

(b) *Environmental requirements.* All projects must have appropriate environmental reviews in accordance with RUS requirements.

(c) *Uniform Relocation and Real Property Acquisition Policies Act (42 U.S.C. 4601 *et seq.*).* All projects must comply with the requirements set forth in 7 CFR Part 21.

(d) *Flood and mudslide hazard area precautions.* If the project is located in a flood or mudslide area, then flood or mudslide insurance must be provided as required in subpart A of part 1806 of this title (RD Instruction 426.2).

(e) *Governmentwide debarment and suspension (nonprocurement) and requirements for drug-free work place.* All projects must comply with the requirements set forth in the U.S. Department of Agriculture regulations 7 CFR part 3017 and RD Instruction 1940-M.

(f) *Intergovernmental review.* All projects funded under this part are

subject to Executive Order 12372 (3 CFR, 1983 Comp., p. 197), which requires intergovernmental consultation with State and local officials. These requirements are set forth in U.S. Department of Agriculture regulations 7 CFR part 3015, Subpart V, and RD Instruction 1940-J.

§§ 1778.15—1778.20 [Reserved]

§ 1778.21 Application processing.

(a) The material submitted with the application should include the Preliminary Engineering Report, population and median household income of the area to be served, description of project, and nature of emergency that caused the problem(s) being addressed by the project. The documentation must clearly show that the applicant has had a significant decline in the quantity or quality of potable water or an acute shortage of potable water, or that such a decline or shortage is imminent, and that the proposed project will eliminate or alleviate the problem. For projects to be funded in accordance with § 1778.11 (a), evidence must be furnished that a significant decline in quantity or quality occurred within two years before filing the application with the Agency, or is expected to occur within one year after filing the application.

(b) When favorable action will not be taken on an application, the applicant will be notified in writing by the State Program Official of the reasons why the request was not favorably considered. Notification to the applicant will state that a review of this decision by the Agency may be requested by the applicant in accordance with 7 CFR part 11.

§ 1778.22 Planning development and procurement.

Planning development and procurement for grants made under this part will be in accordance with subpart C of Part 1780 of this chapter. A certification should be obtained from the State agency or the Environmental Protection Agency if the State does not have primacy, stating that the proposed improvements will be in compliance with requirements of the SDWA.

§ 1778.23 Grant closing and disbursement of funds.

(a) Grants will be closed in accordance with § 1780.45 of part 1780 of this chapter.

(b) RUS Bulletin 1780-12, "Water or Waste Grant Agreement," will be executed by all applicants.

(c) The Agency's policy is not to disburse grant funds from the Treasury until they are actually needed by the

applicant. Grant funds will be disbursed by using multiple advances.

§§ 1778.24–1778.30 [Reserved]

§ 1778.31 Performing development.

(a) Applicable provisions of subpart C of part 1780 of this chapter will be followed in performing development for grants made under this part.

(b) After filing an application in accordance with § 1778.21 and when immediate action is necessary, the State Program Official may concur in an applicant's request to proceed with construction before funds are obligated provided the RUS environmental requirements are complied with. The applicant must be advised in writing that:

(1) Any authorization to proceed or any concurrence in bid awards, contract concurrence, or other project development activity, is not a commitment by the Agency to provide grant funds under this part.

(2) The Agency is not liable for any debt incurred by the applicant in the event that funds are not provided under this part.

§ 1778.32–33 [Reserved]

§ 1778.34 Grant servicing.

(a) Grants will be serviced in accordance with § 1951.215 of subpart E of part 1951 of this title and subpart O of part 1951 of this title.

(b) The grantee will provide an audit report in accordance with § 1780.47 of part 1780 of this chapter.

§ 1778.35 Subsequent grants.

Subsequent grants will be processed in accordance with the requirements set forth in this part. The initial and subsequent grants made to complete a previously approved project must comply with the maximum grant requirements set forth in § 1778.11.

§ 1778.36 [Reserved]

§ 1778.37 Forms, Instructions and Bulletins.

Bulletins, instructions and forms referenced are for use in administering grants made under this part and are available from any USDA/Rural Development office or the Rural Utilities Service, United States Department of Agriculture, Washington, DC 20250–1500.

§§ 1778.38–1778.99 [Reserved]

§ 1778.100 OMB control number.

The information collection requirements contained in this part have been approved by the Office of Management and Budget and assigned OMB control number 0572–0110.

Dated: July 3, 2003.

Hilda Gay Legg,

Administrator, Rural Utilities Service.

[FR Doc. 03–19696 Filed 8–4–03; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301 and 602

[TD 9082]

RIN 1545–AY24

Revision of Income Tax Regulations Under Sections 897, 1445, and 6109 To Require Use of Taxpayer Identifying Numbers on Submissions Under the Section 897 and 1445 Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations to require the use of taxpayer identifying numbers on submissions under sections 897 and 1445. The regulations are necessary to properly identify foreign taxpayers for which submissions are made for the reduction or elimination of tax under sections 897 and 1445. The regulations also address certain additional issues under section 1445.

DATES: *Effective Date:* These regulations are effective August 5, 2003.

Applicability Date: For dates of applicability, see §§ 1.897–3(h), 1.897–5(e), 1.1445–1(h), 1.1445–2(b)(2)(iii), 1.1445–2(d)(2)(iv), 1.1445–2(e), 1.1445–3(h), 1.1445–5(b)(8)(iii), 1.1445–5(h), and 1.1445–6(h).

FOR FURTHER INFORMATION CONTACT: Robert W. Lorence, Jr. (202) 622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1797. The collection of information in these final regulations are in §§ 1.1445–2(d)(2) and 1.1445–3. These collections of information are required to notify the IRS of dispositions of U.S. real property interests by foreign persons that otherwise are subject to taxation under section 897 and the collection of a withholding tax under section 1445.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

The estimated annual burden per respondent varies from 3 to 5 hours, depending on individual circumstances, with an estimated average of 4 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:T:T:SP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to these collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to 26 CFR parts 1 and 301. On July 26, 2002, a notice of proposed rule-making (REG–106876–00), relating to the use of taxpayer identifying numbers on submissions under sections 897 and 1445 of the Internal Revenue Code (Code), was published in the *Federal Register* (67 FR 48823). No public hearing was requested or held. Written comments responding to the notice of proposed rule-making were received. After consideration of the comments, the proposed regulations are adopted as amended by this Treasury decision. The revisions are discussed below.

Summary of Public Comments and Explanation of Revisions

A. Use of Taxpayer Identifying Number

This document contains final regulations under sections 897, 1445, and 6109 that require foreign transferors of U.S. real property interests (and transferees where applicable) to provide their taxpayer identifying numbers (TINs) on withholding tax returns, applications for withholding certificates, and other notices and elections under sections 897 and 1445 and the regulations thereunder. TINs are required so that the IRS can identify foreign taxpayers and more easily match applications, withholding tax returns, notices, and elections with the transferors' income tax returns.

Applications for withholding certificates, and other notices and elections under section 897 and 1445 will be considered incomplete and generally will not be processed by the IRS unless the TIN of the transferor is provided. Amounts withheld under section 1445 must still be reported and paid to the IRS on withholding tax returns (Form 8288, "U.S. Withholding Tax Return for Dispositions by Foreign Persons of U.S. Real Property Interests", and Form 8288-A, "Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests") if the appropriate TINs are not provided. The final regulations provide that although such amounts have been paid, if the transferor's TIN is not included, a receipt (Form 8288-A) for withholding tax paid to the Service will not be stamped to show receipt and will not be mailed to the transferor.

In many cases, the foreign taxpayer will already have a TIN, because the taxpayer will have already filed a U.S. tax return. If the taxpayer does not already have a TIN, the TIN requirement under the regulations merely accelerates the time to obtain a TIN, because the foreign taxpayer must have a TIN to file its U.S. income tax return for the year of the disposition of the U.S. real property interest. In the case of foreign entities (such as foreign corporations) that are required to have employee identification numbers (EINs), the EINs can be obtained without delay through existing procedures.

Commentators have expressed concern about the time it takes nonresident alien individuals to obtain TINs and how it could effect the timing of transactions. The IRS is aware of this concern and is exploring approaches for addressing it. For example, the IRS is considering implementing a program in which applications for withholding certificates will be processed in conjunction with applications for TINs. The need to obtain a TIN generally should not delay the time it takes to get a withholding certificate under § 1.1445-3. In addition, the portion of these regulations that imposes a requirement concerning TINs, will not be applicable until 90 days after the date of publication in the *Federal Register* in order to permit taxpayers that currently own real property additional time to obtain a TIN, if necessary.

B. Section 1031 Like-Kind Exchanges

Section 1031(a) provides for the nonrecognition of gain or loss on the exchange of like-kind property which is held for productive use in a trade or business or held for investment. Section 1031(a)(3) provides for the exchange of

like-kind property in deferred exchanges, where the taxpayer has 45 days after it relinquishes the property to the transferee to identify replacement property and the transferee has until the earlier of 180 days or the due date of the tax return for the year of transfer to deliver such property to the transferor.

Notices of nonrecognition under § 1.1445-2(d) are limited to exchanges (including section 1031 exchanges) that qualify for nonrecognition treatment in their entirety (thus, a notice of nonrecognition may not be used if the transferor receives money or other property, *i.e.*, boot). Consistent with the proposed regulations, these final regulations provide that in the case of a simultaneous exchange of like-kind U.S. real property interests (where there is no boot), the foreign transferor can provide a notice of nonrecognition under § 1.1445-2(d)(2) to the transferee, and the transferee can rely on such notice, because the like-kind exchange will be fully completed on the day of the exchange. In the case of a deferred like-kind exchange of U.S. real property interests, the transferee cannot rely on a notice of nonrecognition, because the transferee cannot be assured that the exchange will qualify for nonrecognition treatment under section 1031 (*e.g.*, that the property to be received by the foreign transferor will be identified within the 45-day period required under section 1031(a)), or even if the exchange qualifies under section 1031, that the foreign transferor will not receive boot in the transaction.

Although a notice of nonrecognition is not available in a deferred like-kind exchange, the transferee may withhold a reduced amount based on a claim of nonrecognition upon receipt of a withholding certificate pursuant to the procedures of § 1.1445-3.

Commentators have proposed that using a notice of nonrecognition for deferred like-kind exchanges should be permitted if a "claim of intent" to engage in an exchange qualifying for nonrecognition under section 1031 is provided. The IRS continues to believe that notices of nonrecognition are inappropriate for deferred like-kind exchanges. In a deferred like-kind exchange, until the replacement property has been identified and a contract for its purchase is executed, the transferor does not know with certainty that the exchange will qualify for nonrecognition under section 1031. Moreover, it is uncertain whether boot will be received in the exchange if the replacement property is not identified at the time the relinquished property is transferred to the transferee. Accordingly, the regulations do not

permit a notice of nonrecognition in the case of a deferred like-kind exchange and require the taxpayer to obtain a withholding certificate.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. These regulations impose no new collection of information on small entities; therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the proposed regulations preceding these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Robert W. Lorence, Jr., Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting, and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR parts 1, 301 and 602 are amended as follows:

PART 1—INCOME TAXES

■ 1. The authority for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.897-1 [Amended]

■ 2. In § 1.897-1, paragraph (p), the first sentence is amended by adding the language "or the identification number assigned by the Internal Revenue Service (see § 301.6109-1 of this chapter)"

immediately after the language "United States social security number".

§ 1.897-2 [Amended]

■ 3. Section 1.897-2 is amended as follows:

■ For each of the paragraphs listed in the first column, remove the language in the second column and add in its place the language in the third column:

Paragraphs	Remove	Add
(g)(1)(i)(B)	Director, Foreign Operations District ("Director").	Commissioner, Small Business/Self Employed Division (SB/SE).
(g)(1)(i), fourth sentence of concluding text immediately following paragraph (g)(1)(i)(B).	Director	Commissioner.
(g)(1)(iii) heading	Director	Commissioner.
(g)(1)(iii)(A), first, fourth, and last sentences	Director	Commissioner.
(g)(1)(iii)(A), third sentence	Director, Foreign Operations District; 1325 K St. NW; Washington, DC 20225.	Commissioner, Small Business/Self Employed Division (SB/SE); S C3-413 NCFB, 500 Ellin Road, Lanham, MD 20706.
(g)(1)(iii)(B) heading	Director's	Commissioner's.
(g)(1)(iii)(B) introductory text	Director	Commissioner
(g)(1)(iii)(B) concluding text immediately following (g)(1)(iii)(B)(2).	Director	Commissioner.
(g)(1)(iii)(C) both places it appears	Director	Commissioner.
(g)(1)(iii)(D) heading	Director	Commissioner.
(g)(1)(iii)(D)	Director	Commissioner.
(g)(2)(i)(B)	Director	Commissioner.
(g)(2)(iii) heading	Director	Commissioner.
(g)(2)(iii)(A), first, fourth, and fifth sentence (both places it appears).	Director	Commissioner.
(g)(2)(iii)(A), third sentence	Director, Foreign Operations District; 1325 K St. NW.; Washington, DC 20225.	Commissioner, Small Business/Self Employed Division (SB/SE); S C3-413 NCFB, 500 Ellin Road, Lanham, MD 20706.
(g)(2)(iii)(B) heading	Director's	Commissioner's.
(g)(2)(iii)(B) introductory text	Director	Commissioner.
(g)(2)(iii)(B) concluding text immediately following (g)(2)(iii)(B)(2).	Director	Commissioner.
(g)(2)(iii)(C), first and second sentences	Director	Commissioner.
(g)(2)(iii)(D) heading	Director	Commissioner.
(g)(2)(iii)(D)	Director	Commissioner.
(g)(2)(iv), fourth sentence	Director	Commissioner.
(h)(2)(v), third sentence	Assistant Commissioner (International), Director, Office of Compliance, OP:I:C:E:666, 950 L'Enfant Plaza South, SW., COMSAT Building, Washington, D.C. 20024.	Director, Philadelphia Service Center, P.O. Box 21086, Drop Point 8731, FIRPTA Unit, Philadelphia, PA 19114-0586.
(h)(4)(ii), first sentence	Assistant Commissioner (International), Director, Office of Compliance, OP:I:C:E:666, 950 L'Enfant Plaza South, SW., COMSAT Building, Washington, D.C. 20024.	Director, Philadelphia Service Center, P.O. Box 21086, Drop Point 8731, FIRPTA Unit, Philadelphia, PA 19114-0586.

4. Section 1.897-3 is amended as follows:

■ 1. For each of the paragraphs listed in the first column, remove the language in

the second column and add in its place the language in the third column:

Paragraphs	Remove	Add
(c), introductory text	Director of the Foreign Operations District, 1325 K St., NW, Washington, DC 20225.	Director, Philadelphia Service Center, P.O. Box 21086, Drop Point 8731, FIRPTA Unit, Philadelphia, PA 19114-0586.
(c)(1), introductory text, last sentence.	which must set forth	which must contain all the following information.
(d)(1), fourth sentence	Foreign Operations District	Philadelphia Service Center.
(d)(2)(i), penultimate sentence	Director, Foreign Operations District	U.S. Treasury.
(f)(1), second sentence	Director, Foreign Operations District, 1325 K St., NW., Washington, DC 20225.	Director, Philadelphia Service Center, P.O. Box 21086, Drop Point 8731, FIRPTA Unit, Philadelphia, PA 19114-0586.
(f)(1), fifth sentence	Foreign Operations District	Philadelphia Service Center
(g)(1), second sentence	Director of the Foreign Operations District	Director, Philadelphia Service Center.

■ 2. In paragraph (c)(1)(i), remove the parenthetical "(if any)" after the words "identifying number".

■ 3. Paragraph (h) is added to read as follows:

§ 1.897-3 Election by foreign corporation to be treated as a domestic corporation under section 897(i).

* * * * *

(h) *Effective date.* The requirement in paragraph (c)(1)(i) of this section that

the statement making the section 897(i) election contain the identifying number of the foreign corporation (in all cases) is applicable November 3, 2003.

■ 5. Section 1.897-5 is added to read as follows:

§ 1.897-5 Corporate distributions.

(a) through (d)(1)(iii)(E) [Reserved]. For further guidance, see § 1.897-5T(a) through (d)(1)(iii)(E).

(d)(1)(iii)(F) Identification by name and address of the distributee or transferee, including the distributee's or transferee's taxpayer identification number;

(d)(1)(iii)(G) through (d)(4) [Reserved]. For further guidance, see § 1.897-5T(d)(1)(iii)(G) through (d)(4).

(e) *Effective date.* This section is applicable to transfers and distributions after November 3, 2003.

■ 6. In § 1.897-5T, paragraph (d)(1)(iii)(F) is revised to read as follows:

§ 1.897-5T Corporate distributions (temporary).

* * * * *

(d) * * * (1) * * *

(iii) * * *

(F) [Reserved]. For further guidance, see § 1.897-5(d)(1)(iii)(F).

* * * * *

§ 1.897-6T [Amended]

■ 7. Section 1.897-6T is amended as follows:

■ 1. In paragraph (a)(2), second sentence, the language “, 1034” is removed.

■ 2. Paragraph (a)(5) (including the undesignated paragraph at the end) is removed and reserved.

■ 3. Paragraph (a)(7), *Example 2* and *Example 3* are removed and reserved.

■ 8. Section 1.1445-1 is amended as follows:

■ 1. In paragraph (c)(1), second sentence, remove the language “filed with the Internal Revenue Service Center, Philadelphia, PA 19255” and add in its place the language “filed at the location as provided in the instructions to Forms 8288 and 8288-A”.

■ 2. In paragraph (c)(1), two sentences are added at the end.

■ 3. In paragraph (c)(2)(i)(B), second sentence, remove the phrase “, if any,” after the words “taxpayer identification number”.

■ 4. In paragraphs (d)(1)(i) and (d)(1)(ii), remove the parenthetical “(if any)” after the words “identifying number”.

■ 5. In paragraphs (d)(2)(i), (d)(2)(iv)(B), and (d)(2)(vi)(B), remove the parenthetical “(if any)” after the words “identifying number”.

■ 6. In paragraph (f)(2), the first sentence is revised, and a sentence is added after the first sentence.

■ 7. In paragraph (f)(3)(i), the last sentence is revised.

■ 8. Paragraphs (g)(9) and (g)(10) are revised.

■ 9. Paragraph (h) is added.

■ The additions and revisions read as follows:

§ 1.1445-1 Withholding on dispositions of U.S. real property interests by foreign persons: In general.

* * * * *

(c) * * *

(1) * * * Forms 8288 and 8288-A are required to include the identifying numbers of both the transferor and the transferee, as provided in paragraph (d) of this section. If any identifying number as required by such forms is not provided, the transferee must still report and pay over any tax withheld on Form 8288, although the transferor cannot obtain a credit or refund of tax on the basis of a Form 8288-A that does not include the transferor's identifying number (see paragraph (f)(2) of this section).

* * * * *

(f) * * *

(2) * * * A stamped copy of Form 8288-A will be provided to the transferor by the Service (under paragraph (c) of this section) if the Form 8288-A is complete, including the transferor's identifying number. Except as provided in paragraph (f)(3) of this section, a stamped copy of Form 8288-A must be attached to the transferor's return to establish the amount withheld that is available as a credit. * * *

(3) * * *

(i) * * * Such a transferor must attach to its return a statement which supplies all of the information required by § 1.1445-1(d), including the transferor's identifying number.

* * * * *

(g) * * *

(9) *Identifying number.* Pursuant to § 1.897-1(p), an individual's identifying number is the social security number or the identification number assigned by the Internal Revenue Service (see § 301.6109-1 of this chapter). The identifying number of any other person is its United States employer identification number.

(10) *Address of the Director, Philadelphia Service Center.* Any written communication directed to the Director, Philadelphia Service Center is to be addressed as follows: P.O. Box 21086, Drop Point 8731, FIRPTA Unit, Philadelphia, PA 19114-0586.

(h) *Effective date for taxpayer identification numbers.* The requirement in paragraphs (c)(2)(i)(B), (d)(1)(i) and (ii), (d)(2)(i), (d)(2)(iv)(B), and (d)(2)(vi)(B) of this section that taxpayer identification numbers be provided (in all cases) is applicable for dispositions of U.S. real property interests occurring after November 3, 2003.

■ 9. Section 1.1445-2 is amended as follows:

■ 1. Paragraph (b)(2)(iii) is redesignated as paragraph (b)(2)(iv), and new paragraph (b)(2)(iii) is added.

■ 2. Newly designated paragraph (b)(2)(iv)(B) is revised.

■ 3. In paragraph (d)(2)(i)(B), the language “Assistant Commissioner (International)” is removed, and “Director, Philadelphia Service Center” is added in its place, and the parenthetical “(if any),” is removed after the words “identifying number”.

■ 4. Paragraphs (d)(2)(iii) and (d)(2)(iv) are added immediately following the concluding text following paragraph (d)(2)(ii)(B).

■ 5. In paragraphs (d)(3)(iii)(A)(2) and (d)(3)(iii)(A)(3), the parenthetical “(if any)” is removed after the words “identifying number”.

6. Paragraph (e) is added.

The revision and additions read as follows:

§ 1.1445-2 Situations in which withholding is not required under section 1445(a).

* * * * *

(b) * * *

(2) * * *

(iii) *Disregarded entities.* A disregarded entity may not certify that it is the transferor of a U.S. real property interest, as the disregarded entity is not the transferor for U.S. tax purposes, including sections 897 and 1445. Rather, the owner of the disregarded entity is treated as the transferor of property and must provide a certificate of non-foreign status to avoid withholding under section 1445. A disregarded entity for these purposes means an entity that is disregarded as an entity separate from its owner under § 301.7701-3 of this chapter, a qualified REIT subsidiary as defined in section 856(i), or a qualified subchapter S subsidiary under section 1361(b)(3)(B). Any domestic entity must include in its certification of non-foreign status with respect to the transfer a certification that it is not a disregarded entity. This paragraph (b)(2)(iii) and the sample certification provided in paragraph (b)(2)(iv)(B) of this section (to the extent it addresses disregarded entities) is applicable for dispositions occurring September 4, 2003.

(iv) * * *

(B) *Entity transferor.*

“Section 1445 of the Internal Revenue Code provides that a transferee of a U.S. real property interest must withhold tax if the transferor is a foreign person. For U.S. tax purposes (including section 1445), the owner of a disregarded entity (which has legal title to a U.S. real property interest under local law) will be the transferor of the property and not the disregarded entity. To inform the transferee that withholding of tax is not required upon the disposition of a U.S. real

property interest by [name of transferor], the undersigned hereby certifies the following on behalf of [name of the transferor]:

1. [Name of transferor] is not a foreign corporation, foreign partnership, foreign trust, or foreign estate (as those terms are defined in the Internal Revenue Code and Income Tax Regulations);
2. [Name of transferor] is not a disregarded entity as defined in § 1.1445-2(b)(2)(iii);
3. [Name of transferor]'s U.S. employer identification number is ____; and
4. [Name of transferor]'s office address is _____.

[Name of transferor] understands that this certification may be disclosed to the Internal Revenue Service by transferee and that any false statement contained herein could be punished by fine, imprisonment, or both.

Under penalties of perjury I declare that I have examined this certification and to the best of my knowledge and belief it is true, correct, and complete, and I further declare that I have authority to sign this document on behalf of [name of transferor].

[Signature(s) and date]

[Title(s)]"

* * * * *

(d) * * *

(2) * * *

(iii) *Contents of the notice.* No particular form is required for a transferor's notice to a transferee that the transferor is not required to recognize gain or loss with respect to a transfer. The notice must be verified as true and signed under penalties of perjury by the transferor, by a responsible officer in the case of a corporation, by a general partner in the case of a partnership, and by a trustee or equivalent fiduciary in the case of a trust or estate. The following information must be set forth in paragraphs labeled to correspond with the designation set forth as follows—

(A) A statement that the document submitted constitutes a notice of a nonrecognition transaction or a treaty provision pursuant to the requirements of § 1.1445-2(d)(2);

(B) The name, identifying number, and home address (in the case of an individual) or office address (in the case of an entity) of the transferor submitting the notice;

(C) A statement that the transferor is not required to recognize any gain or loss with respect to the transfer;

(D) A brief description of the transfer; and

(E) A brief summary of the law and facts supporting the claim that recognition of gain or loss is not required with respect to the transfer.

(iv) *No notice allowed.* The provisions of this paragraph (d)(2) do not apply to exclusions from income under section 121, to simultaneous like-kind exchanges under section 1031 that do not qualify for nonrecognition treatment

in their entirety (see paragraph (d)(2)(ii)(A) of this section), and to non-simultaneous like-kind exchanges under section 1031 where the transferee cannot determine that the exchange has been completed and all the conditions for nonrecognition have been satisfied at the time it is otherwise required to pay the section 1445 withholding tax and file the withholding tax return (Form 8288, "U.S. Withholding Tax Return for Dispositions by Foreign Persons of U.S. Real Property Interests"). In these cases, the transferee is excused from withholding only upon the timely application for and receipt of a withholding certificate under § 1.1445-3 (see § 1.1445-3(b)(5) and (6) for specific rules applicable to transactions under sections 121 and 1031). This paragraph (d)(2)(iv) is applicable for dispositions and exchanges occurring September 4, 2003.

* * * * *

(e) *Effective date for taxpayer identification numbers.* The requirement in paragraphs (d)(2)(i)(B), (d)(2)(iii)(B), and (d)(3)(iii)(A)(2) and (3) of this section that taxpayer identification numbers be provided (in all cases) is applicable for dispositions of U.S. real property interests occurring after November 3, 2003.

* * * * *

■ 10. Section 1.1445-3 is amended as follows:

■ 1. In paragraph (a), after the seventh sentence, one sentence is added.

■ 2. For each of the paragraphs listed in the column below, remove the language "Assistant Commissioner (International)", and add "Director, Philadelphia Service Center" in its place.

Paragraphs

(b)(1), first sentence

(f)(1), first sentence

(f)(2)(iii), heading

(f)(2)(iii), first sentence

(g), third sentence, introductory text

■ 3. In paragraph (b)(1), last sentence, remove the language "of this section" and add ", and to the extent applicable, paragraph (b)(5) or (6) of this section" in its place.

■ 4. Paragraph (b)(2) is revised.

■ 5. Paragraphs (b)(5) and (b)(6) are added.

■ 6. In paragraphs (f)(3)(i) and (g)(1), remove the parenthetical "(if any)" after the words "identifying number".

■ 7. Paragraph (h) is added.

The revision and additions read as follows:

§ 1.1445-3 Adjustments to amount required to be withheld pursuant to withholding certificate.

(a) * * * In no event, however, will a withholding certificate be issued without the transferor's identifying number. * * *

(b) * * *

(2) *Parties to the transaction.* The application must set forth the name, address, and identifying number of the person submitting the application (specifying whether that person is the transferee or transferor), and the name, address, and identifying number of other parties to the transaction (specifying whether each such party is a transferee or transferor). The Service will deny the application if complete information, including the identifying numbers of all the parties, is not provided. Thus, for example, the applicant should determine if an identifying number exists for each party, and, if none exists for a particular party, the applicant should notify the particular party of the obligation to get an identifying number before the application can be submitted to the Service. The address provided in the case of an individual must be that individual's home address, and the address provided in the case of an entity must be that entity's office address. A mailing address may be provided in addition to, but not in lieu of, a home address or office address.

* * * * *

(5) *Special rule for exclusions from income under section 121.* A withholding certificate may be sought on the basis of a section 121 exclusion as a reduction in the amount of tax due under paragraph (c)(2)(v) of this section. The application must include information establishing that the transferor, who is a nonresident alien individual at the time of the sale (and is therefore subject to sections 897 and 1445) is entitled to claim the benefits of section 121. For example, a claim for reduced withholding as a result of section 121 must include information that the transferor occupied the U.S. real property interest as his or her personal residence for the required period of time.

(6) *Special rule for like-kind exchanges under Section 1031.* A withholding certificate may be requested with respect to a like-kind exchange under section 1031 as a transaction subject to a nonrecognition provision under paragraph (c)(2)(ii) of this section. The application must include information substantiating the requirements of section 1031. The IRS may require additional information during the course of the application

process to determine that the requirements of section 1031 are satisfied. In the case of a deferred like-kind exchange, the withholding agent is excused from reporting and paying the withholding tax to the IRS within 20 days after the transfer only if an application for a withholding certificate is submitted prior to or on the date of transfer. See § 1.1445-1(c)(2) for rules concerning delayed reporting and payment where an application for a withholding certificate has been submitted to the IRS prior to or on the date of transfer.

(h) *Effective date for taxpayer identification numbers.* The requirement in paragraphs (b)(2), (f)(3)(i), and (g)(1) of this section that taxpayer identification numbers be provided (in all cases) is applicable for dispositions of U.S. real property interests occurring after November 3, 2003.

§ 1.1445-4 [Amended]

- 11. In § 1.1445-4, paragraph (c)(2), second sentence, is amended by removing the language "Assistant Commissioner (International)" and adding "Director, Philadelphia Service Center" in its place.
- 12. Section 1.1445-5 is amended as follows:
 - 1. In paragraph (b)(2)(ii), first sentence, remove the language "Assistant Commissioner (International)" and add "Director, Philadelphia Service Center" in its place.
 - 2. In paragraphs (b)(2)(ii)(B) and (b)(2)(ii)(C), remove the parenthetical "(if any)" after the words "identifying number".
 - 3. In paragraph (b)(5)(i), second sentence, remove the language "filed with the Internal Revenue Service Center, Philadelphia, PA 19255" and add in its place the language "filed at the location as provided in the instructions to Forms 8288 and 8288-A".
 - 4. In paragraph (b)(5)(i), the fifth sentence is revised.
 - 5. In paragraph (b)(7), the fifth sentence is revised.
 - 6. Paragraph (b)(8)(iii) is revised.
 - 7. In paragraph (c)(3)(v), first and fifth sentences, remove the language "Assistant Commissioner (International)" and add "Director, Philadelphia Service Center" in its place.
 - 8. Paragraph (e)(1)(ii) is revised.
 - 9. Paragraph (e)(2) is redesignated as paragraph (e)(3), and new paragraph (e)(2) is added.
 - 10. In newly designated paragraph (e)(3)(iii)(B), remove the language

"§ 1.1445-5(e)(2)(iii)(B)" and add "§ 1.1445-5(e)(3)(iii)(B)" in its place; and remove the language "paragraph (e)(2)(iii)(B)" and add "paragraph (e)(3)(iii)(B)" in its place.

■ 11. Paragraph (h) is added.

The revisions and additions read as follows:

§ 1.1445-5 Special rules concerning distributions and other transactions by corporations, partnerships, trusts and estates.

(b) * * *
 (5) * * *
 (i) * * * Form 8288-A will be stamped by the Internal Revenue Service to show receipt, and a stamped copy will be mailed by the Service to the interest holder if the Form 8288 is complete, including the transferor's identifying number, at the address shown on the form, for the interest holder's use. * * *

(7) * * * Such an interest-holder must attach to its return a statement which supplies all of the information required by § 1.1445-1(d)(2). * * *

(8) * * *
 (iii) *Distributions by certain domestic corporations to foreign shareholders.* The provisions of section 1445(e)(3) and paragraph (e)(1) of this section, requiring withholding upon distributions in redemption of stock under section 302(a) or liquidating distributions under Part II of subchapter C of the Internal Revenue Code by U.S. real property holding corporations to foreign shareholders, shall apply to distributions made on or after January 1, 1985. The provisions of section 1445(e)(3) and paragraph (e)(1) of this section requiring withholding on distributions under section 301 by U.S. real property holding corporations to foreign shareholders shall apply to distributions made after August 20, 1996. The provisions of paragraph (e) of this section providing for the coordination of withholding between sections 1445 and 1441 (or 1442 or 1443) for distributions under section 301 by U.S. real property holding corporations to foreign shareholders apply to distributions after December 31, 2000 (see § 1.1441-3(c)(4) and (h)).

(e) * * * (1) * * *
 (ii) There is a distribution of property in redemption of stock treated as an exchange under section 302(a), in liquidation of the corporation pursuant to the provisions of Part II of subchapter C of the Internal Revenue Code (sections 331 through section 346), or with respect to stock under section 301 that.

is not made out of earnings and profits of the corporation.

(2) *Coordination rules for Section 301 distributions.* If a domestic corporation makes a distribution of property under section 301 to a foreign person whose interest in such corporation constitutes a U.S. real property interest under the provisions of section 897 and the regulations thereunder, then see § 1.1441-3(c)(4) for rules coordinating withholding obligations under sections 1445 and 1441 (or 1442 or 1443).

(h) *Effective date for taxpayer identification numbers.* The requirement in paragraphs (b)(2)(ii)(B) and (C) of this section that taxpayer identification numbers be provided (in all cases) is applicable for dispositions of U.S. real property interests occurring after November 3, 2003.

■ 13. Section 1.1445-6 is amended as follows:

- 1. The section heading is revised.
- 2. In paragraph (a), after the seventh sentence, one sentence is added.
- 3. Paragraph (b)(3) is revised.
- 4. For each of the paragraphs listed in the column below, remove the language "Assistant Commissioner (International)" and add "Director, Philadelphia Service Center" in its place.

Paragraphs

- (f)(1), first sentence
 - (f)(2)(iii), heading
 - (f)(2)(iii)
 - (g), introductory text, second sentence
 - 5. Paragraphs (f)(3)(i) and (g)(1) are amended by removing the parenthetical "(if any)" after the words "identifying number".
 - 6. Paragraph (h) is added.
- The revision and additions read as follows:

§ 1.1445-6 Adjustments pursuant to withholding certificate of amount required to be withheld under section 1445(e).

(a) * * * In no event, however, will a withholding certificate be issued without the transferor's identifying number. * * *

(b) * * *
 (3) *Relevant taxpayers.* An application for withholding certificate pursuant to this section must include all of the following information: the name, identifying number, and home address (in the case of an individual) or office address (in the case of an entity) of each relevant taxpayer with respect to which adjusted withholding is sought.

(h) *Effective date for taxpayer identification numbers.* The requirement in paragraphs (b)(3), (f)(3)(i), and (g)(1) of this section that taxpayer identification numbers be provided (in all cases) is applicable for dispositions of U.S. real property interests occurring after November 3, 2003.

* * * * *

§ 1.1445-9T [Removed]

■ 14. Section 1.1445-9T is removed.

PART 301—PROCEDURE AND ADMINISTRATION

■ 15. The authority for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 16. Section 301.6109-1 is amended as follows:

- 1. In paragraph (b)(2)(v), remove the word "and".
- 2. In paragraph (b)(2)(vi), remove the period at the end of the paragraph and add "; and" in its place.
- 3. Paragraph (b)(2)(vii) is added.
- 4. In paragraph (c), first and third sentences, remove the language "or (vi) of this section" and add "(vi), or (vii) of this section" in its place.

The addition reads as follows:

§ 301.6109-1 Identifying numbers.

* * * * *

- (b) * * *
- (2) * * *

(vii) A foreign person whose taxpayer identifying number is required to be furnished on any return, statement, or other document as required by the income tax regulations under section 897 or 1445. This paragraph (b)(2)(vii) applies as of November 3, 2003.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ 17. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ 18. In § 602.101, paragraph (b) is amended by revising the entries for 1.1445-2 and 1.1445-3 to read as follows:

§ 601.601 OMB Control numbers.

* * * * *

- (b) * * *

CFR part or section where identified and described	Current OMB control No.
1.1445-2	1545-0902 1545-1060 1545-1797
1.1445-3	1545-0902 1545-1060 1545-1797
* * * * *	* * * * *

Robert E. Wenzel,
Deputy Commissioner for Services and Enforcement.

Approved: July 9, 2003.

Pamela F. Olson,
Assistant Secretary of the Treasury.
[FR Doc. 03-19273 Filed 8-4-03; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD07-03-098]

RIN 1625-AA08

Special Local Regulations; Race Week Miami Super Boat Race, Miami Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being established for the Race Week Miami Super Boat Race held offshore of Miami Beach, Florida. These regulations restrict the movement of non-participating vessels in the regulated area centered around the race course located in the vicinity of Miami Beach, Florida. These are needed to provide for the safety of life on navigable waters during the event.

DATES: This rule is effective from 11 a.m. EST on September 21, 2003 through 4 p.m. EST on September 21, 2003.

ADDRESSES: Documents indicated in the preamble as being available in the docket, are part of docket [CGD07-03-098] and are available for inspection or copying at Coast Guard Group Miami, 100 MacArthur Causeway, Miami Beach, Florida 33139 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: BMC D. Vaughn, Coast Guard Group Miami, Florida at (305) 535-4317.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM, which would incorporate a comment period before a temporary rule could be issued, would be contrary to public safety interests. Immediate action is needed to minimize potential danger to the public, because there will be numerous spectator craft in the vicinity of the powerboat race.

Background and Purpose

Super Boat International Productions Inc. is sponsoring a high speed power boat race that will take place on September 21, 2003 in the Atlantic Ocean off Miami Beach, Florida. The race organizers anticipate 35 participants and 200 spectator watercraft. The event will take place outside of the marked channel and will not interfere with commercial shipping. Recreational vessels and fishing vessels normally operate in the waters being used for the event. This rule is required to provide for the safety of life on navigable waters because of the inherent danger associated with a power boat race. The rule prohibits non-participating vessels from entering the regulated area offshore of Miami Beach, Florida, during the event. A Coast Guard Patrol Commander will be present during this event to monitor compliance with this regulation.

Discussion of Rule

This rule is required to provide for the safety of life on navigable waters because of the inherent danger associated with a power boat race.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). This rule only temporarily modifies the existing published rule.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities.

The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Atlantic Ocean near Miami Beach, Florida from 11 a.m. until 4 p.m. EST on September 21, 2003. The Coast Guard certifies under U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because commercial and recreational vessels may be allowed to transit through the zone during breaks in the racing.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on action by employees of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132. Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have

determined that it does not have implications for Federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that Order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office

of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34) (h), of the Instruction, from further environmental documentation. A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100, as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.

■ 2. Add temporary § 100.35-T07-098 to read as follows:

§ 100.35-T07-098 Race Week Miami Super Boat Race; Miami Beach, Florida.

(a) *Regulated areas.* (1) The *regulated area* encompasses all waters located within 300 yards of the race course. The course is established around the described positions located offshore of Miami Beach, Florida; (1) 26 06.745" N, 080 06.134" W (2) 26 06.752" N, 080 06.13" W (3) 26 06.079" N, 080 05.926" W (4) 26 06.069" N, 080 06.047" W. All coordinates referenced use Datum: NAD 1983.

(2) A *viewing area* has been established by the Miami Super Boat Race committee by a line parallel to the shore passing through 26 06.738" N, 080 05.594" W. All coordinates reference Datum: NAD 1983.

(b) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by Commanding Officer, Coast Guard Group Miami FL.

(c) *Special local regulations.* Non-participant vessels are prohibited from entering the regulated area unless authorized by the Coast Guard Patrol Commander. Spectator craft may remain in the designated viewing area.

(d) *Dates:* This section is effective from 11 a.m. to 4 p.m. on September 21, 2003.

Dated: July 28, 2003.

F.M. Rosa,

Captain, U.S. Coast Guard, Acting
Commander, Seventh Coast Guard District.
[FR Doc. 03-19901 Filed 8-4-03; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OH155-3; FRL-7539-4]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Oxides of Nitrogen Regulations

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: This action is the conditional approval of the Ohio oxides of nitrogen (NO_x) State Implementation Plan (SIP). This document also contains USEPA's response to the adverse comment from American Electric Power Services Corporation (AEP) sent to USEPA following publication of the original direct final approval of the Ohio NO_x plan on January 16, 2003, which was subsequently withdrawn because of receipt of an adverse comment. USEPA is conditionally approving the Ohio NO_x plan following the receipt of a commitment from the Director of Ohio EPA to change the flow control date in the State plan from 2006 to 2005. On June 25, 2003, Ohio sent a letter to USEPA containing a commitment to take specific enforceable measures by which the flow control date will be changed. These enforceable measures include: timing by which Ohio will begin the public process; timing when the amended rule will be filed with the Joint Committee on Administrative Rule Review; timing of the public hearing; and time span when the amended rule process will be complete. Ohio EPA expects the flow control date in the rule to be changed approximately six months from the date of the commitment letter. USEPA found that the commitment is acceptable and, therefore, USEPA is taking action to conditionally approve the Ohio plan based on the commitment from Ohio to submit the revised rule by

December 26, 2003. We will populate the compliance accounts of units listed in the State's rule after September 4, 2003, so that respective Ohio sources can participate in the NO_x trading program.

DATES: This rule is effective on September 4, 2003.

ADDRESSES: You may obtain a copy of the State Implementation Plan revision request at the address below. Please telephone John Paskevich at (312) 886-6084 if you intend to visit the Region 5 office.

You may inspect copies of Ohio's NO_x submittal and subsequent commitment letter at: Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: John Paskevich, Engineer, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Chicago, Illinois, 60604. E-Mail Address: paskevich.john@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, the terms "you" refer to the reader of this rule and/or to sources subject to the State rule, and the terms "we", "us", or "our" refers to USEPA.

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I. Background

A. What Requirements Led to the State's Submittal of the NO_x Emission Control Plan?

On October 27, 1998, the USEPA promulgated a regulation known as the NO_x SIP Call for numerous States, including the State of Ohio. The NO_x SIP Call requires the subject States to develop NO_x emission control regulations sufficient to provide for a prescribed NO_x emission budget in 2007.

Preceding the promulgation of USEPA's NO_x SIP Call, there had been extensive discussions by federal, state, and local environmental agencies, industry, and environmental groups regarding the transport of ozone in the Eastern United States. The Environmental Council of States (ECOS) recommended the formation of a national workgroup to assess the problem and to develop a consensus approach to addressing the transport problem. As a result of ECOS' recommendation and in response to a March 2, 1995 USEPA memorandum, the Ozone Transport Assessment Group (OTAG) was formed to conduct regional ozone transport analyses and to develop a recommended ozone transport control strategy. OTAG was a partnership among USEPA, the 37 eastern States and the District of Columbia, and industrial, academic, and environmental groups. OTAG was given the responsibility of conducting the two years of analyses envisioned in the March 2, 1995 USEPA memorandum.

OTAG conducted a number of regional ozone data analyses and regional ozone modeling analyses using photochemical grid modeling. In July 1997, OTAG completed its work and made recommendations to the USEPA concerning the regional emissions reductions needed to reduce transported ozone as an obstacle to attainment in downwind areas. OTAG recommended a possible range of regional NO_x emission reductions to support the control of transported ozone. Based on OTAG's recommendations and other information, USEPA issued the NO_x SIP Call rule on October 27, 1998. 63 FR 57356.

In the NO_x SIP Call, USEPA determined that sources and emitting activities in 23 jurisdictions¹ emit NO_x in amounts that "significantly contribute" to ozone nonattainment or

¹ Alabama, Connecticut, Delaware, District of Columbia, Georgia, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, West Virginia, and Wisconsin.

interfere with maintenance of the 1-hour ozone national ambient air quality standards (NAAQS) in one or more downwind areas in violation of Clean Air Act (CAA) section 110(a)(2)(D)(1)(I). USEPA identified NO_x emission reductions by source sector that could be achieved using cost-effective measures and set state-wide NO_x emission budgets for each affected jurisdiction for 2007 based on the possible cost-effective NO_x emission reductions.

The source sectors include nonroad mobile, highway mobile, electricity generating units (EGUs), and major non-EGU stationary point sources. EGUs include stationary boilers and turbines that generate at least some electricity, even if they also generate steam for industrial processes. Non-EGUs include other large stationary boilers and turbines, typically for the purpose of generating steam for industrial processes.

USEPA established recommended NO_x emissions caps for large EGUs (serving a generator whose nameplate capacity exceeds 25 megawatts) and for large non-EGUs (maximum design heat input exceeding 250 mmBTU per hour). USEPA determined that significant NO_x reductions using cost-effective measures could be obtained as follows: application of a 0.15 pounds NO_x/mmBtu heat input emission rate limit for large EGUs; a 60 percent reduction of NO_x emissions from large non-EGUs; a 30 percent reduction of NO_x emissions from large cement kilns; and a 90 percent reduction of NO_x emissions from large stationary internal combustion engines. The 2007 state-wide NO_x emission budgets established by jurisdiction were based, in part, by assuming these levels of NO_x emission controls coupled with NO_x emissions projected by source sector to 2007.

Although the state-wide NO_x emission budgets were based on the levels of reduction achievable through cost-effective emission control measures, the NO_x SIP Call allows each State to determine what measures it will choose to meet the state-wide NO_x emission budgets. It does not require the States to adopt the specific NO_x emission rates assumed by the USEPA in establishing the NO_x emission budgets. The NO_x SIP Call merely requires States to submit SIPs, which, when implemented, will require controls that meet the NO_x state-wide emission budget. The NO_x SIP Call encourages the States to adopt a NO_x cap and trade program for large EGUs and large non-EGUs as a cost-effective strategy and provides an interstate NO_x trading program that the USEPA will

administer for the States. If States choose to participate in the national trading program, the States must submit SIPs that conform to the trading program requirements in the NO_x SIP Call.

B. What Requirements Must Ohio Meet?

The State of Ohio has the primary responsibility under the Clean Air Act for ensuring that Ohio meets the ozone air quality standards and is required to submit a SIP that specifies emission limitations, control measures, and other measures necessary for meeting the NO_x emissions budget. The SIP for ozone must meet the ozone transport SIP Call requirements, must be adopted pursuant to notice and comment rulemaking, and must be submitted to the USEPA for approval.

These NO_x emission reductions will address ozone transport in the area of the country primarily east of the Mississippi River. USEPA promulgated the NO_x SIP Call pursuant to the requirements of CAA section 110(a)(2)(D) and our authority under CAA section 110(k). Section 110(a)(2)(D) applies to all SIPs for each pollutant covered by a NAAQS and for all areas regardless of their attainment designation. It requires a SIP to contain adequate provisions that prohibit any source or type of source or other types of emissions within a State from emitting any air pollutants in amounts which will contribute significantly to nonattainment in, or interfere with maintenance of attainment of a standard by any other State with respect to any NAAQS.

Pursuant to its authority under section 110(k)(5), USEPA concluded that the SIPs for Ohio and other states were substantially inadequate to prohibit NO_x emissions that significantly contribute to ozone nonattainment. As a result, Ohio was required to submit SIP revisions that addressed this inadequacy.

USEPA has published a model rule for control of NO_x emissions from boilers and turbines. This model rule, codified at Title 40 of the Code of Federal Regulations Part 96 (40 CFR part 96), reflects USEPA's recommendations for the general design of the necessary NO_x emission control programs as well as detailed recommendations for specific program features. Similarly, at 63 FR 56393 (October 21, 1998), USEPA has published a proposed Federal implementation plan including rules regulating cement kilns, which serve as sample rules for this source type. USEPA recommends the cost-effective levels of control noted above. The budget that USEPA established for states

reflects these control levels. USEPA further recommends that states take the necessary steps to allow their sources to participate in a multi-state NO_x emissions trading program that USEPA will run. While USEPA offers flexibility to states on various elements of program design, particularly in the distribution of projected emission reductions, USEPA can offer more streamlined approval of programs that more closely follow USEPA's model rule. (See 63 FR 57365)

C. What Have Been the Court Rulings Regarding USEPA's NO_x Emission Control Rule?

When the USEPA published the NO_x SIP Call on October 27, 1998, a number of States and industry groups filed petitions challenging the rulemaking before the United States Court of Appeals for the District of Columbia. The court, on May 25, 1999, stayed the States' obligation to submit SIPs in response to the NO_x SIP Call rule. Subsequently, on March 3, 2000, the court upheld most of USEPA's NO_x SIP Call rule. The court, however, vacated the rule as it applied to Missouri and Georgia, and remanded for further consideration the inclusion of portions of Missouri and Georgia in the rule. The court also vacated the rule as it applied to Wisconsin because the court believed that USEPA had not made a showing that sources in Wisconsin significantly contributed to nonattainment or interfered with maintenance of the ozone NAAQS in any other State. Finally, the court remanded to USEPA two issues concerning a limited portion of the NO_x emission budgets. See *Michigan et al. v. EPA*, 213 F.3d 663 (DC Cir. 2000). On April 11, 2000, based on the remanded issues, USEPA initiated a two phase approach to implement the NO_x SIP Call. Phase I of this approach addressed the portion of the NO_x SIP Call upheld by the court. Phase I will achieve the majority of the reductions in the NO_x SIP Call. The Phase I plan was due from Ohio on October 30, 2000.

Phase II will address the few narrow issues that the DC Circuit court remanded to USEPA, including: how a small subclass of facilities that generate electricity (cogeneration units) should be included in the rule; and what control levels should be assumed for large, stationary internal combustion engines. Phase II of the NO_x SIP Call will not require a submittal from the States until USEPA has proposed and finalized rules in response to the court's remand.

On June 22, 2000, the court removed the stay of the state's obligation to submit SIPs in response to the NO_x SIP

Call and denied petitioner's motions for rehearing and rehearing en banc. In removing the stay, the court provided that USEPA should allow 128 days for States to submit SIPs to the USEPA, *i.e.*, by October 30, 2000. Shortly after removing the stay, petitioners requested that the court adjust the NO_x SIP Call compliance date. In an action related to *Michigan v. EPA*, 213 F.3d 663 (D.C. Cir 2000) the court then determined that the compliance date for the SIP Call would be May 31, 2004. Although the court's action affected only the compliance deadline, other dates in the rule for related requirements (such as flow control) were also extended because they were established relative to the original compliance deadline.

II. Summary of the State Submittal

A. When Was the Ohio EPA NO_x Plan Submitted to the USEPA?

Ohio EPA submitted the NO_x plan on July 11, 2002. USEPA had an opportunity to review and comment on earlier draft versions of the rules during the stakeholder review process. USEPA made both formal and informal comments, and these comments are available in the Docket. The plan was submitted in sufficient time for the USEPA to make a finding of completeness, which terminated the imposition of sanctions which were scheduled to go into effect on July 25,

2002, due to Ohio's failure to submit a plan. The Region 5 Regional Administrator signed the completeness finding on July 24, 2002. (see 67 FR 50600)

B. What Are the Basic Components of the Ohio EPA NO_x Plan?

The Ohio EPA plan includes the following documents: (1) A letter from the Director of Ohio EPA requesting a revision to the Ohio EPA plan; (2) A copy of the rules containing the provisions and requirements to implement a NO_x budget trading program to control and reduce emissions of NO_x in Ohio; (3) A copy of the Ohio code indicating the authority of the Ohio EPA Director to develop and submit the revision; (4) A notice of the proposed rulemaking and public hearing; (5) A transcript of the public hearing on the rules containing comments and testimony; (6) The Ohio Director's Findings and Orders announcing the adoption of rules controlling NO_x from sources in Ohio; (7) A list of Ohio's "interested parties" or stakeholders to whom draft rules were distributed for comment; (8) Summary of comments submitted into Ohio's formal hearing record regarding the proposed rules which establish a NO_x budget trading program in Ohio; and, (9) Ohio's budget demonstration including a list of units (operating or

under construction) subject to the State's NO_x rules.

Ohio's NO_x plan and rules apply to, and establish, a trading program for EGUs, non-EGUs, and portland cement kilns. The rules contained in Chapter 3745-14, establish the provisions and requirements to implement a NO_x budget trading program in Ohio. The net effect of the rules is to cap emissions from major emitters and provide allowances to units to operate within the State's budget during the control period. Allowance allocations are made for five year periods with the exception of the first period, which is for a four-year period.

The State's market-based program which follows the model NO_x budget trading rule is the method selected by Ohio to meet its NO_x emissions reduction obligations under the NO_x SIP Call. The trading program caps total emissions in order to ensure that emissions reductions are achieved and maintained. Also, the flexibility in the State's program allows sources to reduce emissions and where possible, and if desired, generate allowances for trading.

The Ohio EPA plan includes Ohio Rule 3745-14. This trading rule contains eleven separate rule elements, listed in Table 1, which correspond with part 96 model rule of the NO_x SIP Call.

TABLE 1.—COMPARISON OF STATE RULE TO MODEL RULE

Ohio rule 3745-14—	Corresponds with USEPA rule . . .
01, General provisions	Subpart A, Sections 96.1, 96.2, and 96.3 Purpose, Definitions and Abbreviations. 96.4, Applicability. 96.5, Retired unit exemptions. 96.6, Standard requirements. 96.7, Computation of time.
02, NO _x authorized account representative	Subpart B, Section 96.10 . . . the NO _x authorized account representative. 96.11, Alternate NO _x authorized account representative. 96.12, Changing the account representative. 96.13, Account certificate of representation. 96.14, Objections re: NO _x account representative.
03, NO _x budget permit	Subpart C, Section 96.20, NO _x budget permit requirements. 96.21, Submission of NO _x budget permit application. 96.22, Information requirements for NO _x budget permit applications. 96.23, content. 96.25, revisions.
04, Compliance certification	Subpart D, Section 96.30, Compliance certification report. 96.31, State and USEPA's action on compliance certification.
05, NO _x allowance allocations (and Appendix A and B, for EGUs and non-EGUs, for the period from 2004 through 2007).	Subpart E, Section 96.40, NO _x allowance allocations. 96.41, Timing requirements. 96.42 NO _x allowance allocations. 96.55 Banking (Early reduction credit and non-portion of this section).
06, NO _x allowance tracking system	Subpart F, Section 96.50, NO _x allowance tracking system (ATS) accounts. 96.51, Establishment of accounts. 96.52, NO _x ATS responsibilities of NO _x authorized account rep. 96.53, Recordation of NO _x allowance allocations. 96.54, Compliance. 96.55, Banking. 96.56, Account error. 96.57, Closing of general accounts.
07, NO _x allowance transfers	Subpart G, Section 96.60, Submission of NO _x allowance transfers. 96.61, EPA recordation. 96.62, Notification.
08, Monitoring and reporting	Subpart H, Monitoring and Reporting. 96.70, General requirements. 96.71, Initial certification and recertification procedures. 96.72, Out of control periods. 96.73, Notifications. 96.74, Recordkeeping and reporting. 96.75, Petitions. 96.76, Additional requirements to provide heat input data for allocations.

TABLE 1.—COMPARISON OF STATE RULE TO MODEL RULE—Continued

Ohio rule 3745-14—	Corresponds with USEPA rule
09, NO _x budget opt-in units	Subpart I, Individual Unit Opt-ins. Section 96.80, Applicability. 96.81, General. 96.82, NO _x authorized account representative. 96.83, Applying for NO _x budget opt-in permit. 96.84, Opt-in process. 96.85, NO _x budget opt-in permit contents. 96.86, Withdrawal from NO _x budget trading program. 96.87, Change in regulatory status. 96.88, NO _x allowance allocations to opt-in units.
10, Alternative compliance plans	This rule allows a source to participate in alternate multi-pollutant reduction schemes such as the President's Clear Skies proposal.
11, Portland cement kilns	Part 98, subpart B, Emissions from cement manufacturing, proposed rules, October 21, 1998.

Ohio's plan includes opportunities for sources to obtain, beginning in 2006, an allocation for energy efficiency/renewable energy projects. The Ohio rule contains a provision which sets aside one percent of the tons of NO_x emissions in the State trading budget. This set-aside is for units that during the control period reduce end-use demand for electricity or displace electrical energy utilization by use of wind power, solar power, biomass or landfill methane gas generation.

Ohio's plan also sets aside one percent of the trading budget beginning in 2006 for innovative technology projects. This means that an industry can compete for a set-aside, using stationary or mobile source technology

which has not yet been adequately demonstrated in practice but where there is a likelihood that the technology will reduce NO_x emissions and increase energy efficiency.

C. Does the Ohio EPA NO_x Plan Meet the Federal NO_x Statewide Emissions Budget?

Yes, on July 11, 2002, Ohio submitted a plan containing rules in OAC Chapter 3745-14 to respond to USEPA's NO_x SIP Call published in the **Federal Register** on October 27, 1998. We reviewed the plan and found it complete on July 23, 2002. (See 67 FR 50600, dated August 5, 2002)

USEPA's NO_x SIP Call affected sources of NO_x in 22 states (including Ohio) and the District of Columbia. The

NO_x SIP Call rulemaking established statewide budgets for NO_x emissions beginning in the 2003 ozone season (May 1 to September 30). Each state was required to submit a State Implementation Plan (SIP) containing rules necessary to reduce NO_x emissions to the NO_x budget levels.

On March 2, 2000, USEPA published a final rule amending state NO_x budgets (65 FR 11222). Ohio used the information from this final rule to develop its budget. Further, Ohio describes the process it used to develop the budget in the budget demonstration contained in its plan submittal. A summary of the base and budget NO_x emissions contained in this rule for Ohio are provided in table 2.

TABLE 2.—NO_x EMISSIONS BUDGET BY SOURCE CATEGORY
[tons]

2007 Final	Source Category					Total
	EGU	Non-EGU	Area source	Non-Road mobile	Highway mobile	
Base	163,132	50,001	21,860	43,380	94,850	373,223
Budget	48,990	40,194	21,860	43,380	94,850	249,274
Reduction	114,142	9,807	0	0	0	123,949

On November 15, 2000, Ohio informally provided draft rules for preliminary review to stakeholders and USEPA to start the rulemaking process. Ohio received comments on these draft rules from USEPA and twenty-two other interested parties. Ohio's draft rules were revised to take into account the comments received, and the revised draft rules were distributed to interested parties on November 19, 2001. Ohio EPA, again, received comments on these draft rules from USEPA and thirty-eight other interested parties. The rules, to be submitted to Ohio's Joint Committee for Administrative Rule Review (JCARR), were revised again taking into consideration the comments. Ohio believes that these rules will achieve the

NO_x reductions required by USEPA's NO_x SIP Call, and has finalized them for inclusion in its submitted NO_x plan.

The budget projections used to prepare Ohio's submission are the same as the State budget established by USEPA in the final rule published in the **Federal Register** on March 2, 2000 (65 FR 11222). A minor change was made by Ohio EPA and is addressed in the State's submittal. This change corresponds with a technical correction to the Ohio inventory made by USEPA on October 31, 2001 (66 FR 54992).

Ohio's budgets for Area Sources, Mobile Sources and Non-Mobile sources reflect emissions during the ozone control period from May 1 through September 30 for each year. The original

USEPA budgets that Ohio used in its analysis can be found on the electronic file entitled "OH.zip" on USEPA's Web site ftp://ftp.epa.gov/EmisInventory/NOxSIPCall_Mar2_2000. Ohio submitted similar budgets for area, mobile and non-mobile source categories on a compact disk (CD) along with the Budget Demonstration. The CD is available in the Region 5 Docket. Table 3 identifies the 2007 base budgets for these sources and the name of the attached file in which they are found. No NO_x reductions from these source categories (mobile, area, and non-mobile) are projected for Ohio's budget demonstration. Furthermore, Ohio does not believe it is necessary to develop additional NO_x emission reduction

measures to meet the statewide budget during the 5-month ozone season.

TABLE 3.—UNAFECTED SOURCE CATEGORIES
[tons]

Source category	2007 base budget	File name
Area Sources	21,860	OH_ar.wb3
Mobile Sources	94,850	OH_mb.wb3
Non-Road Mobile Sources	43,380	OH_nr.wb3

Table 4 contains the base and final NO_x budget for EGUs. Ohio obtained these data from USEPA Clean Air Markets Division. The file was not part of the technical amendment to the NO_x SIP Call of March 2, 2000 (see 65 FR

11222). The files for EGUs on USEPA's Web site "ftp://ftp.epa.gov/EmisInventory/NOxSIPCall_Mar2_2000" did not contain 2007 base or budget numbers. This file contains information which includes

the base and final budgets for EGUs. Ohio submitted this file (along with other files referenced here) on a CD with the Budget Demonstration. The CD is available in the Region 5 Docket.

TABLE 4.—BASE AND FINAL BUDGETS
[tons]

Source category	2007 base budget	2007 final budget	File name
EGU	163,132	48,990	UT_budget.wb3

Table 5 contains the original budget that USEPA calculated for large industrial boilers (non-EGUs) located in Ohio. The information in Table 5 can be found on USEPA's Web site at "ftp://ftp.epa.gov/EmisInventory/NOxSIPCall_Mar2_2000," in the file entitled "OH_pt.wb3." USEPA modified the original non-EGU budget

because on October 31, 2001, we made a determination (66 FR 54992) that Marathon Ashland Petroleum LLC's Plant 1576000301, emissions unit B015 was not a NO_x budget unit. USEPA's original non-EGU budget was modified to remove eighteen NO_x allowances initially designated for B015 and to add thirty-six tons of uncontrolled NO_x

emissions from B015 to the total budget for this source category. The budget submitted by Ohio EPA reflects these changes and the electronic file reflecting these changes is located on the CD submitted by Ohio in the file entitled "NonEGU Adjusted.wb3."

TABLE 5.—SOURCES REGULATED BY STATE RULES

Source	2007 base budget	2007 final budget	File name
Non-EGUs	50,001	40,194	OH_pt.wb3

The information in Table 6, presents the components of Ohio's NO_x budget for EGUs and non-EGUs.

TABLE 6.—OHIO NO_x BUDGET
[tons]

	EGU		Non-EGU
	2004, 2005	2006 and after	2004 and after
Total for source categories	48,990	48,990	40,194
Non-Regulated Units	3,558	3,558	36,127
Set-Asides	*2,272	**3,181	*203
Allowances available for existing units	43,160	42,251	3,846

*In each year, 5% of the Regulated Units' budget will be set aside to be allocated to new units.

**After 2005, an additional 2% of the EGU Regulated Units' budget will be set aside to fund two set-asides: 1% for Energy Efficiency/Renewable Energy Projects and 1% for Innovative Technology Projects.

USEPA believes the Ohio NO_x sources addressed here, which includes a cap and an allowance trading program, will be adequately controlled to ensure the sources in the State will meet the statewide NO_x budget established by USEPA.

D. What Public Review Opportunities Were Provided?

The Director of the Ohio Environmental Protection Agency " * * * may conduct public hearings on any plans for the prevention, control, and abatement of air pollution that the director is required to submit to the federal government." (Ohio Revised Code Chapter 3704.03, Powers of the director of environmental protections.) Ohio's Director held several meetings early on in the rule development process, shortly after the USEPA promulgated the Finding of Significant Contribution and Rulemaking for the Purpose of Reducing Regional Transportation of Ozone Rule (see 63 FR 57356, dated October 27, 1998). During the course of development, Ohio sent draft rules to stakeholders for review and comment. This process was repeated several times until the State was satisfied it had developed an adequate set of rules and fulfilled the public process. Stakeholders included affected utilities, major heavy industry, environmental groups (both local and national), consultants, industry and manufacturing associations, planning commissions and councils of government, and one university.

A public hearing was held in Columbus, Ohio, on April 11, 2002, and Ohio accepted written comments until April 26, 2002. The transcript of the public hearing is included as part of the State's submittal and can be found in the Docket at Region 5. On January 16, 2003, USEPA published a direct final rule approving the Ohio NO_x plan. An adverse comment was made regarding that publication and USEPA announced to the public the withdrawal of the rule on March 17, 2003. See 68 FR 12590.

On June 25, 2003, Ohio sent to USEPA a letter committing to revise the flow control date. This letter was prompted by discussions between USEPA and Ohio EPA that we would conditionally approve the Ohio plan if the State made a commitment to change the flow control date from 2006 to 2005. Ohio submitted the letter and, therefore, we are taking action to conditionally approve the Ohio NO_x plan.

E. What Guidance Did USEPA Use To Evaluate Ohio's NO_x Control Program?

USEPA used the final NO_x SIP Call rule at 40 CFR part 96 for review of

portions of the Ohio submittal. We also used 40 CFR 51.121 and 51.122 to evaluate Ohio's rules and the plan. The Ohio rules also apply to portland cement kilns. To see USEPA's current position on these types of sources the public can consult USEPA's proposed part 98, dated October 21, 1998 (See 63 FR 56394), which USEPA expects to finalize shortly.

F. Does the Ohio Plan Meet Federal NO_x SIP Call Requirements?

USEPA is satisfied that the Ohio plan meets the requirements of the NO_x SIP Call. Ohio's rules are patterned directly from the USEPA model rule and Ohio EPA included in the rules all of the requirements needed for approval by USEPA. The plan includes a budget trading program, and addresses all of the components of the emissions budget listed in the USEPA technical amendment. Ohio's analysis indicates that additional NO_x control strategies will not be necessary to meet the NO_x budget for the State. USEPA has previously determined, on August 5, 2002, (67 FR 50600) that Ohio had satisfied the requirements for submittal of a complete plan to address NO_x controls on major sources of emission.

G. What Deficiencies Were Noted in the Ohio EPA NO_x Plan?

USEPA found a deficiency in Ohio's submittal regarding the flow control date. In reviewing Ohio's July 11, 2002, NO_x SIP Call submittal, USEPA found that the State's rule requires flow control to apply in 2006. (See OAC Chapter 3745-14-06(E)(6)) The NO_x SIP Call model rule requires flow control to apply in the second year of the program. This means Ohio's rule which like the neighboring States implements the NO_x plan in 2004, should require flow control in 2005, the second year of the NO_x program.

Ohio used the model rule (63 FR 57356, dated October 27, 1998) to develop its plan. The State also used language from elements of the Section 126 rule (65 FR 2674, dated January 18, 2000) in place of some of the language from the model rule. An amendment to the Section 126 rule dated April 30, 2002, (see 67 FR 21522) extended the flow control date to 2006. This one year extension corresponds to the extension of the compliance date noted earlier. While the extension by one year of flow control date to 2006 is appropriate for Section 126, it is not appropriate for Ohio's rule in the NO_x SIP Call. A detailed discussion regarding the difference in the dates for flow control between Section 126 program and the NO_x SIP Call can be found in 65 FR

2674, dated January 18, 2000. We do not expect there will be any States subject to Section 126. All affected States are expected to implement an NO_x SIP Call plan by the compliance date of May 2004. In order for flow control to be universally applied to all sources in the NO_x SIP Call region, the flow control date must be established as no later than 2005 (the second year of the NO_x program) for all of the States in the ozone transport region whose programs begin no later than 2004.

USEPA believes the 2006 date in the Ohio rule is a deficiency which can be addressed by Ohio through the submittal of a letter of commitment to revise the flow control date at the soonest possible time before the NO_x compliance date. Therefore, we are conditioning the approval of the Ohio NO_x plan based on Ohio EPA's submittal of the June 25, 2003 letter committing to change the flow control date from 2006 to 2005. The letter included a list of steps and approximate schedule by which the change to the flow control date will occur.

USEPA also found a deficiency in OAC Chapter 3745-14-09(G)(7) entitled NO_x Budget Opt-in Units. The Ohio rule states that opt-in units that have withdrawn from the program can re-apply for a permit after 2 years. A previous version of the Ohio rule had this time period as 4 years, which is the time period found in both the NO_x SIP Call model rule and the Section 126 rule. The purpose of the 4 year period in the model rule is to discourage these opt-in sources from coming in and out of the budget trading program at a frequency that would be disruptive to the operation of the trading program. USEPA recommends Ohio change this time period from 2 years to 4 years.

H. What Was USEPA's Initial Action Regarding the Ohio Plan?

On January 16, 2003, USEPA published a direct final approval of the Ohio NO_x plan. This approval was made with the understanding that Ohio would change the flow control date to 2005. We also noted that if there were no adverse comments received within the 30-day comment period the rule would be effective within 60 days from the date of publication of the **Federal Register** and USEPA would at that time populate the compliance accounts and sources would be able to participate in the trading process.

I. What Comments Were Received on Ohio's Plan?

AEP submitted a comment which, upon review, USEPA determined to be adverse. We then published a

withdrawal of the January 16, 2003 direct final approval noting that an adverse comment was received and that USEPA would address the concerns and the comments from AEP. The withdrawal was published on March 17, 2003, (68 FR 12590).

The comments from AEP included a letter and an attachment which detailed the following: USEPA's Section 126 rule establishes 2006 as the flow control date for sources subject to that rule and AEP does not believe the change (of the flow control date in the Ohio rule to 2005) is required by any provision of federal law; different flow control dates will exist in different States; and USEPA should make a very limited change to the model budget trading rule to revise the flow control date to 2006. The attachment to the letter addressed the proposed rules for the State of Virginia but, the issue of flow control date is shared by both Virginia and Ohio. The AEP letter also states that it prefers to see the Ohio rule retain the 2006 flow control date in order to retain the value of early reduction credits. AEP noted that it anticipates that the issue can be fully explored in any subsequent rulemaking procedure by Ohio EPA.

III. Response to Public Comment

The NO_x SIP Call includes a limitation (referred to as "flow control") on the use of banked allowances for compliance with the requirement to hold allowances covering emissions from affected units. The NO_x SIP Call requires that second year of the program be the earliest year (referred to as the "flow control date") for which flow control may be triggered. Specifically, the NO_x SIP Call established May 1, 2003, as the commencement date for the NO_x Budget Trading Program and required the flow control provisions to apply starting in the second year (2004). 40 CFR 51.121(b)(1)(ii) and (2)(ii)(E). Subsequently, the United States Court of Appeals for the District of Columbia Circuit established May 31, 2004 as the commencement date for the NO_x Budget Trading Program, and so the second year of the program—and the mandated flow control date for state trading programs starting in 2004—became 2005. While § 51.121 and Part 96 were not revised, USEPA has implemented the new flow control date through the notice and comment rulemakings for approval of the SIPs.

Allowing the use of 2006 as the flow control date (as in the version of Ohio's rule reviewed here) would be contrary to the NO_x SIP Call. The SIP Call requires the flow control provisions to apply starting in the second year of the program. USEPA will not approve this

2006 date and is conditioning approval of Ohio's rule on the change of the flow control date to 2005, the second year of the Ohio NO_x trading program. USEPA is taking this position for several reasons.

1. Allowing 2006 to be the flow control date in Ohio could result in an unfair advantage for units in that state over units in other states with an earlier flow control date. USEPA has approved NO_x Budget Trading Program rules under the NO_x SIP Call for 15 other states and the District of Columbia. None of the approved rules provides for a flow control date later than 2005.² The flow control limitation on use of banked allowances is triggered for an upcoming ozone season if the total amount of banked allowances held in allowance accounts as of the allowance transfer deadline (November 30 or, if it is not a business day, the next business day) for the prior ozone season exceeds 10 percent of the total trading budgets for all state programs for the upcoming ozone season. For the 2005 ozone season, banked allowances held for Ohio's units or by Ohio companies as of November 30, 2004 could be a contributing factor for triggering flow control in 2005 for all states with trading programs that are in effect. If Ohio units were to help trigger flow control in 2005 but would not be subject to the flow control limitation on use of banked allowances in 2005, this would give Ohio units an unfair advantage over units in the other states with a flow control date earlier than 2006.³

² In approving trading program rules for Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, New Jersey, New York, and Rhode Island, USEPA approved flow control dates of 2004. The NO_x SIP Call established May 1, 2003 as the commencement date for the NO_x Budget Trading Program and required the flow control provisions to apply starting in the second year. USEPA's approval of the 2004 flow control date was based on the NO_x SIP Call. (USEPA notes that it erroneously approved 2005 as the flow control date for Pennsylvania, whose program also begins in 2003.) When the United States Court of Appeals made May 31, 2004 the commencement date for the NO_x Budget Trading Program, 2005 became the second year for state trading programs beginning in 2004. USEPA approved 2005 as the flow control date for states (i.e., Alabama, Illinois, Indiana, Kentucky, North Carolina, South Carolina, and West Virginia) whose programs begin in 2004. In addressing whether and, if so, how to apply the NO_x SIP Call to the remaining states in the NO_x SIP Call region, USEPA will address how to handle the flow control requirements and will take into account the problems discussed in this section that would result from some states having later flow control dates than other states.

³ Although USEPA approved several state trading programs with a 2004 flow control date (see n.1), those states will not be disadvantaged by the fact that the other states have a 2005 flow control date. This is because 2005 is the earliest year that flow control is likely to be triggered for states with a 2004 flow control date. For 2004, the calculation for

Further, should a 2006 flow control date be approved for Ohio, this would allow some companies to circumvent the earlier flow control dates established by other states. A company with affected units in both Ohio and a state with an earlier flow control date would be particularly advantaged in this regard. Such a company could circumvent the earlier flow control date by exchanging banked allowances held for its units in the state with the earlier flow control date for 2005 allowances held for its units in Ohio. All of these banked allowances could be used in Ohio in 2005 without application of flow control. However, a company with only units in states with earlier flow control dates could also circumvent, to some extent, the flow control provisions of those states. To the extent that the latter company could purchase 2005 allowances and sell banked allowances, it could also avoid the application of the flow control limitation in 2005. In short, allowing a 2006 flow control date for Ohio would allow erosion of the effectiveness of flow control for states with a flow control date before 2006 and would give an unfair advantage to some companies.⁴

2. The fact that Part 97 in the Section 126 program established 2006 as the flow control date does not support allowing 2006 as the flow control date in Ohio's NO_x SIP Call rule. USEPA first notes that, at the time Part 97 was promulgated, there existed the potential for a number of states to have their units subject to the trading program under Section 126 as well as a number of states to have their units governed by trading programs under the NO_x SIP Call. This was due to uncertainty as to whether all states would be able to establish an approved program under the NO_x SIP Call. While the NO_x SIP Call established statewide NO_x emissions budgets, it allowed states the flexibility to adopt whatever NO_x control measures (including the option of participating in the NO_x Budget Trading Program based on the model rule in Part 96) were shown to meet their respective budgets. The states in

triggering flow control is the total number of banked allowances in accounts as of December 1, 2003 (i.e., only the unused allowances allocated for 2003 plus the compliance supplement pool allowances for those states with trading programs beginning in 2003) divided by the total trading budgets for the states with programs in effect in 2004 (i.e., virtually all states in the NO_x SIP Call region). Because, for this calculation for 2004, the number of states reflected in the numerator is so much smaller than the number of states reflected in the denominator, 2005 is effectively the flow control date for all states whose programs begin in 2003.

⁴ Companies in states with a 2004 flow control date are not similarly disadvantaged by the 2005 flow control date for the remaining states. See n. 2.

the NO_x SIP Call region chose to adopt, or are in the process of adopting, trading programs based on Part 96. As long as a state fully meets its obligations under the NO_x SIP Call, USEPA does not intend to apply the Section 126 rule to units in that state. The existing rule provision withdrawing the Section 126 findings for any state is keyed to the NO_x SIP Call compliance date of 2003. USEPA has already withdrawn the Section 126 findings for Connecticut, Maryland, New Jersey, and New York on that basis. USEPA has proposed to revise the Section 126 rule to withdraw the Section 126 findings for states with a May 31, 2004 compliance date. 65 FR 16644 (Apr. 2, 2003). In short, Part 97 (including the later flow control date of 2006) will likely no longer apply to any states in the NO_x SIP Call region. Only the NO_x SIP Call and Part 96 will likely be applicable.

Moreover, in light of this change in circumstances and upon reconsideration of the discussion in the January 18, 2000 and April 30, 2002 preambles (and echoed in the December 1999 response-to-comments document) for Part 97 concerning the flow control date, USEPA concludes that such discussion is not complete and is no longer applicable. In the January 18, 2000 Part 97 preamble, USEPA stated that it was extending the flow control date to 2005 in response to some sources' concern "regarding the feasibility of installing the NO_x control equipment required * * * without any risk to electricity reliability" and their resulting concern that "there would not be enough allowances for compliance in the initial years of the Federal NO_x Budget Trading Program" under Part 97. 65 FR 2674, 2717 (Jan. 18, 2000). That preamble explained that those concerns had been "heightened" by the triggering of an analogous flow control requirement in the second year of Ozone Transport Commission (OTC) NO_x trading program, the predecessor program in the Ozone Transport Region. *Id.*

However, the basis for any potential need for allowances to supplement the trading budget in the initial years of the NO_x SIP Call and Section 126 trading programs is that some units might experience difficulties in installing NO_x emission controls (e.g., selective catalytic reduction (SCR)) before the commencement of the programs and might need to use additional allowances to cover their emissions in the initial years of the programs until the installations are completed. See 63 FR 57356, 57428-32 (Oct. 27, 1998) (explaining that USEPA addressed these concerns in establishing the compliance

deadline, banking as limited by flow control, and the compliance supplement pool of 200,000 additional allowances). The triggering of flow control in the second year (2000) of the OTC program provides no basis for "heightened" concern that units under the Section 126 program or the NO_x SIP Call program might have difficulties in installing NO_x controls and thus in meeting the compliance deadline. OTC flow control was triggered in 2000 because of the presence of extra allowances (in addition to the amount allocated for 1999) awarded in 1999 for early reductions and because OTC units were able to install sufficient NO_x controls to meet the OTC 1999 compliance deadline. This is demonstrated by: the fact that without the 24,635 early reduction allowances, the bank would not have exceeded 10% of the total trading budget and so would not have triggered flow control;⁵ and the fact that, in 1999, total emissions for units participating in the OTC were less than the total number of regular allowances allocated by states participating in the OTC.⁶ Thus, contrary to the January 18, 2000, Part 97 preamble, the triggering of flow control in 2000 in the OTC program does not provide a logical basis for concluding that there will be a greater level of control-installation difficulties than already addressed in the NO_x SIP Call (which has a 2005 flow control date) and that the flow control date should therefore be extended to 2006 in the Section 126 trading program (or for that matter the NO_x SIP Call trading program).

Further, there is an additional factor that was not considered in the January 18, 2000 and April 30, 2002 Part 97 preambles and that affects the applicability of the preamble rationale for the flow-control-date extension to the NO_x SIP Call. The likelihood of there being insufficient allowances in the initial years of the NO_x SIP Call trading program has been reduced because, in addition to the compliance supplement pool (which was considered in the January 18, 2000 Part 97 preamble and represents about 1/3 of the trading

budget), the availability of allowances in those years has been effectively augmented by U.S. Court of Appeal's extension of the commencement of the program from May 1, 2003 to May 31, 2004. See *Michigan v. EPA*, 213 F.3d 663 (D.C. Cir. 2000), *cert. den.*, 121 S. Ct. 1225 (2001) (August 30, 2000 order amending June 22, 2000 order lifting stay of state's SIP submission deadline). Under the Court's decision, the first year for state trading programs commencing in 2004 includes only 4 months (May 31–September 30, 2004). Despite this, USEPA retained the full ozone season trading budget for 2004 reflecting 5 months of emissions, an effective increase of about 20%.

EPA finds it difficult to see how companies could have reasonably relied on a 2006 flow control date in scheduling installation of controls. First, since 1998, the NO_x SIP Call has called for a 2004 (or 2005, after the Court-mandated compliance date delay) flow control date and every state has been developing, through a public notice and comment procedure, NO_x SIP Call rules aimed at avoiding application of the Section 126 rule with a later flow control date. Second, the January 18, 2000 Part 97 preamble reiterated that the NO_x SIP Call continued to have a 2005 flow control date. See 65 FR 2718. Third, except for Ohio and Virginia, no state's NO_x SIP Call rule used a 2006 flow control date, and the Ohio and Virginia NO_x SIP Call rules with a 2006 flow control date were not promulgated until mid-2002.

Finally, in the January 18, 2000 Part 97 preamble, USEPA stated that a "one-year difference" in flow control dates for sources subject to the NO_x SIP Call and Section 126 trading programs "will not interfere with the trading of NO_x allowances" and that there is "no need to restrict trading between" sources in the two programs. 65 FR 2718; see also 67 FR 21522, 21526 (April 30, 2002). However, neither the January 18, 2000 nor the April 30, 2002, Part 97 preamble considered the problems discussed above that can result from some States having a later flow control date than other States. See discussion in section 1 above. The Part 97 preambles also did not address the issue of consistency with the general objective under the Clean Air Act for expeditious as practicable achievement of attainment. See discussion in section 4, below. In short, the rationale for extending the flow control date stated in the January 18, 2000 Part 97 preamble is not applicable here.

3. Although a 2005 flow control date may have the effect of reducing the value of some allowances in the

⁵ The allowance bank as of November 30, 1999, equaled 43,585 allowances. If the 24,635 early reduction allowances had not been provided, the bank would have been 18,950 allowances, which would have been less than the flow control trigger level of 10% of the 2000 trading budget (i.e., 10% of 195,401 allowances or 19,540 allowances). See 1999 and 2000 OTC NO_x Budget Program Compliance Reports (March 27, 2000 and May 9, 2001).

⁶ Total emissions in 1999 for participating units in the OTC program were 174,843 tons, as compared to a total trading budget in 1999 of 194,103 allowances for participating states. *Id.*

compliance supplement pool if flow control is triggered in 2005, this does not support allowing the Ohio NO_x SIP rule to have 2006 as the flow control date. At the outset, USEPA notes that the compliance supplement pool may be used in the first two years of a state NO_x SIP Call trading program, and the compliance supplement pool allowances are treated as banked allowances for purposes of triggering and applying flow control. 40 CFR 51.121(b)(2)(iii)(D) and (E). While compliance supplement pool allowances in states with trading programs beginning in 2003 or 2004 may be subject to flow control in 2005, a unit has the flexibility to use those allowances for compliance before 2005 in lieu of regular allowances and thereby to avoid application of flow control to the compliance supplement pool allowances. USEPA recognizes, of course, that such a strategy may result in regular allowances (*i.e.*, those allocated for 2003 [in states with programs beginning in 2003] and for 2004) being banked and subject to flow control. However, whether compliance supplement pool or regular allowances are subject to flow control, that result was intended under the NO_x SIP Call.

In the NO_x SIP Call, USEPA noted that banking of allowances may "inhibit or prohibit achievement of the desired emissions budget in a given [ozone] season" since the use of banked allowances for compliance for a specific ozone season may result in total emissions for affected units exceeding the trading budget for that ozone season. 63 FR 25902, 25935 (May 11, 1998). The trading budget reflects the emission reductions mandated, and found to be highly cost effective, under the NO_x SIP Call in order to prevent significant contribution to nonattainment in downwind states. Flow control addresses the potential problem caused by banking by continuing to allow banking but discouraging the "excessive use" of banked allowances for compliance. *Id.*; see also 63 FR 57473. Excessive use of banked allowances is discouraged by requiring that banked allowances above a certain amount be used on a 2-allowances-for-1-ton-of-emissions basis. All other allowances are used for compliance on a 1-for-1 basis.

However, the NO_x SIP Call not only required SIPs to include the flow control provisions, but also required that these provisions apply starting in the second year of the program, which was 2004 in the NO_x SIP Call and which became 2005 for many states after the Court's order delaying the commencement of the trading program.

In short, any reduction in the value of allowances in the compliance supplement pool resulting from a 2005 flow control date results from the intentional curbing under the NO_x SIP Call of excessive use of banked allowances and is not a basis for allowing a 2006 flow control date.⁷

4. USEPA maintains that allowing all states to use 2006 as the flow control date would be inconsistent with the Clean Air Act. The Clean Air Act rests on an "overarching" principle that the national ambient air quality standards (NAAQS) be achieved as expeditiously as possible. 63 FR 57449. For example, under section 181 of the Clean Air Act, the "primary standard attainment date for ozone shall be as expeditiously as practicable but not later than [certain statutorily prescribed attainment dates]." 42 U.S.C. 7511; see also 42 U.S.C. 7502(a)(2)(A). As discussed above, the state trading budgets under the NO_x SIP Call reflect the emission reductions mandated under the NO_x SIP Call in order to prevent significant contribution to nonattainment in downwind states. Flow control reduces the likelihood of total emissions in any given ozone season in the NO_x SIP Call region exceeding the total of the state trading budgets by more than 10% and in that way promotes achievement of attainment as expeditiously as practicable. The later the flow control date, the greater the number of ozone seasons that lack this provision preventing, or at least minimizing, excessive use of banked allowances and total emissions in excess of the state budgets. Moreover, emission reductions in 2005 and 2006 may both help some nonattainment areas achieve attainment and help some areas achieve reasonable further progress toward attainment. 63 FR 57449-50.⁸ The NO_x SIP Call balanced various factors, including the potential benefits of banking and the potential problems from excessive banking, and determined that flow

⁷ USEPA notes that, even with the possibility of triggering flow control in 2005, there is still an incentive to make early reductions and obtain compliance supplement pool allowances since, under flow control, the use of banked allowances for compliance is not barred but rather is on a 2-for-1 basis. Further, in establishing flow control in the NO_x SIP Call, USEPA balanced the considerations for and against flow control, including the impact on early reductions, and determined a 2005 flow control date should be established. As discussed above, USEPA maintains that the determination (and the underlying balancing of these considerations and the underlying rationale) in the Section 126 rule to set a later flow control date are not applicable here.

⁸ USEPA notes that the NO_x SIP Call covers a larger number of states, and its emission limitations are aimed at preventing significant contribution to a larger number of states with nonattainment areas, than the Section 126 rule.

control protection should begin in the second year of the trading program. See 63 FR 25934-44; and 40 CFR 51.121(b)(2)(iii)(D) and (E).⁹ Allowing a later flow control date would run contrary to the overarching objective of expeditious as practicable attainment.

5. If Ohio provides EPA a written commitment to meet the condition for approval of the state's NO_x SIP Call rule, *i.e.*, to adopt a 2005 flow control date within one year of issuance of EPA's conditional approval, EPA will record—as soon as practicable after EPA's conditional approval becomes effective—the allowance allocations provided under Ohio's rule. If it becomes necessary to disapprove the state's rule, EPA will have the options of (1) Applying the Section 126 trading program or (2) adopting a trading program through a federal implementation plan. While the Section 126 trading program currently includes a 2006 flow control date, EPA could establish a 2005 flow control date under a federal implementation plan.

IV. USEPA Action

We are giving conditional approval to the Ohio NO_x SIP because it meets the requirements of the USEPA NO_x trading program by meeting Ohio's NO_x budget. Ohio's rule mirrors the USEPA model rule for the NO_x SIP Call and the State adequately responded to all of the concerns of stakeholders during the public process. Ohio's plan is approved with the condition that Ohio EPA will take action to change the date (the flow control date) in OAC 3745-14-06(E)(6) from 2006 to 2005 and submit the change to USEPA for approval by December 26, 2003. If the flow control date is not changed from 2006 to 2005, and Ohio fails to submit the change as a revision to its plan by December 26, 2003, USEPA will remove the approval of Ohio's NO_x SIP and take subsequent rulemaking action, as necessary. USEPA is publishing this action as a final rule in response to the comment received as a result of the January 16, 2003 final rule which received one comment and the proposed rule (published as a proposal in the event an adverse

⁹ In the January 18, 2000 Part 97 preamble, USEPA stated that adoption of the third year of the program as the flow control date "strikes an appropriate balance" between concerns over the feasibility of installing controls by May 1, 2003 and the environmental goal of the program. 65 FR 2717. This is echoed in the December 1999 response-to-comments document (at 71), which stated that a 2006 flow control date will not "jeopardize the environmental goal of this program." As discussed above, USEPA maintains that the determination (and the underlying balancing of these considerations and the underlying rationale) in the Section 126 rule to set a later flow control date are not applicable here. See, *e.g.*, n.7.

comment was filed) published in the **Federal Register**. The public is advised that this action will be effective September 4, 2003.

Ohio EPA submitted a letter to USEPA on June 25, 2003, which commits to revising the State rule (3745-14-06(E)(6)) which addresses the flow control date. The State committed to change this rule to reflect the year 2005 for flow control. USEPA is, therefore, conditionally approving the NO_x SIP for the State of Ohio. As soon as practicable after September 4, 2003, compliance accounts for the sources subject to the rule will be populated and allowance trading may commence. Within one year of the effective date of the conditional approval Ohio must submit an approved State rule which establishes the flow control date as 2005.

If the State fails to submit the required rule and any supporting documents to USEPA by December 26, 2003, the final conditional approval will automatically convert to a disapproval and USEPA will notify the State to this effect. If the SIP is disapproved, this commitment will no longer be a part of the NO_x SIP. The USEPA will subsequently publish a notice in the notice section of the **Federal Register** indicating that the commitment has been disapproved and removed from the SIP. If the State adopts and submits the final rule amendment as a SIP revision to USEPA, within the six-month period it committed to in the commitment letter (and by December 26, 2003, as noted in this rule), the conditionally approved commitments will remain part of the SIP until USEPA takes final action approving or disapproving the new submittal. If USEPA approves the subsequent submittal, the newly approved rule and supporting documentation will become part of the Ohio NO_x SIP.

If after considering the comments on the subsequent submittal, the USEPA issues a final disapproval or if the conditional approval portion is converted to a disapproval, the sanctions clock under section 179(a) will begin. If the State does not submit and USEPA does not approve the rule on which the disapproval is based within 18-months of the disapproval, the USEPA must impose one of the sanctions under 179(b)—highway funding restrictions or the offset sanction. In addition any final disapproval would start the 24-month clock for the imposition of section 110(c) Federal Implementation Plan.

USEPA is making this conditional approval effective September 4, 2003 and source compliance accounts will be

populated shortly thereafter in order to allow sources subject to the Ohio plan to begin to participate in the trading program.

V. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001).

Regulatory Flexibility Act

This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Order 13175: Coordination With Indian Tribal Governments

This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in

Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

National Technology Transfer and Advancement Act

In reviewing SIP submissions, USEPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for USEPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. USEPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective September 4, 2003.

Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of

this action must be filed in the United States Court of Appeals for the appropriate circuit by October 6, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements.

Dated: July 25, 2003.

Bharat Mathur,

Acting Regional Administrator, Region 5.

■ For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52— [AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart KK—Ohio

■ 2. Section 52.1870 is amended by adding paragraph (c)(128) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(128) On July 11, 2002, the Ohio Environmental Protection Agency submitted revisions to Chapter 3745-14- (1 through 11) of the Ohio Administrative Code (OAC), an oxides of nitrogen (NO_x) budget trading program in Ohio, with a request that the Ohio State Implementation Plan be revised to include these NO_x rules.

(i) Incorporation by reference.

(A) Ohio NO_x rules: 3745-14-01, 3745-14-02, 3745-14-03, 3745-14-04, 3745-14-05, 3745-14-06, 3745-14-07, 3745-14-08, 3745-14-09, 3745-14-10, 3745-14-11 in the OAC all with an effective date of July 18, 2002.

(ii) On June 25, 2003, the Ohio Environmental Protection Agency submitted a letter committing to change the flow control date, in rule 3745-14-06(E)(6) from 2006 to 2005, within approximately 6 months of the effective date of the submittal date.

[FR Doc. 03-19925 Filed 8-4-03; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA206-4212a; FRL-7524-9]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revision to Pittsburgh-Beaver Valley Area Ozone Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Pennsylvania State Implementation Plan. The revisions consist of an amendment to the contingency measures portion of the maintenance plan for the Pittsburgh-Beaver Valley ozone maintenance area. EPA is approving these revisions to Pennsylvania SIP in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on October 6, 2003, without further notice, unless EPA receives adverse written comment by September 4, 2003. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the *Federal Register* and inform the public that the rule will not take effect.

ADDRESSES: Comments may be submitted either by mail or electronically. Written comments should be mailed to Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Electronic comments should be sent either to morris.makeba@epa.gov or to <http://www.regulations.gov>, which is an alternative method for submitting electronic comments to EPA. To submit comments, please follow the detailed instructions described in Part III of the Supplementary Information section. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Avenue NW., Room B108, Washington, DC 20460; Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Kathleen Anderson, (215) 814-2173, or

by e-mail at Anderson.Kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 19, 2001, the Pittsburgh-Beaver Valley ozone nonattainment area was redesignated to attainment of the ozone National Ambient Air Quality Standard (NAAQS) [66 FR 53094]. Subsequent to the re-classification of the Pittsburgh area to attainment, the Sierra Club and the Group Against Smog and Pollution (GASP) filed suit against EPA's action in the U.S. Court of Appeals for the Third Circuit. On January 22, 2003, the U.S. Department of Justice signed an agreement with the litigants, represented by EarthJustice, which called for additions to the contingency measures portion of the Pittsburgh-Beaver Valley Ozone Maintenance Plan.

To address the conditions of the agreement, the Commonwealth amended the maintenance plan for the Pittsburgh area. Per the terms of the January 22, 2003 agreement, the Commonwealth of Pennsylvania submitted a formal revision to its State Implementation Plan (SIP) on April 11, 2003, which identifies additional measures the Commonwealth would take in the event of exceedances of the one-hour ozone NAAQS.

II. Summary of SIP Revision

The revised Pittsburgh area maintenance plan identifies additional measures the Commonwealth would take in the event of exceedances of the one-hour ozone NAAQS. These additional measures include incorporating transportation control measures into the SIP if such measures offer a quantifiable ozone reduction benefit; increasing rule effectiveness of Stage II controls at gasoline stations; the convening of a stakeholder group to recommend additional measures; and proposing additional control measures to attain and maintain the ozone NAAQS in the area. The revised plan also includes a detailed schedule for identification and adoption of additional measures if warranted by ozone exceedances or violations.

III. Final Action

EPA is approving the revised Pittsburgh area maintenance plan submitted on April 11, 2003. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment as this revision is a result of an agreement reached among involved parties of the legal action. However, in the "Proposed

Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the revised Pittsburgh area maintenance plan, if adverse comments are filed. This rule will be effective on October 6, 2003, without further notice unless EPA receives adverse comment by September 4, 2003. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

You may submit comments either electronically or by mail. To ensure proper receipt by EPA, identify the appropriate rulemaking identification number PA206-4212 in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *E-mail.* Comments may be sent by electronic mail (e-mail) to morris.makeba@epa.gov, attention PA206-4212. EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly without going through Regulations.gov, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are

included as part of the comment that is placed in the official public docket.

ii. *Regulations.gov.* Your use of Regulations.gov is an alternative method of submitting electronic comments to EPA. Go directly to <http://www.regulations.gov>, then select "Environmental Protection Agency" at the top of the page and use the "go" button. The list of current EPA actions available for comment will be listed. Please follow the online instructions for submitting comments. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in the **ADDRESSES** section of this document. These electronic submissions will be accepted in WordPerfect, Word or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Written comments should be addressed to the EPA Regional office listed in the **ADDRESSES** section of this document.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

Submittal of CBI Comments

Do not submit information that you consider to be CBI electronically to EPA. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any

information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the official public regional rulemaking file. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public file and available for public inspection without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

Considerations When Preparing Comments to EPA

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate regional file/rulemaking identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small

entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 6, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action to approve revisions to the contingency measures for the Pittsburgh-Beaver Valley ozone maintenance plan may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Volatile organic compounds.

Dated: June 30, 2003.

Thomas C. Voltaggio,
Acting Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart 2020—Pennsylvania

■ 2. Section 52.2020 is amended by adding paragraph (c)(210) to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(210) Revisions to the Pennsylvania Regulations which include amendments to the 2001 Pittsburgh-Beaver Valley ozone maintenance plan submitted on April 11, 2003 by the Pennsylvania

Department of Environmental Protection:

(i) Incorporation by reference.

(A) Letter of April 11, 2003 from the Pennsylvania Department of Environmental Protection transmitting revisions to the Pittsburgh-Beaver Valley ozone maintenance plan.

(B) Amendments to the Pittsburgh-Beaver Valley ozone maintenance plan which add sections E-2 and E-3, effective April 2003.

(ii) Additional Material.—Remainder of the State submittal pertaining to the revisions listed in paragraph (c)(210)(i) of this section.

[FR Doc. 03-19739 Filed 8-4-03; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC-97-200319(w); FRL-7539-8]

Approval and Promulgation of Implementation Plans for North Carolina: Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comment, EPA is withdrawing the direct final rule published June 6, 2003, (*see* 68 FR 33873) approving revisions to the North Carolina State Implementation Plan. The purpose of the revision to rule 15A NCAC 2D.0521 was to provide sources using continuous opacity monitors (COM) the same opportunity to comply with the visible emissions rule as sources that do not use COM devices. EPA stated in the direct final rule that if EPA received adverse comment by July 7, 2003, the rule would be withdrawn and not take effect. EPA subsequently received adverse comment. EPA will address the comment in a subsequent final action based upon the proposed action published on June 6, 2003 (*see* 68 FR 33898). EPA will not institute a second comment period on this action.

DATES: The direct final rule is withdrawn as of August 5, 2003.

FOR FURTHER INFORMATION CONTACT:

Rosymar De La Torre Colón, Air Planning Branch, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Phone number: 404/562-8965; E-mail: delatorre.rosymar@epa.gov.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 25, 2003.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 03-19926 Filed 8-4-03; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[FRN-7539-5]

RIN 2060-AK71

Amendments to Project XL Site-Specific Rulemaking for Georgia-Pacific Corporation's Facility in Big Island, VA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is publishing this site-specific rule to implement a project under the Project eXcellence and Leadership (Project XL) program, an EPA initiative which encourages regulated entities to achieve better environmental results at decreased costs at their facilities. As part of the Project XL program, EPA is supporting a project for Georgia-Pacific Corporation's pulp and paper mill located in Big Island, Virginia. Under the project, Georgia-Pacific will attempt the first United States commercial scale demonstration of black liquor gasification, a new technology for the treatment of black liquor wastes that promises significantly lower air emissions and greater energy efficiency compared to conventional treatment methods. The technology, including its environmental and energy benefits, potentially is transferable to the rest of the pulp and paper industry.

As part of its support for the project, EPA issued a site-specific rule on March 26, 2001 (66 FR 16400) that amended a Clean Air Act hazardous air pollutant standard applicable to the Big Island facility. Those amendments, in part, provided Georgia-Pacific's facility up to an additional three years (from March 13, 2004, to March 1, 2007) to comply with the standard in the event the black liquor gasification system fails and the company must revert to installation of conventional means of controlling

emissions from black liquor treatment. Without the amendments, Georgia-Pacific would not have undertaken the project.

At this time, construction is well underway on the new gasification system. However, Georgia-Pacific has experienced certain, largely unavoidable, delays in construction. The delays have been significant enough that the company now projects starting-up the system about one year later than originally anticipated. As a result, Georgia-Pacific has requested that EPA extend the compliance date flexibility up to one year longer than provided in the original Project XL site-specific rule. After reviewing all information concerning Georgia-Pacific's request, we believe it appropriate to amend the original site-specific rule. This action amends the original compliance extension and allows Georgia-Pacific up to March 1, 2008 to comply with the standard, in the event the gasification system fails.

DATES: This direct final rule will be effective on November 3, 2003 without further notice, unless EPA receives adverse comments by September 4, 2003. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

Public Comments. Comments on this direct final rulemaking must be received on or before September 4, 2003. All comments should be submitted in writing or electronically according to the directions below in the **SUPPLEMENTARY INFORMATION** section.

Public Hearing. Commenters may request a public hearing no later than August 19, 2003. Commenters requesting a public hearing should specify the basis for their request.

If EPA determines that there is sufficient reason to hold a public hearing, it will be held on September 8, 2003, at 10 a.m. Requests to present oral testimony must be made by August 25, 2003.

ADDRESSES: To make comments by mail, send (two) 2 copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. A-2002-0072. Comments also may be submitted electronically, or through hand delivery/courier. Follow the detailed instructions as provided below in I.C. of the **SUPPLEMENTARY INFORMATION** section.

Persons interested in requesting a hearing, attending a hearing, or presenting oral testimony at a hearing

should call Mr. David Beck at (919) 541-5421. If a public hearing is held, it will take place at the Big Island Elementary School, 1114 Schooldays Road, Big Island, Virginia.

FOR FURTHER INFORMATION CONTACT: Mr. David Beck, Office of Environmental Policy Innovation (E-143-02), U.S. EPA, Research Triangle Park, NC 27711. Mr. Beck can be reached at 919-541-5421 (or by e-mail at: beck.david@epa.gov). Further information on today's action may also be obtained on the World Wide Web at <http://www.epa.gov/projectxl/>.

SUPPLEMENTARY INFORMATION:**Outline of Today's Document**

The information presented in this preamble is arranged as follows:

- I. General Information
 - A. Regulated Entities
 - B. How Can I Get Copies Of This Document and Other Related Information?
 - C. How and To Whom Do I Submit Comments?
 - D. How Should I Submit CBI to the Agency?
 - E. What Should I Consider as I Prepare My Comments for EPA?
- II. Authority
- III. Background
 - A. What is Project XL?
 - B. Description of Big Island Facility
- IV. The Georgia-Pacific XL Project
 - A. What Are the Basic Elements of the Project?
 - B. What Is the Construction Status Under the Project?
- V. What Regulatory Change Are We Making To Accommodate the Construction Delay?
- VI. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
 - H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer Advancement Act
 - J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
 - K. Congressional Review Act

I. General Information**A. Regulated Entities**

This amendment to the Pulp and Paper MACT II applies to a single source, the Georgia-Pacific Corporation's pulp and paper facility in Big Island, Virginia.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. A-2002-0072. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost 15 cents per page.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected

from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket. Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in I.C.2 and I.D. below. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. A-2002-0072. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to a-and-r-Docket@epa.gov, Attention Docket ID No. A-2002-0072. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in C.2 below. These electronic submissions will be accepted in

WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send two (2) copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. A-2002-0072.

3. *By Hand Delivery or Courier.* Deliver your comments to: Environmental Protection Agency, EPA Docket Center, 1301 Constitution Avenue, NW., Washington, DC 20004, Attention Docket ID No. A-2002-0072. Such deliveries are only accepted during the Docket's normal hours of operation as identified in A.1.

4. *By Facsimile.* Fax your comments to: (202) 566-1741, Attention Docket ID No. A-2002-0072.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the following address: Environmental Protection Agency, EPA Docket Center (EPA/DC), RCRA Docket, 1301 Constitution Avenue, NW., Washington, DC 20004, Attention Docket ID No. RCRA-2002-0032. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in Summary section above.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and Federal Register citation related to your comments.

II. Authority

This rule is being promulgated under the authority of section 112 of the Clean Air Act, as amended in 1990 (42 U.S.C. 7401, *et seq.*).

III. Background

A. What Is Project XL?

Project XL is an EPA initiative developed to allow regulated entities to achieve better environmental results at less cost. Project XL—"eXcellence and Leadership"—was announced on March 16, 1995 (see 60 FR 27282, May 23, 1995). Detailed descriptions of the Project XL program have been published previously in numerous public documents which are generally available electronically via the Internet at <http://www.epa.gov/projectxl/>. Briefly, Project XL gives a limited number of regulated entities the opportunity to develop their own pilot projects and alternative strategies to achieve environmental performance that is superior to what would be achieved through compliance with current and reasonably anticipated future environmental regulations. These efforts are crucial to the Agency's ability to test new regulatory strategies that reduce regulatory burden and promote economic growth while achieving better environmental and public health protection. The Agency intends to evaluate the results of this and other XL projects to determine which specific elements of the projects, if any, should be more broadly applied to other

regulated entities, for the benefit of both the economy and the environment.

Project XL is intended to allow EPA to experiment with new or pilot projects that provide alternative approaches to regulatory requirements, both to assess whether they provide benefits at the specific facility affected, and determine whether these projects should be considered for wider application. Such pilot projects allow EPA to proceed more quickly than would be possible when undertaking changes on a nationwide basis. EPA may modify rules, on a site- or State-specific basis, that represent one of several possible policy approaches within a more general statutory directive, so long as the alternative being used is permissible under the statute.

On May 31, 2000, EPA's Region 3, joined by the Virginia Department of Environmental Quality (DEQ), the U.S. Department of Agriculture Forest Service, and Georgia-Pacific signed the Final Project Agreement (FPA) for the Georgia-Pacific XL project. A copy of the FPA is available to the public at the EPA Air Docket in Washington, DC (Docket No. A-2000-42), at the EPA Region 3 Library in Philadelphia, and on the Internet at <http://www.epa.gov/ProjectXL/georgia/finalfpa.pdf>. The FPA is a non-binding written agreement between the project sponsor and regulatory agencies which describes the project in detail, discusses criteria to be met, identifies performance goals and indicators, and outlines how the agreement will be managed.

B. Description of Big Island Facility

Georgia-Pacific owns and operates a non-sulfur, non-bleaching pulp and paper mill at Big Island, Virginia. The facility produces two products: corrugating medium, which is used by box manufacturing plants to make the fluted inner layer of corrugated boxes; and linerboard, which is used for the inside and outside layers of the boxes. Corrugating medium is made from secondary (recycled) fiber and hardwood pulp produced using a sodium carbonate/sodium hydroxide based pulping liquor, and linerboard is made from fiber recycled from old corrugated containers, clippings and rejects from corrugated container manufacturing plants, and some mixed office waste paper. Overall, the mill produces an average 870 tons per day of corrugating medium and 730 tons per day of linerboard.

The mill currently handles the spent ("black") liquor from wood pulping operations by reducing liquor water content, using a conventional multiple effect evaporation train, and combusting

the concentrated (about 60 percent solids) liquor in two smelters. Molten smelt is drawn from the smelters and dissolved in water to recover the pulping chemical sodium carbonate. Exhaust gases from the smelters pass through a venturi scrubber and are then discharged to the atmosphere.

IV. The Georgia-Pacific XL Project

A. What Are the Basic Elements of the Project?

The mill currently is subject to two air emission standards. The first was promulgated under Clean Air Act (CAA) section 112, as part of the "Cluster Rule," on April 15, 1998 (63 FR 18617). That rule set standards reflecting performance of maximum achievable control technology (MACT) for hazardous air pollutants (HAPs) emitted by certain emission sources in pulp and paper mills. EPA promulgated a second air standard for pulp and paper mills on January 12, 2001 (66 FR 3179). The second standard, likewise reflecting MACT, specifically addresses HAP emissions from combustion sources associated with the recovery of pulping chemicals from liquid pulping wastes (e.g., black liquor) (40 CFR part 63, subpart MM—National Emission Standards for Hazardous Air Pollutants From Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills or "MACT II"). Georgia-Pacific's facility at Big Island is a semi-chemical pulp mill and its two existing smelters (types of combustion units) are subject to the MACT II rule.

The MACT II rule contains emission limitations, but does not require use of a particular technology to meet the limitations. The current emissions from Georgia-Pacific's two existing smelters at Big Island exceed the HAP emission standard in the MACT II rule. For Georgia-Pacific's Big Island facility to meet the standard, the smelters would have to be upgraded substantially. The age and physical condition of the smelters dictate that they either be rebuilt with additional emission control devices or replaced, such as with a conventional recovery boiler commonly used in the industry. Of these two options, Georgia-Pacific would choose to replace the smelters with a conventional recovery boiler.

However, Georgia-Pacific also investigated, and eventually chose, a third alternative for chemical recovery, replacing the smelters with a PulseEnhanced™, steam reforming black liquor gasification system developed by Stone Chem, Inc. This technology uses steam reforming to

convert the organics in black liquor to a hydrogen-rich gas fuel, leaving the residual pulping chemicals (primarily sodium carbonate) for reuse. The gas can then be used as a clean burning energy source for heat in the gasification unit and as an alternative boiler fuel, replacing fossil-fuel based (non-renewable) natural gas. Implementation of such a gasification system is expected to allow the Big Island facility to reduce emissions well below the MACT II HAP emission standards, and to significantly lower emissions of other criteria pollutants, compared to installation of conventional technology. However, the technology has yet to be commercially demonstrated.

The signatories to the FPA, and the other project stakeholders, believe that gasification of black liquor represents a new and better approach for the chemical recovery process and eliminates many of the deficiencies of the conventional recovery furnace and fluid bed combustion technologies. The benefits of gasification to the paper industry generally are expected to include: increased efficiency in energy conversion and chemical recovery, elimination of the smelt-water explosion hazard, reduced operation and maintenance costs, and significantly lower environmental emissions. The emissions expected to be reduced include: particulates, sulfur dioxide (SO₂), total reduced sulfur (TRS), nitrogen oxides (NO_x), volatile organic compounds (VOC), carbon monoxide (CO), hazardous air pollutants (HAP), and greenhouse gases, specifically carbon dioxide (CO₂). These benefits are particularly attractive to pulp mills such as Georgia-Pacific's at Big Island that use a semi-chemical non-sulfur process that requires auxiliary fossil fuel to sustain combustion of the black liquor. Projected benefits to the Big Island facility and surrounding areas include significant reductions in NO_x, VOC, CO, and particulates.

Although Georgia-Pacific's feasibility analysis indicated the risks of attempting to construct and operate the new technology would be within acceptable limits from a technical standpoint, the company had two other concerns. The first concern was the cost of the project. Estimated costs to complete a black liquor gasification project, the first commercial scale implementation of this technology, were quite high and considerably more than the cost of installing a new conventional recovery boiler. Therefore, Georgia-Pacific sought and has received some co-funding from the U.S. Department of Energy (DOE), which has recognized the technology's potential usefulness.

The second concern involved compliance with the MACT II rule. With this demonstration of a new technology come risks that the technology ultimately will not be successful. If this occurs, Georgia-Pacific's Big Island mill will not have a functioning replacement for the smelters in time to meet the MACT II compliance date, which is March 13, 2004. Therefore, for this XL project EPA committed to undertake a rulemaking to provide temporary relief from the MACT II compliance date for this situation (and also for a defined time period in which Georgia-Pacific will run the new gasification system on black liquor from a Kraft pulp mill, to meet an obligation under their funding agreement with DOE). To fulfill this commitment, EPA promulgated amendments to the MACT II rule on March 26, 2001 (66 FR 16400).

The amendments included a provision to allow the Big Island facility until March 1, 2007, to comply with the applicable performance standard, if Georgia-Pacific's attempt to implement commercial scale black liquor gasification at the Big Island mill fails. The compliance extension, nearly three years later than the otherwise applicable compliance date, was intended to allow Georgia-Pacific time to replace the unsuccessful gasifier with a conventional chemical recovery system.

B. What Is the Construction Status Under the Project?

Proceeding according to the FPA and the original site-specific rule, and after signing a co-funding contract with the Department of Energy (DOE), Georgia-Pacific began final design and construction of the black liquor gasification system in early 2001. Since that time, Georgia-Pacific has spent about 13 million dollars, and has made considerable construction progress. As of the end of December 2002, construction was about 50% complete (see Georgia-Pacific's Web site for current project construction information: <http://www.gp.com/containerboard/mills/big/steam.html>). But Georgia-Pacific also has experienced delays. To begin with, in the FPA Georgia-Pacific agreed to begin construction after signing a contract with DOE. That signing was expected to take place in mid-2000, but did not occur until February 15, 2001. Additionally, Georgia-Pacific encountered several unexpected, significant design issues. For example, control of sulfur emissions from the system was originally based on scrubbing hydrogen sulfide from the product gas using green liquor. This strategy proved infeasible. After

evaluating several alternative hydrogen sulfide scrubbing processes, Georgia-Pacific determined that the best alternative was to control the sulfur compounds after combustion of the product gas, with a sulfur dioxide scrubber. This change required major revisions to process design and equipment layout. In another instance, company reviews turned up several design issues with the pulsed jet heaters; moreover, the designer of the gasification process imposed a new requirement for water cooling certain parts of the pulse heaters. The reliability of the pulsed jet heaters is critical to successful operation of the gasification process, and these issues had to be addressed. Georgia-Pacific also identified several design issues with the reformer vessel and green liquor filtering system. In all, the Georgia-Pacific project team identified over 20 significant changes that had to be made in the design phase to enhance the commercial viability of the system.

The design reviews of the entire system have been completed, all identified issues have been resolved, and, as mentioned, construction is well underway. No further significant design changes are anticipated, and the remaining construction phase should be relatively straightforward. Nonetheless, the delayed start under the DOE contract and the numerous design changes have led to a projected one year delay in the construction and commissioning schedule. Previously, the company expected to be able to start-up the gasification system and determine whether it was a success or failure by March 1, 2004. Now that date is projected as March 1, 2005.

V. What Regulatory Change Are We Making To Accommodate the Construction Delay?

As stated in the FPA and the initial site-specific rule, if the full scale implementation of the gasification system is determined to be unsuccessful, Georgia-Pacific will need three years from that determination to remove the gasification system and install and start-up a conventional recovery boiler to meet the MACT II standard (See 66 FR at 16404). Due to the delays noted above, the determination as to whether the gasification system is successful may now occur as late as March 1, 2005, and the subsequent start-up of the replacement boiler thus may occur as late as March 1, 2008. The current site-specific MACT II rule compliance date for the Big Island mill, in the event of gasification system failure, is March 1, 2007, at the latest. This is a year earlier

than the latest projected startup of a replacement boiler (See 66 FR at 16408). To accommodate the delayed construction schedule, we are amending the MACT II rule to allow the Big Island facility up to March 1, 2008, to comply, in the event the new gasification system is declared a failure. Also amended, to reflect this change in the compliance date, are two notification dates in the "Reporting requirements" section (40 CFR 63.867) of the MACT II rule. We note that any additional compliance extensions are subject to the rulemaking process and the rationale for any extensions will be thoroughly analyzed.

This revised compliance extension relies on the same rationale as the original extension. That is, in the event that the gasification system is declared a failure, the Agency would regard the Georgia-Pacific mill in Big Island, Virginia, as a different type of mill, essentially a member of its own subcategory—a mill that had attempted to recover black liquor through gasification. As a separate subcategory, the Big Island mill would be accorded the statutory 3 year compliance period to install conventional recovery technology to meet the MACT II emission standard. The 3 year compliance period would begin on the day that Georgia-Pacific declares the gasification system a failure. The latest date Georgia-Pacific could declare the system a failure is March 1, 2005, and, thus, the latest date for compliance under the failure scenario is March 1, 2008.

The construction delay has created a second problem with respect to compliance. Georgia-Pacific no longer expects to be able to start up the gasification system before March 13, 2004, as the company originally anticipated before the delays. This date is the ordinary compliance date for the MACT II rule and the one that applies to Big Island's existing smelters until such time, if ever, that Georgia-Pacific declares the gasification system a failure. It is now almost certain that any successful gasification system startup will occur after March 13, 2004. This leaves a period of potentially about a year (from March 13, 2004 to March 1, 2005, at the latest) in which Georgia-Pacific will be working toward gasification system startup, but will occasionally need to operate the smelters. Full capacity startup of the complex gasification system is expected to take several months. As the company is working toward startup, the gasification system may operate intermittently and/or at a reduced capacity as Georgia-Pacific makes equipment or process adjustments and

conducts operational trials. Under these conditions, the existing smelters must operate to treat the black liquor generated by the facility but not being treated in the gasifier. Under current regulations, if by March 13, 2004, the gasification system is not started-up, any such operation of the smelters would violate the MACT II rule emission standard.

To avoid potential noncompliance from smelter operation prior to startup (full time, stable operation) of the gasification system, Georgia-Pacific applied to the Virginia Department of Environmental Quality (the applicable CAA Title V permit-issuing authority) for an extension of the MACT II March 13, 2004 compliance date to March 1, 2005, for the Big Island mill. Under section 112(i)(3)(B) of the Clean Air Act, a source may be granted an extension of an applicable compliance date by up to one year, if the extension "is necessary for the installation of controls." The gasification system constitutes the "control" that will achieve the MACT II emission standard, and the extra time is needed for its installation. On December 16, 2002, and after consideration of the information supplied to them, the Virginia DEQ granted Georgia-Pacific's request for the compliance date extension to March 1, 2005.

We are publishing this rule amendment as a direct final promulgation, effective 90 days after publication, because the action is expected to be non-controversial and not generate negative comment. If we receive negative comment on this action, we will publish a timely withdrawal of these rule amendments. In such a case, we will consider a companion notice found elsewhere in today's *Federal Register* as the proposed rule amendments. We will then consider the comments received and subsequently publish a final agency action.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735), the Agency must determine whether this regulatory action is "significant" and therefore subject to formal review by the Office of Management and Budget (OMB) and to the requirements of the Executive Order, which include assessing the costs and benefits anticipated as a result of this regulatory action. The Order defines "significant regulatory" action as one that is likely to result in a rule that may: (1) Have an annual effect on the

economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Because this rule affects only one facility, it is not a rule of general applicability. It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, since it applies to only one facility. It is exempt from OMB review under the Paperwork Reduction Act because it is a site specific rule, directed to fewer than ten persons. 44 U.S.C. 3502(3), (10); 5 CFR 1320.3(c), 1320.4 and 1320.5.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and public comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. The project sponsor, Georgia-Pacific Corporation, is the regulated entity for this pilot project and is not a small business. This rule does not apply to small businesses, small not-for-profit enterprises, nor small governmental jurisdictions. Further, it is a site-specific rule with limited applicability to only one pulp and paper mill in the nation. After considering the economic impacts of today's final rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments in the aggregate or to the private sector of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of the EPA regulatory proposal with significant Federal mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. As used here, "small government" has the same meaning as that contained under 5 U.S.C. 601(5), that is, governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.

As discussed above, this rule will have limited application. It applies only to the Georgia-Pacific facility in Big Island, Virginia. This direct final rule amendment does not impose any costs on Georgia-Pacific, but rather provides an avenue for the company to commercialize a new technology that will comply with the existing rule. EPA has determined that this rule amendment does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local,

or Tribal governments, in the aggregate, or the private sector in any one year. Thus, this rule is not subject to the requirements of section 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." The phrase, "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, nor on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule amendment will affect one local governmental entity and a State, only shifts a conditional compliance date in the existing rule, and, therefore, has a negligible effect on the State and local governmental entities concerned. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop a process that is accountable to ensure "meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." "Policies that have Tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This rule does not have Tribal implications. It will not have substantial direct effects on Tribal governments, on

the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant," as defined in Executive Order 12886; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to potentially effective and feasible alternatives considered by the Agency.

This rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency believes the environmental health or safety risks addressed by this action do not present a disproportionate risk to children. This rule will allow for the commercialization of a promising new technology that is expected to emit lower levels of hazardous air pollutants compared to the conventional technology currently employed. Therefore, no additional risk to public health, including children's health, is expected to result from this action.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It will not result in increased energy prices, increased cost of energy distribution, or an increased dependence on foreign supplies of energy.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law

104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless such practice is inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, material specifications, test methods, sampling procedures, and business practices) developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking however, does not involve any technical standards; therefore EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898, "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations" (February 11, 1994) is designed to address the environmental and human health conditions of minority and low-income populations. EPA is committed to addressing environmental justice concerns and has assumed a leadership role in environmental justice initiatives to enhance environmental quality for all citizens of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, income, or net worth bears disproportionately high adverse human health or environmental impacts as a result of EPA's policies, programs, and activities. Today's action applies to one facility in Big Island, Virginia, and will have no disproportionate impacts on minority or low income communities. Overall, the project being undertaken at Big Island will, if successful, produce environmental performance superior to that expected through compliance with existing regulations.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular

applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 28, 2003.

Marianne L. Horinko,
Acting Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANT SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart MM—[Amended]

■ 2. Amend § 63.863 by revising paragraph (c)(1) to read as follows:

§ 63.863 Compliance dates.

* * * * *

(c) * * *
(1) If Georgia-Pacific Corporation constructs a new black liquor gasification system at Big Island, VA, determines that its attempt to start up the new system has been a failure and, therefore, must construct another type of chemical recovery unit to replace the two existing semichemical combustion units at Big Island, then the two existing semichemical combustion units must comply with the requirements of this subpart by the earliest of the following dates: three years after Georgia-Pacific declares the gasification system a failure, upon startup of the new replacement unit(s), or March 1, 2008.

* * * * *

■ 3. Amend § 63.867 by revising paragraph (a)(2) to read as follows:

§ 63.867 Reporting requirements.

(a) * * *

(2) Notifications specific to Georgia-Pacific Corporation's affected sources in Big Island, Virginia.

(i) For a compliance extension under § 63.863(c)(1), submit a notice that provides the date of Georgia-Pacific's determination that the black liquor gasification system is not successful and the reasons why the technology is not

successful. The notice must be submitted within 15 days of Georgia-Pacific's determination, but not later than March 16, 2005.

(ii) For operation under § 63.863(c)(2), submit a notice providing: a statement that Georgia-Pacific Corporation intends to run the Kraft black liquor trials, the anticipated period in which the trials will take place, and a statement explaining why the trials could not be conducted prior to March 1, 2005. The notice must be submitted at least 30 days prior to the start of the Kraft liquor trials.

* * * * *

[FR Doc. 03-19919 Filed 8-4-03; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 191, 192, and 195

[Docket Number RSPA-99-6132; Amdt. Nos. 191-15, 192-92, 195-72]

RIN 2137-AD42

Pipeline Safety: Producer-Operated Outer Continental Shelf Natural Gas and Hazardous Liquid Pipelines That Cross Directly Into State Waters

AGENCY: U.S. Department of Transportation (DOT), Research and Special Programs Administration (RSPA).

ACTION: Final rule.

SUMMARY: This final rule addresses the safety regulation responsibility for producer-operated natural gas and hazardous liquid pipelines that cross into State waters without first connecting to a transporting operator's facility on the Outer Continental Shelf (OCS). This rule specifies the procedures by which producer operators can petition for approval to operate under safety regulations governing pipeline design, construction, operation, and maintenance issued by either the Research and Special Programs Administration (RSPA) or the Department of the Interior (DOI), Minerals Management Service (MMS).

DATES: This rule is effective September 4, 2003.

FOR FURTHER INFORMATION: You may contact L.E. Herrick by telephone at (202) 366-5523, by fax at (202) 366 4566, by mail at U.S. Department of Transportation, RSPA, DPS-10, Room 7128, 400 Seventh Street, SW., Washington, DC 20590, or via e-mail to

le.herrick@rspa.dot.gov regarding the subject matter of this notice.

For copies of this notice or other material that is referenced herein you may contact the Dockets Facility by telephone at (202) 366-5046 or at the addresses listed above. The public may also review material in the docket by accessing the Docket Management System's home page at *http://dms.dot.gov*.

SUPPLEMENTARY INFORMATION:

1. Background

Notice of Proposed Rulemaking

On April 5, 2002, RSPA's Office of Pipeline Safety (OPS) published a notice of proposed rulemaking (67 FR 16355) that addressed safety regulation responsibility for producer-operated natural gas and hazardous liquid pipelines that cross into State waters without first connecting to a transporting operator's facility on the Outer Continental Shelf (OCS). This final rule implements that proposal.

In May 1996, MMS and RSPA met with a joint industry workgroup, which was led by the American Petroleum Institute (API). The workgroup suggested that the agencies rely upon individual operators of natural gas and hazardous liquid production and transportation pipeline facilities to identify the boundaries of their respective facilities. MMS and RSPA agreed with the industry proposal and entered into an interagency Memorandum of Understanding (MOU) on December 10, 1996. The MOU was published in a joint MMS/RSPA **Federal Register** Notice (February 14, 1997; 62 FR 7037). The MOU placed, to the greatest practical extent, OCS production pipelines under MMS safety regulation and OCS transportation pipelines under RSPA safety regulation.

The MOU established a regulatory boundary on the OCS at the point operating responsibility for the pipeline transfers from a producing operator to a transporting operator. The MOU did not address regulatory responsibility for producer-operated pipelines that cross the Federal/State boundary without a transfer on the OCS or producer-operated pipelines that flow from wells located in State waters to production platforms located on the OCS.

The purpose of this final rule is to address the regulatory question for producer-operated pipeline facilities that cross the Federal/State boundary without first connecting to a transporting operator's facility on the OCS and to establish a procedure whereby OCS operators may petition to have their pipelines regulated by either

RSPA or MMS. This rule amends 49 CFR 191.1(b)(1), 192.1(b)(1), and 195.1(b)(5).

Regardless of the direction of flow, producer pipelines that cross the Federal/State boundary are always subject to RSPA regulation on the portions of the lines located in State waters. However, it does not make operational sense to have a pipeline segment crossing the Federal/State boundary subject to MMS regulations on the OCS side of the boundary and RSPA regulations on the State side of the boundary. A regulatory boundary point is better defined in terms of a specific valve that isolates one segment of a pipeline from another. By contrast, the Federal/State geographic boundary does not allow the isolation of facilities on each side of the boundary.

Therefore, for producer-operated pipeline facilities that cross into State waters without first connecting to a transporting operator's facility on the OCS, the pipeline segments located upstream (generally seaward) of the last valve on the last production facility are exempted from compliance with 49 CFR Parts 190-199. Safety equipment protecting RSPA regulated pipeline segments are not excluded.

Under this arrangement, producer-operated pipeline facilities upstream (generally seaward) of the last valve on the last production facility on the OCS are regulated under MMS regulations. RSPA/OPS will continue to inspect all upstream safety equipment (including valves, overpressure protective devices, cathodic protection equipment, and pigging devices) that protect the integrity of the RSPA/OPS-regulated pipeline segments. This arrangement is consistent with the general intent of the MOU.

However, an important principle of the industry agreement leading to the MOU is to allow the pipeline operators to decide the regulatory boundaries on or near their facilities. Therefore, producer pipeline operators may petition RSPA/OPS under 49 CFR 190.9 for approval to operate under RSPA/OPS regulations governing pipeline design, construction, operation, and maintenance. In considering such petitions, RSPA/OPS will consult with MMS and affected parties.

This rule affects about 215 producer-operated pipelines that are regulated according to a now-superseded 1976 MOU between DOI and DOT. By exempting the producer-operated pipelines from RSPA/OPS regulation, this rule will reduce overlapping regulation in accordance with the MOU of December 10, 1996. The rulemaking

will have minimal economic impact on any of the affected operators.

Comments

We received one comment on the NPRM. The commenter was concerned that the phrase "[p]ipeline on the Outer Continental Shelf" could cause confusion because it could imply that only the portion of the pipeline on the Outer Continental Shelf was affected, when in fact the paragraph applies to both the pipeline section on the OCS and the section in State waters. In order to clarify that the rule applies to either direction of flow, we have made minor modifications to the language proposed in the NPRM.

Technical Advisory Committees

On February 6, 2001, the proposed rule was discussed at a joint meeting of the Technical Hazardous Liquid Pipeline Safety Standards Committee (THPLSSC) and the Technical Pipeline Safety Standards Committee (TPSSC). These statutorily mandated committees include up to fifteen members each from government, industry, and the general public. Each member is qualified to consider the technical feasibility, reasonableness, cost-effectiveness, and practicability of proposed pipeline safety standards.

The committees voted on the proposal through a mail ballot. Thirteen of fifteen members of the TPSSC and seven out of twelve members of the THPLSSC returned ballots. All ballots returned indicated member agreement that the proposed rule is technically feasible, reasonable, cost effective, and practicable. Copies of the returned ballots are available in the docket for this rulemaking on the Dockets Management System at: <http://dms.dot.gov>.

Privacy Act Statement

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the *Federal Register* of April 11, 2000 (Volume 65, Number 70; Pages 19477-78) or you may visit the docket for this rulemaking in our Dockets Management System at: <http://dms.dot.gov>.

Regulatory Analyses and Notices

A. E.O. 12866 and DOT Regulatory Policies and Procedures

The Department of Transportation (DOT) does not consider this final rule

to be a significant regulatory action under section 3(f) of Executive Order 12866 (58 FR 51735; October 4, 1993). Therefore, it was not forwarded to the Office of Management and Budget. This rule is not significant under DOT's regulatory policies and procedures (44 FR 11034; February 26, 1979). A regulatory evaluation of this proposal was prepared and placed in the docket of this action.

Benefits

Without this rule, the pipeline operations of a number of producers with pipelines crossing directly into State waters could remain subject to overlapping regulations for design, construction, operation, and maintenance. This includes about 35 producers in the Gulf of Mexico OCS waters and 10 producers operating in California OCS waters. This would be contrary to the intent of the MOU to regulate producer-operated pipelines under DOI and transporter-operated pipelines under DOT.

By implementing the rule, RSPA will bring these pipelines into compliance with the 1996 MOU. This should minimize confusion among operators concerning which regulations they are expected to follow. We estimate that each OCS producer operator spends on average one-half of a person year annually per OCS pipeline to comply with RSPA regulations. Assuming that a loaded wage for a person year in the pipeline industry is \$50,000, each company could realize a savings of \$25,000 annually ($\$50,000 \times 0.5$ person-years = \$25,000). The annual savings to the entire industry could be as high as \$1,125,000 ($\$25,000 \times 45$ operators = \$1,125,000).

Costs

The administrative costs of the rule are minimal. Paperwork costs would arise only in cases when a producer pipeline operator decided to request that its pipeline continue to be regulated as a RSPA/OPS facility. We estimate that less than 10 producer pipeline operators will request to remain under RSPA regulation. We estimate that the time for developing each request and submitting it to MMS and RSPA/OPS will be about 40 hours. Based on 10 requests at 40 hours each, the total one-time burden of requesting to remain under RSPA/OPS regulation will be less than 400 hours. Based on \$35 per hour, we estimate that the total administrative cost to respondents is less than \$14,000 (\$1,400 per request) during the first year that the rule is implemented. In the first year, nearly all producer pipeline operators would have decided whether

to automatically convert to MMS regulation or apply to remain under RSPA/OPS regulation. We anticipate that in following years, not more than two operators a year would submit a request to change their regulatory status at a total cost of \$2,800. However, for most following years it is highly unlikely that any request would be made as a result of the rule.

The rule does not have a significant economic effect (more than \$100 million). Therefore, RSPA/OPS does not consider it to be a major rule. We do not expect there to be any increases in costs or prices for consumers, individual industries, Federal, State or local governments, agencies, or geographic regions to result from implementing the rule. Any indirect effects on costs or prices are anticipated to be negligible.

This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, materially alter the budgetary impact of entitlement, grants, user fees, or loan programs; or raise novel legal or policy issues.

The minor economic effects of the rule will not have any impact on competition, employment, investment, productivity, innovation, or on the ability of U.S. based enterprises to compete with foreign based enterprises in other markets. Therefore, a Regulatory Impact Analysis is not required under E.O. 12866.

B. Federalism Assessment

The rule would not have substantial direct effects on States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612 (October 30, 1987; 52 FR 41685), we have determined that this notice does not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) RSPA/OPS must consider whether a rulemaking would have a significant impact on a substantial number of small entities.

MMS conducted an analysis of 150 operators on the Gulf of Mexico OCS. For publicly traded operators, numbers of employees and annual sales are readily available on the Internet. MMS was not able to get information for all operators on the OCS. Using the criterion that a small company is one that employs less than 500 employees, 60 operators are medium-to-large-size

entities. Of the remaining operators, 36 are small, based on available data, and 44 others were presumed to be small because no information about them was available on the Internet. In sum, 80 operators on the Gulf of Mexico OCS may be considered to be small.

The above breakdown describes the OCS sector of the natural gas and hazardous liquid industry as a whole and provides the wider context in which to examine the actual community that would be affected by the rule.

Of the 150 production operators in the Gulf of Mexico, only 35 would be directly affected by the rule. Of these 35 operators, 11 are considered to be "small." There are about ten producer pipeline operators on the Pacific OCS that may be affected by the rule, and four of these are considered to be small. Of the small operators affected by the rule, almost all are represented by Standard Industrial Classification (SIC) Code 1311, which represents crude petroleum and natural gas producers.

The larger operators affected by the rule mostly fall into either SIC Code 1311 (crude petroleum and natural gas producers) or SIC Code 2911, (petroleum refining). Companies operating on the OCS and that fall into SIC Code 2911 tend to be the very large integrated natural gas and hazardous liquid companies.

Two of the larger operators in the Gulf of Mexico that have production pipelines are represented under SIC Code 4922 (natural gas transmission) and by SIC Code 4924 (natural gas distribution). These classifications mean that the operators in question normally operate as pipeline companies, and we anticipate that these two operators will choose to remain under RSPA/OPS regulation. Pipeline companies are considered "small" if they have fewer than 1,500 employees, but both of these operators would be considered "large" under the 1,500-employee criterion.

Natural gas and hazardous liquid production and transportation companies are classified under SIC Codes by the Census Bureau. The Small Business Administration further classifies "small businesses" in the various offshore sectors as follows: (1) Oil and gas producers that have fewer than 500 employees; (2) liquid pipeline companies that have fewer than 1,500 employees; (3) natural gas pipeline companies that have gross annual receipts of \$25 million or less; and (4) offshore oil and gas field exploration service or production service companies that have gross annual receipts of \$5 million or less. There are many companies on the OCS that are "small businesses" by these definitions.

However, the technology necessary for conducting offshore oil and gas exploration and development activities is very complex and costly, and most entities that engage in offshore activities have financial resources disproportionate to their numbers of employees and well beyond what would normally be considered "small business." These entities customarily conduct their operations by contracting with offshore drilling or service companies, and therefore, tend to have few employees in relation to their financial resources.

There are up to 150 designated operators of leases and 75 operators of transmission pipelines on the OCS (both large and small operators), and the economic impacts on the oil and gas production and transmission companies directly affected would be minor. All costs imposed by the rule would be small compared to the normal operating and maintenance expenses experienced by offshore pipeline operators. Direct costs to industry for the entire rule total less than \$14,000 for the first year. This rule would not impose any new restrictions on small pipeline service companies or manufacturers, nor will it cause changes in their business practices.

We conclude that the rule would not have a significant economic impact on a substantial number of small entities. Therefore, I certify, pursuant to section 605 of the Regulatory Flexibility Act (5 U.S.C. 605), that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Executive Order 13084

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 ("Consultation and Coordination with Indian Tribal Governments"). Because this rule affects the Federally managed OCS and does not affect the communities of the Indian tribal governments or impose any direct compliance costs, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Executive Order 13132

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This rule does not propose any regulation that:

(1) Has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government;

(2) Imposes substantial direct compliance costs on States and local governments; or

(3) Preempts state law.

Therefore, the consultation and funding requirements of Executive Order 13132 (64 FR 43255; August 10, 1999) do not apply.

F. Unfunded Mandates

This rule would not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It would not result in costs of over \$100 million to either State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objectives.

G. Paperwork Reduction Act

This rule does not contain information collection requirements estimated to affect more than ten respondents per year.

H. National Environmental Policy Act

We have analyzed this action for purposes of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and determined that this rule would not significantly affect the quality of the human environment. The Environmental Assessment of this proposal is available for review in the docket.

List of Subjects

49 CFR Part 191

Gas, Pipeline safety, Reporting and recordkeeping requirements.

49 CFR Part 192

Hazardous liquid, Natural gas, Pipeline safety, Pipelines, Reporting and recordkeeping requirements.

49 CFR Part 195

Ammonia, Carbon dioxide, Petroleum, Pipeline safety, Reporting and recordkeeping requirements.

■ For the reasons described in this final rule, RSPA/OPS is amending Title 49, Parts 191, 192 and 195, Code of Federal Regulations, as follow:

PART 191—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE; ANNUAL REPORTS, INCIDENT REPORTS, AND SAFETY-RELATED CONDITION REPORTS

■ 1. The authority citation for part 191 continues to read as follows:

Authority: 49 U.S.C. 5121, 60102, 60103, 60104, 60108, 60117, 60118, 60124; and 49 CFR 1.53.

■ 2. Amend § 191.1 by revising paragraph (b) to read as follows:

§ 191.1 Scope.

* * * * *

(b) This part does not apply to—
 (1) Offshore gathering of gas in State waters upstream from the outlet flange of each facility where hydrocarbons are produced or where produced hydrocarbons are first separated, dehydrated, or otherwise processed, whichever facility is farther downstream;

(2) Pipelines on the Outer Continental Shelf (OCS) that are producer-operated and cross into State waters without first connecting to a transporting operator's facility on the OCS, upstream (generally seaward) of the last valve on the last production facility on the OCS. Safety equipment protecting RSPA-regulated pipeline segments is not excluded. Producing operators for those pipeline segments upstream of the last valve of the last production facility on the OCS may petition the Administrator, or designee, for approval to operate under RSPA regulations governing pipeline design, construction, operation, and maintenance under 49 CFR 190.9.

(3) Pipelines on the Outer Continental Shelf upstream of the point at which operating responsibility transfers from a producing operator to a transporting operator; or

(4) Onshore gathering of gas outside of the following areas:

(i) An area within the limits of any incorporated or unincorporated city, town, or village.

(ii) Any designated residential or commercial area such as a subdivision, business or shopping center, or community development.

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE; MINIMUM FEDERAL SAFETY STANDARDS

■ 1. The authority citation for Part 192 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60110, 60113, 60118; and 49 CFR 1.53.

■ 2. Amend § 192.1 by revising paragraph (b) to read as follows:

§ 192.1 Scope of part.

* * * * *

(b) This part does not apply to—
 (1) Offshore gathering of gas in State waters upstream from the outlet flange of each facility where hydrocarbons are produced or where produced hydrocarbons are first separated, dehydrated, or otherwise processed, whichever facility is farther downstream;

(2) Pipelines on the Outer Continental Shelf (OCS) that are producer-operated

and cross into State waters without first connecting to a transporting operator's facility on the OCS, upstream (generally seaward) of the last valve on the last production facility on the OCS. Safety equipment protecting RSPA-regulated pipeline segments is not excluded. Producing operators for those pipeline segments upstream of the last valve of the last production facility on the OCS may petition the Administrator, or designee, for approval to operate under RSPA regulations governing pipeline design, construction, operation, and maintenance under 49 CFR 190.9.

(3) Pipelines on the Outer Continental Shelf upstream of the point at which operating responsibility transfers from a producing operator to a transporting operator;

(4) Onshore gathering of gas outside of the following areas:

(i) An area within the limits of any incorporated or unincorporated city, town, or village.

(ii) Any designated residential or commercial area such as a subdivision, business or shopping center, or community development.

(5) Onshore gathering of gas within inlets of the Gulf of Mexico except as provided in § 192.612; or

(6) Any pipeline system that transports only petroleum gas or petroleum gas/air mixtures to—

(i) Fewer than 10 customers, if no portion of the system is located in a public place; or

(ii) A single customer, if the system is located entirely on the customer's premises (no matter if a portion of the system is located in a public place).

PART 195—TRANSPORTATION OF HAZARDOUS LIQUIDS BY PIPELINE

■ 1. The authority citation for Part 195 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60118; and 49 CFR 1.53.

■ 2. Amend § 195.1 by revising paragraph (b), by removing paragraphs (b)(5) and (b)(6) and by adding new paragraphs (b)(5), (b)(6), and (b)(7) to read as follows:

§ 195.1 Applicability.

* * * * *

(b) This part does not apply to —
 (1) * * *

(5) Transportation of hazardous liquid or carbon dioxide in offshore pipelines in State waters which are located upstream from the outlet flange of each facility where hydrocarbons or carbon dioxide are produced or where produced hydrocarbons or carbon dioxide are first separated, dehydrated,

or otherwise processed, whichever facility is farther downstream;

(6) Transportation of hazardous liquid or carbon dioxide in Outer Continental Shelf pipelines which are located upstream of the point at which operating responsibility transfers from a producing operator to a transporting operator;

(7) Pipelines on the Outer Continental Shelf (OCS) that are producer-operated and cross into State waters without first connecting to a transporting operator's facility on the OCS, upstream (generally seaward) of the last valve on the last production facility on the OCS. Safety equipment protecting RSPA-regulated pipeline segments is not excluded. Producing operators for those pipeline segments upstream of the last valve of the last production facility on the OCS may petition the Administrator, or designee, for approval to operate under RSPA regulations governing pipeline design, construction, operation, and maintenance under 49 CFR 190.9.

* * * * *

Issued in Washington, DC on July 29, 2003.

Samuel G. Bonasso,

Acting Administrator.

[FR Doc. 03-19752 Filed 8-4-03; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 032703B]

RIN 0648-AN79, 0648-AP54, 0648-AP55

Fisheries Off West Coast States and in the Western Pacific; Pelagic Fisheries, Amendment 8; Crustacean Fisheries, Amendment 10; Bottomfish and Seamount Groundfish Fisheries, Amendment 6; Precious Corals Fisheries, Amendment 4

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of agency decision.

SUMMARY: NMFS announces the approval of four supplemental amendments to Amendment 4 to the Fishery Management Plan (FMP) for the Precious Coral Fisheries of the Western Pacific Region (Amendment 4); Amendment 6 to the FMP for the Bottomfish and Seamount Groundfish Fisheries of the Western Pacific Region (Amendment 6); Amendment 8 to the

FMP for the Pelagic Fisheries of the Western Pacific Region (Amendment 8); and Amendment 10 to the FMP for the Crustacean Fisheries of the Western Pacific Region (Amendment 10). The supplemental amendments make the four FMPs consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), as amended by the Sustainable Fisheries Act of 1996 (SFA).

DATES: This agency decision is effective July 3, 2003.

ADDRESSES: Copies of the supplemental FMP amendments, including the Environmental Assessment may be obtained from Ms. Kitty Simonds, Executive Director, Western Pacific Regional Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Paul Dalzell, Western Pacific Fishery Management Council, at 808-522-8220.

SUPPLEMENTARY INFORMATION: On July 3, 2003, NMFS approved supplemental amendments to FMP Amendment 4, Amendment 6, Amendment 8, and Amendment 10 to address portions of previously submitted amendments that were disapproved by NMFS in 1999 because of inconsistency with the Magnuson-Stevens Act, as amended by the SFA. Generally, the amendments pertain to overfishing definitions and control rules for the bottomfish and seamount groundfish, pelagics, and crustacean FMPs; bycatch provisions for fisheries operating under the bottomfish and seamount groundfish and pelagic FMPs; and definitions for "fishing communities" in Hawaii under the bottomfish and seamount groundfish, pelagics, crustaceans, and precious corals FMPs. The supplemental FMP amendments do not revise the existing management regime; therefore, rulemaking is not required. Additional background information may be found in the preamble to the Notice of Availability for the supplemental FMP amendments (68 FR 16754, April 7, 2003) and is not presented here.

Comments and Responses

Comment 1: NMFS received comments urging the Secretary of Commerce to enforce the conservation measures in the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve).

Response: The supplemental FMP amendments do not contain management measures that affect management of the Reserve. The specification of status determination criteria for overfishing established for

the four FMPs governing the fisheries in the western Pacific region, including American Samoa, Guam, Hawaii, and the Commonwealth of the Northern Mariana Islands, do not have an impact on Executive Order 13178 and Executive Order 13196, which created the Reserve. These criteria, which are consistent with NMFS' national guidelines, do not in themselves require that fishing take place or that it takes place at any particular level. NMFS recognizes that the Executive Orders are currently in effect, including Reserve Preservation Areas and certain other conservation measures that either completely prohibit fishing or allow fishing in accordance with restrictions that are applicable in the Reserve.

Comment 2: One commenter stated that the supplemental amendments provided incorrect information about the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, specifically that they quoted Section 7(a)(1)(C) of Executive Order 13178 while failing to note that section had been revised by Executive Order 13196, giving it a different meaning.

Response: NMFS concurs that the supplemental FMP amendments could provide a better description of the Executive Orders. Clarification is provided here. Consistent with Executive Order 13196, Section 7(a)(1)(C) of Executive Order 13178 specifies that:

"(C) The annual level of aggregate take under all permits of any particular type of fishing may not exceed the aggregate level of take under all permits of that type of fishing as follows:

(1) Bottomfishing the annual aggregate level for each permitted bottomfisher shall be that permittee's individual average taken over the 5 years preceding December 4, 2000, as determined by the Secretary, provided that the Secretary, in furtherance of the principles of the reserve, may make a one-time reasonable increase to the total aggregate to allow for the use of two Native Hawaiian bottomfishing permits;

(2) All other commercial fishing the annual aggregate level shall be the permittee's individual take in the year preceding December 4, 2000, as determined by the Secretary.

Comment 3: One commenter stated that the overfishing criteria specified in the crustaceans FMP are not consistent with the Executive Orders establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, specifically Section 7(a)(1)(C) of Executive Order 13178. The commenter believes that the proper interpretation of that section is that lobster fishing is prohibited within the Reserve, and

recommends that the discussion of overfishing and control rules for the commercial lobster fishery be removed from the supplemental amendments unless it is clear that they pertain only to areas outside the Reserve.

Response: The preferred alternative of status determination criteria in the supplemental FMP amendments do not introduce any inconsistencies or conflicts with the Executive Orders that established the Reserve. These criteria do not in themselves mandate that commercial lobster fishing take place or that it takes place at any particular level. They only describe how overfishing would be defined, as expressed in terms of the two thresholds: the minimum stock size threshold and the maximum fishing mortality threshold. These definitions are consistent with NMFS' national guidelines.

Comment 4: One commenter stated that the environmental assessments for the three supplemental FMP amendments did not consider a wide enough range of alternatives with respect to the overfishing criteria (including alternative proxies that could be used in those criteria) and the target and rebuilding control rules and associated reference points.

Response: The preferred alternative (control rules and thresholds) in the supplemental FMP amendments is scientifically sound and consistent with the applicable guidelines. NMFS scientists assisted the Council in developing status determination criteria (overfishing definitions), guided by the "Technical Guidance on the Use of Precautionary Approaches to Implementing National Standard 1 of the Magnuson-Stevens Fishery Conservation and Management Act." (NOAA Technical Memo NMFS-F/SPO-31, August 1998). NMFS recognizes that relatively few alternatives were considered, but finds that the range was adequate given the number of reasonable alternatives that were available. That number is relatively small because of the limited data that are available for the stocks. For example, in the case of the Bottomfish and Seamount Groundfish FMP, for which the commenter was specifically concerned about the failure to consider alternative proxies other than catch-per-unit-effort (CPUE), the data-poor nature of the stocks in much of the region means that very few proxies for biomass other than CPUE would be practical.

Comment 5: One commenter stated that a programmatic environmental impact statement on the associated fisheries should be prepared in order to ensure that, in the face of existing uncertainties, the fishery management

regimes for these fisheries are conducted in an environmentally sound manner.

Response: A final environmental impact statement (FEIS) for the Fishery Management Plan for the Pelagic Fisheries of the Western Pacific Region was completed in March 2001. A supplemental pelagic fisheries EIS has been proposed to cover additional issues, such as the potential development of a pelagic squid fishery based in Hawaii. Draft EISs for the Council's Bottomfish, Crustaceans, and Precious Corals Fishery Management Plans are either under review by NMFS or under preparation. NMFS will consider the need for a programmatic EIS apart from these supplemental amendments.

Comment 6: One commenter stated that the definitions of "overfished" and "overfishing" should be broadened to account for adverse effects from ecosystem overfishing and control rules and other management procedures should be developed that require consistent, rigorous, and systematic evaluation of potential adverse effects of fishing activities.

Response: The recommendation to expand the definitions of "overfished" and "overfishing" is acknowledged, but these supplemental FMP amendments are not the appropriate place to implement such changes. In NMFS' National Standard Guidelines, stock or stock complex is used synonymously for "fishery"; that is, as one or more stocks of fish that can be treated as a unit for the purposes of conservation and management and that are identified on the basis of geographic, scientific, technical, recreational, or economic characteristics. The guidelines make the terms operational by requiring that FMPs specify, to the extent possible, objective and measurable status determination criteria, including control rules, for each stock or stock complex. The criteria must specify both a maximum fishing mortality threshold (MFMT) and a minimum stock size threshold (MSST), or reasonable proxies thereof. NMFS finds that the supplemental FMP amendments satisfy these requirements.

Comment 7: One commenter stated that the supplemental amendments do not include a suitable discussion of seamount groundfish species; specifically, what it means exactly that armorhead will serve as an indicator species for the other seamount groundfish species.

Response: Seamount groundfish management unit species in the Fishery Management Plan for Bottomfish and Seamount Groundfish Fisheries of the

Western Pacific Region (Bottomfish FMP) include only alfonsin (*Beryx splendens*), raftfish (*Hyperoglyphe japonica*), and armorhead (*Pseudopentaceros richardsoni*), and of these three species armorhead dominated the historical catch by number, weight, and value. Armorhead is the primary target species in this fishery, which has been closed since 1986. Regarding indicator species, NMFS will manage this fishery on the basis of established reference points for the armorhead (indicator species or key target species) and, to the extent possible, manage the other minor species based on the indicator species.

Comment 8: One commenter stated that using a single natural mortality rate of 0.3 for the entire bottomfish species complex would likely be inaccurate for many of the species; additional alternatives should be considered.

Response: The supplemental FMP amendments for the bottomfish FMP specify that a single natural mortality rate (M) will be used to assess the status of multi-species stock complexes in cases where individual species cannot be assessed, but it does not specify that a natural mortality rate of 0.3 will be used. Instead, the latest available estimate will be used, and the range of M among species within a stock complex will be taken into consideration.

Comment 9: Several commenters questioned the use of multi-species complexes. One commenter stated that individual species should not be combined into complexes for the purpose of allowing fishing on those complexes or assessing the effects of fishing on them. One commenter stated that the use of the mixed stock exception in the national standard guidelines is an inappropriate manner in which to manage marine fish species, that it is contrary to the requirements of the Magnuson-Stevens Act, and that it should not be considered in the amendments. One commenter stated that consideration should be given to breaking down the bottomfish complex into at least three components based on families or other applicable subdivisions as an interim step towards generating individual species status determination criteria.

Response: The overfishing criteria and control rules will be applied to individual species whenever possible, and only where it is not possible will they be applied to indicator species or multi-species complexes. The fishery that targets the bottomfish species complexes fishes simultaneously for many different species. Although catch data by species are available, NMFS

does not have fishing effort data on a species-by-species basis. Since fishing effort cannot be partitioned among the various species, a multi-species approach to the overfishing assessment will be used, consistent with the National Standard Guidelines.

Comment 10: One commenter stated that the supplemental amendment for bottomfish and seamount groundfish provides an unclear definition of the minimum stock size threshold (MSST); specifically, no information is given to clarify the meaning of the phrase " $c = \max(1-M, 0.5)$."

Response: In the specifications of the MSST and MFMT, c is a scaler that modifies B_{msy} . The phrase " $c = \max(1-M, 0.5)$ " means that c is equal to whichever is greater, $1-M$ or 0.5 , where M is the natural mortality rate or instantaneous natural mortality rate. If M is greater than or equal to 0.5 , then c is equal to 0.5 ; if M is less than 0.5 , then c is equal to $1-M$.

Comment 11: One commenter stated that the supplemental amendments need to specify objective and measurable status determination criteria, not merely a framework for doing so.

Response: NMFS finds that the supplemental FMP amendments do more than establish a framework for specifying objective and measurable status determination criteria; they actually specify those criteria, including the MSST and the MFMT, and they do so largely following the default recommendations in NMFS' "Technical Guidance on the Use of Precautionary Approaches to Implementing National Standard 1 of the Magnuson-Stevens Fishery Conservation and Management Act."

Comment 12: One commenter stated that for the pelagic stocks, since the fishing mortality rate associated with maximum sustainable yield (F at MSY), the biomass associated with MSY (B at MSY), and the natural mortality rate (M) can be directly estimated for some species, the supplemental amendments should state where this information is available and propose a range of values for public consideration.

Response: Although M, F at MSY, and B at MSY have been estimated and are currently available for some of the pelagic stocks, the Council has determined that rather than specifying such values in the Pelagics FMP and treating them as constants, the preferred method is to use the best available estimate of each of them at the time of a given assessment. NMFS agrees that this is a sound approach, both because they are in fact variables that are subject to change and because our ability to

estimate them is likely to improve with time. The latest available values will be published in the Stock Assessment and Fishery Evaluation report, which for the pelagics fisheries is the Council's Annual Report on Pelagic Fisheries in the Western Pacific. To give an idea of the range of values that is likely to be used in the assessments, the supplemental FMP amendments refer to previous estimates that have been made.

Comment 13: Several commenters stated that the supplemental amendments should include additional information on stock status; methods of assessment, including a discussion of the methodologies to be used in estimating biomass for the crustacean stocks; potential sources of error, bias, and uncertainty; and the potential consequences of such information (or lack thereof) on management of fisheries at low stock levels.

Response: The supplemental FMP amendments do not provide detailed information regarding available information on stock status; methods of assessment (including assessment of biomass for crustacean stocks); potential sources of error, bias, and uncertainty; and the potential consequences of such information on management of fisheries at low stock levels. The supplemental amendments focus on establishing a control rule framework within which stock assessments would be performed rather than describing the operational aspects of stock assessment. By prescribing assessment methods and information sources in only general terms, the supplemental amendments implicitly allow flexibility in those methods and information sources. As stated in the supplemental FMP amendments, the best available information will be used in the stock assessments. The sources of error, bias, and uncertainty associated with a given assessment will be identified and evaluated to the extent necessary at the time of the assessment, as will their implications in terms of the overfishing thresholds and other reference points and the possible need for management action, as prescribed by the control rules.

Comment 14: Several commenters questioned the use of catch-per-unit-effort (CPUE) as a proxy in the status determination criteria. One commenter stated that the various sources of bias related to CPUE make its use as a measure of fishing mortality rate and stock biomass unacceptable, and that before any fisheries on these stocks are initiated or expanded, NMFS should develop reliable methods for assessing stock status and fishing mortality rate. One commenter stated that the

supplemental amendments for the bottomfish and pelagics FMPs should include a full discussion of the use of CPUE as a proxy for status determination criteria, including how it will be estimated, how CPUE or fishing effort will be used to estimate an unfished biomass, optimum yield (OY) or MSY level, how the use of CPUE will avoid the pitfalls or make the adjustments presented in the Technical Guidance, and consideration of alternative proxies.

Response: NMFS agrees that using CPUE as an indicator of stock biomass is associated with some uncertainty and biases. However, the same is true with all stock assessment methods; there is no practical way to directly measure stock biomass. As indicated in the supplemental FMP amendments, the CPUE estimates will be standardized for all identifiable biases, as will the fishing effort estimates that will be used as proxies for fishing mortality.

Comment 15: One commenter stated that because the supplemental amendments for bottomfish and seamount groundfish and for pelagics do not specify an OY and the supplemental amendment for crustaceans does not specify a biomass at the OY level, the supplemental amendments are inconsistent with the requirements of the Magnuson-Stevens Act and the National Standard Guidelines.

Response: OY has already been specified in each of the FMPs (bottomfish/seamount groundfish, precious corals, crustaceans, and pelagics). The supplemental FMP amendments for the bottomfish and pelagics fisheries do not modify the existing specifications; that is, they do not specify target controls rules that would be associated with those OY specifications. The Council has determined that it would be preferable to continue to manage the fisheries using the existing qualitative OY specifications rather than specifying new OY control rules and associated reference points (e.g., that would be expressed in terms of target harvest levels, target fishing mortality, or target biomass). One reason cited is the lack of information available to quantitatively determine OY and its associated fishing mortality rate with any useful degree of precision. Because of that lack of information, specification of a target control rule could unnecessarily constrain the FMPs' existing definitions of OY. The Council has determined that it would be preferable not to specify an OY control rule at this time rather than to specify one that is likely to be poorly related to actual OY. Although NMFS

finds that the specification of OY control rules can, in some cases, be useful in satisfying the objectives associated with National Standard 1, especially for fisheries in which the relevant social, economic, and ecological factors can be readily identified and measured, they are not necessary and are not always appropriate. NMFS finds that the existing specifications of OY in the bottomfish and pelagics FMPs satisfy the requirements of the Magnuson-Stevens Act.

Comment 16: One commenter stated that the supplemental amendment for the crustaceans FMP provides no information on how biomass (B) will be computed, so it is not possible to analyze the interplay of the coefficient r , which is a fishing mortality rate that would yield a 10-percent risk of the Spawning Potential Ratio (SPR) reaching as low as 20 percent, in the target control rule. There is also insufficient information to analyze the precautionary nature of the target control rule. With no information provided on the MFMT, it is impossible to tell how the target control rule operates. There is no information explaining or justifying the appropriateness of a 20 percent SPR level to serve as a threshold for recruitment overfishing, a level that was established in 1990, in light of the new 1996 requirements of the Magnuson-Stevens Act and its accompanying guidance.

Response: In this case, the target control rule is directly associated with Optimum Yield, the target yield under the Magnuson-Stevens Act. The OY target reference points are a function of M , B , and B at MSY and are precautionary in the sense that they are MSY reference points (i.e., F_{msy}), scaled to account for social and economic factors, as well as biological, environmental, and model parameter uncertainty. The coefficient r , as specified in the control rule (see; Supplemental FMP Amendments on Overfishing Provisions on Page 56, Section 4.3, Fig. 6), is equivalent to $F_{risk-averse}/F_{msy}$. $F_{risk-averse}$ is defined as the fishing mortality that results in a 10-percent chance of the SPR falling below 20 percent, based on a risk-averse stock assessment model. Because of the risk-averse nature of the assessment model, $F_{risk-averse}$ is assumed equivalent to the optimum fishing mortality, F_{OY} , and less than F_{msy} . The current assessment model assumes higher than estimated levels of process and measurement error, as well as conservative estimates of demographic parameters, which when considered together, represent a

worst-case scenario (DiNardo, G.T. and J.A. Wetherall, 1999, "Accounting for Uncertainty in the Development of Harvest Strategies for the Northwestern Hawaiian Islands Lobster-trap Fishery", ICES J. Mar. Sci., 56:943-951). Additional sources of error or uncertainty that influence $F_{\text{risk-averse}}$ and ultimately r , could be easily incorporated using this approach.

Comment 17: One commenter stated that the supplemental amendments fail to consider a broad range of bycatch minimization alternatives and bycatch reporting alternatives.

Response: NMFS agrees that a large number of bycatch minimization tools and bycatch reporting tools exist, and that not all such tools were considered in the supplemental FMP amendments. Some were not considered because they are already being implemented under the existing management regime, as described in sections 4.1 and 4.2 of the supplemental amendment document for bycatch provisions. A relatively small number of alternatives that focused on those areas were then considered. Discussion of the reasons for eliminating alternatives from the broader pool of potential alternatives would have been desirable. However, NMFS finds that the range of alternatives considered is adequate given the existing bycatch patterns and bycatch reporting methodologies in the affected fisheries. The agency recognizes that achieving consistency with the bycatch-related provisions of the Magnuson-Stevens Act is an ongoing process that will require periodic identification of areas in which bycatch might be further reduced and bycatch reporting might be further improved, followed by consideration of a range of reasonable alternatives for each of those areas.

Comment 18: One commenter stated that the supplemental amendments fail to provide bycatch minimization and assessment measures that are consistent with the requirements of the Magnuson-Stevens Act, in part because some of the measures would be implemented only at the discretion of NMFS or the Council.

Response: A central purpose of the supplemental FMP amendments is to describe the existing situation with respect to bycatch patterns, bycatch minimization measures, and bycatch reporting measures. NMFS finds that the supplemental amendments accomplish this purpose. The amendments also serve the purpose of identifying weaknesses in the bycatch reporting systems and identifying areas in which bycatch or bycatch mortality might be successfully further reduced. However, identification of such weaknesses and

areas for improvement does not in itself mean that management action is required. The need to minimize bycatch and bycatch mortality and to establish a standardized bycatch reporting methodology must be balanced against other requirements of the Magnuson-Stevens Act, including the need to achieve OY (National Standard 1), the need to consider efficiency in the utilization of fishery resources (National Standard 5), and the need to minimize costs (National Standard 7). For similar reasons, the fact that some of the management actions under the preferred alternative will be taken at the discretion of the Council and/or NMFS does not mean that the actions are inconsistent with National Standard 9. NMFS finds that the existing bycatch-related management measures in the bottomfish and pelagics FMPs, combined with the additional actions that would be taken under the supplemental amendments, which include outreach to fishermen, research into fishing gear and method modifications, research into market development for discarded species, and improvement of information systems, satisfy the requirements of the Magnuson-Stevens Act. At the same time, NMFS recognizes the need to continue to reduce bycatch and bycatch mortality, and to continue to improve, where cost-effective, the standardized bycatch reporting methodologies.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 31, 2003.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 03-19932 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 021122286-3036-02; I.D. 073003A]

Fisheries of the Exclusive Economic Zone off Alaska; Pelagic Shelf Rockfish in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for pelagic shelf rockfish in the

Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2003 total allowable catch (TAC) of pelagic shelf rockfish in this area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 31, 2003, through 2400 hrs, A.l.t., December 31, 2003.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2003 TAC of pelagic shelf rockfish for the Central Regulatory Area was established as 3,480 metric tons (mt) by the final 2003 harvest specifications for groundfish in the GOA (68 FR 9924, March 3, 2003).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2003 TAC for pelagic shelf rockfish in the Central Regulatory Area will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,450 mt, and is setting aside the remaining 30 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for pelagic shelf rockfish in the Central Regulatory Area of the GOA.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the 2003 TAC for pelagic shelf rockfish in the Central Regulatory Area of the GOA, and therefore reduce the public's ability to use and enjoy the fishery resource.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 30, 2003.

Bruce C. Morehead

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 03-19927 Filed 7-31-03; 2:59 pm]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 021212307-3037-02; I.D. 073003B]

Fisheries of the Exclusive Economic Zone Off Alaska; Greenland Turbot in the Bering Sea Subarea of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for Greenland turbot in the Bering Sea subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2003 total allowable catch (TAC) of Greenland turbot in this area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), August 2, 2003, until 2400 hrs, A.l.t., December 31, 2003.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and CFR part 679.

The 2003 TAC of Greenland turbot in the Bering Sea subarea was established by the final 2003 harvest specifications for groundfish in the BSAI (68 FR 9907, March 3, 2003) as 2,278 metric tons (mt). See § 679.20(c)(3)(iii).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the TAC for Greenland turbot in the Bering Sea subarea will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,278 mt, and is setting aside the remaining 1,000 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for Greenland turbot in the Bering Sea subarea.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the 2003 TAC of Greenland turbot in the Bering Sea subarea of the BSAI, and therefore reduce the public's ability to use and enjoy the fishery resource.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 30, 2003.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 03-19928 Filed 7-31-03; 2:59 pm]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 030417090-3183-02; I.D. 032403C]

RIN 0648-AQ73

Fisheries of the Exclusive Economic Zone Off Alaska; License Limitation Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues a final rule to amend eligibility criteria for Bering Sea and Aleutian Islands (BSAI) crab species licenses issued under the License Limitation Program (LLP) and required for participation in the BSAI crab fisheries. This action is necessary to allow participation in the BSAI crab fisheries in a manner intended by the North Pacific Fishery Management Council (Council). The intended effect of this action is to allow vessels with recent participation in the BSAI crab fisheries to qualify for a LLP crab species license and to conserve and manage the crab resources in the BSAI in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Effective on September 4, 2003.

ADDRESSES: Copies of the Environmental Assessment prepared for Amendment 10 to the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs and the regulatory impact review/initial regulatory flexibility analysis (RIR/IRFA) and the Final Regulatory Flexibility Analysis (FRFA) prepared for this rule are available from NMFS, Alaska Region, P.O. Box 21668, Juneau, AK, 99802, Attn: Lori Durall, telephone 907-586-7247.

FOR FURTHER INFORMATION CONTACT: Gretchen Harrington, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the crab fisheries in the exclusive economic zone off Alaska under the Fishery Management Plan for Bering Sea and Aleutian Islands Management Area for King and Tanner Crabs (FMP). The Council prepared the FMP under the authority of the Magnuson-Stevens Act. Regulations governing U.S. fisheries and implementing this FMP appear at 50 CFR parts 600 and 679.

Background

The background information for this action is included in the preamble to the proposed rule (68 FR 22667, April 29, 2003); for Amendment 10, it is in the preamble to the final rule implementing Amendment 10 (66 FR 48813 September 24, 2001); and for the LLP, it is in the preamble to the final rule implementing the LLP (63 FR 52642, October 1, 1998).

This action amends the regulatory language at 50 CFR 679.4(k)(5)(iii) and (iv) to specify that a person who had purchased a LLP qualifying fishing history and then fished with his or her vessel in the recent participation period (RPP) would qualify for a LLP crab species license.

Response to Comments

NMFS received one comment on the proposed rule.

Comment: In order to effectively implement the intent of the proposed rule, an additional correction to 50 CFR 679.4(k)(5) is necessary. The regulatory language at 50 CFR 679.4(k)(5) restricts license issuance to individuals that owned a single vessel that was used to meet the general qualifying period (GQP), the endorsement qualifying period (EQP), and the RPP. This regulatory language also implies that licenses are issued when a vessel meets the eligibility criteria; however, the LLP program is designed to grant licenses to persons that meet the eligibility criteria.

Response: No additional regulatory change is necessary to implement this rule as intended. The comment is correct that persons, rather than vessels, meet the eligibility requirements and receive licenses. The author's concerns are addressed by the definition of "eligible applicant" in 50 CFR 679.2, which clarifies that licenses are issued to persons who used a vessel to fish or who obtained a LLP qualifying fishing history. The regulatory language at 50 CFR 679.4(k)(5) does not require a single vessel to meet the GQP, EQP, and RPP requirements. Therefore, an additional regulatory change, beyond the scope of the changes in this rule, is not required to continue to accurately implement the LLP program.

Classification

NMFS prepared a Final Regulatory Flexibility Analysis to evaluate the impacts of this action on small entities, in accordance with the provisions of the Regulatory Flexibility Act of 1980 (RFA), as modified by the Small Business Regulatory Fairness Act of

1996 (5 U.S.C. 604(a)). The purposes of this action were described earlier in the preamble to the proposed rule, published on April 29, 2003 (68 FR 22667).

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA) for the proposed rule, which was described in the classifications section of the preamble to the proposed rule. The public comment period ended on May 14, 2003. No comments were received on the economic impacts of the rule.

NMFS issues a final rule to amend eligibility criteria for BSAI crab species licenses issued under the LLP. LLP licenses are required for participation in the BSAI crab fisheries. The intended effect of this action is to allow three entities with recent participation in the BSAI crab fisheries to qualify for an LLP crab species license. This action is necessary to allow these entities to participate in the BSAI crab fisheries in a manner intended by the Council.

The entities directly regulated by this action are defined as those that did not qualify for an LLP crab species license under the regulations implementing Amendment 10, but that would now qualify under this final rule. This rule was found to directly regulate three entities that may have acquired LLP qualifying fishing history from another vessel before making a documented harvest during the RPP. Under the rule, each of these entities will qualify for a license that they do not currently qualify for, to allow these entities to continue to participate in the BSAI crab fisheries. All of these entities were assumed to be small entities on the basis of studies suggesting that crab fishing operations in the BSAI were predominately small entities as defined under the RFA.

This regulation does not impose new recordkeeping or reporting requirements on the regulated small entities.

Each of these three small entities will benefit by qualifying for a LLP crab species license. This action has no adverse impacts on these entities. This action mitigates an adverse impact that would occur if the status quo were to continue because this rule allows these entities to continue to participate in the BSAI crab fisheries.

A status quo alternative to the action was considered but not adopted. Under the status quo, these entities would be denied LLP licenses. Status quo would not achieve the stated objective of the Council for this action, nor would it minimize the potential adverse

economic burden on the small entities identified as subject to direct regulation by this action.

This final rule has been determined to be not significant for purposes of E.O. 12866.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

■ For reasons set out in the preamble, 50 CFR part 679 is amended to read as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

■ 2. In § 679.4, paragraphs (k)(5)(iii)(A) and (k)(5)(iv) are revised to read as follows:

§ 679.4 Permits.

* * * * *

(k) * * *

(5) * * *

(iii) Recent participation period (RPP).

(A) The RPP is the period from January 1, 1996, through February 7, 1998. To qualify for a crab species license, defined at § 679.2, a person must have made at least one documented harvest of any amount of LLP crab species from a vessel during the RPP and must have held a LLP qualifying fishing history at the time of that documented harvest. A LLP qualifying fishing history meets the documented harvest requirements at paragraphs (k)(5)(i) and (k)(5)(ii) of this section.

* * * * *

(iv) Exception to allow purchase of LLP qualifying fishing history after the documented harvest in the RPP. To qualify for a LLP crab species license, a person who made a documented harvest of LLP crab species during the period from January 1, 1998, through February 7, 1998, must have obtained, or entered into a contract to obtain, the LLP qualifying fishing history by 8:36 a.m. Pacific time on October 10, 1998,

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[FR Doc. 03-19933 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-22-S

Proposed Rules

Federal Register

Vol. 68, No. 150

Tuesday, August 5, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1778

RIN 0572-AB90

Emergency and Imminent Community Water Assistance Grants

AGENCY: Rural Utilities Service, USDA.
ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS) is amending its regulation governing Emergency Community Water Assistance Grants (ECWAG). This action is needed to comply with requirements set forth in the 2002 Farm Bill. The intended effect is to amend the regulation so that it allows eligibility for the program to be extended to situations where an emergency is considered imminent.

In the final rule section of this **Federal Register**, RUS is publishing this action as a direct final rule without prior proposal because RUS views this as a non-controversial action and anticipates no adverse comments. If no adverse comments are received in response to the direct final rule, no further action will be taken on this proposed rule and the action will become effective at the time specified in the direct final rule. If RUS receives adverse comments, a timely document will be published withdrawing the direct final rule and all public comments received will be addressed in a subsequent final rule based on this action.

DATES: Comments on this proposed action must be received by RUS via facsimile transmission or carry a postmark or equivalent no later than September 4, 2003.

ADDRESSES: Submit adverse written comments or notice of intent to submit adverse comments to F. Lamont Heppe, Jr., Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., STOP

1522, Room 5168, South Building, Washington, DC 20250, telephone number (202) 720-9550 or via facsimile transmission to (202) 720-4120. RUS requires a signed original and three copies of all comments (7 CFR Part 1700). All comments received will be made available for inspection in room 4034, South Building, Washington, DC, between 8 a.m. and 4 p.m. (7 CFR part 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Robin Pulkkinen, Loan Specialist, Water and Environmental Programs, Rural Utilities Service, Room 2229 South Building, Stop 1570, 1400 Independence Ave. SW, Washington, DC 20250-1570. Telephone: (202) 720-9636, FAX: (202) 690-0649, E-mail: rpulkkin@rus.usda.gov.

SUPPLEMENTARY INFORMATION: See the Supplementary Information provided in the direct final rule located in the Rules and Regulations direct final rule section of this **Federal Register** for the applicable supplementary information on this action.

Dated: July 3, 2003.

Hilda Gay Legg,

Administrator, Rural Utilities Service.

[FR Doc. 03-19697 Filed 8-4-03; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 7 and 34

[Docket No. 03-16]

RIN 1557-AC73

Bank Activities and Operations; Real Estate Lending and Appraisals

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of the Comptroller of the Currency (OCC) proposes to amend parts 7 and 34 of our regulations to add provisions clarifying the applicability of state law to national banks. These provisions would identify types of state laws that are preempted, as well as types of state laws that generally are not preempted, in the context of national bank lending,

deposit-taking, and other authorized activities.

DATES: Comments must be received by October 6, 2003.

ADDRESSES: Please direct your comments to: Office of the Comptroller of the Currency, 250 E Street, SW., Public Information Room, Mailstop 1-5, Washington, DC 20219, Attention: Docket No. 03-16, fax number (202) 874-4448; or Internet address: regs.comments@occ.treas.gov. Due to delays in paper mail delivery in the Washington area, we encourage the submission of comments by fax or e-mail whenever possible. Comments may be inspected and photocopied at the OCC's Public Information Room, 250 E Street, SW., Washington, DC. You can make an appointment to inspect comments by calling (202) 874-5043.

FOR FURTHER INFORMATION CONTACT: Andra Shuster, Counsel, or Mark Tenhundfeld, Assistant Director, Legislative and Regulatory Activities Division, (202) 874-5090.

SUPPLEMENTARY INFORMATION:

Scope of National Bank Preemption

A. Introduction

In recent years, the OCC has received numerous inquiries concerning the applicability of state law to national banks,¹ and the extent to which state law applies to a national bank's exercise of powers authorized by Federal law has been the subject of litigation in different contexts.² The number and variety of

¹ In response to such requests, the OCC has issued a number of interpretive opinions providing our views with respect to the applicability to national banks of various state laws. See, e.g., 67 FR 13405 (Mar. 22, 2002) (Massachusetts insurance sales law); 66 FR 51502 (Oct. 9, 2001) (West Virginia insurance sales law); see also *Cline v. Hawke*, No. 02-2100, 2002 WL 31557392 (4th Cir. Nov. 19, 2002), petition for review dismissed (upholding OCC opinion on the merits); 66 FR 28593 (May 23, 2001) (Michigan motor vehicle sales law); 66 FR 23977 (May 10, 2001) (Ohio automobile dealer licensing law); 65 FR 15037 (Mar. 20, 2000) (Pennsylvania law governing auctioneers and the conduct of auctions); OCC Interpretive Letter No. 866 (Oct. 8, 1999) (multi-state fiduciary operations); OCC Interpretive Letter No. 872 (Oct. 28, 1999) (California restrictions on the exercise of fiduciary powers); and OCC Interpretive Letter No. 695 (Dec. 8, 1995) (multi-state fiduciary operations).

² See, e.g., *Bank of America v. City & County of San Francisco*, 309 F.3d 551 (9th Cir. 2002), cert. denied, 123 S.Ct. 2220 (2003), 2003 U.S. LEXIS 4253 (May 27, 2003) (the National Bank Act and OCC regulations together preempt conflicting state limitations on the authority of national banks to

Continued

these questions reflect a need for clarification of the circumstances when state laws or regulations apply to activities and operations of national banks. Without further clarification, national banks, particularly those with customers in multiple states, face uncertain compliance risks and substantial additional compliance burdens and expense that, for practical purposes, materially impact their ability to offer particular products and services.

A recent inquiry by National City Bank, National City Bank of Indiana, and two operating subsidiaries of these banks (collectively, National City) concerning the Georgia Fair Lending Act (GFLA)³ illustrates the impact that state laws can have on a national bank's lending activities. Our analysis of the issues raised by National City in the response to the bank, which is discussed below and published in full elsewhere in this edition of the *Federal Register* (National City Order), underscores the need for clarity and more predictability in our regulations concerning the extent to which state laws apply to national banks' real estate lending activities as well as other aspects of national bank activities.

Due to the number and significance of the questions that continue to arise with respect to the preemption of state laws in these areas, we believe it is now timely to provide more comprehensive standards regarding the applicability of state laws to lending, deposit-taking, and other authorized activities of national banks. Accordingly, we are proposing to amend our regulations to provide such standards.

B. Principles of Preemption in the National Bank Context

Preemption is not a new concept. It is a doctrine, based on Constitutional principles, that has been recognized by the Supreme Court since the earliest years of our Nation's history. In 1819, in the landmark case of *McCulloch v. Maryland*, the Court held that under the Supremacy Clause of the U.S. Constitution, states "have no power, by taxation or otherwise, to retard, impede,

collect fees for the provision of electronic services through ATMs; municipal ordinances prohibiting such fees are invalid under the Supremacy Clause); *Wells Fargo Bank, Texas, N.A. v. James*, 321 F.3d 488 (5th Cir. 2003) (Texas statute prohibiting certain check cashing fees is preempted by the National Bank Act); *Metrabank v. Fester*, 193 F. Supp. 2d 1156 (S.D. Iowa 2002) (national bank authority to charge fees for ATM use preempted Iowa prohibition on such fees). See also *Bank One, Utah v. Gutttau*, 190 F.3d 844 (8th Cir. 1999), cert. denied sub nom *Foster v. Bank One, Utah*, 529 U.S. 1087 (2000) (holding that Federal law preempted Iowa restrictions on ATM operation, location, and advertising).

³ GA Code Ann. §§ 7-6A-1 et seq.

burden, or in any manner control, the operations" of an entity created under Federal law.⁴ Notably, the entity involved in that case was a bank chartered under Federal law, the Second Bank of the United States. As discussed below, since the creation of the national banking system in 1863, courts have applied comparable principles of Federal preemption in connection with many aspects of national banks' operations, and have repeatedly found that the exercise by Federally-chartered national banks of their Federally-authorized powers is ordinarily not subject to state law.

1. Legislative History of the National Banking Laws

Congress enacted the National Currency Act (Currency Act) in 1863 and modified it with the National Bank Act a year thereafter for the purpose of establishing a new national banking system that would operate distinctly and separately from the existing system of state banks. The Currency Act and the National Bank Act were intended to create a uniform and secure national currency and a system of national banks designed to help stabilize and support the national economy both during and after the Civil War.

Both proponents and opponents of the new national banking system expected that it would replace the existing system of state banks.⁵ Given this anticipated

⁴ *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 436 (1819).

⁵ Representative Samuel Hooper, who reported the bill to the House, stated in support of the legislation that one of its purposes was "to render the law [i.e., the Currency Act] so perfect that the State banks may be induced to organize under it, in preference to continuing under their State charters." Cong. Globe, 38th Cong., 1st Sess. 1256 (Mar. 23, 1864). While he did not believe that the legislation was necessarily harmful to the state bank system, Rep. Hooper did "look upon the system of State banks as having outlived its usefulness." *Id.* Opponents of the legislation believed that it was intended to "take from the States * * * all authority whatsoever over their own State banks, and to vest that authority * * * in Washington." Cong. Globe, 38th Cong., 1st Sess. 1267 (Mar. 24, 1864) (statement of Rep. Brooks). Rep. Brooks made that statement to support the idea that the legislation was intended to transfer control over banking from the states to the Federal government. Given that the legislation's objective was to replace state banks with national banks, its passage would, in Rep. Brooks's opinion, mean that there would be no state banks left over which the states would have authority. Thus, by observing that the legislation was intended to take authority over state banks from the states, Rep. Brooks was not suggesting that the Federal government would have authority over state banks; rather, he was explaining the bill in a context that assumed the demise of state banks. Rep. Pruyn opposed the bill stating that the legislation would "be the greatest blow yet inflicted upon the States." Cong. Globe, 38th Cong., 1st Sess. 1271 (Mar. 24, 1864). See also John Wilson Million, *The Debate on the National Bank Act of 1863*, 2 J. Pol. Econ. 251, 267 (1893-94) regarding the

impact on state banks and the resulting diminution of control by the states over banking in general,⁶ proponents of the national banking system were concerned that states would attempt to undermine it. Remarks of Senator Sumner illustrate the sentiment of many legislators of the time: "Clearly, the [national] bank must not be subjected to any local government, State or municipal; it must be kept absolutely and exclusively under that Government from which it derives its functions."⁷

The allocation of any supervisory responsibility for the new national banking system to the states would have been inconsistent with this need to protect national banks from state interference. Congress, accordingly, established a Federal supervisory regime and created a Federal agency within the Department of Treasury—the OCC—to carry it out. Congress granted the OCC the broad authority "to make a thorough examination of all the affairs of [a national bank],"⁸ and solidified this Federal supervisory authority by vesting the OCC with exclusive visitatorial powers over national banks, except where Federal law provided otherwise. These provisions assured, among other things, that the OCC would have comprehensive authority to examine all the affairs of a national bank and protect national banks from potentially hostile state interference by establishing that the authority to examine, supervise, and regulate

Currency Act ("Nothing can be more obvious from the debates than that the national system was to supersede the system of state banks.")

⁶ See, e.g., *Tiffany v. Nat'l Bank of Missouri*, 85 U.S. 409, 412-413 (1874) ("It cannot be doubted, in view of the purpose of Congress in providing for the organization of National banking associations, that it was intended to give them a firm footing in the different States where they might be located. It was expected they would come into competition with State banks, and it was intended to give them at least equal advantages in such competition. * * * National banks have been National favorites. They were established for the purpose, in part, of providing a currency for the whole country, and in part to create a market for the loans of the General government. It could not have been intended, therefore, to expose them to the hazard of unfriendly legislation by the States, or to ruinous competition with State banks."). See also B. Hammond, *Banks and Politics in America from the Revolution to the Civil War 725-34* (1957); P. Studenski & H. Krooss, *Financial History of the United States 155* (1st ed. 1952).

⁷ Cong. Globe, 38th Cong., 1st Sess., at 1893 (Apr. 27, 1864). See also *Beneficial Nat'l Bank v. Anderson*, 123 S.Ct. 2058, 2064 (2003) ("[T]his Court has also recognized the special nature of Federally chartered banks. Uniform rules limiting the liability of national banks and prescribing exclusive remedies for their overcharges are an integral part of a banking system that needed protection from 'possible unfriendly State legislation.'" (citations omitted).)

⁸ Act of June 3, 1864, c. 106, § 54, 13 Stat. 116, codified at 12 U.S.C. 481.

national banks is vested *only* in the OCC, unless otherwise provided by Federal law.⁹

2. The Supremacy Clause and the Federal Preemption Standards Articulated by the Supreme Court

A state law may be preempted by Federal law and thus rendered invalid by operation of the Supremacy Clause of the Constitution.¹⁰ The Supreme Court has identified three ways in which this may occur. First, Congress can adopt express language setting forth the existence and scope of preemption.¹¹ Second, Congress can adopt a framework for regulation that "occupies the field" and leaves no room for states to adopt supplemental laws.¹² Third, preemption may be found when state law actually conflicts with Federal law. Conflict will be found when either: (i) compliance with both laws is a "physical impossibility,"¹³ or (ii) when the state law stands "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."¹⁴

Because the origins of Federal preemption are Constitutional, the underlying purpose of the state legislation, no matter how salutary, does not determine the essential issue of preemption. As explained in *Association of Banks in Insurance, Inc. v. Duryee*,¹⁵ "[w]here state and federal laws are inconsistent, the state law is pre-empted even if it was enacted by the state to protect its citizens or consumers."¹⁶

⁹ Writing shortly after the Currency Act and the National Bank Act were enacted, then-Secretary of the Treasury, and formerly the first Comptroller of the Currency, Hugh McCulloch observed that "Congress has assumed entire control of the currency of the country, and, to a very considerable extent, of its banking interests, prohibiting the interference of State governments." Cong. Globe, 39th Cong., 1st Sess., Misc. Doc. No. 100, at 2 (Apr. 23, 1866).

¹⁰ "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, cl. 2.

¹¹ See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

¹² See *Rice v. Senta Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

¹³ *Florida Lime & Avocado Growers, Inc. v. Poul*, 373 U.S. 132, 142-43 (1963).

¹⁴ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *Barnett Bank of Marion County v. Nelson*, 517 U.S. 25, 31 (1996) (quoting Hines).

¹⁵ 55 F. Supp. 2d 799 (S.D. Ohio 1999).

¹⁶ *Id.* at 802. Agreeing with this conclusion, the Sixth Circuit stated that "the fact that the state legislature enacted the [state law at issue] to protect general insurance agents and consumers does not, for that reason alone, preclude federal preemption." *Ass'n of Banks in Ins., Inc. v. Duryee*, 270 F.3d 397, 408 (6th Cir. 2001); see also *Franklin Nat'l Bank of*

3. Supreme Court Precedents Leading to Barnett

From the earliest years of the national banking system, up to and including a decision rendered just months ago, the Supreme Court has consistently recognized the unique status of the national banking system and the limits placed on states by the National Bank Act.¹⁷ In one of the first cases to address the role of the national banking system, the Supreme Court stated that "[t]he national banks organized under the [National Bank Act] are instruments designed to be used to aid the government in the administration of an important branch of the public service. They are means appropriate to that end."¹⁸

Subsequent opinions of the Supreme Court have been equally clear about national banks' unique role and status. See *Marquette Nat'l Bank of Minneapolis v. First of Omaha Service Corp.*, 439 U.S. 299, 314-315 (1978) ("Close examination of the National Bank Act of 1864, its legislative history, and its historical context makes clear that, . . . Congress intended to facilitate . . . a 'national banking system'") (citation omitted); *Franklin Nat'l Bank*, 347 U.S. at 375 ("The United States has set up a system of national banks as Federal instrumentalities to perform various functions such as providing circulating medium and government credit, as well as financing commerce and acting as private depositories."); *Davis v. Elmira Sav. Bank*, 161 U.S. 275, 283 (1896) ("National banks are instrumentalities of the federal government, created for a public purpose, and as such necessarily subject to the paramount authority of the United States."); *Guthrie v. Harkness*, 199 U.S. 148, 159 (1905) ("It was the intention that this statute should contain a full code of provisions upon the subject, and that no state law or enactment should undertake to exercise the right of visitation over a national corporation.").

The Supreme Court also has recognized the clear intent on the part of Congress to limit the authority of states over national banks precisely so that the nationwide system of banking that was created in the Currency Act could develop and flourish. For instance, in *Easton v. Iowa*,¹⁹ the Court stated that Federal legislation affecting national banks—

Franklin Square v. New York, 347 U.S. 373, 378 (1954).

¹⁷ See *Beneficial Nat'l Bank*, 123 S.Ct. at 2064.

¹⁸ *Formers' & Mechanics' Nat'l Bank v. Dearing*, 91 U.S. 29, 33 (1875).

¹⁹ 188 U.S. 220 (1903).

has in view the erection of a system extending throughout the country, and independent, so far as powers conferred are concerned, of state legislation which, if permitted to be applicable, might impose limitations and restrictions as various and as numerous as the States. * * * It thus appears that Congress has provided a symmetrical and complete scheme for the banks to be organized under the provisions of the statute. * * * [W]e are unable to perceive that Congress intended to leave the field open for the States to attempt to promote the welfare and stability of national banks by direct legislation. If they had such power it would have to be exercised and limited by their own discretion, and confusion would necessarily result from control possessed and exercised by two independent authorities.²⁰

The Court in *Formers' & Mechanics' National Bank*, after observing that national banks are means to aid the government, stated—

Being such means, brought into existence for this purpose, and intended to be so employed, the States can exercise no control over them, nor in any wise affect their operation, except in so far as Congress may see proper to permit. Any thing beyond this is "an abuse, because it is the usurpation of power which a single State cannot give."²¹

Thus, as recognized by the Supreme Court in *Barnett*, the history of national bank powers is one of "interpreting grants of both enumerated and incidental 'powers' to national banks as grants of authority not normally limited by, but rather ordinarily pre-empting, contrary state law."²² "[W]here Congress has not expressly conditioned the grant of 'power' upon a grant of state permission, the Court has ordinarily found that no such condition applies."²³

4. Recent Lower Federal Court Decisions Concluding that State Laws Are Preempted

These principles have been recognized and applied in a series of recent cases invalidating state and local restrictions upon national bank activities that are authorized under Federal law. In each case, the court determined that the state or local restriction obstructed, in whole or in part, the exercise of an authorized

²⁰ *Id.* at 229, 231-232 (emphasis added).

²¹ *Formers' & Mechanics' Nat'l Bank*, 91 U.S. at 34 (citation omitted).

²² *Barnett*, 517 U.S. at 32 (1996). The Supreme Court has recognized that the "business of banking" is not limited to the powers enumerated in section 24 (Seventh). See *NationsBank v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 258 n.2 (1995). As the scope of the underlying national bank power may evolve, the OCC "may authorize additional activities if encompassed by a reasonable interpretation of § 24 (Seventh)." *Indep. Ins. Agents of Am., Inc. v. Howke*, 211 F.3d 638, 640 (D.C. Cir. 2000). Thus, the effect of a state law on the exercise of a Federal power may change as the character of the power changes.

²³ *Barnett*, 517 U.S. at 34.

national bank power and therefore was preempted by operation of the Supremacy Clause.

For example, ordinances passed by four municipalities in California and New Jersey specifically to prohibit ATM access fees were enjoined by district court order on grounds that included National Bank Act preemption. In California, the district court entered a preliminary injunction against the fee prohibition ordinances adopted by San Francisco and Santa Monica, and the Ninth Circuit affirmed. On remand, the district court entered a permanent injunction against the ordinances, and the Ninth Circuit once again affirmed.²⁴ Similarly, a Federal district court in New Jersey entered temporary restraining orders preventing fee prohibition ordinances adopted by Newark and Woodbridge from becoming effective. The combined case was ultimately settled by each city's consent to a permanent injunction against its ordinance.²⁵ A Federal district court in Des Moines declared a longstanding Iowa prohibition on ATM access fees to be in conflict with the national bank power to charge fees and therefore preempted.²⁶ For similar reasons, the Fifth Circuit upheld a Federal district court ruling that Federal law displaced a Texas statute that prohibited the charging of fees for cashing checks drawn upon accounts at the payor bank.²⁷ A Federal district court in Georgia reached the same conclusion with respect to a Georgia law that similarly attempted to restrict the authority of national banks under Federal law to charge such fees.²⁸

Restrictions on national bank activities other than the charging of fees have also been held preempted. Deferring to the OCC's interpretations of the National Bank Act, the Eighth Circuit held that Federal law preempted Iowa restrictions on ATM location, operation, and advertising as applied to national banks.²⁹ More recently, a Federal district court in California permanently enjoined the California Attorney General and Director of the Department of Consumer Affairs from enforcing a California statute requiring that certain language and information be placed on the billing statements credit

card issuers provide their cardholders.³⁰ In so doing, the Court held that there is "no indication in the NBA that Congress intended to subject that power [to loan money on personal security] to local restriction." Thus, the court applied "the ordinary rule * * * of preemption of contrary state law."³¹ Contrary state law also may be preempted by Federal regulation. "Federal regulations have no less pre-emptive effect than federal statutes."³²

5. Limited Circumstances Under Which State Laws Apply to National Banks

Federal courts apply no general presumption that state laws are applicable to national banks. As explained recently by the Supreme Court, a presumption against preemption is "not triggered when the States regulate in an area where there has been a history of significant federal presence."³³ As further explained by the Ninth Circuit in *Bank of America*, "because there has been a 'history of significant federal presence' in national banking, the presumption against preemption of state law is inapplicable."³⁴

Moreover, no Federal statute endorses the presumptive application of state laws to national banks. Although the national bank branching statute makes applicable the laws of the host state regarding community reinvestment, consumer protection, and fair lending to branches of an out-of-state national bank located in the host state to the same extent as those laws apply to a bank chartered by that state, the statute expressly excepts any case where Federal law preempts the application of state law to national banks.³⁵

In a few situations, Federal law has incorporated provisions of state law for specific purposes,³⁶ and Congress may more generally establish standards that govern when state law will apply to

national banks' activities.³⁷ In such cases, the OCC applies the law or the standards that Congress has required or established.

State laws also may apply to national banks' activities under circumstances that have been described variously by the courts as not altering or conditioning a national bank's ability to exercise a power that Federal law grants to it.³⁸ "Thus, states retain some power to regulate national banks in areas such as contracts, debt collection, acquisition and transfer of property, and taxation, zoning, criminal, and tort law."³⁹ Notably, these types of laws typically do not regulate the manner or content of the business of banking authorized for national banks under Federal law, but rather establish the legal infrastructure that surrounds and supports the conduct of that business. In other words, they promote a national bank's ability to conduct business; they do not obstruct a national bank's exercise of powers granted under Federal law.⁴⁰

6. Examples of Types of State Laws Found to be Preempted

The OCC and Federal courts have thus far concluded that a wide variety of state laws are preempted, either because the state laws fit within the express preemption provisions of an OCC regulation or because the laws

³⁷ See, e.g., 15 U.S.C. 6701 (codification of section 104 of the Gramm-Leach-Bliley Act, Public Law 106-102, 113 Stat. 1338, 1352 (1999), which establishes standards for determining the applicability of state law to different types of activities conducted by national banks, other insured depository institutions, and their affiliates).

³⁸ See *Barnett*, 517 U.S. at 33.

³⁹ *Bank of America*, 309 F.3d at 559. As stated in 12 U.S.C. 548, for the purposes of state tax laws, "a national bank shall be treated as a bank organized and existing under the laws of the State * * * within which its principal office is located." With regard to state criminal laws, it is important to recognize the distinction drawn by the Supreme Court in *Easton* between "crimes defined and punishable at common law or by the general statutes of a State" and "crimes and offenses cognizable under the authority of the United States." 188 U.S. at 238. The Court stated that "[u]ndoubtedly a State has the legitimate power to define and punish crimes by general laws applicable to all persons within its jurisdiction. * * * But it is without lawful power to make such special laws applicable to banks organized and operating under the laws of the United States." *Id.* at 239 (holding that Federal law governing the operations of national banks preempted a state criminal law prohibiting insolvent banks from accepting deposits). Further, as we note *infra* in footnote 86, we will look to the substance and effect of a state law in determining whether a particular state law falls into a category of state laws that are not preempted; a state may not immunize a law from preemption simply by applying a criminal penalty to it. Also, notably, "[c]onsumer protection is not reflected in the case law as an area in which the states have traditionally been permitted to regulate national banks." *Lockyer*, 239 F. Supp. 2d at 1016.

⁴⁰ See *Barnett*, 517 U.S. at 33-34.

²⁴ See *Bank of America, N.A. v. City & County of San Francisco*, 2000 WL 33376673 (N.D. Cal. June 30, 2000), *aff'd*, *Bank of America*, 309 F.3d 551.

²⁵ See *New Jersey Bankers Ass'n v. Township of Woodbridge*, No. CV-00-702 (JAG) (D.N.J. Nov. 8, 2000).

²⁶ See *Metrobank*, 193 F. Supp. 2d 1156.

²⁷ See *Wells Fargo Bank Texas*, 321 F.3d 488.

²⁸ See *Bank of America, N.A. v. Sorrell*, 248 F. Supp. 2d 1196 (N.D. Ga. 2002).

²⁹ See *Bank One, Utah*, 190 F.3d 844.

³⁰ See *American Bankers Ass'n v. Lockyer*, 239 F. Supp. 2d 1000 (E.D. Cal. 2002).

³¹ *Id.* at 1016; see also *Wells Fargo Bank, N.A. v. Boutsis*, 2003 WL 21277203 at *3 (E.D. Cal. May 9, 2003) (*Wells Fargo Bank II*) (The National Bank Act "was enacted to 'facilitate * * * a national banking system,' and 'to protect national banks against intrusive regulation by the States.'") (citations omitted).

³² *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

³³ *United States v. Lacke*, 529 U.S. 89, 108 (2000).

³⁴ 309 F.3d at 559.

³⁵ See 12 U.S.C. 36(f)(1)(A). This provision was added to the branching statute by the Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994, Pub. L. 103-328, 108 Stat. 2338, 2350 (1994).

³⁶ See, e.g., 12 U.S.C. 92a(a) (the extent of a national bank's fiduciary powers is determined by reference to the law of the state where the national bank is located).

conflict with a Federal power vested in national banks. Types of state laws that have been addressed by the OCC or the courts include:

- Licensing laws. State statutes that require national banks to obtain a license or to register with the state before exercising a Federally-granted authority have been found to be preempted.⁴¹

- Filing requirements. State statutes that require national banks to make filings with, or report to, states conflict with the OCC's exclusive visitorial powers over national banks.⁴²

- Terms of real estate loans. The OCC's current regulations in subpart A of part 34 address real estate lending generally. Section 34.4(a) expressly preempts state laws concerning five areas of fixed-rate mortgage lending. Section 34.4(a)(1) preempts state laws concerning loan-to-value ratios. Section 34.4(a)(2) preempts state laws concerning the schedule for repayment of principal and interest. In this regard,

the key elements of any repayment schedule are: (1) the timing of the expected payments, and (2) the amount of expected payments.⁴³ Section 34.4(a)(3) preempts state laws concerning the term to maturity of real estate loans.⁴⁴ Subpart B of part 34, governing adjustable rate mortgages (ARMs), states that national banks may engage in ARM lending without regard to any state law limitation.⁴⁵

- Advertising. Courts have consistently held that state laws limiting the ability of a national bank to advertise are preempted.⁴⁶

- Permissible rates of interest. Federal law establishes that national banks may charge interest (both the rate and amount⁴⁷) permitted by the state where the bank is located without regard to the laws of the state where the borrower is located.⁴⁸

- Permissible fees and non-interest charges. Section 7.4002 of the OCC's rules outlines the framework for national banks' ability to impose non-interest fees and charges; courts have consistently held that state laws limiting the ability of national banks to charge such fees are preempted.⁴⁹

- Management of credit accounts. The OCC has taken the position that state laws that interfere with a national bank's Federally-granted power to lend and to engage in activities incidental to its lending operations are preempted. For example, in our view, a state law that imposed restrictions or requirements that, under the *Barnett* standards, interfere with or burden a

national bank's communication with its credit card holders, management of credit accounts, or terms of offers of credit was preempted. A Federal district court in California recently upheld this position.⁵⁰

- Due-on-sale clauses. Section 34.5 of the OCC's rules and 12 U.S.C. 1701j-3 preempt state restrictions on due-on-sale clauses.

- Leaseholds as acceptable security. The provision set out in proposed § 34.4(a)(14) preempting state laws governing covenants and restrictions that must be contained in a lease to qualify the leasehold as acceptable security for a real estate loan is a restatement of the provision in current § 34.4(a)(5).

- Mandated statements and disclosures. State attempts to require national banks to make disclosures in connection with specified credit card repayment terms have been held preempted as an impermissible interference with the ability to extend credit.⁵¹ OCC regulations already address the applicability of state law to national bank activities in some of these areas,⁵² but to date, unlike the Office of Thrift Supervision (OTS),⁵³ we have not adopted regulations that more broadly codify the application of principles of preemption according to major groupings of activities, such as lending, deposit-taking, and other authorized bank activities. Our positions in some instances also have not clearly reflected whether we were employing an "occupation of the field" or "conflicts" approach, although our individual preemption decisions have more commonly reflected a "conflict" type approach to preemption analysis. The proposal clarifies the types of state law restrictions and requirements that do, and do not, apply to major types of activities and operations of national banks and, for those types of activities and operations, articulates the standards that determine whether particular types of state law restrictions and requirements are preempted.

C. Revisions to Part 34—Real Estate Lending

1. Current OCC Regulations

Part 34 of our rules implements 12 U.S.C. 371, which authorizes national banks to engage in real estate lending

⁴¹ See *First Nat'l Bank of Eastern Arkansas v. Taylor*, 907 F.2d 775 (8th Cir. 1990) (the National Bank Act precludes a state regulator from prohibiting a national bank, through either enforcement action or a licensing requirement, from conducting an authorized activity); and *Bank of America Nat'l Trust & Sav. Ass'n v. Limo*, 103 F. Supp. 916 (D. Mass. 1952) (states have no authority to require national banks to obtain a license to engage in an activity permitted to them by Federal law). See also *Wells Fargo Bank, N.A. v. Boudris*, 252 F. Supp. 2d 1065, 1074 (E.D. Cal. 2003) (*Wells Fargo Bank*) (bank becoming a state licensee does not affect its right to conduct Federally permissible banking activities authorized by the OCC); *Not'l City Bank of Indiono v. Boudris*, Civ. No. S-03-0655-GEB JFM at 14 (May 7, 2003) (when banking activities are governed by Federal preemption, Federal law applies even where an instrumentality of a national bank has needlessly subjected itself to state licensing law); Letter dated May 15, 2001 from Julie L. Williams to Messrs. Thomas Plant and Daniel Morton (66 FR 28593, May 23, 2001) (regarding state license requirement in the sale of motor vehicles); Letter dated Mar. 7, 2000, from Julie L. Williams to Thomas P. Vartanian (65 FR 15037, Mar. 20, 2000) (regarding Pennsylvania auctioneer licensing law); OCC Interpretive Letter No. 866 (Oct. 8, 1999) (regarding state laws requiring national bank to obtain license before soliciting or engaging in proposed fiduciary arrangements); OCC Interpretive Letter No. 749 (Sept. 13, 1996) (regarding state law requiring national banks to be licensed to sell annuities); and OCC Interpretive Letter No. 644 (Mar. 24, 1994) (regarding state registration and fee requirements imposed on mortgage lenders). While several precedents cited address activities other than real estate lending, the principles articulated in the precedents apply to all national bank activities, including making real estate loans.

⁴² See OCC Interpretive Letter No. 616 (Feb. 26, 1993) (state statute requiring national banks to report quarterly to state banking commissioner would be preempted based upon OCC's exclusive visitorial powers); and OCC Interpretive Letter No. 614 (Jan. 15, 1993) (state statutes requiring national banks to keep records and file notifications and data with the state would be preempted because they purport to grant the state visitorial powers over national banks); See, e.g., *Guthrie*, 199 U.S. 148 (discussing OCC's exclusive visitorial powers).

⁴³ See Section III. A. 1. of the National City Order, in which we concluded that state laws governing balloon payments, negative amortization, limitations on advance payments, late fees, prepayment fees, and default rates of interest were preempted because they concerned the schedule for repayment of principal and interest in contravention of 12 CFR 34.4(a)(2).

⁴⁴ See *id.* at Section III. A. 2., in which we concluded that state laws governing acceleration of indebtedness and rights to cure a default were preempted because they concerned the term to maturity in contravention of 12 CFR 34.4(a)(3).

⁴⁵ See 12 CFR 34.21(a).

⁴⁶ See *Franklin Nat'l Bank*, 347 U.S. 373 (state law restricting national bank's ability to advertise its services held preempted); *Bank One, Utah*, 190 F.3d 844 (state law limiting the placement of advertising at ATMs held preempted). See also OCC Interpretive Letter No. 789 (June 27, 1997) (a state law that prohibited the use of a bank's name on ATMs unless the bank put the names of all other banks whose customers may use the ATM was preempted).

⁴⁷ See 12 U.S.C. 1735f-7a; *Wells Fargo Bank II*, 2003 WL 21277203.

⁴⁸ See 12 U.S.C. 85; 12 CFR 7.4001. See, e.g., *Morquette Nat'l Bank*, 439 U.S. 299; *Tiffany*, 85 U.S. 409 (construing 12 U.S.C. 85). See also Section III. B. of the National City Order.

⁴⁹ See *Bank of America*, 309 F.3d 551, *Wells Fargo Bank, Texas*, 321 F.3d 488, and *Metrobank*, 193 F. Supp. 2d 1156. See also Section III. C. of the National City Order.

⁵⁰ See *Lockyer*, 239 F. Supp. 2d 1000.

⁵¹ See *id.*

⁵² See, e.g., 12 CFR 7.4001 (interest); 7.4002 (fees); 7.4006 (operating subsidiaries); 9.7 (fiduciary activities); 34.4 (real estate lending generally); 34.5 (due-on-sale clauses); 34.21 (adjustable-rate mortgage lending); and 34.23 (prepayment fees).

⁵³ See 12 CFR 557.11-.13; 12 CFR 560.2; and 12 CFR 545.2.

subject to "such restrictions and requirements as the Comptroller of the Currency may prescribe by regulation or order." Under subpart A of part 34 (which sets forth the general authority for national banks to engage in real estate transactions), state laws concerning five enumerated areas already are explicitly preempted in their application to national banks and their operating subsidiaries. 12 CFR 34.1(b) and 34.4(a). Section 34.4(b) then states that the OCC will apply recognized principles of Federal preemption in considering whether state laws apply to other aspects of real estate lending by national banks.

2. Codification of Preemption

Pursuant to our authority under section 371, the proposal amends § 34.4(a) and (b) to provide a more complete statement of the types of state law restrictions and requirements that do, and do not, apply to real estate lending activities of national banks. However, as recognized by the Supreme Court, Federal law may preempt state law expressly (by an express statement of preemption in the law) or implicitly (because the Federal law is so complete that it "occupies the field" or because the state law conflicts with a Federal power). Although the regulation proposed today would address state laws by *type*, for reasons discussed below, we invite comment on whether our regulations, like those of the OTS,⁵⁴ should state explicitly that Federal law occupies the entire field of national banks' real estate lending activities.⁵⁵

Section 371 provides a broad grant of authority to national banks to engage in real estate lending. The only qualification in the statute is that these Federal powers are subject "to section 1828(o) of this title [which requires the adoption of uniform Federal safety and soundness standards governing real estate lending] and such restrictions and requirements as the Comptroller of the Currency may prescribe by regulation or order."⁵⁶ On its face, section 371 does not condition the grant of authority to national banks to engage in real estate lending upon engaging in that activity only to the extent that a state permits it.

The breadth of the Federal power and the OCC's rulemaking authority created by section 371 can be understood by

comparing the text and structure of that section to that of 12 U.S.C. 92, a statute similar in both respects and one that vests comparably broad rulemaking authority in the OCC. In *Barnett*, the Supreme Court analyzed the extent to which section 92 leaves room for state regulation of the activities the statute authorizes, and is thus instructive for purposes of analyzing section 371. The Supreme Court stated that— [section 92's] language suggests a broad, not a limited, permission. That language says, without relevant qualification, that national banks "may . . . act as the agent" for insurance sales. 12 U.S.C. 92. It specifically refers to "rules and regulations" that will govern such sales, while citing as their source not state law, but the Federal Comptroller of the Currency.⁵⁷

The Court noted that "[i]n defining the pre-emptive scope of statutes and regulations granting a power to national banks, [prior U.S. Supreme Court decisions] take the view that normally Congress would not want States to forbid, or to impair significantly, the exercise of a power that Congress explicitly granted."⁵⁸ The Supreme Court concluded that "where Congress has not expressly conditioned the grant of 'power' upon a grant of state permission, the Court has ordinarily found that no such condition applies."⁵⁹

This analysis of section 92 by the Supreme Court is instructive in addressing section 371 as well. Like section 92, section 371 creates a broad power for national banks. By its terms, section 371 also is not a limited permission, that is, it does not authorize national banks to engage in real estate lending only to the extent state law allows.⁶⁰ Moreover, section 371 differs from section 92 in two respects that are even more telling. First, section 371 refers expressly and exclusively to the OCC as the entity possessing authority to set *restrictions* and *requirements* that apply to national banks' real estate lending activities. Second, unlike the activity to which section 92 pertains—the sale of insurance—which historically has been predominantly regulated at the state level, national bank real estate lending authority has been extensively regulated at the Federal level since the power first was codified.

Beginning with the enactment of the Federal Reserve Act of 1913, national banks' real estate lending authority has been governed by the express terms of

section 371. As originally enacted in 1913, section 371 contained a limited grant of authority to national banks to lend on the security of "improved and unencumbered farm land, situated within its Federal reserve district."⁶¹ In addition to the geographic limits inherent in this authorization, the Federal Reserve Act also imposed limits on the term and amount of each loan as well as an aggregate lending limit. Over the years, section 371 was repeatedly amended to broaden the types of real estate loans national banks were permitted to make, to expand geographic limits, and to modify loan term limits and per-loan and aggregate lending limits.

In 1982, Congress removed these "rigid statutory limitations"⁶² in favor of a broad provision authorizing national banks to "make, arrange, purchase or sell loans or extensions of credit secured by liens on interests in real estate, subject to such terms, conditions, and limitations as may be prescribed by the Comptroller of the Currency by order, rule, or regulation."⁶³ The purpose of the 1982 amendment was "to provide national banks with the ability to engage in more creative and flexible financing, and to become stronger participants in the home financing market."⁶⁴ In 1991, Congress removed the term "rule" from this phrase and enacted an additional requirement, codified at 12 U.S.C. 1828(o), that national banks (and other insured depository institutions) conduct real estate lending pursuant to uniform standards adopted at the Federal level by regulation of the OCC and the other Federal banking agencies.⁶⁵ Thus, the history of national banks' real estate lending activities under section 371 is one of extensive Congressional involvement gradually giving way to a streamlined approach in which Congress has delegated broad rulemaking authority to the Comptroller. The two versions of section 371—namely, the lengthy and prescriptive approach prior to 1982 and the more recent statement of broad authority qualified only by reference to Federal law—may be seen as evolving articulations of the same idea.

⁶¹ Federal Reserve Act, ch. 6, section 24, 38 Stat. 251, 273 (1913).

⁶² S. Rep. No. 97-536, at 27 (1982).

⁶³ Garn-St Germain Depository Institutions Act of 1982, Public Law 97-320, § 403, 96 Stat. 1469, 1510-11 (1982).

⁶⁴ S. Rep. No. 97-536, at 27 (1982).

⁶⁵ See section 304 of the Federal Deposit Insurance Corporation Improvement Act, codified at 12 U.S.C. 1828(o). These standards governing national banks' real estate lending are set forth in subpart D of part 34.

⁵⁴ See 12 CFR 560.2.

⁵⁵ This issue was raised by National City in its request concerning the GFLA. As explained in the National City Order, we deferred expressing any views on the field preemption issue until we could seek comment in connection with a rulemaking rather than a decision confined to the law of a single state.

⁵⁶ 12 U.S.C. 371(a).

⁵⁷ *Barnett*, 517 U.S. at 32.

⁵⁸ *Id.* at 33.

⁵⁹ *Id.* at 34.

⁶⁰ See *id.* at 31-32.

Prior to 1982, the field of national bank real estate lending was pervasively regulated by the detailed statutory provisions of section 371. After the 1982 amendment, Congress left open the possibility that the OCC would occupy the field by regulation. The statute granted the Federal power and directed that not just "requirements" for the exercise of the power, but any "restrictions" on the power, would come from the OCC. In no respect does the statute express or imply that the power granted is limited, to some variable degree, by application of fifty different state laws.

Although this authority arguably enables the OCC to occupy the field of regulation of national banks' real estate lending, thus far we have not exercised the full authority inherent in section 371. Instead, in § 34.4(a) we have provided that certain types of state requirements and restrictions are not applicable to national banks and have elected to address whether other types of laws are preempted based on the existence of a conflict between a particular state or local law and national banks' Federal power under section 371. Since section 371 conditions the exercise by a national bank of its Federal power to engage in real estate lending only on compliance with Federal law, however, our regulation is more conservative than what the statute arguably allows.

The regulation we propose today further implements our authority under section 371 to identify types of state law restrictions concerning real estate lending that are, and are not, applicable to national banks. We have chosen to identify additional types of state laws that, in various respects, obstruct or condition national banks' exercise of real estate lending powers granted under section 371. As noted above, many of these types of laws have previously been addressed in OCC interpretations or Federal court decisions. We note, however, that our authority under section 371 is not necessarily limited to specifying types of law restrictions that are applicable or inapplicable, nor does section 371 appear to necessitate that the state laws specified be only those that in some manner obstruct or condition national banks' exercise of their powers under section 371. Thus, we invite comment on whether our regulation should state expressly that Federal law occupies the entire field of national bank real estate lending.

3. Federal Safeguards

Preemption of state laws governing national banks' real estate lending does

not mean that that activity would be unregulated. On the contrary, national banks' real estate lending is pervasively regulated under Federal standards and subject to comprehensive supervision.

This Federal framework includes standards governing, and oversight of, national banks' real estate lending activities to prevent abusive or predatory lending. In addition to the many Federal statutory standards that apply to national banks, the OCC recently issued comprehensive supervisory standards to address predatory and abusive lending practices. See OCC Advisory Letter 2003-2, "Guidelines for National Banks To Guard Against Predatory and Abusive Lending Practices" (Feb. 21, 2003) and OCC Advisory Letter 2003-3, "Avoiding Predatory and Abusive Lending Practices in Brokered and Purchased Loans" (Feb. 21, 2003). The OCC standards on predatory lending make clear that national banks should adopt—and vigorously adhere to—policies and procedures to prevent predatory lending practices in direct lending and in transactions involving brokered and purchased loans.

Significantly, AL 2003-2 provides that bank policies and procedures on direct lending should reflect the degree of care that is appropriate to the risk of a particular transaction. In some cases, this will entail making the determination that a loan is reasonably likely to meet the borrower's individual financial circumstances and needs. AL 2003-2 also emphasizes that if the OCC has evidence that a national bank has engaged in abusive lending practices, we will review those practices to determine whether they violate specific provisions of the Federal laws, including the Homeowners Equity Protection Act of 1994 (HOEPA), the Fair Housing Act, or the Equal Credit Opportunity Act. The OCC also will evaluate whether such practices involve unfair or deceptive practices in violation of the Federal Trade Commission Act (FTC Act). Indeed several practices cited in AL 2003-2, such as equity stripping, loan flipping, and the refinancing of special subsidized mortgage loans that originally contained terms favorable to the borrower, can be found to be unfair practices that violate the FTC Act.

The OCC's second advisory, AL 2003-3, addresses concerns that have been raised about the link between predatory lending and non-regulated lending intermediaries, and the risk that a national bank could indirectly and inadvertently facilitate predatory lending through the purchase of loans and mortgage-backed securities and in

connection with broker transactions. Pursuant to our standards, a national bank needs to perform adequate due diligence prior to entering into any relationships with loan brokers, third party loan originators, and the issuers of mortgage-backed securities, to ensure that the bank does not do business with companies that fail to employ appropriate safeguards against predatory lending in connection with loans they arrange, sell, or pool for securitization. AL 2003-3 also advises national banks to take specific steps to address the risk of fraud and deception in brokered loan transactions relating to broker-imposed fees and other broker compensation vehicles.

Evidence that national banks are engaged in predatory lending practices is scant. Based on the dearth of such information—from third parties, our consumer complaint database, and our supervisory activities—we have no reason to believe that national banks are engaged in such practices to any discernible degree. This observation is consistent with an extensive study of predatory lending conducted by HUD and the Treasury Department,⁶⁶ and with comments submitted in connection with an OTS rulemaking concerning preemption of state lending standards by 46 State Attorneys General.⁶⁷

More recently, a coalition of State Attorneys General repeated the same view in a brief filed earlier this year in connection with a challenge to that OTS rulemaking.⁶⁸ In supporting the OTS's

⁶⁶ A Treasury-HUD joint report issued in 2000 found that predatory lending practices in the subprime market are less likely to occur in lending by—

Banks, thrifts, and credit unions that are subject to extensive oversight and regulation. . . . The subprime mortgage and finance companies that dominate mortgage lending in many low-income and minority communities, while subject to the same consumer protection laws, are not subject to as much federal oversight as their prime market counterparts—who are largely federally-supervised banks, thrifts, and credit unions. The absence of such accountability may create an environment where predatory practices flourish because they are unlikely to be detected.

Departments of Housing and Urban Development and the Treasury, "Curbing Predatory Home Mortgage Lending: A Joint Report" 17-18 (June 2000) (Treasury-HUD Joint Report).

In addition, the report found that a significant source of abusive lending practices is non-regulated mortgage brokers and similar intermediaries who, because they "do not actually take on the credit risk of making the loan, . . . may be less concerned about the loan's ultimate repayment, and more concerned with the fee income they earn from the transaction." *Id.* at 40.

⁶⁷ Cited in *Nat'l Home Equity Mortgage Ass'n v. OTS*, Civil Action No. 02-2506 (GK) (D.D.C. 2003) at 26.

⁶⁸ The case involves a revised regulation issued by the OTS to implement the Alternative Mortgage Transaction Parity Act (AMTPA). The revised

decision to distinguish between supervised depository institutions and unsupervised housing creditors and to retain preemption of state laws with respect to the former but not for the latter, the State Attorneys General stated:

Based on consumer complaints received, as well as investigations and enforcement actions undertaken by the Attorneys General, predatory lending abuses are largely confined to the subprime mortgage lending market and to non-depository institutions. Almost all of the leading subprime lenders are mortgage companies and finance companies, not banks or direct bank subsidiaries.

Brief for Amicus Curiae State Attorneys General, *National Home Equity Mortgage Association v. OTS*, Civil Action No. 02-2506 (GK) (D.D.C.) at 10-11 (emphasis added).

Against this background, the OCC's approach to predatory lending, embodied in the anti-predatory lending standards discussed above, implemented through the OCC's comprehensive supervision of national banks, minimizes the potential for harm from predatory or abusive lending without reducing the credit available to subprime borrowers. By focusing on lending practices rather than banning specific lending products, this approach reduces the likelihood of predatory lending rather than the availability of credit to subprime borrowers.

Notwithstanding the foregoing, there are certain principles that should be fundamental to all real estate lending by national banks. First is the principle that national banks should not make loans when they lack a reasonable basis to believe that the borrower has the capacity to repay the loan. This standard addresses a central characteristic of predatory lending, namely, lending based on the foreclosure value of the collateral rather than on the borrower's ability to make the scheduled payments under the terms of the loan, based on consideration of the borrower's current and expected income, current obligations, employment status, and other relevant financial resources. In such a situation, the lender is effectively relying on its ability to seize the equity in the borrower's collateral—often the borrower's home—to satisfy the outstanding debt.⁶⁹

regulation distinguishes between Federally-supervised thrift institutions and non-bank mortgage lenders, making non-bank mortgage lenders subject to state law restrictions on prepayment penalties and late fees. See *id.*

⁶⁹ See, e.g., Treasury-HUD Joint Report, *supra* note 66. The report notes that while factors such as the overall size of the loan, the borrower's credit history, and the value of the collateral also play into

To prevent this, the proposal would prohibit a national bank from making a loan based predominantly on the foreclosure value of the borrower's collateral. Such practices are inconsistent with safe and sound banking and antithetical to the OCC's expectations concerning the prudence and integrity with which national banks do business. The proposal would establish a uniform, national standard, applicable to all national banks and their operating subsidiaries that, consistent with existing OCC guidance,⁷⁰ would prohibit this essential characteristic of predatory lending.

A second principle is that national banks should treat all their customers fairly and honestly. National banks' lending activities also are subject to provisions of section 5 of the FTC Act that prohibit unfair or deceptive practices in connection with real estate lending (as well as other activities authorized for national banks).⁷¹ Section 5 serves as a standard to ensure that national banks conduct all their activities free from unfair or deceptive practices.

Practices may be found to be deceptive and thereby unlawful under section 5 of the FTC Act if three factors are present.⁷² First, practices will be deceptive if there is a representation, omission, act, or practice that is likely

the decision. "[a] creditor's decision on whether to originate a mortgage loan should be guided by his/her assessment of the borrower's ability to repay the loan from liquid sources (e.g., income and non-housing assets)." *Id.* at 76. The report goes on to note that "[t]here is widespread concern * * * that some unscrupulous creditors are making loans to borrowers who clearly cannot afford to repay them." *Id.* The report notes further that the results of predatory lending are "loans with onerous terms and conditions that the borrower often cannot repay, leading to foreclosure or bankruptcy." *Id.* at 17.

⁷⁰ See AL 2003-2, which, as explained above, provides supervisory guidance concerning predatory and abusive lending practices. AL 2003-2 contains a recommendation that national banks establish specific policies and procedures for underwriting to ensure that the appropriate determination has been made that each borrower has the capacity to repay his or her loan. See *id.* at 7-8.

⁷¹ See 15 U.S.C. 45(a)(1). See also AL 2003-2. Courts recently have confirmed the application of the FTC Act to national banks. See, e.g., *Minnesota v. Fleet Mortgage Corp.*, 181 F. Supp. 2d 995, 1002 (D.Minn. 2001); *Roberts v. Fleet Bank*, 2001 WL 1486226, *2 (E.D.Pa. 2001). The Federal Deposit Insurance Corporation (FDIC) and the Board of Governors of the Federal Reserve System recently issued statements recognizing the application of section 5 of the FTC Act to the state banks within each agency's respective jurisdiction. See FIL-57-2002, issued by the FDIC May 30, 2002; Letter from Chairman Greenspan to the Hon. John J. LaFalce, May 30, 2002.

⁷² These principles are derived from the Policy Statement on Deception, issued by the Federal Trade Commission on October 14, 1983.

to mislead. Practices that can be misleading or deceptive include false oral and written representations; misleading claims about costs or benefits of services or products; use of bait-and-switch techniques; and failure to provide promised services or products.

Second, a practice may be found to be deceptive if the act or practice would be deceptive from the perspective of a reasonable consumer. In this context, a reasonable consumer is a member of the group targeted by the acts or practices in question. The totality of the circumstances and the net impression that is made will be evaluated in making this determination. Failure to provide information also may be a deceptive act or practice and will be evaluated from the perspective of whether a reasonable consumer is likely to have been misled by the omission. In this regard, a consumer's reaction to an act or practice may be reasonable even if it is not the only reaction that a consumer might have.

Third, in order for a practice to be found to be deceptive, it must be material. A material misrepresentation or practice is one that is likely to affect a consumer's choice or conduct concerning a product or service. Consumer injury is likely if inaccurate or omitted information is important to the consumer's decision. Generally, information, or omission of information, about costs, benefits, purpose, and efficacy (including significant limitations) related to the product or service would be material.

A practice may be found to be unfair and thereby unlawful under section 5 of the FTC Act if the following factors are present.⁷³ First, the practice causes substantial consumer injury. Generally, monetary harm, such as when a consumer pays a fee or interest charge, or incurs other similar costs to obtain a bank product or service as a result of an unfair practice, is deemed to involve substantial injury. Second, the injury is not outweighed by benefits to the consumer or to competition. To be unfair, a practice must be injurious in its net effects. Third, the injury caused by the practice is one that consumers could not reasonably have avoided. Consumer harm caused by a practice that is coercive or that otherwise effectively inhibits the consumer from making an informed choice would be considered not reasonably avoidable.

Credit practices commonly referred to as predatory, such as loan "flipping,"

⁷³ These principles are derived from the Policy Statement on Unfairness, issued by the Federal Trade Commission on December 17, 1980.

equity "stripping," and the refinancing of special subsidized mortgage loans, may well be indicative of practices that are unfair or deceptive practices that violate section 5 of the FTC Act.⁷⁴ For example, loan flipping is generally understood to mean the refinancing of a loan, which results in little or no economic benefit to the borrower, for the primary or sole objective of generating additional loan points, loan fees, prepayment penalties, and fees from financing the sale of credit-related products.⁷⁵ Loan flipping can have particularly harmful results when it involves the practice of encouraging refinancing of special mortgage loans that contain nonstandard payment terms beneficial to the borrower, such as those originated in conjunction with a subsidized governmental or nonprofit organization program, when such refinancing entails the loss of one or more of the beneficial loan terms or is otherwise detrimental to the borrower.⁷⁶ Home equity stripping typically involves making loans with excessively high, up-front fees that are financed and secured by the borrower's home, often with an excessively high penalty upon prepayment of the loan, for the sole or primary objective of stripping the

⁷⁴ AL 2003-2 contains guidance recommending the establishment by national banks of policies and procedures to specify whether and under what circumstances the banks will make loans involving features or circumstances that have been associated with abusive lending practices.

⁷⁵ Federal law prohibits a creditor within one year of having extended credit subject to HOEPA from refinancing that loan to another loan subject to HOEPA, unless the refinancing is "in the borrower's interest." 12 CFR 226.34(a)(3).

⁷⁶ If a national bank engages in the practice of "steering" a borrower to a loan with higher costs instead of to a comparable loan offered by the bank with lower costs for which the borrower could qualify, and does this on the basis of the borrower's race, national origin, age, or gender, for example, the OCC will take appropriate enforcement action under the Federal fair lending laws.

⁷⁷ Frequently equity stripping occurs in connection with loan flipping. "Lenders who flip loans tend to charge high origination fees with each successive refinancing, and may charge these fees based on the entire amount of the new loan. * * * In addition, each refinancing may trigger prepayment penalties, which could be financed as part of the total loan amount, adding to the borrower's debt burden. * * * Each time the loan is flipped, more equity is lost in the home." Treasury-HUD Joint Report, *supra* note 66, at 73-74.

⁷⁸ Case-by-case enforcement actions by the OCC to address such predatory lending practices also is particularly appropriate because such activities appear to be limited, if not rare, in the national banking system. See Treasury-HUD Joint Report, *supra* note 66, at 13 ("[T]here is a growing body of anecdotal evidence that an unscrupulous subset of * * * subprime actors—lenders (often those not subject to federal banking supervision), as well as mortgage brokers, realtors, and home improvement contractors—engage in abusive lending practices that strip borrowers' home equity and place them at increased risk of foreclosure.").

borrower's home equity.⁷⁷ Because the nature and impact of such practices are inherently highly fact-specific, the application of the standards of section 5 and use of the OCC's authority to enforce compliance with those standards are a particularly appropriate approach to ensure that such practices are not occurring in the national banking system.⁷⁸

Section 8 of the Federal Deposit Insurance Act, 12 U.S.C. 1818, provides the OCC with the authority to bring enforcement actions against national banks and their subsidiaries for violations of any law or regulation, which necessarily includes section 5 of the FTC Act.⁷⁹ The OCC has taken enforcement actions against banks involved in practices the OCC believed were unfair or deceptive and will continue to exercise its enforcement authority in this area where appropriate. Thus, while many types of state laws are not applicable to national banks' deposit-taking and lending activities, the OCC's guidance, the new, national anti-predatory lending standard of the proposed rule, the OCC's enforcement of the FTC Act, and a host of other Federal regulations⁸⁰ will apply on a uniform basis to ensure that the real estate lending activities of national banks are conducted according to high standards.

4. Description of the Proposed Amendments to Part 34

Current § 34.3 states the general rule that national banks may "make, arrange, purchase, or sell loans or extensions of credit, or interests therein, that are secured by liens on, or interests in, real estate, subject to terms, conditions, and limitations prescribed by the Comptroller of the Currency by regulation or order." The proposal would leave this statement of the general rule unchanged, other than

⁷⁹ In section 8, Congress gave the OCC broad powers to compel national banks' compliance with Federal and state laws. This includes the ability to issue cease and desist orders when the OCC determines that a national bank is violating or has violated any "law, rule, or regulation." 12 U.S.C. 1818(b)(1). Recent decisions have acknowledged the OCC's authority to enforce national banks' compliance with the FTC Act. See, e.g., *Chavers v. Fleet Bank*, 2002 WL 481797 (R.I. Super. Feb. 25, 2002); *Rossman v. Fleet Bank, C.A. No. PB01-0479* (R.I. Super. 2001) (transcript of hearing on Nov. 26, 2001, pp. 25-28). See also *Roberts*, 2001 WL 1486226 at *2.

⁸⁰ As set forth above, there is an existing network of Federal laws applicable to national banks that protect consumers in a variety of ways. For lending activities, in addition to the Truth in Lending Act (TILA), Real Estate Settlement Procedures Act, Equal Credit Opportunity Act, and the Fair Housing Act, the Home Mortgage Disclosure Act, the Fair Credit Reporting Act, the Consumer Leasing Act, and the Fair Debt Collection Practices Act may also apply.

designating it as paragraph (a) of § 34.3.⁸¹

A new paragraph (b) would add an explicit safety and soundness-based anti-predatory lending standard to the general statement of authority concerning lending. As proposed, § 34.3(b) states that a national bank shall not make a loan subject to 12 CFR part 34 based predominantly on the foreclosure value of the borrower's collateral, rather than on the borrower's repayment ability, including current and expected income, current obligations, employment status, and other relevant financial resources. This requirement reflects a bedrock principle of sound banking practices and is consistent with views repeatedly expressed by the OCC concerning the safety and soundness implications arising from loans made in reliance on the foreclosure value of the borrower's home or other collateral.⁸² The OCC believes that it is axiomatic that lenders following safe and sound lending practices will take reasonable steps to assure themselves and to verify that the borrower has the capacity to make scheduled payments to repay a loan, taking into account all of the borrower's obligations, including other indebtedness, insurance, and taxes, as well as principal and interest.⁸³

The new prudential standard proposed in § 34.3(b), the preexisting standard under the FTC Act, which the OCC enforces, and the many other applicable Federal laws that we have mentioned, ensure that national banks are subject to consistent and uniform Federal standards, administered and enforced by the OCC, that provide strong and extensive customer protections and appropriate safety and soundness-based criteria for their real estate lending activities. We invite interested parties to suggest other

⁸¹ We note that in a notice of proposed rulemaking to amend 12 CFR parts 3.5, 6, 7, 9, 28, and 34, published on February 7, 2003, we have proposed to amend 12 CFR 34.3 to reflect the amendment to 12 U.S.C. 371 that added a reference to 12 U.S.C. 1828(o). See 68 FR 6363.

⁸² See, e.g., Testimony of John D. Hawke, Jr. Before the Committee on Banking and Financial Services of the U.S. House of Representatives, May 24, 2000; AL 2003-2. See also OCC Advisory Letter 2000-7 (July 25, 2000). The standard is reflected elsewhere in Federal law. HOEPA prohibits creditors from engaging in a pattern or practice of extending credit subject to HOEPA "based on the consumers' collateral without regard to the consumers' repayment ability, including the consumers' current and expected income, current obligations, and employment." 15 U.S.C. 1639(h).

⁸³ OCC regulations provide that a national bank must "establish and maintain loan documentation practices that * * * [i]dentify the * * * source of repayment, and assess the ability of the borrower to repay the indebtedness in a timely manner." 12 CFR part 30, App. A, II. C.

general standards that would be appropriate to apply to national bank real estate lending activities that would further these objectives.

State laws that are preempted. Pursuant to section 371, we propose to amend § 34.4(a) to specify more completely the types of state law restrictions and requirements that are not applicable to national banks. This list, promulgated under our authority under section 371 to prescribe the types of restrictions and requirements to which national banks' real estate lending activities shall be subject, reflects our experience with types of state laws that obstruct, in whole or in part, or condition, national banks' exercise of real estate lending powers granted under Federal law. The list is not intended to be exhaustive. Other types of state laws that similarly affect the exercise of national banks' real estate lending powers may be identified. Under the regulation, those would be addressed by the OCC on a case-by-case basis.

State laws that are not preempted. Section 34.4(b) also provides that certain types of state laws are not preempted and would be applicable to national banks to the extent that they do not materially affect the real estate lending powers of national banks or are otherwise consistent with national banks' Federal authority to engage in real estate lending.⁸⁴ These types of laws generally pertain to contracts, debt collection, acquisition and transfer of property, taxation, zoning, crimes, torts,⁸⁵ and homestead rights. In addition, any other law that the OCC determines to interfere to only an insignificant extent with national banks' real estate lending powers or is otherwise consistent with national banks' authority to engage in real estate lending would not be preempted under the proposal.⁸⁶ In general, these would

be laws that do not attempt to regulate the manner or content of national banks' real estate lending, but that instead form the legal infrastructure that surrounds and supports the conduct of that business. In general, the types of laws that are not preempted are those that promote national banks' ability to conduct business, rather than obstruct national banks' exercise of their real estate lending powers.

D. Revisions to Part 7—Deposit-Taking, Other Lending, and Bank Activities

1. Background

Preemption issues arising in the context of national bank deposit-taking, other lending activities, and bank activities, while involving the application of different sources of Federal authority than that of real estate lending, nevertheless need similar rules that address more completely the types of state law restrictions and requirements that are, and are not, applicable to national banks and the standard employed to produce that result. Here, the proposal again focuses on state laws that obstruct, in whole or in part, or condition, national banks' exercise of powers granted under Federal law.⁸⁷

This result recognizes the Federal source of national bank powers and the inherent design of the national banking system as a nationwide system of Federally-empowered banks operating under Federal standards, as discussed in section B., above.

Consistent with the purpose of establishing a national banking system subject to uniform standards, Congress has vested the OCC with broad authority to facilitate the safe and sound exercise by national banks of their Federal powers. For example, 12 U.S.C. 93a vests the OCC with the authority to "prescribe rules and regulations to carry

out the responsibilities of the office * * *," except "to the extent that authority to issue such rules and regulations has been *expressly* and *exclusively* granted to another regulatory agency."⁸⁸ Clearly, one of the "responsibilities of the office" is to administer the National Bank Act to enable national banks to employ the powers vested in them by Congress, free of obstacles to their ability to fully exercise those powers, and governed under the framework of Federal regulation and national standards envisioned by Congress in its design of the national banking system. The OCC fulfills this responsibility in part by setting the Federal standards under which national banks operate and clarifying when state standards do, and do not, affect their operations.

In this regard, we believe it is appropriate to provide greater certainty and clarity to national banks concerning the extent to which state laws governing deposit-taking, non-real estate lending, and other authorized bank activities are applicable to national banks. The proposed amendments thereby further the OCC's responsibility to administer the National Bank Act by allowing national banks to conduct these activities, free of the specified types of state-imposed obstacles to their ability to fully exercise their powers in these areas. The amendments also further the ability of national banks to operate pursuant to the framework of national standards envisioned by Congress and enhance the safe and sound exercise by national banks of their Federal authority, to conduct the business of banking by promoting efficiency of national bank activities.

2. Description of the Proposed Amendments to Part 7

The proposal adds three new sections to part 7, § 7.4007 regarding deposit-taking activities, § 7.4008 regarding non-real estate lending activities, and § 7.4009 regarding other authorized national bank activities. The structure of the amendments is the same for §§ 7.4007 and 7.4008 and is similar for § 7.4009. For §§ 7.4007 and 7.4008, the proposed rule first sets out a statement of the authority to engage in the activity. Second, the rule notes that state laws that obstruct, in whole or in part, or condition, a national bank's exercise of powers granted under Federal law are not applicable, and lists several types of state laws that are preempted. Finally,

⁸⁴ As set forth above in note 36, there are instances where Federal law specifically requires the application of state law to national banks, such as in 12 U.S.C. 92a(a). The language used in the regulation "unless otherwise made applicable . . . by Federal law" refers to this type of situation. Federal statutes such as TILA that contain clauses that preserve state law from preemption by that statute do not make those state laws applicable to national banks; in fact, such state laws may still be preempted by other Federal law such as the National Bank Act. See, e.g., *Bank One, Utah*, 190 F.3d at 850; and *Bank of America*, 309 F.3d at 565.

⁸⁵ See *Bank of America*, 309 F.3d at 559 ("[S]tates retain some power to regulate national banks in areas such as contracts, debt collection, acquisition and transfer of property, and taxation, zoning, criminal, and tort law.")

⁸⁶ We note that the label a state attaches to its laws will not affect the analysis of whether that law is preempted. We will analyze the substance of any state law to determine whether the state law has only an incidental impact on the Federal powers.

For instance, laws related to the transfer of real property may contain provisions that give borrowers the right to "cure" a default upon acceleration of a loan if the lender has not foreclosed on the property securing the loan. Viewed one way, this could be seen as part of the state laws governing foreclosure, which historically have been within a state's purview. However, as we concluded in the National City Order, to the extent that this type of law also limits the ability of a national bank to adjust the terms of a loan once there has been a default, it would be a state law limitation "concerning * * * (2) The schedule for repayment of principal and interest; [or] (3) The term to maturity of the loan." 12 CFR 34.4(a). In such a situation, we would look to the effect of the state statute. If the primary effect of the state law is to regulate in the areas listed in our regulation, the state law would be preempted.

⁸⁷ See *Hines v. Davidowitz*, 312 U.S. 52, 67 (state law is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."); *Barnett*, 517 U.S. at 33-34.

⁸⁸ 12 U.S.C. 93a (emphasis added). Section 93a also contains exceptions to our rulemaking authority in areas unrelated to deposit-taking or lending.

the rule lists several types of state laws that, as a general matter, are not preempted. In § 7.4009, the proposal first states that national banks may exercise all powers authorized to it under Federal law. Second, the proposal states that except as otherwise made applicable by Federal law, state laws that obstruct, in whole or in part, or condition, a national bank's exercise of powers granted under Federal law are not applicable. Finally, the proposal lists several types of state laws that, as a general matter, are not preempted.

As with the proposed amendments to part 34, the proposed amendment to part 7 governing non-real estate lending includes a safety and soundness-based anti-predatory lending standard. As proposed, § 7.4008(b) states that a national bank shall not make a loan described in § 7.4008 based predominantly on the foreclosure value of the borrower's collateral, rather than on the borrower's repayment ability, including current and expected income, current obligations, employment status, and other relevant financial resources. As noted in the discussion of proposed amendments to part 34, this requirement reflects a bedrock principle of sound banking practices and is consistent with views repeatedly expressed by the OCC concerning the safety and soundness implications arising from loans made in reliance on the foreclosure value of the borrower's home or other collateral.

Non-real estate lending also is subject to section 5 of the FTC Act, which makes unlawful "unfair or deceptive acts or practices" in interstate commerce.⁸⁹ Together, the new prudential standard proposed in § 7.4008(b) and the preexisting standard under the FTC Act, plus Federal laws such as the Truth-in-Savings Act, ensure that national banks are subject to consistent and uniform Federal standards, administered and enforced by the OCC, that provide strong and extensive customer protections and appropriate safety and soundness-based criteria for their deposit-taking and lending activities. We invite interested parties to suggest other general standards that would be appropriate to apply to national bank lending activities that would further these objectives.

Deposit-taking and lending are powers specifically enumerated in statute. The same Federal statute—12 U.S.C. 24 (Seventh)—also grants to national banks the broader power to engage in activities that are part of, or incidental to, the business of banking. Questions about the applicability of

state law are resolved, as we have described, with reference to the Federal character of the national bank charter; the fact that national bank powers derive exclusively from Federal law; and the purposes of the National Bank Act, including Congress's creation of a "complete" national banking system, free from state control, and subject to uniform, national standards. In this context, the Supreme Court and the lower Federal courts have said that state laws affecting the exercise of Federally authorized powers ordinarily do not apply to national banks.⁹⁰ This is so whether the Federal grant of authority is specific, as in the case of deposit-taking or lending, or general, like the powers clause in section 24 (Seventh).

The OCC's regulations already address the applicability of state law with respect to a number of specific types of activities. The question may persist, however, about the extent to which state law may govern powers or activities that have not been addressed by Federal court precedents or OCC opinions or orders. Accordingly, proposed new § 7.4009 provides that state laws do not apply to national banks if they obstruct, in whole or in part, or condition, a national bank's exercise of powers granted under Federal law.⁹¹

In some circumstances, of course, Federal law directs the application of state standards to a national bank. The wording of § 7.4009 reflects the fact that a Federal statute may require the application of state law,⁹² or it may incorporate—or "Federalize"—state standards.⁹³ In those circumstances, the state standard applies. State law may also apply if it has only an incidental

⁸⁹ See *Bornett*, 517 U.S. at 32.

⁹⁰ We note that the OTS has issued a regulation providing generally that state laws purporting to address the operations of Federal savings associations are preempted. See 12 CFR 545.2. The extent of Federal regulation and supervision of Federal savings associations under the Home Owners' Loan Act is substantially the same as for national banks under the national banking laws, a fact that warrants similar conclusions about the applicability of state laws to the conduct of the Federally authorized activities of both types of entities. Compare, e.g., 12 U.S.C. 1464(a) (OTS authorities with respect to the organization, incorporation, examination, operation, regulation, and chartering of Federal savings associations) with 12 U.S.C. 21 (organization and formation of national banking associations), 481 (OCC authority to examine national banks and their affiliates), 484 (OCC's exclusive visitatorial authority), 93a (OCC authority to issue regulations).

⁹¹ See, e.g., 15 U.S.C. 6711 (insurance activities of national banks are "functionally regulated" by the states, subject to the provisions on the operation of state law contained in section 104 of the Gramm-Leach-Bliley Act).

⁹² See, e.g., 12 U.S.C. 92a (permissible fiduciary activities for national banks determined by reference to state law).

effect on a national bank's exercise of its Federally authorized powers or if it is otherwise consistent with national banks' uniquely Federal status. Like the other provisions we are proposing, § 7.4009 recognizes the potential applicability of state law in these circumstances. This approach is consistent with the Supreme Court's observation that national banks "are governed in their daily course of business far more by the laws of the state than of the nation."⁹⁴ As the Ninth Circuit recently has said: "[S]tates retain some power to regulate national banks in areas such as contracts, debt collection, acquisition and transfer of property, and taxation, zoning, criminal, and tort law."⁹⁵ However, as noted previously, these types of laws typically do not regulate the manner or content of the business of banking authorized for national banks, but rather establish the legal infrastructure that surrounds and supports the conduct of that business. They promote national banks' ability to conduct business; they do not obstruct the ability of national banks to exercise their Federally-granted powers.

E. Application of Proposed Changes to Operating Subsidiaries

In accordance with our regulation set out in 12 CFR 7.4006, the rules governing national bank deposit-taking and lending apply equally to national bank operating subsidiaries. The OCC and Federal courts long have recognized that national banks may exercise permissible Federal powers through the separately incorporated operating subsidiary. Our regulations make clear that activities conducted in operating subsidiaries must be permissible for a national bank to engage in directly either as part of, or incidental to, the business of banking.⁹⁶ Moreover, the operating subsidiary is acting "pursuant to the same authorization, terms and conditions that apply to the conduct of such activities by its parent national bank."⁹⁷ These regulations reflect express Congressional recognition in section 121 of the Gramm-Leach-Bliley Act that national banks may own subsidiaries that engage "solely in activities that national banks are permitted to engage in directly and are conducted subject to the same terms and

⁹⁴ *Nat'l Bank v. Commonwealth*, 76 U.S. (9 Wall.) 353, 362 (1869) (holding that shares held by shareholders of a national bank were lawfully subject to state taxation) ("All [national banks'] contracts are governed and construed by State laws. Their acquisition and transfer of property, their right to collect debts, and their liability to be sued for debts, are also based on State law.").

⁹⁵ *Bank of America*, 309 F.3d at 559.

⁹⁶ See 12 CFR 5.34(e)(3).

⁹⁷ *Id.*

⁸⁹ 15 U.S.C. 45(a)(1).

conditions that govern the conduct of such activities by national banks."⁹⁸ Courts have consistently treated operating subsidiaries and their parent banks as equivalents, unless Federal law requires otherwise, in considering whether a particular activity is permissible.⁹⁹

In accordance with the longstanding regulatory and judicial recognition of operating subsidiaries as corporate extensions of the parent bank, OCC regulations specifically provide that "[u]nless otherwise provided by Federal law or OCC regulation, State laws apply to national bank operating subsidiaries to the same extent that those laws apply to the parent national bank."¹⁰⁰ The only court to have considered the application of state law to an operating subsidiary after § 7.4006 was promulgated agreed with our position.¹⁰¹ We also note that the OTS takes the same approach with respect to operating subsidiaries of Federal thrifts. 12 CFR 559.3(n) of the OTS regulations provides that state law applies to Federal savings associations' operating subsidiaries to the extent that the law applies to the parent thrift. This OTS regulation was upheld by a Federal district court.¹⁰²

Accordingly, the proposed amendments to parts 7 and 34 apply equally to operating subsidiaries of national banks.

Request for Comments

In addition to the specific issues noted previously on which comment is specifically invited, the OCC invites comment on all aspects of the proposed regulation.

⁹⁸ Pub. L. 106-102, § 121, 113 Stat. 1338, 1373 (1999), codified at 12 U.S.C. 24a(g)(3)(A).

⁹⁹ See, e.g., *NationsBank of North Carolina, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251 (sale of annuities by operating subsidiary); *Clarke v. Securities Industry Ass'n*, 479 U.S. 388 (1987) (securities brokerage operating subsidiary); *Marquette Nat'l Bank*, 439 U.S. 299 (credit card subsidiary); *American Ins. Ass'n v. Clarke*, 865 F.2d 278 (D.C. Cir. 1988) (bond insurance subsidiary); *M & M Leasing Corp. v. Seattle First Nat'l Bank*, 563 F.2d 1377 (9th Cir. 1977) (auto leasing subsidiary); and *Valley Nat'l Bank v. Lavecchia*, 59 F. Supp. 2d 432 (D.N.J. 1999) (title insurance subsidiary).

¹⁰⁰ 12 CFR 7.4006.

¹⁰¹ See *Wells Fargo Bank I*, 252 F. Supp. 2d 1065, and *Wells Fargo Bank II*, 2003 WL 21277203, granting plaintiff's motion for preliminary and permanent injunction on Supremacy Clause preemption claims, respectively. See also *Nat'l City Bank of Indiana v. Bauris*, Civ. No. S-03-0655 GEB JFM (E.D. Cal. May 7, 2003), and *Nat'l City Bank of Indiana v. Bauris*, 2003 WL 21536818 (E.D. Cal. July 2, 2003).

¹⁰² See *WFS Financial, Inc. v. Dean*, 79 F. Supp. 2d 1024 (W.D. Wis. 1999); see also *Chaires v. Chevy Chase Bank, F.S.B.*, 748 A.2d 34, 44 (Md. App. 2000).

Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106-102, sec. 722, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. We invite your comments on how to make this proposal easier to understand. For example:

- Have we organized the material to suit your needs? If not, how could this material be better organized?
- Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be more clearly stated?
- Does the proposed regulation contain language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes to the format would make the regulation easier to understand?
- What else could we do to make the regulation easier to understand?

Community Bank Comment Request

In addition, we invite your comments on the impact of this proposal on community banks: The OCC recognizes that community banks operate with more limited resources than larger institutions and may present a different risk profile. Thus, the OCC specifically requests comments on the impact of this proposal on community banks' current resources and available personnel with the requisite expertise, and whether the goals of the proposed regulation could be achieved, for community banks, through an alternative approach.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b) (RFA), the regulatory flexibility analysis otherwise required under section 604 of the RFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short, explanatory statement in the *Federal Register* along with its rule.

Pursuant to section 605(b) of the RFA, the OCC hereby certifies that this proposal will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not needed. The amendments address the applicability of state law to national banks' deposit-taking, lending, and

other authorized activities. These amendments simply provide the OCC's analysis and do not impose any new requirements or burdens. As such, they will not result in any adverse economic impact.

Executive Order 12866

The OCC has determined that this proposal is not a significant regulatory action under Executive Order 12866.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4 (2 U.S.C. 1532) (Unfunded Mandates Act), requires that an agency prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC has determined that the proposed rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, this rulemaking is not subject to section 202 of the Unfunded Mandates Act.

Executive Order 13132

Executive Order 13132 requires Federal agencies, including the OCC, to certify their compliance with that Order when they transmit to the Office of Management and Budget any draft final regulation that has Federalism implications. Under the Order, a regulation has Federalism implications if it has "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." In the case of a regulation that has Federalism implications and that preempts state law, the Order imposes certain consultation requirements with state and local officials; requires publication in the preamble of a Federalism summary impact statement; and requires the OCC to make available to the Director of the Office of Management and Budget any written communications submitted by state and local officials. By the terms of the Order, these requirements apply to the extent that they are practicable and permitted by law and, to that extent, must be

satisfied before the OCC promulgates a final regulation.

This proposal may have Federalism implications, as that term is used in the Order. Therefore, before promulgating a final regulation based on this proposal, the OCC will, to the extent practicable and permitted by law, seek consultation with state and local officials, include a Federalism summary impact statement in the preamble to the final rule, and make available to the Director of OMB any written communications we receive from state or local officials.

List of Subjects

• 12 CFR Part 7

Credit, Insurance, Investments, National banks, Reporting and recordkeeping requirements, Securities, Surety bonds.

12 CFR Part 34

Mortgages, National banks, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, parts 7 and 34 of chapter I of title 12 of the Code of Federal Regulations are proposed to be amended as follows:

PART 7—BANK ACTIVITIES AND OPERATIONS

1. The authority citation for part 7 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 71, 71a, and 93a.

Subpart D—Preemption

2. A new § 7.4007 is added to read as follows:

§ 7.4007 Deposit-taking.

(a) *Authority of national banks.* A national bank may receive deposits and engage in any activity incidental to receiving deposits, including issuing evidence of accounts, subject to such terms, conditions, and limitations as the Comptroller of the Currency may prescribe by regulation or order and any other applicable Federal law.

(b) *Applicability of state law.* (1) Except where made applicable by Federal law, state laws that obstruct, in whole or in part, or condition, a national bank's exercise of its Federally-authorized deposit-taking powers are not applicable to national banks.

(2) The types of state laws referenced in paragraph (b)(1) of this section include state laws concerning—

- (i) Abandoned and dormant accounts;³
- (ii) Checking accounts;
- (iii) Mandated statements and disclosure requirements;
- (iv) Funds availability;
- (v) Savings account orders of withdrawal;
- (vi) State licensing or registration requirements; and
- (vii) Special purpose savings services.⁴

(c) Except where made applicable by Federal law, state laws on the following subjects apply to national banks to the extent that they only incidentally affect the deposit-taking activities of national banks or are otherwise consistent with the purposes set out in paragraph (a) of this section:

- (1) Contracts;
- (2) Torts;
- (3) Criminal law;⁵
- (4) Debt collection;
- (5) Acquisition and transfer of property;
- (6) Taxation;
- (7) Zoning; and
- (8) Any other law that the OCC, upon review, determines to have only an incidental effect on the deposit-taking operations of national banks or is otherwise consistent with the purposes set out in paragraph (a) of this section.

3. A new § 7.4008 is added to read as follows:

§ 7.4008 Lending.

(a) *Authority of national banks.* A national bank may make, sell, purchase, participate in, or otherwise deal in loans and interests in loans that are not secured by liens on, or interests in, real estate, subject to any terms, conditions, and limitations as the Comptroller of the Currency may prescribe by regulation or

³This does not apply to state laws of the type upheld by the United States Supreme Court in *Anderson Nat'l Bank v. Lockett*, 321 U.S. 233 (1944), which obligate a national bank to "pay [deposits] to the persons entitled to demand payment according to the law of the state where it does business." *Id.* at 248-249. State escheat laws are not included in this category. See also 12 CFR 557.12; 62 FR 55759, 55761 (Oct. 22, 1997).

⁴State laws purporting to regulate national bank fees and charges are addressed in 12 CFR 7.4002.

⁵But see the distinction drawn by the Supreme Court in *Easton v. Iowa*, 188 U.S. 220, 238 (1903) between "crimes defined and punishable at common law or by the general statutes of a State" and "crimes and offences cognizable under the authority of the United States." The Court stated that "[u]ndoubtedly a State has the legitimate power to define and punish crimes by general laws applicable to all persons within its jurisdiction. * * * But it is without lawful power to make such special laws applicable to banks organized and operating under the laws of the United States." *Id.* at 239 (holding that Federal law governing the operations of national banks preempted a state criminal law prohibiting insolvent banks from accepting deposits).

order and any other applicable Federal law.

(b) *Standards for loans.* A national bank shall not make a loan described in paragraph (a) based predominantly on the foreclosure value of the borrower's collateral, without regard to the borrower's repayment ability, including the borrower's current and expected income, current obligations, employment status, and other relevant financial resources.

(c) *Applicability of state law.* (1) Except where made applicable by Federal law, state laws that obstruct, in whole or in part, or condition, a national bank's exercise of its Federally-authorized non-real estate lending powers are not applicable to national banks.

(2) The types of state laws referenced in paragraph (c)(1) of this section include state laws concerning—

- (i) Licensing, registration, filings, or reports by creditors;
- (ii) The ability of a creditor to require or obtain insurance for collateral or other credit enhancements or risk mitigants, in furtherance of safe and sound banking practices;
- (iii) Loan-to-value ratios;
- (iv) The terms of credit, including schedule for repayment of principal and interest, amortization of loans, balance, payments due, minimum payments, or term to maturity of the loan, including the circumstances under which a loan may be called due and payable upon the passage of time or a specified event external to the loan;
- (v) Escrow accounts, impound accounts, and similar accounts;
- (vi) Security property, including leaseholds;
- (vii) Access to, and use of, credit reports;
- (viii) Mandated statements, disclosure and advertising, including laws requiring specific statements, information, or other content to be included in credit application forms, credit solicitations, billing statements, credit contracts, or other credit-related documents;
- (ix) Disbursements and repayments; and
- (x) Rates of interest on loans.⁶

(d) Except where made applicable by Federal law, state laws on the following subjects apply to national banks to the extent that they only incidentally affect

⁶The limitations on charges that comprise rates of interest on loans by national banks are determined under Federal law. Federal law applies a state's limits on rates of interest to loans made by national banks located in that state. See 12 U.S.C. 85; 12 CFR 7.4001. State laws purporting to regulate national bank fees and charges that do not constitute interest are addressed in 12 CFR 7.4002.

the non-real estate lending activities of national banks or are otherwise consistent with national banks' Federal lending authority:

- (1) Contracts;
- (2) Torts;
- (3) Criminal law;⁷
- (4) Debt collection;
- (5) Acquisition and transfer of property;
- (6) Taxation;
- (7) Zoning; and
- (8) Any other law that the OCC, upon review, determines to have only an incidental effect on the non-real estate lending operations of national banks or is otherwise consistent with the purposes set out in paragraph (a) of this section.

4. A new § 7.4009 is added to read as follows:

§ 7.4009 Applicability of state law to other authorized national bank activities.

(a) *Authority of national banks.* A national bank may exercise all powers authorized to it under Federal law, including conducting any activity that is part of, or incidental to, the business of banking, subject to such terms, conditions, and limitations as are imposed by the OCC or by any other applicable Federal law.

(b) *Applicability of state law generally.* Except where made applicable by Federal law, state laws that obstruct, in whole or in part, or condition, a national bank's exercise of powers granted under Federal law do not apply to national banks.

(c) *Applicability of state law to particular national bank activities.* (1) The provisions of this section govern with respect to any national bank power or aspect of a national bank's activities that is not covered by another OCC regulation specifically addressing the applicability of state law.

(2) Except where made applicable by Federal law, state laws on the following subjects apply to national banks to the extent that they only incidentally affect the exercise of national bank powers:

- (i) Contracts;
- (ii) Torts;
- (iii) Criminal law;
- (iv) Debt collection;
- (v) Acquisition and transfer of property;
- (vi) Taxation;
- (vii) Zoning; and
- (viii) Any other law that the OCC, upon review, determines to have only

⁷ See note 5 in 12 CFR 7.4007 regarding the distinction drawn by the Supreme Court in *Easton v. Iowa*, 188 U.S. 220, 238 (1903) between "crimes defined and punishable at common law or by the general statutes of a State" and "crimes and offenses cognizable under the authority of the United States."

an incidental effect on the exercise of national bank powers or is otherwise consistent with purposes set out in paragraph (a) of this section.

PART 34—REAL ESTATE LENDING AND APPRAISALS

Subpart A—General

5. The authority citation for part 34 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 29, 93a, 371, 1701j-3, 1828(o), and 3331 *et seq.*

6. In § 34.3, the existing text is designated as paragraph (a), and a new paragraph (b) is added to read as follows:

§ 34.3 General rule.

* * * * *

(b) A national bank shall not make a loan described in this part based predominantly on the foreclosure value of the borrower's collateral, without regard to the borrower's repayment ability, including the borrower's current and expected income, current obligations, employment status, and other relevant financial resources.

7. Section 34.4 is revised to read as follows:

§ 34.4 Applicability of State law.

(a) Except where State law is made applicable by Federal law, a national bank may make real estate loans under 12 U.S.C. 371 and § 34.3, without regard to State law limitations concerning:

- (1) Licensing, registration, filings, or reports by creditors;
- (2) The ability of a creditor to require or obtain private mortgage insurance, insurance for other collateral, or other credit enhancements or risk mitigants, in furtherance of safe and sound banking practices;
- (3) Loan-to-value ratios;
- (4) The terms of credit, including schedule for repayment of principal and interest, amortization of loans, balance, payments due, minimum payments, or term to maturity of the loan, including the circumstances under which a loan may be called due and payable upon the passage of time or a specified event external to the loan;
- (5) The aggregate amount of funds that may be loaned upon the security of real estate;
- (6) Escrow accounts, impound accounts, and similar accounts;
- (7) Security property, including leaseholds;
- (8) Access to, and use of, credit reports;
- (9) Mandated statements, disclosure and advertising, including laws requiring specific statements,

information, or other content to be included in credit application forms, credit solicitations, billing statements, credit contracts, or other credit-related documents;

- (10) Processing, origination, servicing, sale or purchase of, or investment or participation in, mortgages;
 - (11) Disbursements and repayments;
 - (12) Rates of interest on loans;¹
 - (13) Due-on-sale clauses except to the extent provided in 12 U.S.C. 1701j-3 and 12 CFR part 591; and
 - (14) Covenants and restrictions that must be contained in a lease to qualify the leasehold as acceptable security for a real estate loan.
- (b) Except where made applicable by Federal law, State laws on the following subjects apply to national banks to the extent that they only incidentally affect the real estate lending powers of national banks:
- (1) Contracts;
 - (2) Torts;
 - (3) Criminal law;²
 - (4) Homestead laws specified in 12 U.S.C. 1462a(f);
 - (5) Debt collection;
 - (6) Acquisition and transfer of real property;
 - (7) Taxation;
 - (8) Zoning; and
 - (9) Any other law that the OCC, upon review, determines to have only an incidental effect on the real estate lending powers of national banks or is otherwise consistent with the purposes set out in § 34.3(a).

Dated: July 30, 2003.

John D. Hawke, Jr.,
Comptroller of the Currency.

[FR Doc. 03-19906 Filed 8-4-03; 8:45 am]

BILLING CODE 4810-33-P

¹ The limitations on charges that comprise rates of interest on loans by national banks are determined under Federal law. See 12 U.S.C. 85 and 1735f-7a; 12 CFR 7.4001. State laws purporting to regulate national bank fees and charges that do not constitute interest are addressed in 12 CFR 7.4002.

² But see the distinction drawn by the Supreme Court in *Easton v. Iowa*, 188 U.S. 220, 238 (1903) between "crimes defined and punishable at common law or by the general statutes of a State" and "crimes and offenses cognizable under the authority of the United States." The Court stated that "[u]ndoubtedly a State has the legitimate power to define and punish crimes by general laws applicable to all persons within its jurisdiction. * * * But it is without lawful power to make such special laws applicable to banks organized and operating under the laws of the United States." *Id.* at 239 (holding that Federal law governing the operations of national banks preempted a state criminal law prohibiting insolvent banks from accepting deposits).

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****18 CFR Part 284**

[Docket No. RM03-10-000]

Amendments to Blanket Sales Certificates; Extension of Comment Period

July 25, 2003.

AGENCY: Federal Energy Regulatory Commission, DOE.**ACTION:** Notice of proposed rulemaking; extension of comment period.

SUMMARY: On June 26, 2003, the Federal Energy Regulatory Commission issued a Notice of Proposed Rulemaking (NOPR) (68 FR 40207, July 7, 2003) seeking comments on amending the blanket certificates for unbundled gas sales services held by interstate natural gas pipelines and the blanket marketing certificates held by persons making sales for resale of gas at negotiated rates in interstate commerce. The date for filing comments is being extended at the request of various interested parties.

DATES: Comments on issues posed by the NOPR shall be filed on or before August 18, 2003. Reply comments shall be filed on or before September 18, 2003.

ADDRESSES: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Magalie R. Salas, Secretary 888 First Street, NE., Washington, DC 20426, (202) 502-8400.

On July 23 and 24, 2003 Duke Energy Corporation (Duke) and Public Service Electric and Gas Company (PSE&G) filed respective motions for a 60-day extension of time for the filing of initial comments in response to the Commission's Notice of Proposed Rulemaking (NOPR) regarding blanket sales certificates, issued June 26, 2003, in the above-docketed proceeding. In their motions, Duke and PSE&G state that permitting a 60-day extension to comment will allow interested parties to adequately review, analyze and formulate appropriate and constructive comments for the Commission to consider in its final rule on amendments to blanket sales certificates.

Upon consideration, notice is hereby given that the time for filing initial comments in response to the Commission's June 25, 2003 NOPR is extended from August 6, 2003, to and including August 18, 2003. Reply

comments shall be filed on or before September 18, 2003.

Magalie R. Salas,
Secretary.

[FR Doc. 03-19879 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 310 and 334**

[Docket No. 1978N-036L]

RIN 0910-AA01

Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record and proposing to amend the tentative final monograph (proposed rule) for over-the-counter (OTC) laxative drug products to reclassify the bulk-forming laxative psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond)), psyllium seed husks, plantago ovata husks, and plantago seed) in a granular dosage form from Category I (generally recognized as safe and effective and not misbranded) to Category II (not generally recognized as safe and effective or misbranded). The granular dosage form affected by this proposal includes, but is not limited to, any granules that are swallowed dry prior to drinking liquid; any granules that are dispersed, suspended, or partially dissolved in liquid prior to swallowing; any granules that are chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid; and any granules that are sprinkled over food. FDA is issuing this proposed rulemaking after considering data and information on the safety of some currently marketed products containing psyllium in a granular dosage form. This proposed rulemaking does not apply to nongranular dosage forms of psyllium, such as powders. FDA has determined that psyllium in a granular dosage form presents an unacceptable safety risk to consumers because esophageal obstruction continues to occur despite currently required label warnings and directions.

This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by November 3, 2003; submit written or electronic comments on the FDA's economic impact determination by November 3, 2003. See section IX for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Arlene Solbeck, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:**I. Background**

In the advance notice of proposed rulemaking (ANPRM) for OTC laxative, antidiarrheal, emetic, and antiemetic drug products (40 FR 12902 at 12906, March 21, 1975), the advisory review panel on OTC laxative, antidiarrheal, emetic, and antiemetic drug products (the Panel) recommended Category I status for the OTC bulk laxative psyllium ingredients, which include plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), and psyllium seed husks. FDA concurred with the Panel's Category I classification of these ingredients in the tentative final monograph (TFM) published in the *Federal Register* of January 15, 1985 (50 FR 2124 at 2152).

In the ANPRM, the Panel recommended a warning statement (§ 334.52(a)(1) 21 CFR 334.52(a)(1)) for bulk forming laxatives that advised drinking a full glass, 8 ounces (oz), of liquid with each dose and direction statements (§ 334.10(f)) advising adequate fluid intake. The Panel concluded that adequate fluid intake was necessary for the proper use of bulk-forming laxatives because esophageal and intestinal obstruction had occurred from ingesting bulk-forming laxatives with insufficient water or in the presence of certain disease conditions (40 FR 12902 at 12908). FDA discussed the risk of esophageal obstruction from certain bulk laxative ingredients, including water-soluble gums, and the need for adequate fluid intake (8 oz) with each dose in comments 36 and 37 of the TFM (50 FR 2124 at 2131 and 2132). FDA

proposed the direction "Drink a full glass (8 oz) of liquid with each dose" to define adequate fluid intake.

In the **Federal Register** of October 1, 1986 (51 FR 35136), FDA amended the TFM and proposed that bulk laxative ingredients be administered in divided doses rather than a single daily dose. The amendment was based on data that indicated the maximum daily dose of some bulk laxatives was so large that it may pose a risk of esophageal obstruction if taken at one time (51 FR 35136).

After receiving reports of cases of esophageal obstruction due to ingestion of laxative products containing water-soluble gums, hydrophilic gums, and hydrophilic mucilloids, including psyllium, FDA published a proposed rule in the **Federal Register** of October 30, 1990 (55 FR 45782), to require a warning in the labeling of all OTC drug products containing water-soluble gums as active ingredients. FDA added the warning to alert users to take adequate fluid and to avoid using these products if the person had previously experienced any difficulty in swallowing. FDA published a final rule requiring new warning and direction statements in the **Federal Register** of August 26, 1993 (58 FR 45194) and amended that rule in the **Federal Register** of March 17, 1999 (64 FR 13254 at 13292). The current warnings and directions (in § 201.319(b) (21 CFR 201.319(b)) state:

"Choking" [highlighted in bold type]: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention;" and
 "Directions" [highlighted in bold type]: (Select one of the following, as appropriate: "Take" or "Mix") "this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning."

II. Adverse Events Regarding Psyllium Ingredients in a Granular Dosage Form

A granular dosage form of psyllium, as a single ingredient product or a combination product containing psyllium (82 percent) and senna (18 percent), was introduced into the OTC market around 1979. In 1989, a major manufacturer of psyllium granular dosage form products reported to FDA 61 cases of esophageal obstruction and choking that occurred between February 1980 and December 1988 (Ref. 1). No deaths occurred, but these reports indicated that 19 people were

hospitalized and 31 people required medical intervention in the form of endoscopy to dislodge the esophageal obstructions. The same manufacturer had submitted a comment in 1985 (Ref. 2) to the laxative TFM stating that consumer labeling of psyllium containing laxatives should: (1) State that bulk-forming laxatives have the potential to block the esophagus, particularly in the presence of esophageal narrowing or when consumed with insufficient liquid, (2) bear a warning to drink sufficient amounts of fluid, (3) advise people with esophageal narrowing against using the product, and (4) direct individuals who experience esophageal obstruction, regurgitation, and difficulty swallowing to seek immediate medical attention. In response to the comment (Ref. 3), FDA suggested that the cases of esophageal blockage may be related to the manufacturer's directions for use, which instruct consumers to place the granules in the mouth and swallow, without chewing, prior to drinking liquid. FDA noted that other psyllium-containing OTC laxative drug products are mixed into liquid or food or, in the case of wafers and chewable tablets, chewed before swallowing. FDA indicated that it did not consider the manufacturer's directions for its products adequate to provide for their "safe OTC use" and suggested that, to retain OTC status, the manufacturer should consider reformulating the products to be suspended in "no less than 8 ounces of liquid per dose prior to consumption" or provide more specific labeling information indicating that the product is "not to be taken directly by spoon or swallowed dry." FDA stated that the manufacturer's products might require a new drug application (NDA) for use under medical supervision. FDA mentioned other reports of esophageal obstruction and asphyxiation associated with the ingestion of water-soluble gums, hydrophilic gums, and hydrophilic mucilloids, including psyllium.

In response to FDA's concerns (Ref. 4), the manufacturer noted that it took the following actions to resolve the problems of esophageal obstruction and choking: (1) In 1985, the directions for use were modified to emphasize the need to have adequate fluid intake, (2) a patient package insert was placed inside each package stressing the importance of taking sufficient liquid, and (3) a "dear doctor" letter was issued in February 1985 to U.S. physicians calling attention to the need for adequate fluid intake to avoid the risk of esophageal obstruction. The

manufacturer stated that only 15 of the 61 cases occurred after it took these actions.

As noted previously, on August 26, 1993, FDA published a final rule in the **Federal Register** requiring warning and direction statements in the labeling of all OTC drug products containing water-soluble gums as active ingredients, including psyllium. Additional warnings and directions were added to alert users to consume adequate fluid and to avoid using such products if the person had previously experienced any difficulty in swallowing.

Despite the new required warnings and directions and other labeling changes initiated by the manufacturer, FDA continued to receive reports of choking and esophageal obstruction associated with psyllium, particularly the granular dosage form. In November 2000, FDA reviewed reports (postmarketing safety review) from its adverse event reporting system (AERS) database and the medical literature for the time between 1966 and 2000 (Ref. 5). FDA identified 98 reported cases of esophageal obstruction and choking associated with the use of psyllium products (Ref. 6). Four deaths occurred and 66 cases required medical intervention and/or hospitalization. Of these 98 cases, 78 (80 percent), including 1 death and 59 cases that required medical intervention and/or hospitalization, were related to the granular dosage form that is swallowed unchewed while drinking liquid. Medical intervention included endoscopy (in 41 cases), esophageal dilatation, surgery, nasogastric tube, Heimlich maneuver, and polypectomy snare. The mean age in these cases (27 cases not reporting age) was 69 years. Possible risk factors were identified in 52 percent of the cases, although there were 37 cases with no reported or apparent risk factors.

FDA also identified 13 (11 percent) cases of choking-related events (and two cases of esophageal obstruction (2 percent)) related to a powder or wafer psyllium product. The label of these products stated that the powder should be mixed with 8 oz of liquid and the wafers should be consumed with 8 oz of liquid. The mean age in these cases was 71 years. There were three deaths (two from asphyxiation and one from bronchus obstruction) and seven people who required hospitalization. Three cases (4 percent) of choking and/or difficulty swallowing and four cases (5 percent) of esophageal obstruction were related to the use of another psyllium product available as a powder or toasted granules. The product directions indicated to mix the powder with liquid

and sprinkle the granules on food. All seven cases (mean age was 64 years) required hospitalization.

Although these reports indicate there were fewer deaths related to the granular dosage form that was swallowed unchewed while drinking liquid (one out of four), there were significantly more overall cases of esophageal obstruction (78 out of 98) and cases that required medical intervention (59 out of 66) with this dosage form.

In January 2001, FDA requested and obtained updated adverse event reports from a current major manufacturer of psyllium laxative products in granular dosage form for the time period between January 1999 and January 2001 (Ref. 7). In April 2002, FDA received an update from this manufacturer for the time period after January 2001 (Ref. 8). This manufacturer's product labeling contained the following directions:

(1) Moisten your mouth with a drink of water or any cool beverage, (2) Place a teaspoonful of granules on your tongue. If you prefer, take only a partial teaspoonful at a time, (3) Without chewing, wash granules down with water or any cool beverage, (4) Repeat steps 1-3 until the recommended dose has been swallowed. Be sure to drink at least 8 ounces of cool liquid.

FDA's reviews (Refs. 9 and 10) of these reports identified 44 additional cases of adverse events related to esophageal obstruction between January 1999 and May 2002. No deaths were reported, but 13 of the reported cases were considered serious events requiring medical intervention (11 underwent endoscopy). The adverse event reports suggested that most of the people using the products followed the directions on the label (information on the dose taken was available in 36 out of 44 cases). Most people (27 out of 35) took sufficient fluid with the product, while insufficient fluid intake may have contributed to the esophageal obstruction in 7 cases.

In summary, FDA has received 142 cases of adverse events regarding esophageal obstruction and choking associated with psyllium between 1966 and May 2002. Of these 142 cases, 59 occurred after publication of the 1993 required warning (58 FR 45194) with 45 reported to have occurred during the last 3 years alone. Eleven of these 45 reported cases (25 percent) involved hospitalization and/or the need for invasive procedures.

Based on the data reviewed, and despite the warnings it has mandated, FDA now believes that there still exists a significant safety problem with esophageal obstruction associated with psyllium laxative products in granular dosage form, particularly products that

are swallowed dry, swallowed partially moistened prior to drinking liquid, and swallowed unchewed while drinking liquid. FDA is concerned that a consumer ingesting this granular dosage form is less likely to drink adequate amounts of fluid with the product than a consumer instructed to mix the product in 8 oz of fluid prior to ingestion. Multiple labeling changes, including additional warnings and enhanced directions to take adequate fluid, have not alleviated this problem. Rather, the problem seems to have worsened. During the first 10 years of marketing, 61 cases of esophageal obstruction were reported compared to 44 cases during the last 3 years alone. In addition, FDA is concerned that the incidence of serious adverse events for these products is underreported because reporting for products marketed under an OTC drug monograph is not currently mandatory.

III. FDA's Tentative Conclusion on OTC Psyllium Ingredients in a Granular Dosage Form

FDA now considers OTC laxative drug products containing psyllium ingredients in granular dosage form as presenting an unacceptable health risk to consumers. These drug products include, but are not limited to: (1) Any granules that are swallowed dry prior to drinking liquid, (2) any granules that are dispersed, suspended, or partially dissolved in liquid prior to swallowing, (3) any granules that are chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid, and (4) any granules that are sprinkled over food.

FDA continues to receive reports of esophageal obstruction and choking associated with these products despite the warning and direction statements required for all water soluble gums in § 201.319. Therefore, due to the significant safety risk these products pose, FDA is proposing to reclassify bulk laxative psyllium ingredients in granular dosage form from Category I (monograph) to Category II (nonmonograph). FDA proposes to add these ingredients in granular dosage form to the list of bulk laxatives in § 310.545(a)(12)(i) (21 CFR 310.545(a)(12)(i)) and to amend proposed § 334.10 (bulk-forming laxative active ingredients) to exclude the granular dosage form.

Mandating warnings in an OTC drug monograph does not require a finding that any or all of the OTC drug products covered by the monograph actually caused an adverse event, and FDA does not find so. Nor does FDA's requirement of warnings repudiate the prior OTC

drug regulations and monograph rulemakings under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that warnings are necessary to ensure that OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are defined in the Federal Food, Drug, and Cosmetic Act (the act). This judgment balances the benefits of these drug products against their potential risks (see § 330.10(a) 21 CFR 330.10(a)). In the current situation, FDA has determined that warnings are not adequate to address the significant safety risks that these products pose.

FDA's decision to act in this instance need not meet the standard of proof required to prevail in a private tort action (*Glatte v. Novartis Pharmaceuticals, Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)). To mandate warnings or take similar regulatory action, FDA need not show, nor do we allege, actual causation. For an expanded discussion of case law supporting FDA's authority to require such warnings, see "Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use, final rule" (67 FR 72555, December 6, 2002).

Accordingly, if a final rule based on this proposal issues any drug product containing any psyllium ingredients in granular dosage form will be considered nonmonograph and misbranded under section 502 of the act (21 U.S.C. 352). This type of drug product would also be considered a new drug under section 201(p) of the act (21 U.S.C. 321(p)) for which an approved application under section 505 of the act (21 U.S.C. 355), and set forth in part 314 of the regulations, is required for marketing. If a final rule is based on this proposal issues, it would apply to any OTC drug product containing psyllium ingredients in granular dosage form that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of the final rule. Further, any OTC drug product that was previously initially introduced or initially delivered for introduction into interstate commerce could not then be repackaged or relabeled after the effective date of the final rule.

IV. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-12), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and

benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

FDA believes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditures that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this proposed rule is to establish conditions under which OTC bulk-forming laxative psyllium ingredients in a granular dosage form are not generally recognized as safe and effective. FDA's drug listing system (DLS) identifies nine currently marketed OTC laxative drug products containing psyllium ingredients in granular dosage form and FDA is aware of at least one other product not in its DLS. One manufacturer currently markets three stock keeping units (SKUs) (individual products, packages, and sizes) of the granular dosage form that requires the product to be swallowed dry while drinking liquid; two manufacturers market two SKUs each, and one manufacturer markets one SKU. It is likely that there may be a few additional products that are currently not included in FDA's DLS. This proposed rule, when finalized, will result in the reformulation or removal of probably less than a dozen products.

- Reformulation Costs

Some manufacturers may elect not to reformulate (i.e., they may elect to

discontinue marketing of the product). For those products that need reformulation, the cost can be significant. The cost to reformulate a product will vary greatly depending on the nature of the change in the formulation, the product, the process, and the size of the firm. A manufacturer may elect to change the dosage form of the psyllium product or to substitute other monograph ingredients. This would require the manufacturer to redo the validation (product, process, new supplier), conduct stability tests, change master production records in order to insure compliance with good manufacturing practice, and, for some dosage forms, conduct palatability tests. (See section 501(a)(1)(B) of the act (21 U.S.C. 351(a)(1)(B) and 21 CFR parts 210 and 211.) FDA estimates the cost of reformulation to range from \$100,000 to \$500,000 per product. Therefore, if 10 products are reformulated, the midpoint of the cost estimate implies total costs of \$3,000,000. However, FDA believes the total costs will be much smaller because not all manufacturers will elect to reformulate and some may choose to discontinue a product line if sales are too low to justify the added cost, and/or they also produce substitute products that do not require reformulation. Manufacturers may also elect to purchase reformulated products from another manufacturer and then be a distributor of that product. Competitive market forces and increased public awareness of a potential safety hazard of these ingredients in a granular dosage form would most likely lead all manufacturers to move to alternative products over time.

- Relabeling Costs

Manufacturers of these products will also incur costs to relabel their products to reflect the new formulation. Estimates of relabeling costs vary greatly and range from \$3,000 to \$5,000 per SKU depending on whether the products are nationally branded or private label. FDA estimates that manufacturers with more than one affected SKU will likely discontinue one or more SKUs. If some SKUs are discontinued, FDA estimates that only three to six SKUs will need to be relabeled as a result of reformulation. If these SKUs are relabeled, the total one-time cost of relabeling could range from \$9,000 (three SKUs x \$3,000) to \$30,000 (six SKUs x \$5,000). This relabeling cost should not be a significant economic impact on a substantial number of small entities.

Some manufacturers may choose to submit an NDA deviation for their psyllium product in accordance with § 330.11. Overall, there may be fewer

costs incurred by this process than by submission of a full NDA.

Because these products must be manufactured in compliance with the pharmaceutical current good manufacturing practices (21 CFR parts 210 and 211), all firms have the necessary skills and personnel to perform the tasks of reformulation, validation, and relabeling either in-house or by contractual arrangement. The rule will not require any new reporting and recordkeeping activities. No additional professional skills are needed.

- Regulatory Alternatives Considered

FDA considered but rejected the following additional alternatives: (1) Leave these products in the monograph, and (2) an exemption from coverage for small entities. FDA does not consider either of these approaches acceptable because they do not assure that consumers will have safe OTC psyllium laxative drug products in a granular dosage form. FDA does not believe that there are any significant alternatives to the proposed rule that would adequately provide for the safe use of these OTC drug products.

FDA does not believe that this proposed rule would have a significant economic impact on a substantial number of small entities. However, FDA recognizes the uncertainty of its estimates with respect to the number of affected small entities and products, as well as the economic impact of the rule on those small entities. Thus, this economic analysis, together with other relevant sections, serves as FDA's initial regulatory flexibility analysis.

Finally, FDA specifically invites public comment regarding any substantial or significant economic impact that this proposed rule would have on OTC laxative drug products containing psyllium ingredients in a granular dosage form. Types of impact may include, but are not limited to, the costs associated with reformulation, relabeling, or repackaging. Comments regarding the impact of this rulemaking on OTC laxative drug products containing these ingredients should be accompanied by appropriate documentation. FDA is providing a period of 90 days from the date of publication of this proposed rule in the **Federal Register** for comments on this subject to be developed and submitted. FDA will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that any relabeling resulting from this proposed rule is not subject to review by the Office of Management and Budget because it does not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the relabeling statements are in the TFM for OTC laxative drug products (50 FR 2124 and 51 FR 35136) and are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order, and, consequently, a federalism summary impact statement has not been prepared.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal

become effective 180 days after its date of publication in the *Federal Register*.

X. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) under Docket No. 78N-036L, unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Adverse Drug Reaction Reports, Ref. 7 in OTC vol. AF, Docket No. 90N-0200, Division of Dockets Management.
2. Comment No. C00100.
3. Comment No. LET45.
4. Comment No. LET46.
5. Adverse Event Reports from 1966 to 2000 for Psyllium Laxative Products (Perdiem, Metamucil, and Serutan) collected by FDA's Office of Compliance, in OTC vol. 090TFM6.
6. FDA, Office of Postmarketing Drug Risk Assessment (OPDRA) (Project ID (PID) 000607) regarding Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, November 17, 2000, in OTC vol. 090TFM6.
7. Adverse Event Reports from January 1999 to January 2001 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in January 2001, in OTC vol. 090TFM6.
8. Adverse Event Reports from October 2000 to January 2002 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in April 2002, in OTC vol. 090TFM6.
9. FDA, Cases of Esophageal Obstruction Associated with PERDIEM (January 1999 to January 2001), in OTC vol. 090TFM6.
10. FDA, OPDRA Postmarketing Safety Review (PID D020201) regarding Senokot and Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, May 15, 2002, in OTC vol. 090TFM6.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 334

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310 and 334 (as proposed in the *Federal Register* of January 15, 1985 (50 FR 2124), October 1, 1986 (51 FR 35136), September 2, 1993 (58 FR 46589), March 31, 1994 (59 FR 15139), September 2, 1997 (62 FR 46223), May 21, 1998 (63 FR 27886), and June 19, 1998 (63 FR 33592)), be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e, 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by redesignating paragraph (a)(12)(i) as paragraph (a)(12)(i)(A), by adding new paragraph (a)(12)(i)(B), by revising paragraph (d) introductory text and paragraph (d)(1), and by adding new paragraph (d)(38) to read as follows:

§ 310.545 Drug products containing active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(12) * * *

(i)(B) *Bulk laxatives*—Approved as of [date of publication of final rule in the *Federal Register*].

Psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), psyllium seed husks, plantago husks, plantago seed, in a granular dosage form including, but not limited to any granules that are:

- (1) Swallowed dry prior to drinking liquid,
- (2) Dispersed, suspended, or partially dissolved in liquid prior to swallowing,
- (3) Chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid, or
- (4) Sprinkled over food.

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(38) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4)(i), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), paragraphs (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i)(A), (a)(12)(ii) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), (a)(16) through (a)(18)(i)(A), (a)(18)(ii) (except as covered by paragraph (d)(22) of this section), paragraphs (a)(18)(iii), (a)(18)(iv), (a)(18)(v)(A), and (a)(18)(vi)(A) of this section.

* * * * *

(38) [Date 180 days after date of publication of final rule in the *Federal Register*], for products subject to paragraph (a)(12)(i)(B) of this section.

PART 334—LAXATIVE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 334 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 334.10 [Amended]

4. Section 334.10 *Bulk-forming laxative active ingredients* as proposed on January 15, 1985 (50 FR 2124), is proposed to be amended by revising paragraph (f) to read as follows:

* * * * *

(f) Psyllium ingredients, except those listed in § 310.545(a)(12)(i)(B) of this chapter.

Dated: July 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-19808 Filed 8-4-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 522

[BOP-1113-P]

RIN 1120-AB13

Civil Contempt of Court Commitments: Revision to Accommodate Commitments Under the DC Code

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) revises its rules on Civil Contempt of Court Commitments to include references to relevant DC Code provisions regarding civil contempt commitments. We make this revision to accommodate DC Code offenders in Bureau institutions or Bureau contract facilities under the National Capital Revitalization and Self-Government Improvement Act of 1997 (DC Revitalization Act), DC Code section 24-101(a) and (b). We also revise this rule to clarify existing provisions by using simpler organization and language. For further simplification, we remove language relating solely to internal agency practices and procedures. We do not, however, make any substantive changes to the current rules.

DATES: Comments are due by October 6, 2003.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT:

Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307-2105.

SUPPLEMENTARY INFORMATION:

What Will This Rule Do?

Through this rule, the Bureau will revise its regulations in 28 CFR part 522, on Civil Contempt of Court Commitments (civil contempt commitments).

Why Are We Making This Rule?

We are making this rule to comply with the DC Revitalization Act, enacted August 5, 1997. This Act makes the Bureau responsible for the "custody, care, subsistence, education, treatment and training" of "the felony population sentenced pursuant to the District of Columbia Code" (DC Code offenders). (DC Code section 24-101 (a) and (b).)

As a result of absorbing approximately 8000 DC Code offenders, we revise our rules on Civil Contempt of Court Commitments to address DC Code offenders.

We also revise this rule to clarify existing provisions by using simpler organization and language. To clarify § 522.11, which is long and unnecessarily complex, we divided it into five separate rules with clearer headings. For further simplification, we remove language relating solely to internal agency practices and procedures. We do not, however, make any substantive changes to the current rules.

Where To Send Comments

You can send written comments on this rule to the Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

We will consider comments we receive during the comment period before we take final action. We will try to consider comments we receive after the end of the comment period. In light of comments we receive, we may change the rule.

We do not plan to have oral hearings on this rule. All the comments we receive remain on file for public inspection at the above address.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review", section 1(b), Principles of Regulation. The Director of the Bureau of Prisons has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), and accordingly this rule has not

been reviewed by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications for which we would prepare a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation. By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: This rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 28 CFR Part 522

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we amend 28 CFR part 522 as follows.

SUBCHAPTER B—INMATE ADMISSION, CLASSIFICATION, AND TRANSFER**PART 522—ADMISSION TO INSTITUTION**

1. Revise the authority citation for 28 CFR part 522 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3568 (Repealed November 1, 1987 as to offenses committed on or after that date), 3585, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to conduct occurring on or after November 1, 1987), 4161–4166, (repealed October 12, 1984, as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; DC Code § 24–101(b).

2. Revise the table of contents for Subpart B, Civil Contempt of Court Commitments, to read as follows:

Sec.

522.10 What is the purpose of this subpart?

522.11 How do inmates come into Bureau custody for civil contempt commitments?

522.12 What happens if a criminal sentence imposed under either the U.S. or DC Code exists when a civil contempt commitment is ordered?

522.13 What happens if a civil contempt commitment order is in effect when a criminal sentence is imposed under the U.S. or DC Code?

522.14 How does the Bureau treat inmates serving civil contempt commitments?

522.15 Do inmates serving only civil contempt commitments receive good time credits?

3. Revise Subpart B, Civil Contempt of Court Commitments, to read as follows:

§ 522.10 What is the purpose of this subpart?

(a) This subpart describes the procedures for Federal civil contempt of court commitments (civil contempt commitments) referred to the Bureau of Prisons (Bureau). These cases are not commitments to the custody of the Attorney General for service of terms of imprisonment following criminal convictions.

(b) We cooperate with the Federal courts to implement civil contempt commitments by making our facilities and resources available. When we receive notification from the Federal court that the reason for the civil contempt commitment has ended or that the inmate is to be released for any other reason, we will terminate the inmate's civil contempt commitment.

§ 522.11 How do inmates come into Bureau custody for civil contempt commitments?

Inmates can come into Bureau custody for civil contempt commitments in two ways:

(a) The U.S. Marshals Service may request a designation from the Bureau for a civil contempt commitment if local jails are not suitable due to medical, security or other reasons; or

(b) The committing court may specify a Bureau institution as the place of incarceration in its contempt order. We will designate the facility specified in the court order unless there is a reason for not placing the inmate in that facility.

§ 522.12 What happens if a criminal sentence imposed under either the U.S. or DC Code exists when a civil contempt commitment is ordered?

If a criminal sentence imposed under the U.S. Code or DC Code exists when a civil contempt commitment is ordered, we delay or suspend credit towards service of the criminal sentence for the duration of the civil contempt commitment, unless the committing judge orders otherwise.

§ 522.13 What happens if a civil contempt commitment order is in effect when a criminal sentence is imposed under the U.S. or DC Code?

(a) Except as stated in (b), if a civil contempt commitment order is in effect when a criminal sentence of imprisonment is imposed under the U.S. or DC Code, the criminal sentence runs consecutively to the commitment order, unless the sentencing judge orders otherwise.

(b) *For Federal criminal sentences imposed for offenses committed before November 1, 1987, under 18 U.S.C. Chapter 227:* If a civil contempt commitment order is in effect when a criminal sentence of imprisonment is imposed, the criminal sentence runs concurrent with the commitment order, unless the sentencing judge orders otherwise.

§ 522.14 How does the Bureau treat inmates serving civil contempt commitments?

We treat inmates serving civil contempt commitments in Bureau institutions the same as pretrial inmates. If an inmate is serving a civil contempt commitment and a concurrent criminal sentence, we treat the inmate the same as a person serving a criminal sentence.

§ 522.15 Do inmates serving only civil contempt commitments receive good time sentence credit?

No. While serving only the civil contempt commitment, an inmate is not entitled to good time sentence credit.

[FR Doc. 03–19853 Filed 8–4–03; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[CGD07–03–088]

RIN 1625–AA09

Drawbridge Operation Regulations; Miami River, North Fork, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating regulations and the name of the Seaboard System Railroad Bridge, across the Miami River, mile 5.3, Miami, Florida. The proposed rule would require the bridge to open only after a 48-hour advance notice to the owner. In addition, the Coast Guard is proposing a name change, from Seaboard System Railroad Bridge to CSX Railroad Bridge, to reflect the current owner of the bridge.

DATES: Comments and related material must reach the Coast Guard on or before October 6, 2003.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, Florida 33131. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket [CGD07–03–088] and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, Florida 33131 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Seventh Coast Guard District, Bridge Branch, 909 SE. 1st Avenue Miami, Florida 33131, telephone number 305–415–6743.

SUPPLEMENTARY INFORMATION:**Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07–03–088], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8 1/2 x 11 inches, suitable for copying. If you would like to know they reached us,

please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Bridge Branch, Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, Florida 33131, explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the *Federal Register*.

Background and Purpose

The Seaboard System Railroad Bridge across the Miami River, mile 5.3, is a railroad bridge with a vertical clearance of 6 feet at mean high water and a horizontal clearance of 60 feet. The current operating regulations published in 33 CFR 117.307 require the bridge to open on signal from 8:30 a.m. to 5:30 p.m., Monday through Friday. At all other times, the draw must open on signal if at least three hours notice is given. The last time the bridge was opened for vessel traffic, however, was December 2, 2001, though a full time bridge tender is on site. The proposed rule would improve the efficiency of the bridge system and meet the reasonable needs of navigation by providing for openings with a 48-hour advance notice to the CSX System Operating Headquarters, at (800) 232-0144, and would still meet the reasonable needs of navigation. In addition, the owner is requesting that the Coast Guard change the name of the bridge, which has been sold, from the Seaboard System Railroad Bridge to the CSX Railroad Bridge.

Discussion of Proposed Rule

Under the proposed rule, the bridge would open only with a 48-hour advance notice to the CSX System Operating Headquarters, at (800) 232-0144. The bridge is the last moveable bridge on the waterway approximately 1000 yards from a salinity dam, which marks the end of navigability on the waterway of the Miami River. The bridge has not opened for navigation since December 2, 2001, and, except for normal maintenance, experienced the same pattern of no openings for the year 2002. Accordingly, this proposed schedule would meet the reasonable needs of navigation. Moreover, in order to accurately refer to the bridge, this proposed rule would change the name

from Seaboard System Railroad Bridge to the CSX Railroad Bridge.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary, because the proposed rule would provide for openings with advanced notice.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities, because the past few years of the bridge's history indicates that it rarely opens. The proposed rule provides for openings and meets the reasonable needs of navigation.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see ADDRESSES*) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If this proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact

the person listed under **FOR FURTHER INFORMATION CONTACT**. Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order, because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (32)(e), of the Instruction, from further environmental documentation. Under figure 2-1, paragraph (32)(e), an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05-1(g); Section 117.255 also issued under authority of Pub. L. 102-587, 106 Stat. 5039.

2. Section 117.307 is revised to read as follows:

§ 117.307 Miami River, North Fork.

The draw of the CSX Railroad Bridge, mile 5.3 at Miami, shall open on signal if at least forty-eight hours notice is given to CSX System Operating Headquarters at (800) 232-0144.

Dated: July 25, 2003

H.E. Johnson, Jr.,

Rear Admiral, Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 03-19900 Filed 8-4-03; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA206-4212b; FRL-7525-1]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revision to Pittsburgh-Beaver Valley Area Ozone Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania. The revisions consist of an amendment to the contingency measures portion of the maintenance plan for the Pittsburgh-Beaver Valley ozone maintenance area. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a

second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 4, 2003.

ADDRESSES: Comments may be submitted either by mail or electronically. Written comments should be mailed to Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Electronic comments should be sent either to Morris.Makeba@epa.gov or to <http://www.regulations.gov>, which is an alternative method for submitting electronic comments to EPA. Follow the detailed instructions of the Supplementary Information section. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Avenue NW., Room B108, Washington, DC 20460; and the Pennsylvania Department of Environmental Resources Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Kathleen Anderson, (215) 814-2173, or by e-mail at Anderson.Kathleen@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication.

You may submit comments either electronically or by mail. To ensure proper receipt by EPA, identify the appropriate rulemaking identification number PA206-4212 in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any

cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *E-mail*. Comments may be sent by electronic mail (e-mail) to morris.makeba@epa.gov, attention PA206-4212. EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly without going through [Regulations.gov](http://www.regulations.gov), EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket.

ii. *Regulations.gov*. Your use of [Regulations.gov](http://www.regulations.gov) is an alternative method of submitting electronic comments to EPA. Go directly to <http://www.regulations.gov>, then select "Environmental Protection Agency" at the top of the page and use the "go" button. The list of current EPA actions available for comment will be listed. Please follow the online instructions for submitting comments. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in the ADDRESSES section of this document. These electronic submissions will be accepted in WordPerfect, Word or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail*. Written comments should be addressed to the EPA Regional office listed in the ADDRESSES section of this document.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other

information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

Submittal of CBI Comments

Do not submit information that you consider to be CBI electronically to EPA. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the official public regional rulemaking file. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public file and available for public inspection without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT SECTION**.

Considerations When Preparing Comments to EPA

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate regional file/ rulemaking identification number in the

subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

Dated: June 30, 2003.

Thomas C. Voltaggio,
Acting Regional Administrator, Region III.
[FR Doc. 03-19740 Filed 8-4-03; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRN-7539-6]

RIN 2060-AK71

Amendments to Project XL Site-Specific Rulemaking for Georgia-Pacific Corporation's Facility in Big Island, VA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is publishing this site-specific rule to implement a project under the Project eXcellence and Leadership (Project XL) program, an EPA initiative which encourages regulated entities to achieve better environmental results at decreased costs at their facilities. EPA is taking direct final action to amend a site-specific rulemaking for the Georgia-Pacific Corporation facility in Big Island, Virginia. The amendments concern revision of a compliance date for certain combustion sources at the facility that are subject to a hazardous air pollutant standard. EPA is proposing these amendments to accommodate delay in construction of the first commercial scale installation of black liquor gasification in the United States.

In the "Rules and Regulations" section of today's **Federal Register**, EPA is issuing the amendments as a direct final rule without prior proposal because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for the amendments in the preamble to the direct final rule. If EPA receives no adverse comment, we will not take further action on this proposal. If EPA receives adverse comment, we will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties

interested in commenting must do so at this time.

DATES: Comments on this rulemaking must be received on or before September 4, 2003. All comments should be submitted in writing or electronically according to the directions below in the **SUPPLEMENTARY INFORMATION** section.

Public Hearing. Commenters may request a public hearing no later than August 19, 2003. Commenters requesting a public hearing should specify the basis for their request. If EPA determines that there is sufficient reason to hold a public hearing, it will be held on September 8, 2003, at 10 a.m. Requests to present oral testimony must be made by August 25, 2003. Persons interested in requesting a hearing, attending a hearing, or presenting oral testimony at a hearing should call Mr. David Beck at (919) 541-5421.

ADDRESSES: To make comments by mail, send (two) 2 copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. A-2002-0072. Comments also may be submitted electronically, or through hand delivery/courier. Follow the detailed instructions as provided in I.C. of the **SUPPLEMENTARY INFORMATION** section in the related direct final action that is located in the "Rules and Regulations" section of this **Federal Register**.

If a public hearing is held, it will take place at the Big Island Elementary School, 1114 Schooldays Road, Big Island, Virginia.

FOR FURTHER INFORMATION CONTACT: Mr. David Beck, Office of Environmental Policy Innovation (E-143-02), U.S. EPA, Research Triangle Park, NC 27711. Mr. Beck can be reached at (919) 541-5421 (or by e-mail at: beck.david@epa.gov). Further information on today's action may also be obtained on the World Wide Web at <http://www.epa.gov/projectxl/>.

SUPPLEMENTARY INFORMATION: This document concerns an "Amendment to Project XL Site-Specific Rulemaking for Georgia-Pacific Corporation's Facility in Big Island, Virginia." For further information, please see the related direct final action that is located in the "Rules and Regulations" section of this **Federal Register** publication.

Dated: July 28, 2003.

Marianne L. Horinko,
Acting Administrator.

[FR Doc. 03-19920 Filed 8-4-03; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AI77

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for *Astragalus magdalenae* var. *peirsonii* (Peirson's milk-vetch)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for the federally threatened *Astragalus magdalenae* var. *peirsonii* (Peirson's milk-vetch). We propose to designate a total of approximately 52,780 acres (ac) (21,359 hectares (ha)) of critical habitat in Imperial County, California.

Critical habitat identifies specific areas that are essential to the conservation of a listed species, and that may require special management considerations or protection. If this proposal is made final, section 7(a)(2) of the Act requires that Federal agencies ensure that actions they fund, authorize, or carry out are not likely to result in the destruction or adverse modification of critical habitat. The regulatory effect of the critical habitat designation does not extend beyond those activities funded, permitted, or carried out by Federal agencies. State or private actions, with no Federal involvement, are not affected.

Section 4 of the Act requires us to consider the economic and other relevant impacts of specifying any area as critical habitat. We will conduct an analysis of the economic impacts of designating these areas, in a manner that is consistent with the ruling of the 10th Circuit Court of Appeals in *N.M. Cattle Growers Ass'n v. USFWS*. We hereby solicit data and comments from the public on all aspects of this proposal, including data on economic and other impacts of the designation. We may revise this proposal prior to final designation to incorporate or address new information received during public comment periods.

DATES: We will accept comments until October 6, 2003. Public hearing requests must be received by September 19, 2003.

ADDRESSES: If you wish to comment, you may submit your comments and

materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 6010 Hidden Valley Road, Carlsbad, CA 92009.

2. You may hand-deliver written comments and information to our Carlsbad Fish and Wildlife Office, at the above address, or fax your comments to 760-731-9618.

3. You may send your comments by electronic mail (e-mail) to FW1PMV@r1.fws.gov. For directions on how to submit electronic filing of comments, see the "Public Comments Solicited" section.

All comments and materials received, as well as supporting documentation used in preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Jim Bartel, Field Supervisor, Carlsbad Fish and Wildlife Service (telephone (760) 431-9440; facsimile (760) 431-9618).

SUPPLEMENTARY INFORMATION:

Public Comments Solicited

It is our intent that any final action resulting from this proposal will be as accurate as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. Based on public comment, in developing the final rule we may find that areas proposed are not essential, appropriate for exclusion under section 4(b)(2), or not appropriate for exclusion, in which case, they would be made part of the final designation. We particularly seek comments concerning:

(1) The reasons why any areas should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of designation will outweigh any threats to the species resulting from the designation;

(2) Specific information on the amount and distribution of *Astragalus magdalenae* var. *peirsonii* and its habitat, and which habitat or habitat components are essential to the conservation of this species and why;

(3) Land use designations and current or planned activities in or adjacent to the areas proposed and their possible impacts on proposed critical habitat;

(4) Any foreseeable economic or other potential impacts resulting from the

proposed designation, in particular, any impacts on small entities;

(5) Economic and other values associated with designating critical habitat for *Astragalus magdalenae* var. *peirsonii* such as those derived from non-consumptive uses (e.g., hiking, camping, photography, improved air quality, increased soil retention, and "existence values"); and

(6) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods (see ADDRESSES section). Please submit electronic comments in ASCII file format and avoid the use of special characters or any form of encryption. Please also include "Attn: RIN1018-A177" in your e-mail subject header and your name and return address in the body of your message. If you do not receive a confirmation from the system that we have received your internet message, contact us directly by calling our Carlsbad Fish and Wildlife Office at phone number 760-431-9440. Please note that the e-mail address "FW1PMV@r1.fws.gov" will be closed out at the termination of the public comment period.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

Background

We listed *Astragalus magdalenae* var. *peirsonii* as threatened on October 6,

1998 (63 FR 53596) due to threats of increasing habitat loss from Off-Highway Vehicle (OHV) use and associated recreational development, destruction of plants, and lack of protection afforded the plant under State law. It is our intent, in this proposed rule, to reiterate and discuss only those topics directly relevant to the development and designation of critical habitat or relevant information obtained since the final listing. Please refer to our final listing rule for a more detailed discussion of the plant's taxonomic history and physical description.

The current name, *Astragalus magdalenae* var. *peirsonii* (Munz and Mc Burney) Barneby (Barneby 1958), is accepted in both systematic (Barneby 1964) and floristic treatments (Barneby 1959, Munz 1974, and Spellenberg 1993). Surveys conducted in the Borrego Valley, have failed to document a historical reference to an occurrence of *Astragalus magdalenae* var. *peirsonii* (Bureau of Land Management (BLM) 2001); consequently this population is thought to be extirpated. A collection from the Yuma Dunes of Arizona thought to represent *A. m.* var. *peirsonii* was found to be misidentified. In Mexico, *A. m.* var. *peirsonii* is known from the Gran Desierto of northwestern Sonora (Felger 2000) and from northeastern Estado de Baja California (Barneby 1959, 1965; Spellenberg 1993). Currently, the only known population of *A. m.* var. *peirsonii* remaining in the United States is located in the Algodones Dunes of Imperial County, California. This dune field is one of the largest in the United States and one of the most popular for OHV use.

Astragalus magdalenae var. *peirsonii* is a stout, short-lived perennial member of the Fabaceae (Legume Family). Plants develop extremely long tap roots (Barneby 1964) that penetrate deeply to the more moist sand and anchor the plants in the shifting dunes. The root crown is often exposed by wind action moving the sand away from the base of the plants. The flowers are arranged in 10 to 17 flowered racemes. The inflated fruits are large and contain 11 to 16 large flattened black seeds—among the largest seeds of any *Astragalus* in North America. Seeds are either dispersed locally by falling out of partly opened fruits on the parent plant salt-shaker style or by their release from fruits blown across the sand after falling from the parent plant. Seeds require no pre-germination treatment to induce germination, but show increased germination success when scarified (outer cover is broken) (Romspert and Burk 1979; Porter *in litt.* 2002). Dispersed seeds that do not germinate

during the subsequent growing season become part of the seed bank (Given 1994). In laboratory studies, seeds germinated more readily at lower and intermediate temperatures of 59 to 77 degrees Fahrenheit (15 to 25 degrees Celsius) in the cooler fall and winter months as might be expected (Romspert and Burk 1979).

Astragalus magdalenae var. *peirsonii* seedlings reportedly mature rapidly, and although perennial, some plants may bear fruit within several months of germination (Barneby 1964; Romspert and Burk 1979). Romspert and Burk (1979) noted that older plants were the primary seed producers, and plants that become reproductive in the first season do not make significant contributions to the seedbank. It is therefore important that plants survive for more than 1 year in order to replenish the existing seedbank.

Astragalus magdalenae var. *peirsonii* exhibits temporal variability in plant numbers apparently associated with annual precipitation patterns. In dune-wide surveys conducted in 1997, 1998, 1999, and 2000, the species was most abundant in 1998, the highest rainfall year, and least abundant in 2000, the lowest rainfall year (BLM 2001). Based on current understanding of the species' life history, sufficient rain in conjunction with wetter-than-average fall weather appears to trigger significant germination events. Seedlings may be generally present in suitable habitat throughout the dunes, especially during above-normal precipitation years. In intervening drier years, plant numbers decrease as individuals die and are not replaced by new seedlings. The species likely depends on the production of seeds in the wetter years and the persistence of the seed banks until appropriate conditions for production and germination occur. Further research and modeling are necessary to better understand the dynamics of this system and how the species may be responding to natural and man-made disturbances within its range.

Astragalus magdalenae var. *peirsonii* occurs on open sand dunes in a vegetation community referred to as psammophytic scrub (Westec 1977; BLM 2000). Desert psammophytic scrub is described as being distinguished by a rather large number of plants restricted entirely or largely to an active dune area (Thorne 1982). Desert psammophytic scrub transitions into the sandier phases of creosote bush scrub, which is generally only present at the lower, more stabilized margins of the dunes (Thorne 1982). *Astragalus magdalenae* var. *peirsonii*, *Helianthus niveus* ssp.

tephrodes (Algodones Dunes sunflower), *Croton wigginsii* (Wiggins' croton), *Palafoxia arida* ssp. *gigantea* (giant Spanish needle), *Pholisma* (as *Ammobroma*) *sonorae* (sand food), *Ephedra trifurca* (three-forked ephedra), and *Eriogonum deserticola* (desert eriogonum), are restricted desert psammophytic scrub taxa in the Algodones Dunes (Thorne 1982) while the same author included *Astragalus lentiginosus* var. *borreanus* (Borrego milk-vetch), *Dicoreia canescens* (dune bugseed), *Petalonyx thurberi* (sandpaper plant), and *Tiquilia* species as more widely distributed species found off the dunes. Many of these taxa are also found in association with *A. m.* var. *peirsonii* in the Gran Desierto of Sonora, Mexico (Felger 2000). *Astragalus magdalenae* var. *peirsonii* is found on deep, active dunes generally under 20

degrees slope. Usually, one or more of the other psammophytic scrub taxa (Thorne 1982) are also found with *A. m.* var. *peirsonii*. Creosote bush scrub is rarely found in deep sand dunes, but may encroach in adjacent areas especially where the base soil is exposed.

The current known geographical range of *Astragalus magdalenae* var. *peirsonii* in the United States is limited to a narrow band in the central portion of the Algodones Dunes of Imperial County, California. This band runs parallel to the active, linear dunes on the western edge of the dune field in a northwest to southeast direction. The band is between these active linear dunes on the west and transverse ridge dunes to the east. The dunes in this band are composed of a series of transitional crescentic ridges (Muhs et

al. 1995). Historically *A. m.* var. *peirsonii* was found in Borrego Valley, San Diego County (Barneby 1964). In Mexico, *A. m.* var. *peirsonii* occurs in northeastern Estado de Baja California (Barneby 1959, 1964; Westec 1977; Spellenberg 1993), and in the Gran Desierto of Sonora (Felger 2000).

The Algodones Dunes are one of the largest dune fields in North America. The Algodones Dunes are often referred to as the Imperial Sand Dunes, a designation derived from their inclusion in the Imperial Sand Dunes Recreation Area (ISDRA) established by the BLM. Virtually all lands in the Algodones Dunes are managed by BLM. However, the State of California and private parties own some small inholdings in the dune area (see Table 1).

TABLE 1.—APPROXIMATE AREAS IN ACRES (AC) AND HECTARES (HA) OF PROPOSED CRITICAL HABITAT FOR *Astragalus magdalenae* VAR. *peirsonii* BY LAND OWNERSHIP.

Unit	Federal	State	Private	Total
Algodones	50,441 ac	833 ac	1,506 ac	52,780 ac.
Dunes	(20,413 ha)	(337 ha)	(609 ha)	(21,359 ha).

The dunes extend about 40 miles (mi) (64 kilometers (km)), trending from northwest to southeast (Norris and Norris 1961). Winds from the northwest are prevalent in the winter, while in the summer the winds are from the southeast (Romsper and Burk 1979). This regime is likely responsible for the dune-building (Norris and Norris 1961) and fruit dispersal that result in the persistence of the plants in the dune system. The dunes are generally considered to have formed from sands from Lake Cahuilla that historically occupied the Cahuilla Basin. The western boundary of the dunes is marked by a series of parallel, longitudinal generally southeast trending ridges. The northern third of the dunes is narrow, about 2 mi (3 km) wide, and increases in elevation from 200 to 300 feet (ft) (60–91 meters (m)) in the northern portion to 300 to 400 ft (91 to 121 m) in the southern portion north of Highway 78. Areas in the central portion of the dunes reach an elevation 500 ft (152 m) south of State Highway 78, but reach elevations of only 200 ft (60 m) for most areas just north of Interstate 8. The central portion of the dunes is wider, about 5 mi (8 km), and is characterized by deep bowls (hollows among the dunes) and slip faces (areas so steep that the loose sand naturally cascades downward) that run transverse to the primary ridge line (Norris and Norris 1961). The area south

of Interstate 8 is generally characterized by lower elevation, under 300 ft (91 m), dunes.

The Algodones Dunes are one of the driest and hottest regions in the United States. Romsper and Burk (1979) reported average yearly precipitation between 1941–1970 was 2.6 in (67.8 mm). The rainfall is often described as scattered or patchy. Rainfall amounts differ from place to place and from year to year with areas to the northwest being generally dryer than those to the southeast (BLM 2001). A soil survey for the Imperial Valley area of Imperial County (Zimmerman 1981) did not include the areas east of the Coachella Canal but did depict a few adjacent portions of the Algodones Dunes as Rositas fine sand with 9 to 30 percent slopes. Rositas fine sand are described as deep, somewhat excessively drained, sloping soils formed in wind-blown sands of diverse origin. Dean (1978) describes the sand as quartz with a mean grain size of 0.006 in (0.17 mm). Norris and Norris (1961) report that the dunes contain 60 to 70 percent quartz and 30 to 40 percent feldspar sand. Further analysis of the sands of the Algodones Dunes found its source was likely sediment from the Colorado River that flowed into the Cahuilla Basin (Muhs et al. 1995).

Destruction of plants and modification of habitat associated with OHV activity is considered the primary

threat to *Astragalus magdalenae* var. *peirsonii*. Vehicles may have a direct impact on the plants by crushing and killing them or reducing their reproductive output. Vehicles can alter dune structure by altering hydrological traits of the dune, cover standing plants with encroaching sand, or expose standing plants by causing sand to fall away from the plants. Willoughby (BLM 2001), however, concluded that healthy populations of *A. m.* var. *peirsonii* persist in OHV "open areas" in the Algodones Dunes and that populations in both "open" and "closed" areas respond to precipitation patterns. This likely results from the observation that OHV use does not tend to encroach on habitat of the plants in more distant regions of the open area away from concentrated OHV staging sites (BLM 2001). Significant impacts from OHV use on *A. m.* var. *peirsonii* have been observed at and near OHV staging areas and have been previously documented (WESTEC 1977; ECOS 1990; BLM 2000). Since the species' listing, recreational use has steadily increased in the Algodones Dunes.

Another threat is herbivory by seed weevils, in the family Bruchidae, which contributes to the mortality of seeds and reduces seed crop for *Astragalus magdalenae* var. *peirsonii* (Romsper and Burk 1979). Fruits collected in April and stored in a bottle continued to release these seed weevils into

October (Romspert and Burk 1979). However, the overall impact of seed weevils on the reproductive output of *A. m. var. peirsonii* is not known at this time. Weevils were noted on nearly all of the *A. m. var. peirsonii* plants encountered in 2003 by Porter (Porter, *in litt.* 2003). Herbivory of leaves, leaflets, and stem tips by rodents was also noted by Porter (*in litt.* 2002a; *in litt.* 2003).

We have not yet developed a recovery plan or a conservation strategy for *Astragalus magdalenae* var. *peirsonii*. Based on our current understanding of the species' biology, the primary conservation needs include: maintenance of the major occurrences of *A. m. var. peirsonii* to conserve genetic diversity; management of the species' habitat to prevent catastrophic population declines; and collection of additional information concerning recreational use-patterns in the Algodones Dunes, the direct and indirect effects of OHV use on this species, and biological factors affecting milk-vetch demographics.

Previous Federal Action

The final rule listing *A. m. var. peirsonii* as threatened was published in the **Federal Register** on October 6, 1998 (63 FR 53596). At the time we listed the plant we determined that designation of critical habitat was not prudent based on concerns about potential, deliberate acts of vandalism that could result from such a designation.

On October 25, 2001, we received a petition to delist *Astragalus magdalenae* var. *peirsonii*, dated October 24, 2001, from David P. Hubbard, Ted. J. Griswold, and Philip J. Giacinti, Jr. of Procopio, Cory, Hargreaves & Savitch LLP on behalf of the American Sand Association (ASA), San Diego Off-Road Coalition (SDO-RC), and Off-Road Business Association (O-RBA). On November 20, 2001, we sent a letter to David P. Hubbard of Procopio, Cory, Hargreaves & Savitch LLP acknowledging receipt of their petition. The Service is in the process of making the 90-day finding on the petition.

On November 15, 2001, the Center for Biological Diversity and California Native Plant Society filed a lawsuit in the U.S. District Court for the Southern District of California challenging our determination not to designate critical habitat for eight desert plants, including *Astragalus magdalenae* var. *peirsonii* (*Center for Biological Diversity et al. v. Norton*, No. 01 CV 2101). A second lawsuit also asserting the same challenge was filed on November 21, 2001, by the *Building Industry Legal Defense Fund v. Norton*, No. 01 CV

2145). Following the filing of these suits, the ASA, California Off-Road Vehicle Association, American Motorcycle Association, Inc.—District 37, the SDO-RC, and the O-RBA filed a motion to intervene. The motion was granted by the Court but limited the interveners' participation to resolution of an appropriate timeline for reconsideration of the critical habitat determination for *A. m. var. peirsonii*. On July 1, 2002, the court ordered the Service to complete a review of the prudency determination and, if prudent, to propose critical habitat for the plant on or before July 28, 2003.

Designation of Critical Habitat Provides Little Additional Protection to Species

In 30 years of implementing the ESA, we have found that the designation of statutory critical habitat provides little additional protection to most listed species, while consuming significant amounts of available conservation resources. Our present system for designating critical habitat has evolved since its original statutory prescription into a process that provides little real conservation benefit, is driven by litigation and the courts rather than biology, limits our ability to fully evaluate the science involved, consumes enormous agency resources, and imposes huge social and economic costs. We believe that additional agency discretion would allow our focus to return to those actions that provide the greatest benefit to the species most in need of protection.

Role of Critical Habitat in Actual Practice of Administering and Implementing the Act

While attention to and protection of habitat is paramount to successful conservation actions, we have consistently found that, in most circumstances, the designation of critical habitat is of little additional value for most listed species, yet it consumes large amounts of conservation resources. Sidle (1987) stated, "Because the ESA can protect species with and without critical habitat designation, critical habitat designation may be redundant to the other consultation requirements of section 7." Currently, only 306 species or 25 percent of the 1,211 listed species in the United States under our jurisdiction have designated critical habitat. We address the habitat needs of all 1,211 listed species through conservation mechanisms such as listing, section 7 consultations, the Section 4 recovery planning process, the Section 9 protective prohibitions of unauthorized take, Section 6 funding to the States, and the Section 10 incidental

take permit process. We believe that it is these measures that may make the difference between extinction and survival for many species.

Procedural and Resource Difficulties in Designating Critical Habitat

We have been inundated with lawsuits for our failure to designate critical habitat, and we face a growing number of lawsuits challenging critical habitat determinations once they are made. These lawsuits have subjected us to an ever-increasing series of court orders and court-approved settlement agreements, compliance with which now consumes nearly the entire listing program budget. This leaves us with little ability to prioritize our activities to direct scarce listing resources to the listing program actions with the most biologically urgent species conservation needs.

The consequence of the critical habitat litigation activity is that limited listing funds are used to defend active lawsuits, to respond to Notices of Intent (NOIs) to sue relative to critical habitat, and to comply with the growing number of adverse court orders. As a result, listing petition responses, our own proposals to list critically imperiled species, and final listing determinations on existing proposals are all significantly delayed.

The accelerated schedules of court ordered designations have left us with almost no ability to provide for adequate public participation or to ensure a defect-free rulemaking process before making decisions on listing and critical habitat proposals due to the risks associated with noncompliance with judicially-imposed deadlines. This in turn fosters a second round of litigation in which those who fear adverse impacts from critical habitat designations challenge those designations. The cycle of litigation appears endless, is very expensive, and in the final analysis provides relatively little additional protection to listed species.

The costs resulting from the designation include legal costs, the cost of preparation and publication of the designation, the analysis of the economic effects and the cost of requesting and responding to public comment, and in some cases the costs of compliance with NEPA; all are part of the cost of critical habitat designation. None of these costs result in any benefit to the species that is not already afforded by the protections of the Act enumerated earlier, and they directly reduce the funds available for direct and tangible conservation actions.

Critical Habitat

Section 3(5)(A) of the Act defines critical habitat as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" means the use of all methods and procedures that are necessary to bring an endangered or a threatened species to the point at which listing under the Act is no longer necessary.

The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. It does not allow government or public access to private lands. Under section 7 of the Act, Federal agencies must consult with us on activities they undertake, fund, or permit that may affect critical habitat and lead to its destruction or adverse modification. However, the Act prohibits unauthorized take of listed species and requires consultation for activities that may affect them, including habitat alterations, regardless of whether critical habitat has been designated. We have found that the designation of critical habitat provides little additional protection to most listed species.

To be included in a critical habitat designation, habitat must be either a specific area within the geographic area occupied by the species on which are found those physical or biological features essential to the conservation of the species (primary constituent elements, as defined at 50 CFR 424.12(b)) and which may require special management considerations or protections, or be specific areas outside of the geographic area occupied by the species which are determined to be essential to the conservation of the species. Section 3(5)(C) of the Act states that not all areas that can be occupied by a species should be designated as critical habitat unless the Secretary determines that all such areas are essential to the conservation of the species. Our regulations (50 CFR 424.12(e)) also state that, "The Secretary shall designate as critical habitat areas outside the geographic area presently occupied by the species only when a designation limited to its present range

would be inadequate to ensure the conservation of the species."

Regulations at 50 CFR 424.02(j) define special management considerations or protection to mean any methods or procedures useful in protecting the physical and biological features of the environment for the conservation of listed species. When we designate critical habitat, we may not have the information necessary to identify all areas which are essential for the conservation of the species. Nevertheless, we are required to designate those areas we consider to be essential, using the best information available to us. Accordingly, we do not designate critical habitat in areas outside the geographic area occupied by the species unless the best available scientific and commercial data demonstrate that unoccupied areas are essential for the conservation needs of the species.

Section 4(b)(2) of the Act requires that we take into consideration the economic, and any other relevant impact, of specifying any particular area as critical habitat. We may exclude areas from critical habitat designation when the benefits of exclusion outweigh the benefits of including the areas within critical habitat, provided the exclusion will not result in extinction of the species.

Our Policy on Information Standards Under the Endangered Species Act, published in the *Federal Register* on July 1, 1994 (59 FR 34271), provides criteria, establishes procedures, and provides guidance to ensure that our decisions represent the best scientific and commercial data available. It requires our biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge.

Section 4 of the Act requires that we designate critical habitat on the basis of what we know at the time of designation. Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the

habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery.

Areas that support populations, but are outside the critical habitat designation, will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as determined on the basis of the best available information at the time of the action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Relationships to Sections 3(5)(A) and 4(b)(2) of the Act

Section 3(5)(A) of the Act defines critical habitat as the specific areas within the geographic area occupied by the species on which are found those physical and biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection. As such, for an area to be designated as critical habitat for a species it must meet both provisions of the definition. In those cases where an area does not provide those physical and biological features essential to the conservation of the species, it has been our policy not to include these specific areas in designated critical habitat. Likewise, if we believe, based on an analysis, that an area determined to be biologically essential has an adequate conservation management plan that covers the species and provides for adaptive management sufficient to conserve the species, then special management and protection are already being provided, so those areas do not meet the second provision of the definition and are also not proposed as critical habitat.

Further, section 4(b)(2) of the Act states that critical habitat shall be designated, and revised, on the basis of the best available scientific data available after taking into consideration the economic impact, and any other relevant impact, of specifying any

particular area as critical habitat. An area may be excluded from critical habitat if it is determined, following an analysis, that the benefits of such exclusion outweigh the benefits of specifying a particular area as critical habitat, unless the failure to designate such area as critical habitat will result in the extinction of the species. Consequently, we may exclude an area from designated critical habitat based on economic impacts, or other relevant impacts such as preservation of conservation partnerships and national security, if we determine the benefits of excluding an area from critical habitat outweigh the benefits of including the area in critical habitat, provided the action of excluding the area will not result in the extinction of the species.

In our critical habitat designations we have used both the provisions outlined in sections 3(5)(A) and 4(b)(2) of the Act to evaluate those specific areas which are proposed for designation as critical habitat and those areas which are subsequently finalized (*i.e.*, designated).

Prudency Determination

Section 4(a)(3) of the Act and its implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, we designate critical habitat at the time a species is listed as endangered or threatened. Our regulations at 50 CFR 424.12(a)(1) state that the designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species or (2) such designation of critical habitat would not be beneficial to the species. In our October 6, 1998, final rule (63 FR 53596), we determined that designation of critical habitat would provide little conservation benefit over that provided by listing. We determined that designation of critical habitat was not prudent based on the increased threat of vandalism and stated that designation of critical habitat could lead to acts of vandalism, may provoke deliberate incidents of vandalism by OHV users and may serve to encourage acts of vandalism.

However, in the past few years, several of our determinations that the designation of critical habitat would not be prudent have been overturned by court decisions. For example, in *Conservation Council for Hawaii v. Babbitt*, the United States District Court for the District of Hawaii ruled that the Service could not rely on the "increased threat" rationale for a "not prudent" determination without specific evidence

of the threat to the species at issue (2 F. Supp. 2d 1280 [D. Hawaii 1998]). Additionally, in *Natural Resources Defense Council v. U.S. Department of the Interior*, the United States Court of Appeals for the Ninth Circuit ruled that the Service must balance, in order to invoke the "increased threat rationale," the threat against the benefit to the species of designating critical habitat (113 F. 3d 1121, 1125 [9th Cir. 1997]).

We continue to be concerned that Peirson's milk-vetch is vulnerable to impacts from OHV use in the area, vandalism, or disturbance of their habitat and that these threats might be increased by the designation of critical habitat, publication of critical habitat maps, and further dissemination of location and habitat information. The periodically low numbers and restricted range of this plant taxon make it vulnerable. At this time, we do have some limited specific evidence for vandalism, and other unauthorized human disturbance specific to this plant and its habitat.

The courts also have ruled that, in the absence of a finding that the designation of critical habitat would increase threats to a species, the existence of another type of protection, even if it offers potentially greater protection to the species, does not justify a "not prudent" finding (*Conservation Council for Hawaii v. Babbitt* 2 F. Supp. 2d 1280). We are already working with Federal and State agencies and organizations in carrying out conservation activities for this plant and conducting surveys for additional occurrences of the species and to assess habitat conditions. These entities are fully aware of the distribution, status, and habitat requirements for this plant.

We have reconsidered our evaluation of the threats posed by vandalism in the prudency determination. We have determined that the threats to Peirson's milk-vetch from specific instances of vandalism we previously identified are limited, if not speculative. Accordingly, we withdraw our previous determination that the designation of critical habitat is not prudent for Peirson's milk-vetch. Therefore, we determine that the designation of critical habitat is prudent for Peirson's milk-vetch. At this time, we have sufficient information necessary to identify specific areas as essential to the conservation of this plant taxon and are therefore proposing critical habitat (see "Methods and Analysis used to Identify Proposed Critical Habitat" section below for a discussion of information used in our reevaluation).

Methods

As required by section 4(b)(2) of the Act and regulations at 50 CFR 424.12, we used the best scientific information available to determine areas that contain the physical and biological features that are essential for the conservation of *Astragalus magdalenae* var. *peirsonii*. This included information from our own documents on this plant and related taxa, available information that pertains to the biology and habitat requirements of this taxon, including data from research and survey observations, such as Westec (1977), BLM surveys conducted from 1998 to 2002 primarily summarized by Willoughby (BLM 2000, 2001), Thomas Olsen Associates (TOA) (2001), and Phillips and Kennedy (2002); the California Natural Diversity Database (2003); peer-reviewed journal articles and book excerpts regarding *A. m.* var. *peirsonii*, similar species, or more generalized issues of conservation biology; unpublished biological documents and discussions with botanical experts regarding *A. m.* var. *peirsonii* and related species; site visits; and discussions.

The area proposed for critical habitat is occupied by *Astragalus magdalenae* var. *peirsonii* as demonstrated by repeated surveys summarized by BLM (BLM 2000, 2001), and independently confirmed by TOA (TOA 2001). This plant may be present as standing plants, as seed bank in the sand or as plants persisting as perennial root crowns in the sand. During any given year, the suitable habitat for *A. m.* var. *peirsonii* may be occupied by various combinations of these three life history phases. The dynamics of dune morphology, local rainfall patterns and amounts, as well as the spatial distribution of the seed bank, and seed scarification each contribute to the patchy or mosaic nature of the distribution of standing plants of *A. m.* var. *peirsonii*. Local rainfall patterns and amounts are likely to cause shifts in the proportions of these three life history phases. All areas proposed as critical habitat contain at least one of the primary constituent elements and have been determined to be essential to the conservation of the species, as described below.

Areas proposed as critical habitat are occupied, in any given year, by standing plants, root crowns, or the soil seed bank. Likewise, areas of unsurveyed, suitable habitat that are contiguous with areas where standing plants have been documented by BLM surveys (BLM 2000, 2001), are reasonably likely to support standing plants, root crowns, or

a portion of the soil seed bank. BLM did not survey every west-to-east transect across the dunes, however, interpolation of earlier survey data (WESTEC 1977) and census data (TOA 2001) confirms the presence of *Astragalus magdalenae* var. *peirsonii* and the continuity of the northwest-to-southeast habitat. These data sustain our inclusion of these areas in the proposed critical habitat. These areas are not likely any bigger than naturally occurring gaps in the spatial distribution. As a result, these intervening areas, where standing plants may not have been documented are determined to be essential to the conservation of *A. m. var. peirsonii* because they contain the primary constituent elements and will accommodate the natural fluctuations and movement of populations as well as connectivity across the plants' range. Surveys need not have identified standing plants for an area to be considered occupied because a species may still be present at a site as part of the seed bank (Given 1994) or unsprouted root crowns.

The most extensive survey of the Algodones Dunes was conducted in 1977 (Westec 1977). This survey used 66 transects that ran across the dunes from west to east. Along the transects they recorded presence and relative abundance of standing plants of *Astragalus magdalenae* var. *peirsonii* and four other rare psammophytic scrub species. In 1998 the BLM began surveying for rare plants in the dunes repeating the methodology used by Westec in their 1977 survey; however, the BLM surveyed only 34 of the original 66 transects and employed a different abundance measure. The BLM conducted these surveys for 5 consecutive years (1998, 1999, 2000, 2001, and 2002) recording the presence and abundance of the rare plant taxa along the transects.

To determine the general range of *Astragalus magdalenae* var. *peirsonii* in the Algodones Dunes, we used survey information from published and unpublished documents and maps including Westec (1977), BLM (2000, 2001), and TOA (2001). Westec (1977) devised a grid system overlay for the Algodones Dunes. Each quadrant of the grid was approximately 0.45 mi (0.72 km) on a side. BLM reproduced this grid system to present data from their subsequent annual surveys from 1998 to 2002 (BLM 2000, 2001). Both Westec and BLM considered a grid square occupied if *A. m. var. peirsonii* was encountered anywhere within that grid square. For comparison, we also superimposed census data included by TOA (2001) on this same grid system.

We produced maps based on Westec (1977), BLM (2000, 2001), and TOA (2001) data. Because of the differences in survey methodologies and abundance classes used by these surveys, we considered each of these records to represent presence or absence only. Due to fluctuations in both the presence and abundance of *A. m. var. peirsonii* from year to year, we combined the data from multiple years of survey data. Also the various surveys recorded standing plants as the only measure of occupancy, not taking into account a dormant soil seed bank or root crowns.

The survey efforts, discussed above, provided us with the data necessary to construct a model showing which regions of the Algodones Dunes represent essential habitat for the *Astragalus magdalenae* var. *peirsonii*. The model that we created used the data collected by the BLM from 1998 to 2002 as the input data and the data collected by Westec 1977 and TOA 2001 as a means of verifying the information generated by the model. The BLM data was used as the input data source for the model because it was more current, covered multiple years, and used the same methodology each year. Time and resources precluded us from conducting independent surveys. Outlier occurrences evidenced only by Westec 1977 were not included because of the age of the report and the lack of substantiation by more recent BLM surveys.

In order to create this model we used the BLM data to extrapolate the values for four variables: (1) The presence or absence of standing plants of *A. m. var. peirsonii*; (2) the abundance of *A. m. var. peirsonii*; (3) the frequency of occurrence of *A. m. var. peirsonii*; and (4) the number of associated rare psammophytic plant taxa present. These variables were scored, then standardized, and finally compiled. We grouped the data into five categories and created a map depicting the distribution of the model's output. This map showed a strong band of high values that ran from the Northeast to the Southwest of the dune field. The portion of the dunes that corresponded to the top three categories represented the portion of the Algodones Dunes that is essential to the conservation of this species.

Analysis of four variables depicted on GIS-based maps provided us with information necessary for determining which areas of the Algodones Dunes are essential for the conservation of the species and contain the primary constituent elements. The first variable was that of the presence or absence of standing plants. This indicated localities where *Astragalus magdalenae*

var. *peirsonii* had been found in each of the five survey years either as seedlings or as older plants. The second variable gave us information about the relative abundance of *A. m. var. peirsonii* in each of the five survey years. The highest abundance class value recorded for each grid cell during the five survey years was used as the cell's value for this variable. This provided us with information to depict areas that seem to have higher plant densities, and thus presence of primary constituent elements. The third variable provided us with information about the frequency with which *A. m. var. peirsonii* occurred from year to year. This variable was calculated based on the number of times *A. m. var. peirsonii* was reported in a grid cell throughout the 5-year survey period. This was important in determining areas that continued to function as good habitat for *A. m. var. peirsonii* and were most likely to contain the primary constituent elements. Finally, we used the presence and absence data for the other rare psammophytic scrub taxa that occur in the Algodones dunes and are often found with *A. m. var. peirsonii* as the fourth variable. These plants included *Croton wigginsii*, *Helianthus niveus* ssp. *tephrodes*, *Palafoxia arida* var. *gigantea*, and *Pholisma sonora*. For each grid cell, scores were assigned based on the number of these associated plants that were found over the course of the 5 years of surveys. Higher scores may indicate a greater abundance and persistence of *A. m. var. peirsonii* and/or the diversity of associated psammophytic scrub species. Therefore, by this measure higher scores indicate the presence of higher quality psammophytic scrub habitat, and thus the presence of primary constituent elements.

Intrinsic to the creation of the essential habitat model for *Astragalus magdalenae* var. *peirsonii* was the application of several assumptions related to the (1) BLM study design (Willoughby 2000 and Willoughby 2001), (2) habitat and weather variability across the entire dune system, (3) paved roads as barriers to dispersal, (4) occurrences of plants and seeds in grid cells over different survey periods, and (5) model protocol. These assumptions are described to allow the reviewer to understand the potential strengths and limitations of the results of the habitat modeling. Based on the BLM study design, a consistent survey methodology was used for the plant surveys conducted in 1998, 1999, and 2000 (Willoughby 2000 and Willoughby 2001). Vegetation maps (BLM 2003),

wind patterns (Romsper and Burk 1979 and Norris and Norris 1961), and precipitation patterns (Willoughby 2000 and Willoughby 2001) supported our assumption that the habitat, in terms of dune action, precipitation, and vegetation, was uniform in variation and continuous throughout the dune system. Based on rainfall data collected from November 16, 2000 to March 16, 2001 (1.40 inches of precipitation was recorded at Cahuilla Ranger Station in the northwest part of the dunes and 2.67 inches of precipitation was reported at Buttercup Campground in the southern end of the dunes (Willoughby 2001)), BLM indicated that more precipitation may fall in the southern portion of the Algodones Dunes compared to the northern end of the dunes. However, given the limited precipitation data available for the Algodones Dunes (5 months) and the relatively short linear extent of the dunes (40 mi long) (64 km long), we could not project a rainfall gradient and, instead, assumed that the precipitation was uniformly variable and continuous throughout the dune system. Based on observations of unimpeded sand and wind movement across existing paved roads, we did not expect that the paved roads would represent a barrier to the dispersal of the fruits and seeds of *Astragalus magdalenae* var. *peirsonii*. Surveys conducted by BLM indicate variability in occurrences of standing plants from year to year (Willoughby 2000 and Willoughby 2001) and that at any given time, these occurrences may represent standing plants, root crown regrowth, or seedlings of *Astragalus magdalenae* var. *peirsonii*. We assumed that if standing plants were not found in a particular grid cell during a survey, but were recorded as present in other survey years, then that grid cell may be occupied by either root crowns or seeds of this species. BLM randomly selected survey transects and, as expected, this random selection results in gaps between transects. We projected the distribution of *Astragalus magdalenae* var. *peirsonii* across the gaps by assuming that the values of unknown grid cells are more closely related to nearby cells rather than distant cells.

From the data provided by BLM we were able to calculate scores for each of these variables and then extrapolate the values for each variable for the entire dune area. We made this extrapolation based on a statistical method called Kriging, which calculates new values for unsurveyed areas based on the known values for the cells that were surveyed. The data for these four variables was then standardized to a scale of 0 to 5

points so that the range of scores, from low to high, would be comparable to one another. The standardized scores were then totaled for each cell, for a possible high score of 20 points. This set of values was then further refined using the Kriging method to generate a map similar in appearance to a topographic map, showing the resulting scores of the model in the same way a topographic map shows variations in elevation. A line was then drawn around those areas of higher-quality psammophytic scrub habitat described above and considered essential to the conservation of *Astragalus magdalenae* var. *peirsonii*.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat, we consider those physical and biological features (primary constituent elements) that are essential to the conservation of the species and that may require special management considerations or protection. These include but are not limited to: Space for individual and population growth and for normal behavior; food, water, air, light, minerals or other nutritional or physiological requirements; cover or shelter; sites for germination or seed dispersal; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

Much of what is known about the specific physical and biological requirements of *Astragalus magdalenae* var. *peirsonii* is described in the Background section of this proposal and in the final listing rule. The proposed critical habitat is designed to provide sufficient habitat to maintain self-sustaining populations of *A. m.* var. *peirsonii* throughout its range and to provide those habitat components essential for the conservation of the species. These habitat components provide for: (1) Individual and population growth, including sites for germination, pollination, reproduction, pollen and seed dispersal, and seed bank; (2) intervening areas that allow gene flow and provide connectivity or linkage within segments of the larger population; and (3) areas that provide basic requirements for growth, such as water, light, and minerals.

The conservation of *Astragalus magdalenae* var. *peirsonii* is dependent upon a number of factors including the protection and management of existing population sites and habitat, the maintenance of normal ecological functions within these sites, including connectivity between groups of plants

within close geographic proximity to facilitate gene flow among the sites by pollinator activity and fruit as well as seed dispersal. Some of the factors associated with the observed and potential distribution of this species include: seeds will likely germinate if germination requirements of scarification and moisture are met within a germination time frame for the species (Porter, *in litt.* 2003); germination patterns likely reflect the distribution of the seed bank in the shifting sands. (seeds will not effectively germinate below a certain depth); and distribution patterns of standing plants may, in large part, reflect the distribution pattern of adequate rainfall for a particular year.

The areas we are proposing to designate as critical habitat provide some or all of the habitat components essential for the conservation of *Astragalus magdalenae* var. *peirsonii*. These habitat components and primary constituent elements are generally associated with psammophytic scrub (e.g., *Croton wigginsii*, *Eriogonum deserticola*, *Helianthus niveus* ssp. *tephrodes*, *Palafoxia arida* var. *gigantea*, *Pholisma sonora*, and *Tiquilia plicata*). Based on the best available information at this time, the primary constituent elements of critical habitat for *A. m.* var. *peirsonii* consist of:

- (1) Intact, active sand dune systems (defined as sand areas that are subject to sand-moving winds that result in natural expanses of slopes and swales) within the historical range of *A. m.* var. *peirsonii* that are characterized by:
 - (A) substrates of the Rositas soil series, specifically Rositas fine sands of sufficient depth to promote *A. m.* var. *peirsonii* and discourage creosote bush scrub; and
 - (B) wind-formed slopes of less than 30 degrees, but generally less than 20 degrees.

Criteria Used To Identify Critical Habitat

We identified critical habitat essential to the conservation of *Astragalus magdalenae* var. *peirsonii* in the primary locations where it currently occurs or has been known to occur in the Algodones Dunes. We are proposing to designate critical habitat to maintain self-sustaining populations of *A. m.* var. *peirsonii* within the range of the taxon in the United States.

Astragalus magdalenae var. *peirsonii* has a very limited range even within the Algodones Dunes. Less than one-third of the area delineated by the ISDRA has documented occurrences of *A. m.* var. *peirsonii*. Extreme fluctuations in populations have been demonstrated.

As a result, it is likely in some years that few, if any, seeds are added to the soil seed bank. The patchy distribution of the plants in any given year is likely a combination of several factors including the dynamics of dune morphology, local rainfall patterns and amounts, as well as the spatial distribution of the seed bank, and seed scarification.

We delineated the proposed critical habitat by creating data layers in a GIS format. Because of the dynamic nature of the distribution of this plant, the cyclic nature of suitable climatic regimes, and the presence of a seed bank for *Astragalus magdalenae* var. *peirsonii*, grid squares where this plant has not been encountered are included as critical habitat if they are contiguous with grid squares where the plant has been found and possess the primary constituent elements and are considered occupied. Another reason for their inclusion is that there are gaps in those transects surveyed by Westec and BLM. The TOA (2001) survey bridged some of these gaps and leave little doubt that additional surveys in previously unsurveyed transects would likely fill in the east-to-west pattern as well. The BLM surveys serve as the basis for the mapping of critical habitat. An exception to this is instances where Westec (1977) data is the only source of a record. Because BLM has included only 34 west-east transects along the length of the dunes, and additional data from TOA (2001) and Westec (1977) tend to bridge the gaps between BLM's transects, we considered the northwest to southeast distribution to be generally continuous.

In order to provide legal descriptions of the critical habitat boundaries, we then used an overlaid 100-meter grid to establish Universal Transverse Mercator (UTM) North American Datum 27 (NAD 27) coordinates which, when connected, provided the critical habitat unit boundaries.

In designating critical habitat, we made an effort to avoid developed areas, OHV staging areas, and disturbed areas along roadways that are unlikely to contain the primary constituent elements and therefore contribute to the conservation of *Astragalus magdalenae* var. *peirsonii*. However, we did not map critical habitat in sufficient detail to exclude all developed areas, or other lands unlikely to contain the primary constituent elements essential for the conservation of *A. m.* var. *peirsonii*. Areas within the boundaries of the mapped units, such as buildings, roads, parking lots, railroad tracks, canals, and other paved areas, will not contain one or more of the primary constituent elements. Federal actions limited to

these areas, therefore, would not trigger a consultation under section 7 of the Act, unless they affect the species or primary constituent elements in adjacent critical habitat.

Special Management Considerations

Special management considerations or protections may be needed to maintain the physical and biological features as well as the primary constituent elements that are essential for the conservation of *Astragalus magdalenae* var. *peirsonii* within the unit being proposed as critical habitat. As noted in the Critical Habitat section, "special management considerations or protection" is a term that originates in section 3(5)(A) of the Act under the definition of critical habitat. We believe that the proposed critical habitat unit may require the special management considerations or protections outlined below.

1. The dune composition and structure should be maintained in a manner compatible with the natural distribution pattern of *Astragalus magdalenae* var. *peirsonii* and be conducive to the persistence of associated psammophytic scrub species and discourage creosote bush scrub.

2. The direct and indirect impacts of OHVs on individual plants, as well as on the plants reproductive capacity, must be scientifically determined. These impacts must be assessed at a relevant time scale to determine seasonal impact, frequency of impact, duration of impacts, and pattern of impacts. This may allow an objective application of acceptable levels and timing of OHV activity in each of the BLM recreation management areas.

Recently, the BLM issued a Recreation Area Management Plan (RAMP) for the Imperial San Dunes (BLM 2003). A specified major focus of the RAMP is to ensure that the "world class opportunities" of Imperial Sand Dunes Recreation Area (ISDRA) are continuously available while responding to increased need for protection of plant and animal species in the dunes (BLM 2003). Species specific management needs and measures for *Astragalus magdalenae* var. *peirsonii* are not addressed in the RAMP. In the RAMP, BLM does include a monitoring/study plan that they propose to implement. The results of this monitoring would be incorporated into a management plan developed for *Astragalus magdalenae* var. *peirsonii*.

Within the ISDRA only the North Algodones Dune Wilderness Area (Wilderness Area) will remain closed to public motorized vehicle use. Although the Wilderness Area does not allow

motorized recreational use, it is open to non-motorized public uses including hiking and horseback riding. Additionally, vehicular use by the California Department of Fish and Game, the Border Patrol and other permitted entities will be allowed. The Wilderness Area is not actively managed for the conservation of plant and animal species, rather management will take the form of "minimal and subtle on-site controls and restrictions."

Proposed Critical Habitat Designation

Lands proposed for critical habitat designation include Federal and private lands. The approximate areas of proposed critical habitat by land ownership are shown previously in this document in table 1.

The proposed critical habitat areas constitute our best assessment of the areas essential for the conservation of *Astragalus magdalenae* var. *peirsonii* and provide the primary constituent elements described above. The critical habitat includes locations where standing plants of *A. m.* var. *peirsonii* have been observed during BLM and Westec surveys. Because of the natural fluctuations in population numbers and timing of rainfall and pattern of seed germination, standing plants may not appear in all areas of critical habitat every year. Within the boundary of critical habitat we also include areas contiguous to those where standing plants have been recorded, and where, because of plant proximity and habitat continuity, we have no reason to doubt the presence of plants as a seed bank. This has been supported by recent findings from a single survey by TOA (2001) that found plants in areas of the dunes interspersed with those included in the BLM transects.

The Algodones Dunes Critical Habitat Unit is in eastern Imperial County, California. This is the only region in the United States where there are deep dunes maintained by dune-building winds that result in natural expanses of swales and slopes under 20 degrees slope, and appropriate Rositas soils. This is also the only region of the United States that supports an extant population of *Astragalus magdalenae* var. *peirsonii*, and we have no evidence that another such area exists. It extends, as an elongate triangle shape, from the International Boundary northward in a northwesterly direction. The western boundary parallels the Coachella Canal. The eastern boundary is generally half way between this and Ted Kipf Road to the east. The northern end attenuates to a point near the convergence of the Coachella Canal and Ted Kipf Road.

The Algodones Dunes Critical Habitat Unit has three separate portions separated by highways. The discontinuities associated with the highways are likely traversed occasionally by mature fruits dispersed by the wind as well as by pollinators. The northern portion of the Unit is north of State Highway 78. The majority of the northern portion of the critical habitat lies within the North Algodones Dunes Wilderness. The central portion of the Unit is south of State Highway 78 and north of Interstate 8. This portion of the Unit extends from the leeward side of the dunes east of the Coachella Canal eastward to approximately one half the distance to Ted Kipf Road on the eastern side of the Algodones Dunes. West of the central portion of the critical habitat, there are at least 11 campgrounds mostly associated with the Gecko Road area. The southern portion of the Unit is south of Interstate 8 and includes campgrounds and a major OHV staging area. *Astragalus magdalenae* var. *peirsonii* has consistently been found in the Buttercup Management Area. A primary feature of the area are the barchan dunes that between 1953 and 1968 were determined to migrate toward the southeast (Smith 1978). This pattern is likely still operative. This area is important to the conservation of *A. m.* var. *peirsonii* because it provides the only potential connectivity between the range of the plant in the United States and that in Mexico.

Effects of Critical Habitat Designation Section 7 Consultation

Section 7(a) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, permit, or carry out do not destroy or adversely modify critical habitat. Destruction or adverse modification of critical habitat occurs when a Federal action directly or indirectly alters critical habitat to the extent that it appreciably diminishes the value of critical habitat for the conservation of the species. Individuals, organizations, States, local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding.

In our regulations at 50 CFR 402.02, we define destruction or adverse modification as "a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to: alterations adversely

modifying any of those physical or biological features that were the basis for determining the habitat to be critical." However, in a March 15, 2001, decision of the United States Court of Appeals for the Fifth Circuit (*Sierra Club v. U.S. Fish and Wildlife Service et al.*, F.3d 434), the Court found our definition of destruction or adverse modification to be invalid. In response to this decision, we are reviewing the regulatory definition of adverse modification in relation to the conservation of the species.

Section 7(a) of the Act requires Federal agencies, including the Service, to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat, if any is designated or proposed. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist Federal agencies in eliminating conflicts that may be caused by their proposed actions. The conservation measures in a conference report are advisory.

We may issue a formal conference report, if requested by the Federal action agency. Formal conference reports include an opinion that is prepared according to 50 CFR 402.14, as if the species was listed or critical habitat designated. We may adopt the formal conference report as the biological opinion when the species is listed or critical habitat designated, if no substantial new information or changes in the action alter the content of the opinion (50 CFR 402.10(d)).

If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Through this consultation, the Federal action agency would ensure that the permitted actions do not destroy or adversely modify critical habitat.

If we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we also

provide "reasonable and prudent alternatives" to the project, if any are identifiable. Reasonable and prudent alternatives are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies to reinstate consultation on previously reviewed actions under certain circumstances, including instances where critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiating of consultation or conference with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat, or adversely modify or destroy proposed critical habitat.

Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and require that a section 7 consultation be conducted include, but are not limited to:

- (1) Activities that disturb or degrade the structure of the dunes (ridges, slip faces, bowls, and swales);
- (2) Activities that irreversibly compact or disturb the sand such that seeds of *Astragalus magdalenae* var. *peirsonii* are not capable of germinating or plants are not able to survive; and,
- (3) Activities that alter the existing hydrology or reduce soil moisture by lowering the groundwater table or redirecting surface flows.

Activities that may destroy or adversely modify critical habitat include those that alter the primary constituent elements to an extent that the value of critical habitat for both the survival and recovery of Peirson's milk-vetch is appreciably reduced. We note that such activities may also jeopardize the continued existence of the species.

We recognize that the proposed designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, we want to ensure that the public is aware that

critical habitat designations do not signal that habitat outside the proposed designation is unimportant or may not be required for recovery. Areas outside the proposed critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the prohibitions of section 9 of the Act. Critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Section 4(b)(8) of the Act requires us to evaluate briefly and describe, in any proposed or final regulation that designates critical habitat, those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat would be those that alter the primary constituent elements to the extent that the value of critical habitat for the conservation of the *Astragalus magdalenae* var. *peirsonii* is appreciably reduced. The actions listed previously are activities that may affect critical habitat and are not necessarily actions that would result in adverse modification. We also note that such activities may also jeopardize the continued existence of the species.

Moreover, we completed a section 7 consultation with BLM on the Imperial Sand Dunes Recreational Area Management Plan (RAMP) (FWS-IMP-3419.2) dated April 3, 2003. In that biological opinion, we concluded that the implementation of the RAMP is not likely to jeopardize the continued existence of *Astragalus magdalenae* var. *peirsonii*. BLM will modify the monitoring plan to include (1) dune-wide monitoring of *A. m. var. peirsonii*, (2) dune-wide monitoring and calibration of OHV use patterns, (3) two experimental studies on the effects of OHVs on *A. m. var. peirsonii*, (4) examination for correlation between OHV use patterns and *A. m. var. peirsonii* population levels, (5) modeling of *A. m. var. peirsonii* populations under various management scenarios, and (6) an implementation schedule. In addition, BLM proposes to establish triggers to activate alternative management actions when visitation exceeds target levels and to reinstate consultation (1) if *A. m. var. peirsonii*

population levels in individual Management Areas fall to 50 percent of baseline in a comparable rainfall year (at or above the long-term mean), and (2) after accumulation of 4 years of monitoring information. This information will be valuable in determining the effects of the RAMP on critical habitat. While BLM's proposed action has not been analyzed in the context of a final designation of critical habitat, we expect that a similar approach would be used to evaluate whether the implementation of the RAMP would result in destruction or adverse modification of critical habitat.

If you have questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat, contact the Field Supervisor, Carlsbad Fish and Wildlife Office (see ADDRESSES section). Requests for copies of the regulations on listed wildlife and plants and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Branch of Endangered Species, 911 N.E. 11th Ave, Portland, OR 97232 (telephone 503/231-2063; facsimile 503/231-6243).

All lands proposed as critical habitat are within the geographical area occupied by the species and are necessary for the conservation of *Astragalus magdalenae* var. *peirsonii*. Federal agencies already consult with us on actions that may affect *A. m. var. peirsonii* to ensure that their actions do not jeopardize the continued existence of the species. Thus, we do not anticipate substantial additional regulatory protection will result from critical habitat designation.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial data available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species.

An analysis of the economic impacts of proposing critical habitat for the *Astragalus magdalenae* var. *peirsonii* is being prepared. We will announce the availability of the draft economic analysis as soon as it is completed, at which time we will seek public review and comment. At that time, copies of the draft economic analysis will be available for downloading from the

Internet at <http://carlsbad.fws.gov>, or by contacting the Carlsbad Fish and Wildlife Office directly (see ADDRESSES section).

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will solicit the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the 60-day comment period on this proposed rule as we prepare our final rulemaking. Accordingly, the final designation may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days of the date of publication of the proposal in the **Federal Register**. Such requests must be made in writing and be addressed to the Field Supervisor (see ADDRESSES section). We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings in the **Federal Register** and local newspapers at least 15 days prior to the first hearing.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations and notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical jargon that interferes with the clarity? (3) Does the format of the proposed rule (grouping and order of the sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Is the description of the notice in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? (5) What else could we do to make this proposed rule easier to understand?

Send a copy of any comments on how we could make this proposed rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You may e-mail your comments to this address: Exsec@ios.doi.gov.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is not a significant rule and, therefore, was not reviewed by the Office of Management and Budget (OMB). We will be preparing a draft economic analysis of this proposed action; we will use this analysis to meet the requirement of section 4(b)(2) of the Act to determine the economic consequences of designating the specific areas as critical habitat and excluding any area from critical habitat if it is determined that the benefits of such exclusion outweigh the benefits of specifying such areas as part of the critical habitat, unless failure to designate such area as critical habitat will lead to the extinction of the *Astragalus magdalenae* var. *peirsonii*. This draft economic analysis will be made available for public review and comment before we finalize this designation. At that time, copies of the analysis will be available for downloading from the Carlsbad Fish and Wildlife Office's Internet website at <http://carlsbad.fws.gov> or by contacting the Carlsbad Fish and Wildlife Office directly (see ADDRESSES section).

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. SBREFA also amended the Regulatory Flexibility Act

to require a certification statement. Based on the information that is available to us at this time, we are certifying that this proposed designation of critical habitat will not have a significant economic impact on a substantial number of small entities. The following discussion explains our rationale.

According to the Small Business Administration (SBA), small entities include small organizations, including any independent nonprofit organization that is not dominant in its field, and small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents, as well as small businesses. The SBA defines small businesses categorically and has provided standards for determining what constitutes a small business at 13 CFR 121-201 (also found at <http://www.sba.gov/size/>), which the Regulatory Flexibility Act requires all Federal agencies to follow. To determine if potential economic impacts to these small entities are significant, we consider the types of activities that might trigger regulatory impacts under this rule as well as the types of project modifications that may result.

The Regulatory Flexibility Act does not explicitly define either "substantial number" or "significant economic impact." Consequently, to assess whether a "substantial number" of small entities is affected by this designation, this analysis considers the relative number of small entities likely to be impacted in the area. Similarly, this analysis considers the relative cost of compliance on the revenues/profit margins of small entities in determining whether or not entities incur a "significant economic impact." Only small entities that are expected to be directly affected by the designation are considered in this portion of the analysis. This approach is consistent with several judicial opinions related to the scope of the Regulatory Flexibility Act. (*Mid-Tex Electric Co-Op, Inc. v. F.E.R.C.* and *American Trucking Associations, Inc. v. EPA*).

To determine if the rule would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities (e.g., housing development, grazing, oil and gas production, timber harvesting). We applied the "substantial number" test individually to each affected industry to determine if certification is appropriate. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement; some kinds of

activities are unlikely to have any Federal involvement and so will not be affected by critical habitat designation.

Designation of critical habitat only affects activities conducted, funded, or permitted by Federal agencies; non-Federal activities are not affected by the designation if they lack a Federal nexus. In areas where the species is present, Federal agencies funding, permitting, or implementing activities are already required to avoid jeopardizing the continued existence of the *Astragalus magdalenae* var. *peirsonii* through consultation with us under section 7 of the Act. If this critical habitat designation is finalized, Federal agencies must also consult with us to ensure that their activities do not destroy or adversely modify designated critical habitat through consultation with us.

Should a federally funded, permitted, or implemented project be proposed that may affect designated critical habitat, we will work with the Federal action agency and any applicant, through section 7 consultation, to identify ways to implement the proposed project while minimizing or avoiding any adverse effect to the species or critical habitat. In our experience, the vast majority of such projects can be successfully implemented with at most minor changes that avoid significant economic impacts to project proponents.

Based on our experience with section 7 consultations for all listed species, virtually all projects—including those that, in their initial proposed form, would result in jeopardy or adverse modification determinations in section 7 consultations—can be implemented successfully with, at most, the adoption of reasonable and prudent alternatives. These measures, by definition, must be economically feasible and within the scope of authority of the Federal agency involved in the consultation. The kinds of actions that may be included in future reasonable and prudent alternatives include avoidance, conservation set-asides, management of competing non-native species, restoration of degraded habitat, construction of protective fencing, and regular monitoring. These measures are not likely to result in a significant economic impact to project proponents.

In the case of *Astragalus magdalenae* var. *peirsonii*, our review of the consultation history for this plant suggests that the proposed designation of critical habitat is not likely to have a significant impact on any small entities or classes of small entities. The only class of small entities that could be affected by this designation is the off-

highway vehicle industry. To identify potential small entities related to off-highway vehicle use that may be affected by the proposed designation, we considered the membership list of the Off-Road Business Association (updated June 11, 2003) to be an indication of the potential number of small entities that may be affected by the proposed designation of critical habitat. Based on the June 11, 2003, list, 247 companies were members of the Off-Road Business Association. Most of the Off-Road Business Association members represented business primarily located in California.

We considered the potential relative cost of compliance to these small entities and evaluated only small entities that are expected to be directly affected by the proposed designation of critical habitat. Based on the consultation history for *Astragalus magdalenae* var. *peirsonii*, we do not anticipate that the proposed designation of critical habitat will result in increased compliance costs for small entities. The business activities of these small entities and their effects on *Astragalus magdalenae* var. *peirsonii* or its proposed critical habitat have not directly triggered a section 7 consultation with the Service under the jeopardy standard and likely would not trigger a section 7 consultation under the adverse modification standard after designation of critical habitat. The proposed designation of critical habitat does not, therefore, create a new cost for the small entities to comply with the proposed designation. Instead, proposed designation only impacts Federal agencies that conduct, fund, or permit activities that may affect critical habitat for *Astragalus magdalenae* var. *peirsonii*. Moreover, none of the small entities have been applicants with a Federal agency for a section 7 consultation with the Service. On April 3, 2003, we also completed a section 7 consultation with BLM on the Imperial Sand Dunes RAMP. In that biological opinion, we concluded that the implementation of the RAMP is not likely to jeopardize the continued existence of *Astragalus magdalenae* var. *peirsonii*. Thus, we conclude that the proposed designation of critical habitat is not likely to result in a significant impact to this group of small entities.

In addition, we completed an informal section 7 consultation with BLM on the potential effects to *Astragalus magdalenae* var. *peirsonii* of a private company filming a movie on Federal lands within the Algodones Dunes. Given the relatively small number of consultations related to film-making activities on Federal lands

within the Algodones Dunes, we anticipate that the proposed designation of critical habitat is not likely to have a significant impact on this group of small entities.

As required under section 4(b)(2) of the Act, we will conduct an analysis of the potential economic impacts of this proposed critical habitat designation and will make that analysis available for public review and comment before finalizing this designation. However, court deadlines require us to publish this proposed rule before the economic analysis can be completed.

In summary, we have considered whether this proposed designation would result in a significant economic impact on a substantial number of small entities and find that it would not. This rule would result in project modifications only when proposed activities with a Federal nexus would destroy or adversely modify critical habitat. While this may occur, it is not expected to occur frequently enough to affect a substantial number of small entities. Even if a small entity is affected, we do not expect it to result in a significant economic impact, as the measures included in reasonable and prudent alternatives must be economically feasible and consistent with the proposed action. The kinds of measures we anticipate we would recommend can usually be implemented at low cost. Therefore, we are certifying that the proposed designation of critical habitat for the *Astragalus magdalenae* var. *peirsonii* will not have a significant economic impact on a substantial number of small entities, and an initial regulatory flexibility analysis is not required. This determination will be revisited after the close of the comment period and revised, if necessary, in the final rule.

This discussion is based upon the information regarding potential economic impact that is available to us at this time. This assessment of economic effect may be modified prior to final rulemaking based upon development and review of the draft economic analysis prepared pursuant to section 4(b)(2) of the ESA and Executive Order 12866. This analysis is for the purpose of compliance with the Regulatory Flexibility Act and does not reflect our position on the type of economic analysis required by *New Mexico Cattle Growers Assn. v. U.S. Fish & Wildlife Service* 248 F.3d 1277 (10th Cir. 2001).

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 802(2))

In the draft economic analysis, we will determine whether designation of

critical habitat will cause (a) any effect on the economy of \$100 million or more; (b) any increases in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (c) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Executive Order 13211

On May 18, 2001, the President issued an Executive Order (E.O. 13211) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This proposed rule to designate critical habitat for the *Astragalus magdalenae* var. *peirsonii* is not a significant regulatory action under Executive Order 12866, and it is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.), the Service will use the economic analysis to further this rule's effect on nonfederal governments.

Takings

In accordance with Executive Order 12630 ("Government Actions and Interference with Constitutionally Protected Private Property Rights"), we have analyzed the potential takings implications of designating critical habitat for *Astragalus magdalenae* var. *peirsonii*. This preliminary assessment concludes that this proposed rule does not pose significant takings implications. However, we have not yet completed the economic analysis for this proposed rule. Once the economic analysis is available, we will review and revise this preliminary assessment as warranted.

Federalism

In accordance with Executive Order 13132, this rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior policies, we requested information from and coordinated development of this proposed critical habitat designation with appropriate State resource agencies in California. The proposed designation of critical

habitat in areas currently occupied by the *Astragalus magdalenae* var. *peirsonii* imposes no additional significant restrictions beyond those currently in place and, therefore, has little incremental impact on State and local governments and their activities.

The proposed designation of critical habitat may have some benefit to the State and local resource agencies in that the areas essential to the conservation of this species are more clearly defined, and the primary constituent elements of the habitat necessary to the conservation of this species are specifically identified. While this definition and identification does not alter where and what federally sponsored activities may occur, it may assist local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor has determined that this rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order. We are proposing to designate critical habitat in accordance with the provisions of the Endangered Species Act. The rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of the *Astragalus magdalenae* var. *peirsonii*.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain new or revised information collection for which OMB approval is required under the Paperwork Reduction Act. Information collections associated with

certain Act permits are covered by an existing OMB approval and are assigned clearance No. 1018-0094, Forms 3-200-55 and 3-200-56, with an expiration date of July 31, 2004. Detailed information for Act documentation appears at 50 CFR 17. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have determined that an Environmental Assessment and/or an Environmental Impact Statement as defined by the National Environmental Policy Act of 1969 need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. A notice outlining our reason for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244). This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We

have determined that there are no Tribal lands essential for the conservation of the *Astragalus magdalenae* var. *peirsonii*. Therefore, designation of critical habitat for the *A. m.* var. *peirsonii* has not been proposed on Tribal lands.

References Cited

A complete list of all references cited in this proposed rule is available upon request from the Carlsbad Fish and Wildlife Office (see ADDRESSES section).

Author

The primary authors of this notice are the Carlsbad Fish and Wildlife Office staff (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Pub. L. 99-625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.12(h) revise the entry for "*Astragalus magdalenae* var. *peirsonii*," under "FLOWERING PLANTS," to read as follows:

§ 17.12 Endangered and threatened plants.
 * * * * *
 (h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
<i>Astragalus magdalenae</i> var. <i>peirsonii</i> .	Peirson's milkvetch	U.S.A. (CA)	Fabaceae—Pea	T	647	17.96(a)	NA

3. In § 17.96, amend paragraph (a) by adding an entry for *Astragalus magdalenae* var. *peirsonii* in alphabetical order under Family Fabaceae to read as follows:

§ 17.96 Critical habitat—plants.
 (a) * * *

Family Fabaceae: *Astragalus magdalenae* var. *peirsonii* (Peirson's Milk-Vetch)

(1) Critical habitat units are depicted for Algodones Dunes in Imperial County, California, on the maps below.

(2) The primary constituent elements of critical habitat for *Astragalus magdalenae* var. *peirsonii* consist of intact, active sand dune systems (defined as sand areas that are subject to sand-moving winds that result in natural expanses of slopes and swales) within the historical range of *A. m.* var. *peirsonii* that are characterized by:

(i) Substrates of the Rositas soil series, specifically Rositas fine sands of sufficient depth to promote *A. m.* var. *peirsonii* and discourage creosote bush scrub; and

(ii) Wind-formed slopes of less than 30 degrees, but generally less than 20 degrees.

(3) Critical habitat does not include existing features and structures, such as buildings, roads, aqueducts, railroads, airport runways and buildings, other paved areas, lawns, and other urban landscaped areas not containing one or more of the primary constituent elements.

(4) Critical Habitat Map Units.

(i) Map Unit 1: Algodones Dunes, Imperial County, California. From USGS 1:24,000 quadrangle maps Acolita, Amos, Cactus, Glamis, Glamis NW, Glamis SE, Grays Well, Grays Well NE, and Tortuga, California.

(A) Unit 1a: lands bounded by the following UTM NAD27 coordinates (E,N): 657200, 3668800; 658100,

3668800; 658100, 3668500; 658000, 3668500; 658000, 3668000; 658100, 3668000; 658100, 3667800; 658200, 3667600; 658300, 3667600; 658300, 3667300; 658400, 3667300; 658400, 3667100; 658500, 3666800; 658600, 3666800; 658700, 3666600; 658700, 3666600; 658800, 3666500; 658800, 3666500; 658900, 3666400; 658900, 3666300; 659000, 3666300; 659000, 3666200; 659100, 3666200; 659100, 3666100; 659300, 3666100; 659300, 3666000; 659400, 3666000; 659400, 3666000; 659400, 3665900; 659500, 3665900; 659500, 3665800; 659600, 3665800; 659600, 3665700; 659700, 3665700; 659700, 3665600; 659800, 3665600; 659800, 3665600; 659800, 3665500; 660000, 3665500; 660000, 3665400; 660100, 3665400; 660100, 3665300; 660200, 3665300; 660200, 3665300; 660200, 3665200; 660300, 3665200; 660300, 3665100; 660500, 3665100; 660500, 3665000; 660700, 3665000; 660700, 3664900; 660800, 3664900; 660900, 3664700; 660900, 3664500; 661000, 3664500; 661000, 3664400; 661200, 3664400; 661200, 3664300; 661400, 3664300; 661500, 3664100; 661500, 3663900; 661600, 3663900; 661600, 3663700; 661700, 3663700; 661700, 3663600; 661700, 3663600; 661800, 3663600; 661800, 3663500; 662000,

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 the ISDRA, MWMA boundary to UTM
 NAD27 x-coordinate 659200; thence
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(B) Unit 1b: lands bounded by the
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(C) Unit 1c: beginning at the U.S./Mexico border at UTM NAD27 x-

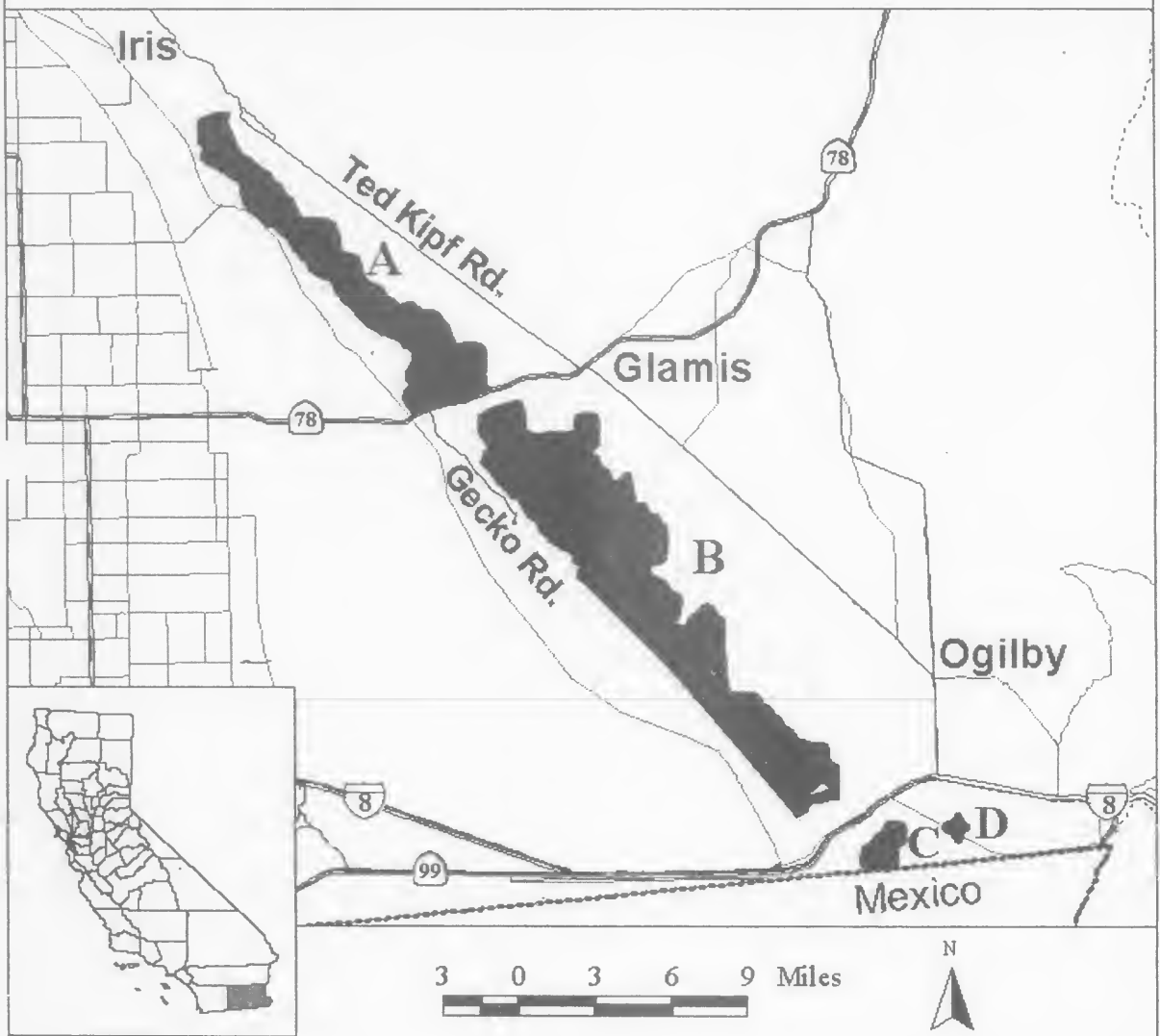
coordinate 698400, lands bounded by the following UTM NAD27 coordinates (E,N): 698400, 3620800, 698200, 3620800; 698200, 3620900; 698000, 3620900; 698000, 3621100; 697900, 3621100; 697900, 3621700; 698000, 3621700; 698000, 3622200; 698200, 3622200; 698200, 3622300; 698400, 3622300; 698400, 3622400; 698500, 3622400; 698500, 3622500; 698600, 3622500; 698600, 3622600; 698700, 3622600; 698700, 3622800; 698800, 3622800; 698800, 3622900; 698900, 3622900; 698900, 3623000; 699000, 3623000; 699000, 3623000; 699000, 3623100; 699200, 3623100; 699200, 3623200; 699300, 3623200; 699300, 3623400; 699400, 3623400; 699400, 3623600; 699500, 3623600; 699500, 3623700; 699600, 3623700; 700300, 3623800; 700300, 3623800; 700300, 3623700; 700700, 3623700; 700700, 3623500; 700800, 3623500; 700800, 3622500; 700700, 3622500; 700700, 3622400; 700600, 3622400; 700600, 3622300; 700400, 3622300; 700400, 3622200; 700300, 3622200; 700300, 3622200; 700200, 3622200; 700200, 3620900; thence south to the U.S./Mexico border at UTM x-coordinate 700200; returning to the point of beginning on the U.S./Mexico border at UTM x-coordinate 698400.

(D) Unit 1d: lands bounded by the following UTM NAD27 coordinates (E,N): 703900, 3624300; 704200, 3624300; 704200, 3624200; 704300, 3624200; 704300, 3624000; 704400, 3624000; 704400, 3623800; 704500, 3623800; 704500, 3623700; 704600, 3623700; 704600, 3623600; 704800, 3623600; 704800, 3623300; 704700, 3623300; 704700, 3623200; 704500, 3623200; 704500, 3623100; 704400, 3623100; 704400, 3622700; 704300, 3622700; 704300, 3622500; 704100, 3622500; 704100, 3622400; 704000, 3622400; 704000, 3622500; 703800, 3622500; 703800, 3622700; 703700, 3622700; 703700, 3622800; 703600, 3622800; 703600, 3623000; 703400, 3623000; 703400, 3623100; 703200, 3623100; 703200, 3623200; 703100, 3623200; 703100, 3623300; 703000, 3623300; 703000, 3623500; 703100, 3623500; 703100, 3623700; 703300, 3623700; 703300, 3623800; 703600, 3623800; 703700, 3623900; 703700, 3624000; 703800, 3624000; 703800, 3624200; 703900, 3624200; returning to UTM NAD27 coordinates 703900, 3624300.

(ii) Map of Algodones Dunes Critical Habitat Unit follows:

BILLING CODE 4310-55-P

Unit 1a-d. Algodones Dunes Critical Habitat Unit



* * * * *

Dated: July 28, 2003.

Signed:
 Craig Manson,
 Assistant Secretary for Fish and Wildlife and
 Parks.
 [FR Doc. 03-19670 Filed 8-4-03; 8:45 am]
 BILLING CODE 4310-55-C

Notices

Federal Register

Vol. 68, No. 150

Tuesday, August 5, 2003

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) has submitted the following information collections to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Comments should be addressed to: Desk Officer for USAID, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503. Copies of submission may be obtained by calling (202) 712-1265.

SUPPLEMENTARY INFORMATION:

OMB Number: OMB 0412-0017.

Form Number: AID 1440-3.

Title: Contractor's Certificate and Agreement with the U.S. Agency for International Development/Contractor's Invoice and Contract Abstract.

Type of Submission: Renewal of information collection.

Purpose: USAID finances host country contracts, for technical and professional services and for the construction of physical facilities, between the contractors for such services and entities in the country receiving assistance under loan or grant agreements with the recipient country. USAID is not a party to these contracts, and the contracts are not subject to the FAR. In its role as the financing agency, USAID needs some means of collecting information directly from the contractors supplying such services so that it may take appropriate action in the event that the contractor does not comply with applicable USAID regulations. The information collection, recordkeeping, and reporting requirements are necessary to assure

that USAID funds are expended in accordance with statutory requirements and USAID policies.

Annual Reporting Burden:

Respondents: 25.

Total annual responses: 300.

Total annual hours requested: 175 hours.

Dated: July 31, 2003.

Joanne Paskar,

Chief, Information and Records Division, Office of Administrative Services, Bureau for Management.

[FR Doc. 03-19937 Filed 8-4-03; 8:45 am]

BILLING CODE 6116-01-M

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) has submitted the following information collections to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Comments should be addressed to: Desk Officer for USAID, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503. Copies of submission may be obtained by calling (202) 712-1365.

SUPPLEMENTARY INFORMATION:

OMB Number: 0412-0020.

Form Number: AID 1450-4.

Title: Supplier's Certificate and Agreement with the U.S. Agency for International Development for Project Commodities/Invoice and Contract Abstract.

Type of Submission: Renewal of information collection.

Purpose: When USAID is not a party to a contract which it finances, it needs some means of collecting information directly from the suppliers of such commodities and related services to enable it to take appropriate action in the event that they do not comply with applicable USAID regulations. The information collection, recordkeeping, and reporting requirements are necessary to assure that USAID funds are expended in accordance with statutory requirements and USAID

policies. It also allows for positive identification of transactions where overcharges occur.

Annual Reporting Burden:

Respondents: 60.

Total annual responses: 360.

Total annual hours requested: 231 hours.

Dated: July 31, 2003.

Joanne Paskar,

Chief, Information and Records Division, Office of Administrative Services, Bureau for Management.

[FR Doc. 03-19938 Filed 8-4-03; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

National Advisory Council on Maternal, Infant and Fetal Nutrition; Notice of Meeting

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council on Maternal, Infant and Fetal Nutrition.

DATES: September 3-5, 2003, 9 a.m.-5 p.m.

ADDRESSES: The meeting will be held at the Food and Nutrition Service, 3101 Park Center Drive, Conference Room 204-C, Alexandria, Virginia 22302.

FOR FURTHER INFORMATION CONTACT: Jackie Rodriguez, Supplemental Food Programs Division, Food and Nutrition Service, Department of Agriculture, (703) 305-2747.

SUPPLEMENTARY INFORMATION: The Council will continue its study of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Commodity Supplemental Food Program (CSFP). The agenda items will include a discussion of general program issues. Meetings of the Council are open to the public. Members of the public may participate, as time permits. Members of the public may file written statements with the contact person named above, before or after the meeting.

Dated: July 28, 2003.

Roberto Salazar,
Administrator.

[FR Doc. 03-19892 Filed 8-4-03; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Forest Service

Crupina Integrated Management Project, Okanogan and Wenatchee National Forests, Chalen County, WA

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environment impact statement.

SUMMARY: On October 17, 2002, the USDA, Forest Service, Okanogan and Wenatchee National Forests, published a Notice of Intent in **Federal Register** (67 FR 64082) to prepare an environmental impact statement (EIS) for Crupina Vegetation Management. A revised Notice of Intent was published in the **Federal Register** on April 15, 2003 (68 FR 19184) changing the name of the project to "Crupina Integrated Management Project" and notifying the public that filing of the draft and final environmental impact statements had been delayed. The Notice of Intent is again being revised to change the Responsible Official for the EIS. The original Notice of Intent identified the Responsible Official as the Regional Forester for the Pacific Northwest Region, USDA Forest Service. On July 11, 2003, the Regional Forester delegated the responsibility for preparing the EIS to the Acting Forest Supervisor for the Okanogan and Wenatchee National Forests.

FOR FURTHER INFORMATION CONTACT: Jim Archambeault, Crupina Project Team Leader, Okanogan-Wenatchee National Forest, Forest Service, (509) 997-9738 or Mallory Lenz, Wildlife Biologist, Chelan Ranger District (509) 682-2576.

Dated: July 23, 2003.

Darrel Kenops,
Acting Forest Supervisor.

[FR Doc. 03-19839 Filed 8-4-03; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

North Fork Eel Grazing Allotments EIS—Six Rivers National Forest

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environmental impact statement.

SUMMARY: This notice revises the original notice of intent (67FR68089) published in the **Federal Register** on November 8, 2002. The Six Rivers National Forest will prepare an environmental impact statement (EIS) on a proposal to: (1) Authorize grazing up to 10 years, under changed seasons of use and grazing practices, of about 500 Cow/Calf Pairs on the Hoaglin, Zenia, Long Ridge, and Van Horn cattle allotments encompassing about 116,000 acres of National Forest System (NFS) lands; and (2) amend the Six Rivers National Forest Land and Resources Management Plan (LRMP) to close the vacant Soldier Creek Allotment encompassing about 10,000 acres of NFS lands.

The analysis area is located predominantly within the North Fork Eel River Watershed and includes all or portions of the following townships: T2SR6E, T2SR7E, T3SR6E, T3SR7E, T3SR8E, T4SR6E, T4S7E, T4SR8E, T5SR6E, T5SR7E, Humboldt Meridian; T25NR12W, T26NR12W, Mount Diablo Meridian; Trinity County, California.

The proposal is designed to meet the following needs: (1) Continued livestock grazing in the currently active allotments; (2) achievement of soil compaction and bank stability standards as stated in the LRMP; (3) achievement of forage utilization standards in riparian areas and annual grasslands as stated in the LRMP; and (4) meeting the management goals for the Soldier Basin Recommended Research Natural Area (RRNA) as directed in the LRMP. The EIS will satisfy the requirements of the National Environmental Policy Act of 1969 and implementing regulations (40 CFR 1500).

DATES: Comments concerning the proposed action must be received on or before 14 days after publication of this notice in the **Federal Register**. The draft EIS is expected to be published in October 2003 and the final EIS is expected in February 2004.

ADDRESSES: Send written comments to S.E. "Lou" Woltering, Forest Supervisor, Six Rivers National Forest, 1330 Bayshore Way, Eureka, CA 95501-3834. Comments may be mailed electronically to rescatell@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Ruben Escatell or Clara Cross EIS Team Leaders, Mad River Ranger District, Star Route Box 300, Bridgeville, CA 95526. Phone (707) 574-6233. E-mail rescatell@fs.fed.us.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Six Rivers National Forest has determined the following needs concerning the Van Horn, Long Ridge, Hoaglin, Zenia and Soldier Creek Allotments: (1) Continued livestock grazing under updated allotment Management Plans on the Van Horn, Long Ridge, Hoaglin, and Zenia allotments; (2) achievement of soil compaction and bank stability standards and guidelines as stated in the LRMP; (3) achievement of forage utilization standards in riparian areas and annual grasslands as stated in the LRMP; and (4) meeting the management goals, as directed in the LRMP, for the Soldier Basin Recommended Research Natural Area (RRNA) which is located in the Soldier Creek Allotment. In achieving the aforementioned needs the following purposes will be met: (1) fulfill a trust responsibility to the Round Valley Indian Tribes to manage grazing activities so as to not adversely impact tribal trust properties and rights down river of the allotments, namely water quality and anadromous fish; (2) minimize impacts to anadromous fisheries along the North Fork Eel River system; (3) redistribute cattle away from identified heritage sites; (4) maintain the permittees' ability to graze livestock efficiently and economically, and (5) maintain rangeland productivity on suitable rangelands while providing forage for livestock production consistent with demand and other resource values and uses.

Proposed Action

The Forest Service proposes to (1) authorize grazing up to 10 years, under changed seasons of use and grazing practices, of about 500 Cow/Calf Pairs on the Hoaglin, Zenia, Long Ridge and Van Horn Allotments encompassing about 116,000 acres of National Forest System (NFS) lands; and (2) amend the Six Rivers National Forest Land and Resource Management Plan (LRMP) to close the currently vacant Soldier Creek allotment encompassing about 10,000 acres of NFS lands. The proposed action includes change to Allotment Management Plans that address grazing practices, construction of new range improvements, restoration and/or removal of existing range improvements, allotment boundary modifications, and monitoring provisions. Closure of the Soldier Creek allotment would constitute a Forest Plan amendment. A detailed description of the proposed action can be obtained by contacting Ruben Escatell at the address listed above.

Responsible Official

S.E. "Lou" Woltering, Forest Supervisor, Six Rivers National Forest, USDA Forest Service, 1330 Bayshore Way, Eureka, CA 95501-3834, is the Responsible Official for any decision to authorize grazing, manage rangelands, or close any allotment on affected National Forest System lands within the Six Rivers National Forest. His decisions and rationale will be documented in a Record of Decision.

Nature of Decision To Be Made

The Forest Supervisory will make the following decisions: Whether or not to authorize cattle grazing in allotments considered in this analysis and, if so, the terms and conditions required for the term grazing permits and AMPs; and, whether or not to close the Soldier Creek Allotment, thereby removing its rangeland from the LRMP suitable forage base.

Scoping Process

Scoping is the procedure by which the Forest Service identifies important issues and determines the extent of analysis necessary for an informed decision on a proposed action. The public is encouraged to comment on this proposal and is encouraged to visit with Forest Service Officials at any time during the analysis and prior to the decision. The Forest Service will be seeking information, comments and assistance from Federal, State and local agencies and other individuals or organizations who may be interested in, or affected by, the proposed action. While public participation in this analysis welcome at any time, comments received within 14 days of the publication of this notice will be especially useful in the preparation of the Draft EIS

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the *Federal Register*.

The Forest Service believes, at this early stage, it is important to give reviewers notice of service court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the

reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1344, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections be made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement.

Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: July 30, 2003.

William D. Metz,

Deputy Forest Supervisor, Six Rivers National Forest.

[FR Doc. 03-19838 Filed 8-4-03; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE**Natural Resources Conservation Service****Rehabilitation of Floodwater Retarding Structure No. 5 of the Martinez Creek Watershed, Bexar County, TX**

AGENCY: Natural Resources Conservation Service.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR part 1500); and the Natural Resources Conservation Service Regulations (7 CFR part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the rehabilitation of Floodwater Retarding Structure No. 5 of the Martinez Creek Watershed, Bexar County, Texas.

FOR FURTHER INFORMATION CONTACT: Larry D. Butler, State Conservationist, Natural Resources Conservation Service, 101 South Main, Temple, Texas 76501-7682, Telephone (254) 742-9800.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Larry D. Butler, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project will rehabilitate Floodwater Retarding Structure No. 5 to maintain the present level of flood control benefits and comply with the current performance and safety standards.

Rehabilitation of the site will require the dam to be modified to meet current performance and safety standards for a high hazard dam. The modification will consist of raising the top of dam 3.7 ft and installing a roller compacted concrete (RCC) curtain in the auxiliary spillway. The RCC curtain will be constructed near the upstream level section of the auxiliary spillway. A splitter dike will also be installed in the auxiliary spillway to decrease the bay width. All disturbed areas will be planted to plants that have wildlife values. The proposed work will not affect any prime farmland, endangered or threatened species, wetlands, or cultural resources.

Federal assistance will be provided under authority of the Small Watershed Rehabilitation Amendments of 2000 (Section 313, Pub. L. 106-472). Total project costs is estimated to be \$1,166,000, of which \$842,900 will be paid from the Small Watershed Rehabilitation funds and \$323,700 from local funds.

The notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental

Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Larry D. Butler, State Conservationist.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the *Federal Register*.

Dated: July 25, 2003.

Larry D. Butler,

State Conservationist.

[FR Doc. 03-19825 Filed 8-4-03; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-803]

Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, From the People's Republic of China: Second Extension of Time Limit for Final Results of Antidumping Duty Administrative Review on Bars/Wedges

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for final results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (the Department) is extending the time limit for the final results of the administrative review of the antidumping duty order on Bars/Wedges from the People's Republic of China, covering the period February 1, 2001 through January 31, 2002, until no later than September 2, 2003.

EFFECTIVE DATE: August 5, 2003.

FOR FURTHER INFORMATION CONTACT: Thomas Martin at (202) 482-3936, AD/CVD Enforcement, Office 4, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On March 27, 2002, the Department published a notice of initiation of administrative reviews of the antidumping duty orders on heavy forged hand tools from the People's Republic of China (PRC), covering the period February 1, 2001 through January 31, 2002. See *Initiation of Antidumping and Countervailing*

Duty Administrative Reviews and Requests for Revocations in Part, 67 FR 14696 (March 27, 2003). The deadline for the preliminary results of review for the order on bars/wedges was extended on October 22, 2002. See *Heavy Forged Hand Tools from the People's Republic of China: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review*, 67 FR 64869 (October 22, 2002). The preliminary results were published on March 6, 2003. See *Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review of the Order on Bars and Wedges*, 68 FR 10690 (March 6, 2003). On July 14, 2003, the Department extended the deadline for the final results by 33 days, from July 4, 2003, to August 7, 2003. See *Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, From the People's Republic of China: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review on Bars/Wedges*, 68 FR 41557 (July 14, 2003).

Extension of Time Limits for Final Results of Review

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to complete its final results of review within 120 days after the date on which the preliminary results were published. However, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit. Section 751(a)(3)(A) of the Act allows the Department to extend the deadline for completion of the final results to 180 days from the date of publication of the preliminary results. As a result of the complex issues involved in this review, it is not practicable to complete this review by the current deadline of August 7, 2003. Therefore, we are now extending the time limit an additional 26 days, to September 2, 2003. See Memorandum from Thomas F. Futtner, Acting Office Director, to Holly A. Kuga, Acting Deputy Assistant Secretary, dated concurrently with this notice, which is on file in the Central Records Unit, Room B-099 of the main Commerce building.

This notice is published in accordance with section 735(a)(2) of the Act and 19 CFR 351.210(g).

Dated: July 30, 2003.

Holly A. Kuga,

Acting Deputy Assistant Secretary, Import Administration, Group II.

[FR Doc. 03-19911 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-808]

Stainless Steel Wire Rod from India: Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for the preliminary results of antidumping duty administrative review.

EFFECTIVE DATE: August 5, 2003.

SUMMARY: The Department of Commerce ("the Department") is extending the time limit for the final results of the review of stainless steel wire rod from India. This review covers the period December 1, 2001 through November 30, 2002.

FOR FURTHER INFORMATION CONTACT: Kit Rudd, Eugene Degnan, or Jonathan Herzog, AD/CVD Enforcement, Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone: (202) 482-1385, (202) 482-0414 and (202) 482-4271 respectively.

Background

On January 22, 2003, the Department published a notice of initiation of a review of Stainless Steel Wire Rod ("SSWR") from India covering the period December 1, 2001 through November 30, 2002. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*: 68 FR 3009 (January 22, 2003).

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Act states that if it is not practicable to complete the review within the time specified, the administering authority may extend the 245-day period to issue its preliminary results by up to 120 days. Completion of the preliminary results of this review within the 245-day period is not practicable for the following reasons:

• The review involves three companies, all including sales and cost investigations which require the Department to gather and analyze a significant amount of information pertaining to each company's sales practices, manufacturing costs and corporate relationships.

• Additionally, responses from the three companies required the Department to issue multiple supplemental questionnaires which further delayed the planned verification schedules.

Therefore, in accordance with section 751(a)(3)(A) of the Act, we are extending the time period for issuing the preliminary results of review by 90 days until December 1, 2003. The final results continue to be due 120 days after the publication of the preliminary results.

Dated: July 30, 2003.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration, Group III.

[FR Doc. 03-19912 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee (ETTAC)

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

DATES: September 12, 2003; Time: 9 a.m. to 12 p.m.

PLACE: U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, Room 4830 (Room 3407 has also been reserved as a backup).

SUMMARY: The Environmental Technologies Trade Advisory Committee (ETTAC) will hold a plenary meeting on September 12, 2003 at the U.S. Department of Commerce.

The ETTAC will discuss administrative and trade issues including the status of trade negotiations in regards to environmental technologies trade liberalization, China's export market, and subcommittee action plans. Time will be permitted for public comment. The meeting is open to the public.

Written comments concerning ETTAC affairs are welcome anytime before or after the meeting. Minutes will be available within 30 days of this meeting.

The ETTAC is mandated by Public Law 103-392. It was created to advise

the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce and the interagency Environmental Trade Working Group (ETWG) of the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently rechartered until May 30, 2004.

For further information phone Corey Wright, Office of Environmental Technologies Industries (ETI), International Trade Administration, U.S. Department of Commerce at (202) 482-5225. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to ETI.

Dated: July 31, 2003.

Carlos F. Montoulieu,

Director, Office of Environmental Technologies Industries.

[FR Doc. 03-19910 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration, North American Free Trade Agreement, Article 1904 NAFTA Panel Reviews; Notice of Panel Decision

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of panel decision.

SUMMARY: On July 17, 2003, the binational panel issued its decision in the review of the final results of the antidumping duty determination made by the International Trade Administration (ITA) respecting Certain Softwood Lumber Products from Canada (Secretariat File No. USA-CDA-2002-1904-02) affirmed in part and remanded in part the determination of the Department of Commerce. The Department will return the determination on remand no later than September 15, 2003. A copy of the complete panel decision is available from the NAFTA Secretariat.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482-5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial

review of final determinations in antidumping and countervailing duty cases involving imports from the other country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* ("Rules"). These rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

Panel Decision: On July 17, 2003, the Binational Panel affirmed in part and remanded in part the Department of Commerce's final antidumping duty determination. The following issues were remanded to the Department:

1. To explain the factual background of Commerce's determination that, for purposes of determining Constructed Value (CV) profit, the "foreign like product" should be defined as each Canadian Respondent's aggregate sales of subject merchandise during the period of investigation was reasonable and in accordance with law;

2. To re-allocate joint production costs using a value-based allocation methodology which takes into account dimensional differences between different jointly produced softwood lumber products;

3. To make an adjustment pursuant to 19 U.S.C. 1677b(a)(6)(c)(ii) to reflect dimensional differences between different softwood lumber products being compared;

4. To exclude exports made by Scieries Saguenay Ltee. (SSL) from the final LTFV determination rendered in respect of Abitibi-Consolidated Inc.;

5. To exclude from the cost of production and constructed value of softwood lumber products produced during the period of investigation by Abitibi the costs of redemption of stock options issued to executives of Donohue, Inc.;

6. To treat "trim blocks" produced by Abitibi Inc. as subject merchandise rather than by-products, and to allocate production costs to the trim blocks produced by Abitibi during the period of the investigation;

7. To explain the agency's reason for determining why, based upon an examination of the entire record, general and administrative expenses incurred in

production of softwood lumber by Tembec Inc. according to parent company consolidated financial statements is reasonable and lawful consistent with the agency's obligation, set out at 19 U.S.C. 1677b(b)(3)(B), to calculate such expenses "based on actual data pertaining to production and sales of the foreign like product";

8. To explain why Commerce's final determination concerning Tembec's credit expenses does not contain a clerical error with respect to programming language used to make currency conversions; or, if the final determination does contain such an error, to identify and correct the error;

9. To explain why Commerce's decision to use Tembec's internal prices for wood chips was representative of the cost of producing such wood chips, and why such prices constituted a reasonable and permissible basis for calculating an offset to Tembec's production costs;

10. To consider the claims of West Fraser Mills that Commerce erred in adjusting the offset to production costs resulting from West Fraser's by-product sales of wood chips to unaffiliated purchasers in British Columbia during the period of investigation, and particularly, to consider whether the timing of West Fraser's wood chip sales to unaffiliated parties during the early part of the period of investigation, and the existence of a long term contract, cause those sales to be not fairly representative of West Fraser's wood chip prices during the POI;

11. To provide a complete explanation of Commerce's decision that finger-jointed flangestock (FJF) does not constitute a separate "class or kind" of merchandise for purposes of this investigation; and in so doing, to explain how the agency applied each of the Diversified Products factors to its consideration of FJF, the determinations reached with respect to each such factor, and how the agency weighed these factors in reaching its determination; and

12. To provide a complete explanation of Commerce's determination not to treat square-end bed frame components as a separate "class or kind" of merchandise for purposes of this investigation; and in so doing, to explain how the agency applied each of the Diversified Products factors to its consideration of square-end bed frame components, and how the agency weighed these factors in reaching its determination; and

13. To publish revised less than fair value (LTFV) margins for the investigated Respondents, including a revised "all others" rate, as determined

after carrying out the above remand instructions.

Commerce was directed to issue its determination on remand within 60 days of the issuance of the decision or not later than September 15, 2003.

Dated: July 28, 2003.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 03-19820 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-GT-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 110802A]

Endangered Species; File No. 1405

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that the South Carolina Department of Natural Resources, Charleston, SC 29422-2559, has been issued a permit to take loggerhead (*Caretta caretta*), Kemp's ridley (*Lepidochelys kempi*), green (*Chelonia mydas*), leatherback (*Dermochelys coriacea*), and hawksbill (*Eretmochelys imbricata*) sea turtles for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713-2289; fax (301)713-0376;

Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702-2432; phone (727)570-5301; fax (727)570-5320.

FOR FURTHER INFORMATION CONTACT: Ruth Johnson (301)713-2289 or Patrick Opay (301) 713-1401.

SUPPLEMENTARY INFORMATION: On November 25, 2002, notice was published in the *Federal Register* (67 FR 70583) that a request for a scientific research permit to take loggerhead, Kemp's ridley, leatherback, hawksbill, and green sea turtles had been submitted by the above-named individual. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of

endangered and threatened species (50 CFR parts 222-226).

The applicant will handle, tag, measure, weigh, photograph and release the above mentioned sea turtles in order to collect data from in-water captures that can be used by management agencies and scientists for better understanding of these species and to promote their protection and recovery.

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of the endangered or threatened species which are the subject of this permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: July 30, 2003.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03-19934 Filed 8-4-03; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice. The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 4, 2003.

Title, Form, and OMB Number: Technical Assistance for Public Participation (TAPP) Application; DD Form 2749; OMB Number 0704-0392.

Types of Request: Reinstatement.

Number of Respondents: 25.

Responses Per Respondent: 2.

Annual Responses: 50.

Average Burden Per Response: 4 hours.

Annual Burden Hours: 200.

Needs and Uses: The collection of information is necessary to identify products or services requested by community members of restoration advisory boards or technical review committees to aid in their participation in the Department of Defense's environmental restoration program, and to meet Congressional reporting requirements. Respondents are community members of restoration advisory boards or technical review committees requesting technical

assistance to interpret scientific and engineering issues regarding the nature of environmental hazards at an installation. This assistance will assist communities in participating in the cleanup process. The information, directed by 10 U.S.C. 2705, will be used to determine the eligibility of the proposed project, begin the procurement process to obtain the requested products or services, and determine the satisfaction of community members of restoration advisory boards and technical review communities receiving the products and services.

Affected Public: Not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jackie Zeiher. Written comments and recommendations on the proposed information collection should be sent to Ms. Zeiher at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DoD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302.

Dated: July 30, 2003.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03-19871 Filed 8-4-03; 8:45 am]

BILLING CODE 5001-08-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Class Tuition Waiver

AGENCY: Department of Defense Education Activity (DoDEA).

ACTION: Notice.

SUMMARY: The Secretary of Defense is authorized by section 1404(c) of Public Law 95-561, Defense Dependents' Education Act of 1978," as amended, 20 U.S.C. 923(c) to identify classes of dependents who may enroll in DoD Dependent Schools (DoDDS) if there is space available and to waive tuition for any such classes. Through DoD Directive 1342.13, "Eligibility Requirements for Education of Minor Dependents in Overseas Areas," dated July 8, 1982, as amended, paragraph 5.3.4, the Secretary has delegated to the Office of the Principal Deputy Under Secretary of Defense for Personnel and Readiness (PDUSD)(P&R) the authority

to identify those classes of dependents for whom tuition may be waived.

This notice announces that on June 27, 2003, the PDUSD(P&R) revised the class tuition waiver dated July 11, 2002, to allow an enrolled Partnership for Peace dependent to continue enrollment in Department of Defense Dependent School (DoDDS) on a space-available, tuition-free basis, if his sponsoring nation has received and accepted a NATO invitation by November 30, 2002, and until such time that his sponsoring nation is officially seated by NATO or through School Year (SY) 2004-05, whichever comes first. This revision is only applicable to Partnership for Peace dependents enrolled in DoDDS in School Year 2002-03 pursuant to the July 11, 2002, waiver.

FOR FURTHER INFORMATION CONTACT: Mr. David Labuhn, 4040 North Fairfax Drive, Arlington, VA 22203-1635.

SUPPLEMENTARY INFORMATION: DoD Directive 1342.13 is published at 32 CFR Part 71 and at the DoDEA Web site: <http://www.odedodea.edu>.

Dated: July 30, 2003.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03-19872 Filed 8-4-03; 8:45 am]

BILLING CODE 5001-08-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Panel To Review Sexual Misconduct Allegations at the United States Air Force Academy

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee meeting.

SUMMARY: The Panel to Review Sexual Misconduct Allegations at the United States Air Force Academy met in a closed session from 2 p.m. to 5 p.m. on July 31, 2003. The Panel discussed individual sexual misconduct allegations and investigations at the Academy during this session. Congress directed the establishment of this seven member panel in Pub. L. 108-11, Emergency Wartime Supplemental Appropriations Act, 2003.

The session was closed to the public in accordance with 5 U.S.C. 552b(c)(6) because the panel members discussed matters of a personal nature, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published after the meeting took place due to last minute changes in the agenda and the

short time frame Congress allowed for the Panel to complete their review and produce a final report.

DATES: July 31, 2003.

ADDRESSES: Conference Room, Boards, Commissions and Task Force Offices, 1235 Jefferson Davis Highway, Suite 900, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT:

Sheila Earle, Designated Federal Official, 703-601-2553.

Dated: July 28, 2003.

Patricia L. Toppings,

Alternate Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03-19819 Filed 8-4-03; 8:45 am]

BILLING CODE 5001-08-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to add systems of records.

SUMMARY: The Office of the Secretary of Defense proposes to add a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The changes will be effective on September 4, 2003 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to Directives and Records Division, Directives and Records Branch, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301-1155.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Cragg at (703) 601-4722.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on July 17, 2003, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: July 29, 2003.

Patricia L. Toppings.

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

DPR 29

SYSTEM NAME:

Language and Skills Participation Program.

SYSTEM LOCATION:

Defense Applicant Assistance Office,
PO Box 12708, Arlington, VA 22219-
2708.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are proficient in Arabic or other languages, and who possess skills, vocational and otherwise, who desire to support U.S. efforts in the war on terrorism and related national security objectives.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name; age; gender; home address (street, city, state, country, and zip code); type of employment or service being sought, *i.e.*, Federal Limited Term Appointment, Contractor, or Military Ready Reserve, or other; desired length of service (interim, part time, as needed, short term, long term); contact information (telephone number, email address); citizenship; immigration status (permanently admitted alien, student work visa); language type and skill level; source of language (native speaker, education); current profession/vocation; highest level of education; major field of study; where/when degree obtained; other special skills based on previous experience; and security clearance (type and date granted).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 131, Office of the Secretary of Defense; and DoD Directive 5124.2, Under Secretary of Defense for Personnel and Readiness.

PURPOSE(S):

To identify individuals with language and special skills who potentially may qualify for employment or service opportunities in the public or private sector. Information will also be used to track and monitor the resulting actions taken by governmental or private activities when such information is received and forwarded for evaluation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may

specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To governmental agencies and to private entities for purposes of evaluating whether an individual's language ability and skills meet or satisfy a requirement or need that the public or private activity may have in its support of U.S. efforts on the war on terrorism or in furtherance of national security objectives.

The DoD "Blanket Routine Uses" set forth at the beginning of OSD's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper files and on electronic mediums.

RETRIEVABILITY:

Information is retrieved by the individual's name.

SAFEGUARDS:

Locked cabinets accessible to authorized personnel only and IT servers behind "firewall" protection and password-protected access.

RETENTION AND DISPOSAL:

Disposition pending. Until the National Archives and Records Administration has approved the retention and disposition of these records, treat records as permanent.

SYSTEM MANAGER(S) AND ADDRESS:

Program Manager, Defense Applicant Assistance Office, PO Box 12708, Arlington, VA 22219-2708.

Chief, Information Systems Division, PO Box 12708, Arlington, VA 22219-2708.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to Program Manager, Defense Applicant Assistance Office, PO Box 12708, Arlington, VA 22219-2708.

Requests for information must be signed and contain the individual's full name, mailing address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Program Manager, Defense Applicant Assistance Office, PO Box 12708, Arlington, VA 22219-2708.

Requests for information must be signed and contain the individual's full name, mailing address, and telephone number.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction No. 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Subject individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 03-19873 Filed 8-4-03; 8:45 am]

BILLING CODE 5001-08-P

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Army is altering a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The alteration consists of adding new records being maintained and adding two new purposes to the existing system of records.

DATES: This proposed action will be effective without further notice on September 4, 2003, unless comments are received which result in a contrary determination.

ADDRESSES: Army Systems of Records Notices Manager, Department of Army Freedom of Information and Privacy Acts Office, 7798 Cissna Road, Suite 205, Springfield, VA 22153-3166.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806-7137.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the *Federal Register* and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on July 17, 2003, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management

and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A-130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: July 29, 2003.

Patricia Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0027-10a DAJA

SYSTEM NAME:

Prosecutorial Files (December 8, 2000, 65 FR 77008).

Changes

* * * * *

SYSTEM NAME:

Delete entry and replace with 'Military Justice Files'.

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Any individual who is the subject of a military justice investigation, trial by courts-martial, or other administrative or disciplinary proceeding.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Add to the end of the entry 'Non-judicial punishment (Article 15) actions; administrative separation actions; suspension of favorable personnel actions; Trial Defense Service and trial defense counsel personnel information, and attorney work-product, Trial judiciary personnel information, dockets; and trial records; Army Court of Criminal Appeals, judicial orders, and opinions; and all other documents related to the administration of Military Justice, administrative separations, memoranda of reprimand, and investigations.'

* * * * *

PURPOSE(S):

Add to the end of the first paragraph; and to provide support for non-judicial and other administrative or disciplinary proceedings.'

Add a new paragraph 'Records will be used to conduct statistical studies for assisting The Judge Advocate General and servicing Staff Judge Advocates in the management and administration of military justice.'

* * * * *

RETRIEVABILITY:

Add to entry 'Social Security Number'.

SAFEGUARDS:

Delete entry and replace with 'Paper records are located in file cabinets and electronic records are located in the worldwide eJustice computer database. Computerized records are maintained in controlled areas accessible only to authorized personnel. In addition, automated files are password protected and in compliance with the applicable laws and regulations. Information located in file cabinets is accessible only to authorized personnel who are properly instructed in the permissible use. The files are not accessible to the public or to persons within the command without an official need to know. Some file cabinets have locking capabilities. Offices are locked during non-work hours.'

* * * * *

A0027-10a DAJA

SYSTEM NAME:

Military Justice Files.

SYSTEM LOCATION:

Primary location: Office of The Judge Advocate General, Headquarters, and Department of the Army, Washington, DC 20310-2200.

Secondary locations: Staff Judge Advocate Offices at major Army commands, field operating agencies, installations and activities Army-wide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual who is the subject of a military justice investigation, trial by courts-martial, or other administrative or disciplinary proceeding.

CATEGORIES OF RECORDS IN THE SYSTEM:

Witness statements; pretrial advice; documentary evidence; exhibits, evidence of previous convictions; personnel records; recommendations as to the disposition of the charges; explanation of any unusual features of the case; charge sheet; and criminal investigation reports; convening orders; appointment orders; investigative reports of federal, state, and local law enforcement agencies; local command investigations; immunity requests; search authorizations; general correspondence; legal research and memoranda; motions; forensic reports; pretrial confinement orders; personal, financial, and medical records; report of Article 32, UCMJ investigations; subpoenas; discovery requests; correspondence reflecting pretrial negotiations; requests for resignation or

discharge in lieu of trial by court-martial; results of trial memoranda; and forms to comply with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program and the Victim's Rights and Restitution Act of 1990. Non-judicial punishment (Article 15) actions; administrative separation actions; suspension of favorable personnel actions; Trial Defense Service and trial defense counsel personnel information, and attorney work-product, Trial judiciary personnel information, dockets; and trial records; Army Court of Criminal Appeals, judicial orders, and opinions; and all other documents related to the administration of Military Justice, administrative separations, memoranda of reprimand, and investigations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; 42 U.S.C. 10606 et seq., Victims' Rights; Department of Defense Directive 1030.1, Victim and Witness Assistance; Army Regulation 27-10, Military Justice and E.O. 9397 (SSN).

PURPOSE(S):

To prosecute or otherwise resolve military justice cases; to obtain information and assistance from federal, state, local, or foreign agencies, or from individuals or organizations relating to an investigation, allegation of criminal misconduct, or court-martial; and to provide information and support to victims and witnesses in compliance with Victim and Witness Assistance Statutes and regulations; and to provide support for non-judicial and other administrative or disciplinary proceedings. Records will be used to conduct statistical studies for assisting The Judge Advocate General and servicing Staff Judge Advocates in the management and administration of military justice.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information from this system of records may be disclosed to law students participating in a volunteer legal support program approved by The Judge Advocate General of the Army.

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the

Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

To attorney licensing and/or disciplinary authorities as required to support professional responsibility investigations and proceedings.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Retrieved by individual's surname and Social Security Number.

SAFEGUARDS:

Paper records are located in file cabinets and electronic records are located in the worldwide eJustice computer database. Computerized records are maintained in controlled areas accessible only to authorized personnel. In addition, automated files are password protected and in compliance with the applicable laws and regulations. Information located in file cabinets is accessible only to authorized personnel who are properly instructed in the permissible use. The files are not accessible to the public or to persons within the command without an official need to know. Some file cabinets have locking capabilities. Offices are locked during non-work hours.

RETENTION AND DISPOSAL:

Records are destroyed two years after final review/appellate action.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Criminal Law Division, Office of The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Chief, Criminal Law Division, Office of The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200. Individual should provide his/her full name, current address and telephone number, case number and office symbol of Army element which furnished correspondence to the individual, other personnel identifying data that would assist in locating the records. The inquiry must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Chief, Criminal Law Division, Office of The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200.

Individual should provide his/her full name, current address and telephone number, case number and office symbol of Army element which furnished correspondence to the individual, other personal identifying data that would assist in locating the records. The inquiry must be signed.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340-21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From official Army records and reports, investigative documents, law enforcement agencies; Court-martial, Article 32; UCMJ investigations; convening authorities; Federal, state, and local law enforcement agencies; witness interviews; personnel, financial, and medical records; medical facilities; financial institutions; information provided by the defense/accused; and the attorney work-product and other individuals assisting them on a particular case; non-judicial (Article 15) punishment documents; and administrative separation action documents and memoranda of reprimand.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt pursuant to 5 U.S.C. 552a(j)(2) if the information is compiled and maintained by a component of the agency, which performs as its principle function any activity pertaining to the enforcement of criminal laws.

An exemption rule for this exemption has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 505. For additional information contact the system manager.

[FR Doc. 03-19874 Filed 8-4-03; 8:45 am]

BILLING CODE 5001-08-P

DEPARTMENT OF EDUCATION

**Submission for OMB Review;
Comment Request**

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 4, 2003.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren_Wittenberg@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: July 20, 2003.

Angela C. Arrington,
Leader, Regulatory Information Management Group, Office of the Chief Information Officer.

Institute of Education Sciences

Type of Review: Revision.
Title: Survey on Dual Credit and Exam-Based Courses.
Frequency: One time.
Affected Public: State, local or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 1,500.

Burden Hours: 750.

Abstract: This FRSS survey is designed to collect information from public secondary schools nationwide on dual credit and exam-based courses. Dual credit, whereby high school students can earn both high school and postsecondary credits for the same courses, is an area that has grown rapidly over the past decade. High school advanced placement courses and international baccalaureate programs are also offered by many schools and may affect subsequent postsecondary options. This survey is designed to obtain a variety of information on this growing area. This information can provide education policymakers with important baseline information about the prevalence and characteristics of dual credit courses.

Requests for copies of the submission for OMB review; comment request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2321. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address Vivan.Reese@ed.gov. Requests may also be electronically mailed to the Internet address OCIO_RIMG@ed.gov or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her e-mail address Kathy.Axt@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 03-19826 Filed 7-28-03; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY**Office of Energy Efficiency and Renewable Energy****Hydrogen Production and Delivery Research; Solicitation Number DE-PS36-03G093007**

AGENCY: Golden Field Office, Department of Energy (DOE).

ACTION: Notice of issuance of solicitation for financial assistance applications.

SUMMARY: The Office of Hydrogen, Fuel Cell, and Infrastructure Technologies of the Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy is soliciting financial assistance Applications with the objective of supporting industry efforts and the President's Hydrogen Fuel Initiative for research in several specific hydrogen production and delivery technologies. DOE intends to provide financial support under provisions of the Hydrogen Future Act of 1996.

DATES: The Solicitation was issued on July 24, 2003 with a closing date for preliminary applications of September 4, 2003 and submittal of final applications on December 19, 2003.

ADDRESSES: To obtain a copy of the Solicitation, interested parties should access the DOE Industry Interactive Procurement System (IIPS) web site. The Solicitation can be obtained directly through IIPS at <http://e-center.doe.gov> by browsing opportunities by Program Office, Financial Assistance, Golden Field Office, and then selecting this Solicitation number. DOE will not issue paper copies of the Solicitation.

FOR FURTHER INFORMATION CONTACT: James Damm, Contracting Officer, via facsimile to (303) 275-4788 or electronically to h2production@go.doe.gov. Solicitation questions must be submitted through IIPS per the instructions contained in the Solicitation. Responses to questions will be posted on the IIPS web site. Further information on DOE's Hydrogen, Fuel Cells, and Infrastructure Technologies Program can be viewed at <http://www.eere.energy.gov/hydrogenandfuelcells>.

SUPPLEMENTARY INFORMATION: Under this Solicitation, DOE is soliciting Applications for research in several specific hydrogen production and delivery technologies. Through an Expression of Program Interest (EOPI) issued earlier in 2003, DOE requested input from interested parties regarding recommended research topics to be included in this Solicitation. EOPI submissions were used by DOE to develop portions of the Technical Topics for this Solicitation. The following ten Topics (some including Sub-Topics) are allowable areas for applications: Hydrogen From Biomass; Photolytic Processes; Distributed Production Technologies; Separation and Purification Technologies; Advanced Electrolysis Systems; Hydrogen Production Using High Temperature Thermochemical Water Splitting Cycles; Hydrogen Production Infrastructure Analysis; Hydrogen

Delivery; Crosscutting Projects; and University Projects.

Awards under this Solicitation will be Cooperative Agreements with terms of two to four years beginning in fiscal year 2004. DOE anticipates selecting 28 Applications for negotiation of Award. Subject to the availability of annual congressional appropriations, the total cumulative DOE funding available under this Solicitation for all projects is anticipated to be up to \$80 million over the four-year period. The minimum required cost share varies by type and stage of development of the technology and will be specified in the Solicitation.

Issued in Golden, Colorado, on July 25, 2003.

Jerry L. Zimmer,
Director, Office of Acquisition and Financial Assistance.

[FR Doc. 03-19708 Filed 8-4-03; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Office of Energy Efficiency and Renewable Energy****"Grand Challenge" for Basic and Applied Research in Hydrogen Storage; Solicitation Number DE-PS36-03G093013**

AGENCY: Golden Field Office, U.S. Department of Energy (DOE).

ACTION: Notice of issuance of solicitation for financial assistance applications.

SUMMARY: The Office of Hydrogen, Fuel Cell, and Infrastructure Technologies of the Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy is soliciting financial assistance Applications with the objective of supporting industry efforts and the President's Hydrogen Fuel Initiative in developing a path to a hydrogen economy. Under this Solicitation, DOE is seeking Applications for basic and applied research in hydrogen storage materials technologies. DOE intends to provide financial support under provisions of the Hydrogen Future Act of 1996.

DATES: The Solicitation was issued on July 24, 2003 with a closing date of September 30, 2003.

ADDRESSES: To obtain a copy of the Solicitation, interested parties should access the DOE Industry Interactive Procurement System (IIPS) web site. The Solicitation can be obtained directly through IIPS at <http://e-center.doe.gov> by browsing opportunities by Program Office, Financial Assistance, Golden Field Office, and then selecting this

Solicitation number. DOE will not issue paper copies of the Solicitation.

FOR FURTHER INFORMATION CONTACT: James Damm, Contracting Officer, via facsimile to (303) 275-4788 or electronically to h2storage@go.doe.gov. Solicitation questions must be submitted through IIPS per the instructions contained in the Solicitation. Responses to questions will be posted on the IIPS web site. Further information on DOE's Hydrogen, Fuel Cells, and Infrastructure Technologies Program can be viewed at <http://www.eere.energy.gov/hydrogenandfuelcells>.

SUPPLEMENTARY INFORMATION: Under this Solicitation, DOE is issuing a "Grand Challenge" to the scientific community by soliciting Applications for research, development and demonstration of hydrogen storage materials and technologies. In addition to applied research and development, Applications can include substantial basic research aimed at improving the understanding of the fundamental mechanisms of hydrogen storage in materials. This solicitation requests applications in two Categories.

Category 1, Research and development to be conducted by virtual Centers of Excellence led by DOE national laboratories and including universities, industry, and/or other federal/national laboratories as partners. Focus areas are Metal hydrides, Chemical hydrides, and Carbon-based hydrogen storage materials. Only DOE national laboratories may submit joint application packages in response to Category 1. The proposed university and industry efforts must be part of those application packages.

Category 2, Research and development through cooperative agreements in the following areas: New materials or technologies for hydrogen storage; Compressed and liquid hydrogen tank technologies; and Off-board hydrogen storage systems. Category 2 is open to Applicants from universities and industry; federal or national laboratories may be partners.

Awards under this Solicitation will be Cooperative Agreements with terms of three to five years beginning in fiscal year 2004. DOE anticipates selecting 15 to 20 Applications for negotiation of Award. Subject to the availability of annual congressional appropriations, the total cumulative DOE funding available under this Solicitation for all projects is anticipated to be between \$95 million and \$125 million over the five-year period. The minimum required cost share varies with the type of Applicant and type of proposed project and is

specified in the Solicitation along with specific application instructions.

Issued in Golden, Colorado, on July 25, 2003.

Jerry L. Zimmer,
Director, Office of Acquisition and Financial Assistance.

[FR Doc. 03-19710 Filed 8-4-03; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC03-567-001, FERC-567]

Commission Information Collection Activities, Proposed Collection; Comment Request; Submitted for OMB Review

July 29, 2003.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice.

SUMMARY: In compliance with the requirements of Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission) has submitted the information collection described below to the Office of Management and Budget (OMB) for review and extension of the current expiration date. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received no comments in response to an earlier *Federal Register* notice of May 16, 2003 (68 FR 26589-90) and has made this notation in its submission to OMB.

DATES: Comments on the collection of information are due by August 26, 2003.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may be reached by fax at 202-395-7285 or by e-mail at pamelabevery.oirasubmission@omb.eop.gov. A copy of the comments should also be sent to the Federal Energy Regulatory Commission, Office of the Executive Director, ED-30, Attention: Michael Miller, 888 First Street NE., Washington, DC 20426. Comments may be filed either in paper format or electronically. Those persons filing electronically do not need to make a paper filing. For paper filings, such comments should be submitted to the

Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426 and should refer to Docket No. IC03-567-001.

Documents filed electronically via the Internet must be prepared in WordPerfect, MS Word, Portable Document Format, or ASCII format. To file the document, access the Commission's Web site at <http://www.ferc.gov> and click on "Make an E-filing," and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgment to the sender's E-mail address upon receipt of comments. User assistance for electronic filings is available at 202-502-8258 or by e-mail to efiling@ferc.gov. Comments should not be submitted to the e-mail address.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the FERRIS link. User assistance for FERRIS and the FERC's Web site during business hours by contacting, FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, for TTY (202)502-8659 or the Public Reference at (202)-8371 or by e-mail to public.reference.room@ferc.gov.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202)502-8415, by fax at (202)273-0873, and by e-mail at michael.miller@ferc.gov.

SUPPLEMENTARY INFORMATION:

Description

The information collection submitted for OMB review contains the following:

1. *Collection of Information:* FERC-567 "Gas Pipeline Certificates: Annual Reports of System Flow Diagrams and System Capacity."
2. *Sponsor:* Federal Energy Regulatory Commission.
3. *Control No.:* 1902-0005.

The Commission is now requesting that OMB approve a three-year extension of the expiration date, with no changes to the existing collection. The information filed with the Commission is mandatory.

4. *Necessity of the Collection of Information:* Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing the statutory provisions of Sections 4, 5, 6, 7, 9, 10(a) and 16 of the Natural Gas Act (NGA)(Pub. L. 75-688), and Title III, Sections 301(a)(1), 303(a), 304(d), Title IV, Sections 401 and 402, Title V,

Section 508 of the Natural Gas Policy Act (Pub. L. 95-621). The information collected under the requirements of FERC-567 is used by the Commission to obtain accurate data on pipeline facilities. Specifically, the FERC-567 data is used in determining the configuration and location of installed pipeline interconnections and receipt and delivery points; and developing and evaluating alternatives to proposed facilities as a means to mitigate the environmental impact of new pipeline construction.

FERC-567 also contains valuable information that can be used to assist federal officials in maintaining adequate natural gas service in times of national emergency. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR part 260.8 and 284.13.

5. *Respondent Description*: The respondent universe currently comprises approximately 91 natural gas pipeline companies.

6. *Estimated Burden*: 12,724 total hours, 91 respondents (average), 1,714 response per respondent (derived by dividing the total number of responses expected annually (156) by the number of respondents (91) and rounding to three places), 81.58 hours per response (average).

7. *Estimated Cost Burden to respondents*: 12,724 hours/2080 hours per years \times \$117,041 per year = \$715,976. The cost per respondent is equal to \$7,868.

Statutory Authority: Sections 4, 5, 6, 7, 9, 10(a) and 16 of the Natural Gas Act (15 U.S.C. 717-717w) and Title III Sections 301(a), 303(a), 304(d), Title IV, Sections 401, 402, Title V, Section 508 of the Natural Gas Policy Act (Pub. L. 95-621).

Magalie R. Salas,
Secretary.

[FR Doc. 03-19832 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC03-587-001, FERC-587]

Commission Information Collection Activities, Proposed Collection; Comment Request; Submitted for OMB Review

July 29, 2003.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice.

SUMMARY: In compliance with the requirements of Section 3507 of the

Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission) has submitted the information collection described below to the Office of Management and Budget (OMB) for review and extension of the current expiration date. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received no comments in response to an earlier **Federal Register** notice of April 11, 2003 (68 FR 17789) and has made this notation in its submission to OMB. (A companion **Federal Register** notice was published April 24, 2003 (68 FR 20124-25) providing a copy of the proposed form.)

DATES: Comments on the collection of information are due by August 27, 2003.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may be reached by fax at 202-395-7285 or by e-mail at pamelabevery.oirasubmission@omb.eop.gov. A copy of the comments should also be sent to the Federal Energy Regulatory Commission, Office of the Executive Director, ED-30, Attention: Michael Miller, 888 First Street NE., Washington, DC 20426. Comments may be filed either in paper format or electronically. Those persons filing electronically do not need to make a paper filing. For paper filings, such comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426 and should refer to Docket No. IC03-587-001.

Documents filed electronically via the Internet must be prepared in WordPerfect, MS Word, Portable Document Format, or ASCII format. To file the document, access the Commission's Web site at <http://www.ferc.gov> and click on "Make an E-filing," and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgment to the sender's E-mail address upon receipt of comments. User assistance for electronic filings is available at 202-502-8258 or by e-mail to efiling@ferc.gov. Comments should not be submitted to the e-mail address.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the

FERRIS link. User assistance for FERRIS and the FERC's Web site during business hours by contacting, FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, for TTY (202)502-8659 or the Public Reference at (202)-8371 or by e-mail to public.reference.room@ferc.gov.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202)502-8415, by fax at (202)273-0873, and by e-mail at michael.miller@ferc.gov.

SUPPLEMENTARY INFORMATION:

Description

The information collection submitted for OMB review contains the following:

1. *Collection of Information*: FERC-587 "Land Description."
2. *Sponsor*: Federal Energy Regulatory Commission.

3. *Control No.*: 1902-0143.

The Commission is now requesting that OMB approve the reinstatement of a former information collection requirement. The information filed with the Commission is mandatory. Requests for confidential treatment of the information are provided for under Section 388.112 of the Commission's regulations.

4. *Necessity of the Collection of Information*: Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing the statutory provisions of Section 24 of the Federal Power Act (FPA), 16 U.S.C. 818. Section 24 requires applicants proposing to construct hydroelectric projects, or to make changes to existing hydroelectric projects located on lands owned by the United States are required to provide a description of the U.S. lands affected to the Commission and to the Secretary of Interior. FERC Form 587 identifies project boundary maps associated with lands of the United States. The Commission verifies the accuracy of the information supplied and coordinates with the Bureau of Land Management State Offices (BLM) so that U.S. lands can be reserved as hydroelectric and withdrawn from other uses.

The Commission uses the information to determine the appropriateness of the lands that have been set aside for hydroelectric projects and their proposed location. The determination includes among several factors cost, environmental acceptability and in the public interest. FERC Form 587 is organized to account for lands surveyed in Public and Non-Public Land States. The Public Land States' format is used

to describe projects contained on the western side of the United States while the Non-Public Land States' format is used to identify most of the projects located on the eastern side of the United States, including Texas, and is based on county information. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR part 4.

5. *Respondent Description:* The respondent universe currently comprises approximately 250 applicants (on average) subject to the Commission's jurisdiction.

6. *Estimated Burden:* 250 total hours, 250 respondents (average), 1 response per respondent, 1 hour per response (average).

7. *Estimated Cost Burden to respondents:* 250 hours/2080 hours per years \times \$117,041 per year = \$14,067.

Statutory Authority: Section 24 of the Federal Power Act (16 U.S.C. 818).

Magalie R. Salas,
Secretary.

[FR Doc. 03-19833 Filed 8-4-03; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL03-212-000]

Ameren Services Company, et al.; Notice of Initiation of Proceedings and Refund Effective Dates

July 30, 2003.

On behalf of: Union Electric Company, Central Illinois Public Service Company.

American Electric Power Service Corporation on behalf of: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company.

Dayton Power and Light Company.
Exelon Corporation on behalf of: Commonwealth Edison Company, Commonwealth Edison Company of Indiana, Inc.

FirstEnergy Corporation on behalf of: American Transmission Systems, Inc., Cleveland Electric Illuminating Power Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company.

Illinois Power Company.
Northern Indiana Public Service Company.

Take notice that on July 23, 2003, the Commission issued an Order on Initial Decision in the above-captioned dockets that initiates proceedings in Docket No. EL03-212-000 under section 206 of the Federal Power Act.

The refund effective date in Docket No. EL03-212-000 pursuant to section 206(b) of the Federal Power Act is 60 days after publication of this notice in the **Federal Register**.

Magalie R. Salas,
Secretary.

[FR Doc. 03-19880 Filed 8-4-03; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP00-6-010]

Gulfstream Natural Gas System, L.L.C.; Notice of Application

July 29, 2003.

On July 23, 2003, Gulfstream Natural Gas System, L.L.C. (Gulfstream), 2701 Rocky Point Drive, Tampa, Florida 33607, filed an application pursuant to Section 7 of the Natural Gas Act (NGA), as amended, and the Federal Energy Regulatory Commission's (Commission) Rules and Regulations. Gulfstream requests authorization to extend the date that the previously certificated Phase II facilities must commence operation to February 21, 2006, and to phase the in-service date of the Phase II facilities so that some of the facilities comprising Phase II are placed in service earlier than the remainder of the Phase II facilities. Gulfstream states that the modifications are necessary due to changes in the Florida natural gas market, as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866) 208-3676 or for TTY, contact (202) 502-8659.

Gulfstream requests authority to: (1) Amend ordering Paragraph B of the Commission's Order Amending Certificate, 98 FERC ¶ 61,349 (2002), to allow phasing of the in-service date of the Phase II facilities; (2) modify the Phase II initial recourse rates to reflect updated construction costs and limited modifications to the Phase II facilities; (3) adopt its negotiated rate agreement with the Florida Power & Light Company (FPL); and, (4) increase the diameter of approximately five miles of

pipeline facilities from 24 to 30 inches. The estimated cost of all construction is approximately \$389,050,000. Gulfstream states that the completed facilities will provide 350,000 dekatherms per day of long-term firm transportation service for two FPL electric power plant expansions. Gulfstream further states that full service to these plants is expected to commence by May 1, 2005, with initial deliveries for plant startup testing beginning by December 31, 2004. Also, Gulfstream asks that requested authorizations be granted by October 15, 2003.

Questions regarding the application may be directed to P. Martin Teague, Assistant General Counsel, Gulfstream Natural Gas System, L.L.C., 2701 Rocky Point Drive, Tampa, Florida 33607, or call (813) 282-6609.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: August 19, 2003.

Dated:

Magalie R. Salas,
Secretary.

[FR Doc. 03-19830 Filed 8-4-03; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP03-338-000, CP03-339-000
and CP03-340-000]

Panther Interstate Pipeline Energy, L.L.C.; Notice of Application

July 29, 2003.

Take notice that on July 18, 2003, Panther Interstate Pipeline Energy, L.L.C. (Panther Interstate), 14405 Walters Road, Houston, Texas 770141337, filed in Docket Nos. CP03-338-000, CP03-339-000, and CP03-340-000, an application pursuant to Section 7(c) of the Natural Gas Act, as amended (NGA), and Subpart A of part 157 and part 284 of the Federal Energy Regulatory Commission's (Commission) Regulations thereunder, for certificates of public convenience and necessity authorizing Panther Interstate to acquire and operate certain facilities in on and off-shore Texas from the Natural Gas Pipeline Company of America (Natural), all as more fully set forth in the application which is on file with the Commission and open to public inspection. Panther Interstate states that Natural is simultaneously filing a related application requesting, in Docket No. CP03-337-000, authorization to abandon, by sale, the subject facilities. This filing, as well as the Natural filing are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866)208-3676, or for TTY, contact (202)502-8659.

Panther Interstate states that pursuant to a purchase and sale agreement between Natural and Prism and Panther dated December 21, 2001, as amended on March 20, 2003, May 22, 2003, and

June 26, 2003 ("PSA Agreement"), Natural has agreed to sell and Panther Interstate has agreed to acquire both the jurisdictional and non-jurisdictional facilities for \$400,000 plus additional consideration. Upon receipt of the requisite acquisition authority and the blanket certificates sought in the present application, Panther Interstate states that it will:

- Acquire and operate 22 miles of 16inch diameter offshore and related onshore pipeline and appurtenances originating at, but not including a sub-sea tap assembly in High Island Block 48, offshore, Texas, and terminating onshore near a connection with Natural's 30inch Louisiana Mainline No. 1 in Jefferson County, Texas (*i.e.*, a portion of what is known as Natural's High Island Block 71A Lateral), a dual 8inch meter and appurtenances located onshore at Natural's Booster Station No. 344 property in Jefferson County, Texas ("BS 344") and a 12inch sub-sea tap located in High Island Block 11;

- Acquire and operate 3.12 miles of 20inch onshore pipeline (known as Natural's Sabine Pass Lateral) and appurtenances originating near Natural's BS 344 in Jefferson County, Texas and terminating near a connection with Natural's 30inch Louisiana Mainline No. 2 in Jefferson County, Texas and a dual 12inch meter and appurtenances located at BS 344;

- Undertake selfimplementing interstate transportation of natural gas under part 284, Subpart G, of the Commission's Regulations; and
- Engage in any of the activities specified in Subpart F, part 157, of the Commission's Regulations.

Any questions regarding the application should be directed to Philip D. Gettig, Prism Gas Systems, Inc., 2350 Airport Freeway, Suite 200, Bedford, Texas, at (817)684-0158 Ext. 225, Luis M. Guzman, Panther Pipeline, Ltd., 14405 Walters Road, Suite 960, Houston, Texas, 77014 at (832)-552-3600, or Douglas F. John, John & Hengerer, 1200 17th Street, NW., Suite 600, Washington, DC, 20036-3013 at (202)429-8801.

Panther Interstate states that by the Commission's order issued September 20, 2002, in Docket No. CP0281000 (September 20th Order), Natural was authorized to abandon a portion of the facilities in the High Island Area, offshore Texas by sale to Prism Gas Systems, Inc. and Panther Pipeline, Ltd. (Prism/Panther), two existing non-jurisdictional gathering companies, which facilities the Commission found to be non-jurisdictional gathering facilities (non-jurisdictional facilities). However, Panther Interstate states, the

Commission also found in the September 20th Order that a portion of the facilities that Natural had sought to abandon by sale to Prism/Panther in the High Island Area and onshore in Jefferson County, Texas were jurisdictional gas transmission facilities (jurisdictional facilities), and the Commission did not grant Natural authority to abandon these facilities. Therefore, Prism/Panther have set up a subsidiary, Panther Interstate, to be an interstate pipeline natural gas company subject to the jurisdiction of the Commission, to acquire, own and operate the jurisdictional facilities. Panther Interstate notes that it will also acquire and operate the facilities Natural was authorized to abandon, which were found to be non-jurisdictional by the September 20th Order. Panther Interstate states that by a separate related application (CP03-337-000), being filed simultaneously, Natural is seeking abandonment authority to sell the jurisdictional facilities to Panther Interstate.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to

the party or parties directly involved in the protest.

Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

August 19, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03-19831 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC03-59-000, et al.]

Entergy Gulf States, Inc., et al.; Electric Rate and Corporate Filings

July 29, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Entergy Gulf States, Inc.

[Docket No. AC03-59-000]

Take notice that on July 17, 2003, the Entergy Gulf States, Inc. made a compliance filing pursuant to the accounting and reporting requirements set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

2. Dominion Transmission, Inc.

[Docket No. AC03-61-000]

Take notice that on July 18, 2003, Dominion Transmission, Inc. made a compliance filing pursuant to the accounting and reporting requirements set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional

entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

3. Virginia Electric and Power Company

[Docket No. AC03-62-000]

Take notice that on July 18, 2003, the Virginia Electric and Power Company made a compliance filing pursuant to the accounting and reporting requirements set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

4. Illinois Power Company

[Docket No. AC03-63-000]

Take notice that on July 21, 2003, the Illinois Power Company made a compliance filing pursuant to the accounting and reporting requirements set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

5. Cincinnati Gas & Electric Company

[Docket No. AC03-64-000]

Take notice that on July 21, 2003, Cincinnati Gas & Electric Company made a compliance filing pursuant to the accounting and reporting requirements set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

6. El Paso Electric Company

[Docket No. AC03-67-000]

Take notice that on July 22, 2003, El Paso Electric Company made a compliance filing pursuant to the accounting and reporting requirements

set forth by the Commission in Order 631, Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations. The Commission directed jurisdictional entities to file journal entries and supporting information for any adjustments made that affect net income as a result of implementing the accounting rules contained in Order 631. *Comment Date:* August 19, 2003.

7. Conectiv Delmarva Generation, Inc.

[Docket No. EG03-84-000]

Take notice that on July 24, 2003, Conectiv Delmarva Generation, Inc. (CDG) filed an Application for Determination of Exempt Wholesale Generator Status, pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935 (PUHCA).

CDG states that it owns and operates certain generating units located in the States of Delaware, Maryland and Virginia. CDG asserts that all of the CDG Generating Units are interconnected to the PJM Interconnection, LLC transmission system through interconnection with Delmarva Power & Light Company's transmission facilities. CDG further states that it has obtained orders from the regulatory commissions of Delaware, New Jersey, Maryland, Virginia and the District of Columbia that the CDG Generating Units are "Eligible Facilities" for the purposes of PUHCA and the Commission's exempt wholesale generator regulations.

CDG states that it has served this filing on the Maryland Public Service Commission, the Delaware Public Service Commission, the New Jersey Board of Public Utilities, the Virginia State Corporation Commission, the District of Columbia Public Service Commission and the Securities and Exchange Commission. *Comment Date:* August 19, 2003.

8. Conectiv Atlantic Generation, L.L.C.

[Docket No. EG03-85-000]

Take notice that on July 24, 2003, Conectiv Atlantic Generation, L.L.C. (CAG) filed with the Federal Energy Regulatory Commission (Commission) an Application for Determination of Exempt Wholesale Generator Status pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935 (PUHCA).

CAG states that it owns and operates certain generating units located in the State of New Jersey and that all of the CAG Generating Units are interconnected to the PJM Interconnection, LLC transmission system through interconnection with Atlantic City Electric Company's

transmission facilities. CAG asserts that it has obtained orders from the regulatory commissions of Delaware, New Jersey, Maryland, Virginia and the District of Columbia that the CAG Generating Units are "Eligible Facilities" for the purposes of PUHCA and the Commission's exempt wholesale generator regulations.

CAG states that it has served this filing on the Maryland Public Service Commission, the Delaware Public Service Commission, the New Jersey Board of Public Utilities, the Virginia State Corporation Commission, the District of Columbia Public Service Commission and the Securities and Exchange Commission.

Comment Date: August 19, 2003.

9. Alliance Companies, et al., and National Grid USA

[Docket No. EL02-65-011]

Take notice that on July 24, 2003, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) and PJM Interconnection, L.L.C. (PJM) jointly filed with the Commission, for informational purposes, an implementation progress report in accordance with the Commission's July 31, 2002 order in the above-referenced docket, 100 FERC ¶ 61,137. This is fifth in a series of similar filings to be made on or about every 60 days.

Comment Date: August 25, 2003.

10. Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric and Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool

[Docket Nos. ER97-1523-079, OA97-470-071, and ER97-4234-069]

Take notice that on July 23, 2003, Niagara Mohawk Power Corporation, a National Grid company and one of the Member Systems of the Transmission Owners Committee of the Energy Association of the State of New York, submitted a Compliance Filing pursuant to the Commission's May 7, 2003 Order issued in Docket Nos. ER9701523-070, OA97-470-065 and ER97-4234-063.

Comment Date: August 13, 2003.

11. California Independent System Operator Corporation

[Dockets Nos. ER02-1656-015 and EL01-68-028]

Take notice that on July 22, 2003, the California Independent System Operator Corporation (ISO) submitted an amendment to its Comprehensive Market Design Proposal filed on May 1,

2002 in the captioned proceedings. In its filing, the ISO seeks approval of its market redesign proposal.

The ISO states that copies of the this filing have been served on the Public Utilities Commission of California, the California Energy Commission, the California Electricity Oversight Board, all entities with effective ISO Scheduling Coordinator Agreements and all parties in these proceedings.

Comment Date: August 12, 2003

12. NorthWestern Energy, Division of NorthWestern Corporation

[Docket No. ER03-329-001]

Take notice that on July 22, 2003, NorthWestern Energy, a division of NorthWestern Corporation tendered for filing with the Federal Energy Regulatory Commission (Commission), in compliance with the Commission's Order dated February 13, 2002, revisions to its tariffs, rate schedules, and service agreements to reflect the name change and other designations and revised filing requirements pursuant to Section 35.9 of the Commission's rules and regulations and Order No. 614.

Comment Date: August 12, 2003.

13. New York Independent System Operator, Inc.

[Docket Nos. ER03-552-003, and ER03-984-001]

Take notice that on July 23, 2003, the New York Independent System Operator, Inc. (NYISO) submitted responses to the Commission's Data Request, dated July 8, 2003, regarding proposed creditworthiness requirements for customers participating in the NYISO-administered markets. NYISO states that the responses serve to amend the NYISO's March 6, 2003, filing in Docket Nos. ER03-552-002 and ER03-984-000.

The NYISO states it has served a copy of this filing upon all parties named on the official service list for this proceeding.

Comment Date: August 13, 2003.

14. Entergy Services, Inc.

[Docket No. ER03-599-003]

Take notice that on July 22, 2003, Entergy Services, Inc., (Entergy Services) on behalf of Entergy Arkansas, Inc. (Entergy Arkansas), tendered for filing revisions to Entergy Arkansas' 2003 Wholesale Formula Rate Update.

Comment Date: August 12, 2003.

15. Southern Company Services, Inc.

[Docket No. ER03-1099-000]

Take notice that on July 22, 2003, Southern Company Services, Inc., acting

on behalf of Alabama Power Company (APC), filed with the Federal Energy Regulatory Commission (Commission) a Notice of Cancellation of the Interconnection Agreement between GenPower Kelley, L.L.C. and APC (Service Agreement No. 360 under Southern Companies' Open Access Transmission Tariff, Fourth Revised Volume No. 5). An effective date of February 14, 2003 has been requested.

Comment Date: August 12, 2003.

16. Cleco Power LLC

[Docket No. ER03-1100-000]

Take notice that on July 22, 2003, Cleco Power LLC (Cleco) filed changes to Section 30.2 of its Open Access Transmission Tariff. FERC Electric Tariff, Original Volume No. 1, Original Sheet No. 41A to implement a new procedure for designating Replacement Network Resources for generating facilities directly connected to Cleco's transmission system on a firm basis for periods shorter than one-year and for additional resources not directly connected to Cleco's transmission system. Cleco submits First Revised Sheets No. 41A to its FERC Electric Tariff, Original Volume No. 1 and proposes that it be made effective July 23, 2003.

Comment Date: August 12, 2003.

17. California Independent System Operator Corporation

[Docket No. ER03-1102-000]

Take notice that on July 22, 2003, the California Independent System Operator Corporation (CAISO), submitted Amendment No. 55 to the ISO Tariff. CAISO states that Amendment No. 55 would modify the ISO Tariff in several respects to provide the CAISO with a necessary and effective Oversight and Investigation Program. The CAISO requests that the Commission make the proposed Tariff changes effective September 20, 2003.

CAISO states that it has served this filing to the California Public Utilities Commission, the California Energy Commission, the California Electricity Oversight Board, and all parties with effective Scheduling Coordinator Service Agreements under the ISO Tariff. In addition, the CAISO has posted a copy of the filing under its Home Page.

Comment Date: August 12, 2003.

18. FPL Energy South Dakota Wind, LLC

[Docket No. ER03-1103-000]

Take notice that on July 22, 2003, FPL Energy South Dakota Wind, LLC tendered for filing an application for

authorization to sell energy and capacity at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: August 12, 2003.

19. FPL Energy North Dakota Wind, LLC

[Docket No. ER03-1104-000]

Take notice that on July 22, 2003, FPL Energy North Dakota Wind, LLC tendered for filing an application for authorization to sell energy and capacity at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: August 12, 2003.

20. FPL Energy North Dakota Wind II, LLC

[Docket No. ER03-1105-000]

Take notice that on July 22, 2003, FPL Energy North Dakota Wind II, LLC tendered for filing an application for authorization to sell energy and capacity at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: August 12, 2003.

21. Timber Energy Resources, Inc.

[Docket No. ER03-1106-000]

Take notice that on July 22, 2003, Timber Energy Resources, Inc. submitted pursuant to Section 35.15 of the Federal Energy Regulatory Commission's regulations, 18 CFR 35.15, a notice canceling Timber Energy Resources Inc.'s FERC Rate Schedule No. 1. Timber Energy Resources, Inc. requests that the cancellation be made effective July 18, 2003.

Comment Date: August 12, 2003.

22. Ameren Services Company

[Docket No. ER03-1107-000]

Take notice that on July 23, 2003, Ameren Services Company (ASC) tendered for filing executed Service Agreements for Firm Point-to-Point Service and Non-Firm Point-to-Point Transmission Service between ASC and Eagle Energy Partners I, L.P. ASC states that the purpose of the Agreements is to permit ASC to provide transmission service to Eagle Energy Partners I, L.P. pursuant to Ameren's Open Access Transmission Tariff.

Comment Date: August 13, 2003.

23. Power Contract Financing II, L.L.C.

[Docket No. ER03-1108-000]

Take notice that on July 23, 2003, Power Contract Financing II, L.L.C. (PCF II, LLC) petitioned the Commission for acceptance of PCF II, LLC's Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

Comment Date: August 13, 2003.

24. Power Contract Financing II, Inc.

[Docket No. ER03-1109-000]

Take notice that on July 23, 2003, Power Contract Financing II, Inc. (PCF II, Inc.) petitioned the Commission for acceptance of PCF II, Inc.'s Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

Comment Date: August 13, 2003.

25. Idaho Power Company

[Docket No. OA03-8-000]

Take notice that on July 24, 2003, Idaho Power Company (Idaho Power) tendered for filing with the Federal Energy Regulatory Commission (Commission) revised Standards of Conduct Procedures.

Comment Date: August 25, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866)208-3676, or for TTY, contact (202)502-8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Linda Mitry,

Acting Secretary.

[FR Doc. 03-19894 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 469-013 -Minnesota]

Allete, Inc., d.b.a. Minnesota Power, Inc.; Notice of Availability of Environmental Assessment

July 29, 2003.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for a new license for the Winton Hydroelectric Project located on the Kawishiwi River, in Lake and St. Louis Counties, Minnesota, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission's staff has analyzed the potential environmental effects of the project and has concluded that approval of the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

A copy of the EA is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866)208-3676, or for TTY, contact (202)502-8659.

Any comments should be filed within 30 days from the date of this notice and should be addressed to the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1-A, Washington, DC 20426. Please affix "Winton Project No. 469" to all comments. Comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. For further information, contact Tom Dean at (202) 502-6041.

Magalie R. Salas,

Secretary.

[FR Doc. 03-19835 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[Project No. 2197-064]

Notice of Application for Non-Project
Use of Project Lands and Soliciting
Comments, Motions To Intervene, and
Protests

July 29, 2003.

Take notice that the two following application has been filed with the Commission and are available for public inspection:

- a. *Application Type*: Non-Project Use of Project Lands.
- b. *Project No*: 2197-064.
- c. *Date Filed*: June 24, 2003.
- d. *Applicant*: Alcoa Power Generating Inc.
- e. *Name of Project*: Yadkin Project.
- f. *Location*: The project is located on the Yadkin/Pee Dee River in Montgomery, Stanley, Davidson, Rowan, and Davie Counties, North Carolina.
- g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791 (a) 825(r) and 799 and 801.
- h. *Applicant Contact*: Mr. David R. Poe, BeBoeuf, Lamb, Greene, & MacRae, LLP, Suite 1200, 1875 Connecticut Avenue, NW., Washington, DC 20009-5728, (202) 986-8039.
- i. *FERC Contact*: Any questions on this notice should be addressed to Ms. Shana High at (202) 502-8674, or e-mail address: shana.high@ferc.gov.
- j. Deadline for filing comments and or motions: August 29, 2003.

All documents (original and eight copies) should be filed with: Ms. Magalie Roman Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. Please include the project number (P-2197-064) on any comments or motions filed. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages e-filings.

k. Description of Request:

Alcoa Power Generating Inc. (APGI) is seeking Commission authorization to issue a permit for non-project use of project lands and waters. The permit would be issued to Lake Forest of Badin Lakes, Inc. for the modification and use of an existing marina to accommodate a total of 51 watercraft within the project boundary on Narrows Reservoir, located in Davidson, Stanly, and Montgomery Counties.

l. Location of the Application: This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866)208-3676, or for TTY, contact (202)502-8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*: Federal, state, and local agencies are invited to file comments on the described applications. A copy of the applications may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,
Secretary.

[FR Doc. 03-19834 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[Docket No. PL02-6-000]

Natural Gas Pipeline, Negotiated Rate
Policies and Practices; Modification of
Negotiated Rate Policy

July 25, 2003.

Before Commissioners: Pat Wood, III,
Chairman; William L. Massey, and Nora
Mead Brownell.

1. This order addresses the Commission's Negotiated Rate Policy and concludes that several modifications of that policy are necessary in order to continue to permit the flexible, efficient pricing of pipeline capacity in a transparent manner, while ensuring the mitigation of market power.

Background

2. In 1996, the Commission issued its Policy Statement concerning negotiated rates.¹ In summary, this policy, as modified by Order No. 637,² permitted interstate pipelines under part 284 of the Commission's regulations to negotiate rates with a shipper that vary from the otherwise applicable cost of service pipeline tariff, subject to certain limitations, such as the Commission's prohibition against pipelines negotiating terms and conditions of service.³ Moreover, under the Commission's

¹ The Commission's current policies were originally established in, *Alternatives to Traditional Cost-of-Service Ratemaking for Natural Gas Pipelines, Regulation of Negotiated Transportation Services, Statements of Policy and Comments*, 74 FERC ¶ 61,076 (1996), *order on clarification*, 74 FERC ¶ 61,194 (1996), *order on reh'g*, 75 FERC ¶ 61,024 (1996).

² Regulation of Short-Term Natural Gas Transportation Services and Regulation of Interstate Natural Gas Transportation Services, FERC Stats. & Regs. Regulations Preambles (July 1996-December 2000) ¶ 31,091 at 61,343 (2000) (Order No. 637); *order on rehearing*, Order No. 637-A, FERC Stats. & Regs. Regulations Preambles (July 1996-December 2000) ¶ 31,099 at 31,648 (2000) (Order No. 637-A); and Order No. 637-B, 92 FERC ¶ 61,062 (2000) (Order No. 637-B), *aff'd in part and remanded in part, Interstate Natural Gas Association of America v. FERC*, 285 F.3d 18 (DC Cir. Apr. 5, 2002), *Order on Remand*, 101 FERC ¶ 61,127 (2002).

³ The Commission has determined that negotiated terms and conditions of service include any provisions that result in a customer receiving a different quality of service than that provided other customers under the pipeline's tariff. *Dominion Transmission, Inc.*, 93 FERC ¶ 61,177 (2000). The Commission will, however, permit the implementation of negotiations resulting in deviations from the pipeline's form of service agreement, so long as such changes do not change the conditions under which service is provided and do not present an undue risk of undue discrimination. *Columbia Gas Transmission Corp.*, 97 FERC ¶ 61,221 at 62,001-02 (2001).

policy, pipelines must permit shippers to opt for use of a traditional cost of service "recourse" rate instead of requiring them to negotiate for rates for any particular service.⁴ The Commission determined that the availability of a recourse rate would prevent pipelines from exercising market power by assuring that the customer can fall back to cost-based, traditional service if the pipeline unilaterally demands excessive prices or withholds service.⁵

3. On July 17, 2002, in Docket No. PL02-6-000, the Commission issued a Notice of Inquiry (NOI) concerning its Negotiated Rate Policy.⁶ There, the Commission stated that it was undertaking a review of issues related to its negotiated rate program and requested comments from, and posed questions to, the gas industry regarding the Commission's negotiated rate policies and practices. The Commission has received responses from all segments of the gas industry that raise a variety of issues related to the Commission's negotiated rate policies.⁷ As discussed below, upon consideration of its experience with the existing negotiated rate program, and the comments received from the industry in the NOI proceeding, the Commission has determined to modify several aspects of its Negotiated Rate Policy.

Discussion

4. The Commission finds that its negotiated rate program has been generally successful in providing flexible, efficient pricing of pipeline capacity while mitigating pipeline use of market power by means of a recourse rate. This view is supported by the majority of commenters as they support the negotiated rates program and want it to continue. However, certain commenters suggest various changes to increase transparency of the negotiated rates and methodologies for limiting pricing options for negotiated rates. The Commission has reviewed these comments and has determined to revise its filing requirements to increase the transparency of negotiated rates in order to minimize the potential for discrimination. In addition, the

Commission has determined to address the pricing mechanisms permitted under negotiated rates in order to ensure adequate mitigation of any pipeline market power. The Commission will begin its discussion with a consideration of the use of natural gas based index prices; in particular, the use of such indices to determine basis differentials, as a pricing methodology for the negotiation of rates.

Gas Index Pricing Mechanisms

5. In its Policy Statement, the Commission set forth a mechanism by which a pipeline that does not attempt to establish a lack of market power to justify market-based rates and does not wish to embark on an incentive rate program, may seek a negotiated rate alternative to traditional cost of service ratemaking and thus achieve flexible, efficient pricing. The Commission determined that, under this policy, the availability of a cost of service based recourse rate would protect shippers from the exercise of any market power by the transporters. As such, in its efforts to permit parties to establish flexible, efficient pricing for transportation service, the Commission did not seek to limit mechanisms used in transportation price negotiations.

6. Since the establishment of this policy, pipelines have availed themselves of the flexibility of the Commission's policies to negotiate many different types of pricing mechanisms. These have included negotiated rates for transportation based upon gas commodity price indices. These gas commodity price indices, when used as a negotiated pricing mechanism, usually reflect gas prices at different points such as at natural gas production basins or certain receipt and delivery points and citygates. This transportation pricing mechanism is based upon the difference between the gas price indices at the two points that is commonly referred to as the basis differential. The foundation for this pricing mechanism is that the difference in price between two points, as shown by the respective price indices, reflects the value of transportation between the two points.

7. Several commenters oppose the use of basis differentials as a pricing mechanism for negotiated transportation rates.⁸ Those opposed to the use of such pricing mechanisms argue that the use of such basis differentials in establishing transportation prices leads to rates far in excess of the recourse rate; gives the pipeline an interest in the

commodity price of gas; and permits shippers to lock-in a profit margin and mitigate price risk, which provides increased price protection not available to recourse shippers.

8. IPAA states that the fundamental problem with negotiated transportation rates is that they tempt pipeline monopolies with negotiated rate authority to focus more attention on the opportunity to market gas than on their statutory obligation to provide non-discriminatory transportation. On this general note, the Industrials argue that negotiated transportation rate deals based on price differentials give pipelines a stake in the commodity price of gas on a particular day or at a particular location, thus effectively allowing pipelines to re-enter the gas commodity sales business. CPUC adds that transportation rates based upon commodity sales prices allow the pipeline to capture part of the commodity gas price and essentially makes it a partner in a merchant transaction. Mirant also asserts that index-based deals allow pipelines to compete directly with shippers in commodity markets.

9. Oklahoma and NASUCA argue that the use of basis differentials for negotiating transportation rates at best operates as a contractual mechanism to make additional profits, and at worst, operates as an incentive to withhold capacity. BP adds that such contracts provide an incentive for the pipeline to maximize revenue by selling any unutilized firm transportation as interruptible transportation and competing against the shipper's capacity. As such, it argues that this type of arrangement gives the pipeline an incentive to withhold operationally available capacity from the market for the purpose of increasing the commodity basis differential. Mirant states that the shippers and pipelines are not on an equal footing, because of the pipeline's control over capacity, the pivotal component of such trades. In addition, Mirant states that pipelines may have more information regarding the factors leading to differentials between index prices and may actually be able to influence such differentials through the operation of their systems.

10. CPUC opposes the use of negotiated rates in general and index-based rates in particular. CPUC states that evidence indicates that the California energy markets have been manipulated by traders and that spot market published commodity indices are not verifiable. Therefore, CPUC argues that it is unreasonable to continue the use of negotiated rates in

⁴ See Natural Gas Pipeline Co. of America, 101 FERC ¶ 61,125 (2002) (finding that a pipeline may not restrict the use of recourse rate bids and, thereby, deprive bidders of a cost of service rate alternative, by declaring that only negotiated rate bids would be considered valid for bidding in an open season to determine interest in a pipeline expansion project).

⁵ 74 FERC ¶ 61,076 at 61,240.

⁶ Notice of Inquiry Concerning Natural Gas Pipeline Negotiated Rate Policies and Practices, 100 FERC ¶ 61,061 (2002).

⁷ See Appendix for list of commenters.

⁸ See generally, comments of Oklahoma, Mirant, CPUC, NASUCA, BP, IPAA, and Calpine.

place of tariff rates to serve markets or to simulate market behavior.

11. Other commenters argue that the Commission should continue to permit the use of basis differentials as a mechanism by which to set negotiated transportation rates. In essence, they maintain that these pricing methodologies represent a reasonable proxy for the value of the transportation and that the indexed rates allow shippers to easily engage in hedging programs and gas supply cost-management.⁹ For example, INGAA argues that there is a relationship between the unregulated gas commodity price and the value of a pipeline's transportation, and that to achieve the Commission's goals of price transparency and market efficiency, the Commission should not place unwarranted restrictions on the ability to negotiate rates using basis differentials. INGAA argues that there is nothing inherently wrong about rates that reflect this market reality and that such rates protect shippers because the rate cannot exceed the basis differential.

12. The KM Pipelines and Williams argue that the Commission has recognized, in the context of evaluating the lifting of price caps in the short-term secondary market for released capacity, that basis differentials reflect the value placed by the market on the transportation capacity. Peoples and Duke Trading state that the price differential between points is a commonly accepted proxy for the value of transportation between such points. In the same vein, the KM Pipelines assert that, whether index-based pricing is permitted or not, the expected level of basis differentials will be a fundamental underlying consideration in contracting and, therefore, eliminating this pricing mechanism will not change the basic dynamics of the transaction.

13. Many commenters argue that the Commission should assume that most shippers that negotiate rates are sophisticated market participants, and that the Commission should not get involved in the pricing of such transactions beyond ensuring that the shipper always has the option of taking the recourse rate.¹⁰ The AGA states that flexible and creative negotiations should not be inhibited by proscriptions against certain types of transactions such as those predicated on basis differentials.

⁹ See, e.g., Comments of Alliance, ProLiance, Dominion, KM Pipelines, KeySpan, AGA, Peoples, EnCana, APSA, Northern Natural, MidAmerican, El Paso, Williston Basin, TransColorado, INGAA, Peoples, Duke Trading, Williams, EPSA and NGSA.

¹⁰ See, e.g., Comments of NEG, El Paso, Peoples, Encana, WDG, MidAmerican and Alliance.

MidAmerican adds that deals based upon price differentials are no different than fixed price negotiated rate deals, because in either circumstance, the shipper can always revert to a recourse rate. EPSA, Dominion, NGSA and Alliance argue, in essence, that restrictions on the types of rates that can be negotiated may unnecessarily reduce flexibility and the value of the program.

14. Williston Basin, TransColorado and EnCana maintain that it is difficult for pipelines to manipulate hub prices to increase profits. They assert that while the risk of manipulation is low, the potential benefits to shippers and pipelines are high, and shippers are more willing to acquire capacity when they can share the risk with the pipeline.

15. The Canadian Association of Petroleum Producers (CAPP) argues that the Commission should allow indexed-based rates, but that the Commission should ensure that pipelines entering into such arrangements do not withhold capacity from the market in order to affect commodity prices. CAPP asserts that the popularity of indexed rates demonstrates their appeal and that to prohibit them would potentially undermine the purposes of the negotiated rate program. KeySpan asserts that negotiated rate frameworks, such as those based on gas price differentials, respond to the needs of shippers and consumers and that there is no risk associated with these pricing structures that is not outweighed by their potential benefits.

Discussion of Basis Differential Pricing Mechanisms

16. The Commission has determined to modify its negotiated rates policy and will no longer permit the use of gas basis differentials to price negotiated rate transactions. Gas commodity price indices, when used as a negotiated pricing mechanism, usually reflect gas prices at different points, such as at gas basins or certain receipt and delivery points and citygates. The pricing mechanism is based upon the difference between the gas price indices at the two points. As discussed above, the basis differential pricing mechanism uses the difference in gas prices between two points, to reflect the value of transportation between such points. Thus, under this mechanism, the wider the difference between the points, the greater the value of the transportation. In the Commission's view, allowing the use of gas commodity basis differentials by a pipeline as a mechanism for pricing transportation by a pipeline with market power threatens the Commission's regulatory structure for the

transportation of gas as well as the Commission's attempts to improve and maintain a competitive natural gas commodity market.¹¹ This is because such mechanisms provide pipelines with an incentive to withhold capacity in an attempt to manipulate the gas commodity market by widening the differences between the indices.

17. In Order No. 637, the Commission discussed how its policies under traditional cost of service rate regulation limit the pipeline's market power stating:

The principal reason for limiting pipeline rates to a level that would permit recovery of a pipeline's annual revenue replacement is to limit the ability of the pipelines to exercise market power, so that the pipeline does not charge excessive rates. Without rate regulation, pipelines would have the economic incentive to exercise market power by withholding capacity (including not building new capacity) in order to raise rates and earn greater revenue by creating scarcity. Because pipelines are regulated, however, there is little incentive for a pipeline to withhold capacity, because even if it creates scarcity, it cannot charge rates above those set by its cost of service. Since pipelines cannot increase revenues by withholding capacity, rate regulation has the added benefit of providing pipelines with a financial incentive to build new capacity when demand exists.¹²

18. Subsequently, in *Tennessee*, the Commission examined the pipeline's incentive to withhold capacity in spite of the Commission's part 284 regulations prohibiting such action and determined that its traditional cost of service regulation that does not permit the pipeline to charge more than the maximum cost of service rate provided an adequate check on such incentives.¹³

19. However, the Commission's negotiated rate policy permits pipelines

¹¹ In Order No. 636, the Commission reviewed the House Committee Report leading to the Natural Gas Wellhead Decontrol Act of 1989, [Pub. L. 101-60, 103 Stat. 157 (1989)], which stated that the Commission's competitive open-access pipeline system should be maintained and that:

The Committee stresses that these new rules, and especially the wide adoption of blanket certificates for nondiscriminatory open access interstate transportation of non-pipeline gas, are essential to its decision to complete the decontrol process. All sellers must be able to reach the highest-bidding buyer in an increasingly national market. All buyers must be free to reach the lowest-selling producer, and to obtain shipment of its gas to them on even terms with other supplies. Order No. 636 at 30,397, H.R. Rep. No. 29 101st Cong. 1st Sess., at p. 6.

In addition, the Commission noted that the House Committee Report urged the Commission "to retain and improve this competitive structure in order to maximize the benefits of decontrol." *Id.* (emphasis in original)

¹² Order No. 637 at 31,270.

¹³ *Tennessee Gas Pipeline Co.*, 91 FERC ¶ 61,053 at 61,191 (2000), *order on reh'g*, 94 FERC ¶ 61,097 (2001), *aff'd*, *Process Gas Consumers Group v. FERC*, 292 F.3d. 831 (DC Cir. 2002). (*Tennessee*)

to charge rates above the maximum cost of service rate thus presenting the possibility that a pipeline could increase revenues by withholding capacity. The Commission has relied on the availability of recourse service to prevent such an exercise of market power "by assuring that the customer can fall back to cost-based traditional service if the pipeline unilaterally demands excessive rates or withholds service."¹⁴ As a general matter, this should be sufficient to prevent the pipeline's exercise of market power, since ordinarily a shipper would be expected to choose the recourse rate in preference to a significantly higher negotiated rate.

20. However, this may not be true where the negotiated transportation rate is tied to the commodity price of gas. Such a negotiated rate may render the shipper indifferent to the actual costs of transportation. For example, a shipper may agree to an index differential-based, negotiated transportation rate with a pipeline. The shipper may then enter into gas sales agreements with its customers based upon the downstream price index that, in effect, lock in this transportation rate and/or a profit on the transaction. As a result, the shipper is indifferent to the price of gas at the downstream point and the pipeline's withholding of capacity to manipulate the downstream commodity gas price (and the effect of such manipulation on the negotiated transportation rate). It has, in effect, shifted the possible risks of the pipeline's abuse of its market power to the gas commodity market as a whole. In other words, negotiated transportation rates that use basis differentials to price transportation give the pipeline an incentive to withhold capacity so as to widen the basis differentials. In addition, the shipper may have little incentive not to agree since it is either held harmless or may, in fact, share in the profits from the increased price differential.¹⁵

21. In Order No. 636, the Commission stated that its primary goal was to improve the competitive structure of the natural gas industry and, at the same time, maintain adequate and reliable service. The Commission stated that its intent was to further "facilitate the unimpeded operation of market forces to stimulate the production of natural gas * * *."¹⁶ The Commission thus

undertook the task of improving the benefits of the decontrol of natural gas prices—chiefly, abundant gas supplies at lower prices—through the maintenance and improvement of its competitive pipeline transportation system. To permit pipelines to utilize pricing mechanisms, such as those based upon natural gas commodity prices, which create powerful incentives for the pipelines to attempt to use their monopoly power to manipulate the prices of the competitive natural gas commodity market, is contrary to the Commission's goal of improving the competitive pipeline transportation system set forth in Order No. 636.¹⁷

22. Pricing mechanisms that invest pipelines with an incentive to use market power to manipulate the commodity price of gas hinder the Commission's attempt to maintain and improve the competitive natural gas market. To allow pipelines to acquire an interest in commodity prices, or more precisely the difference between the commodity prices at separate points, reverses the regulatory trend which is based upon the competitive transportation structure acting to ensure competitive natural gas markets. This interest in the prices of the natural gas commodity presents pipelines with an incentive to withhold existing capacity in order to manipulate natural gas prices and may also create a disincentive to invest in the expansion of capacity.¹⁸

23. While such pricing mechanisms may be useful in permitting parties to the negotiated agreement to engage in various hedging programs and gas supply cost-management programs, in the Commission's view this flexibility cannot justify the increased risk of market manipulation faced by market participants. This slight limitation of transportation pricing flexibility is offset by the fact that negotiated rates may be based upon a virtually unlimited number of non-gas indices or other financial mechanisms that have no relationship with the commodity price of gas and are therefore not subject to manipulation through the withholding of pipeline capacity.

24. Accordingly, the Commission will no longer permit the pricing of negotiated rates based upon natural gas

commodity price indices. Negotiated rates based upon such indices may continue until the end of the contract period for which such rates were negotiated, but such rates will not be prospectively approved by the Commission.

Filing Requirements

25. As the Commission's negotiated rate program has evolved, the Commission has clarified the filing requirements necessary for implementing such rates. In its original Policy Statement, the Commission stated that pipelines would need to file a tariff sheet indicating that the negotiated rate for a service would be either the rate stated on its existing rate schedule or a rate mutually agreed to by the pipeline and its customer. The Commission stated that when a rate is negotiated, the pipeline would need to file a numbered tariff sheet stating the exact legal name of the customer and the negotiated rate for the service.¹⁹

26. The Commission then modified this filing requirement to require that the pipeline file either the negotiated contract itself or a tariff sheet reflecting the essential elements of the negotiated rate agreement necessary to permit shippers that believe they are similarly situated to the shipper receiving the negotiated rate to make such a determination.²⁰ The Commission determined that if the pipeline chose to file a tariff sheet, the tariff sheet must contain the essential details of the transaction.²¹ In addition, the Commission required that the tariff sheet must include a statement affirming that the negotiated rate contract does not deviate in any material aspect from the form of service agreement in the pipeline's tariff.²² The

¹⁴ 74 FERC ¶ 61,076 at 61,241.

²⁰ NorAm Gas Transmission Co., 75 FERC ¶ 61,091 (1996), *order on reh'g*, 77 FERC ¶ 61,011 at 61,037 (1996). 18 CFR § 154.1(b) (2003) provides that pipelines must file all contracts related to their services. An exception to this general requirement is permitted by 18 CFR 154.1(d) (2003) which states that although any contract which "deviates in any material aspect from the form of service agreement in the tariff" must be filed, it also states that any contract that conforms to the pipeline's form of service agreement set forth in the pipeline's tariff need not be filed.

²¹ The Commission stated that the tariff sheet "must state the name of the shipper, the negotiated rate, the type of service, the receipt and delivery points applicable to the service and the volume of gas to be transported." 77 FERC ¶ 61,011 at 61,037 (1996).

²² The Commission's regulations provide that the *pro forma* service agreement must refer to the service to be rendered and the applicable rate schedule of the tariff; and, provide spaces for insertion of the name of the customer, effective date, expiration date, and term. Blank spaces may be provided for the insertion of receipt and delivery

¹⁷ In Order No. 636, the Commission determined that because of firm transportation available under the rules promulgated by Order No. 636, and because of the abundance of uncommitted gas supplies available to replace pipeline sales of gas throughout North America, it would not be profitable for a pipeline to attempt to exercise market power over the sale of natural gas. Order No. 636 at 30,440.

¹⁸ See Tennessee Gas Pipeline Co., 91 FERC ¶ 61,053 (2000), *order on reh'g*, 94 FERC ¶ 61,097 (2001).

¹⁴ 74 FERC ¶ 61,076 at 61,240.

¹⁵ See, e.g., Transwestern Pipeline Co., 100 FERC ¶ 61,058 (2002), in which a shipper agreed to a negotiated transportation rate based upon a basis price differential that led to prices many times the pipeline's maximum rate.

¹⁶ Order No. 636 at 30,393, *citing*, S.Rep. No. 39, 101 Cong., 1st Sess., at p. 2 (1989).

Commission found that this information was necessary so that the Commission could evaluate whether the transaction was unduly discriminatory.²³

27. Subsequently, the Commission defined a material deviation as any provision of a service agreement that goes beyond the filling-in of the spaces in the form of service agreement with the appropriate information provided for in the tariff and that affects the substantive rights of the parties.²⁴ Therefore, if a negotiated rate agreement contains any such deviation from the form of service agreement, the pipeline must file the agreement for the Commission's review. The Commission will only accept negotiated rate agreements with such material deviations from the pipeline's form of service agreement if such deviations do not change the conditions under which service is provided and do not present a risk of undue discrimination.²⁵

28. Many commenters assert that the Commission's filing requirements for negotiated rates provide sufficient information for the necessary transparency of negotiated transactions.²⁶ Duke Trading, WDG and NEG state that the current filing requirements permit the Commission and other interested parties to monitor the contracting activity of the pipelines for undue discrimination, and to allow market participants to undertake a full commercial analysis of each negotiated rate deal. El Paso asserts that there is no evidence to justify a change in the filing requirements, or that additional requirements are necessary for transparency. The KM Pipelines add that additional information may actually obscure the important terms of the agreement.

29. On the other hand, Calpine states that the filing requirements do not provide sufficient transparency of information for negotiated rate transactions and joins BP and EPSA in asserting that the lack of a consistent format complicates any assessment of the options available to a shipper when reviewing multiple pipeline filings and comparing the negotiated rates granted to other shippers. Mirant states that the current filing requirements are insufficient to ensure transparency and

states that the Commission should not permit the pipelines to file a mere contract summary because the summaries may fail to disclose all meaningful and negotiated contract terms. NCSA joins Mirant and requests that the Commission require pipelines to file both the negotiated rate contract and a tariff sheet describing the contract. NCSA states that there is too much risk that the pipeline could omit details of a transaction that shippers see as important, and without full disclosure of the contract, the Commission and shippers have only limited ability to monitor negotiated transactions.

30. NASUCA and BP state that negotiated rate transactions lack transparency because of their bilateral nature, despite the posting and filing requirements. NASUCA states that recourse shippers and regulatory agencies often lack access to essential information. BP states that, even when the contracts are filed, it is sometimes hard to determine what elements are negotiated.

Discussion of Negotiated Rate Filing Requirements

31. The Commission's experience with negotiated rate filings has shown that the filings on occasion lack the information necessary for the Commission's Staff and the pipelines' shippers to analyze the negotiated agreement. First, even where the agreement contains no deviation from the form of service agreement, the tariff sheet summary may not describe the primary rate formula or the other essential elements of the transaction in sufficient detail. Second, pipelines have sometimes failed to file a service agreement even though it contained a material deviation. Finally, and most importantly, where pipelines have filed service agreements with material deviations, the deviations have often not been clearly identified, requiring the Commission to carefully compare the negotiated rate agreement with the form of service agreement in order to determine how the two may differ. Indeed, on some occasions, parties have drafted the entire service agreement independently of the form of service agreement in the tariff. As a result, provisions may be worded differently from similar provisions in the form of service agreement, but it is not immediately apparent whether the parties intended the provisions to be substantively different. These circumstances hinder the Commission's ability to assess whether the transaction is unduly discriminatory as well as the assessment of the transaction by

shippers attempting to determine if they are similarly situated to the shipper in the negotiated transaction.²⁷

32. The Commission will permit a pipeline filing a negotiated rate transaction that does not deviate from its *pro forma* service agreement to file a tariff sheet reflecting the terms of the agreement, together with a statement that the agreement conforms in all material respects with its *pro forma* service agreement.²⁸ However, pipelines are reminded that the tariff sheet summaries must fully describe the essential elements of the transaction, including the name of the shipper, the negotiated rate, the type of service, the receipt and delivery points applicable to the service and the volume of gas to be transported. Also, where the price term of the negotiated rate agreement is a formula, the formula should be fully set forth in the tariff sheet.²⁹ Pipelines are also reminded that, in order to file a tariff sheet summary, they must certify that the agreement contains no deviation from the form of service agreement that goes beyond filling in the blank spaces or that affects the substantive rights of the parties in any way. Since there would appear to be no reason for the parties to use language different from that in the form of service agreement other than to affect the substantive right of the parties, this effectively means that all language that is different from the form of service agreement should be filed with the Commission.

33. In addition, in order to provide greater transparency and to assist the Commission and interested parties in analyzing negotiated rate transactions, the Commission has determined that the form of service agreement must be used as a starting point in drafting any negotiated rate contract. Therefore, the Commission will henceforward require that a pipeline filing a contract proposing material changes from its form of service agreement must clearly

points, contract quantity and other specifics of each transaction as appropriate. 18 CFR § 154.110 (2003).

²³ 77 FERC ¶ 61,011 at 61,037 (1996).

²⁴ Columbia Gas Transmission Corp., 97 FERC ¶ 61,221 at 62,002 (2001).

²⁵ *Id.* at 62,001-02.

²⁶ See Comments of Northern Natural, Peoples, MidAmerican, Alliance, The Industrials, ProLiance, El Paso, EnCana, INGAA, Vector, CAPP, Williston Basin, Dominion, Williams, and Duke Transmission.

²⁷ See, e.g., Gulfstream Natural Gas System, L.L.C., 103 FERC ¶ 61,312 (2003); CenterPoint Energy Gas Transmission Co., 102 FERC ¶ 61,094 (2003) and CenterPoint Energy Gas Transmission Co., 102 FERC ¶ 61,059, *order on reh'g*, 103 FERC ¶ 61,228 (2003).

²⁸ This action merely emphasizes the Commission's current regulations which require that if the pipeline contends that its filing implements a negotiated contract that conforms to its form of service agreement in all material aspects, and therefore, it is not necessary to file the contract, such a filing will contain a statement that the pipeline's filing complies with the requirements of 18 CFR 154.1(d) (2003). Violation of this regulation may result in the rejection of the filing or suspension of the pipeline's negotiated rate authority.

²⁹ In the case of complicated formula, the pipeline may, as an alternative, simply file the agreement.

delineate differences between its negotiated contractual terms and that of its form of service agreement in redline and strikeout. In addition, the pipeline shall provide a detailed narrative outlining the terms of its negotiated contract, the manner in which such terms differ from its form of service agreement, the effect of such terms on the rights of the parties, and why such deviation does not present a risk of undue discrimination.

34. Information presented in such a manner, in conjunction with the tariff sheets, will permit the Commission and the parties to efficiently ascertain whether the proposed negotiated transaction entails such a risk of undue discrimination that it cannot be permitted or whether other similarly situated shippers may be able to obtain such service.

By the Commission, Commissioner Brownell dissenting with a separate statement attached.

Linda Mitry,
Acting Secretary.

Appendix

Commenters

Alliance Pipeline L.P. (Alliance)
American Gas Association (AGA)
American Public Gas Association (APGA)
BP Energy Company (BP) Calpine Energy Services, L.P. (Calpine)
Canadian Association of Petroleum Producers (CAPP)
Connecticut Department of Public Utility Control (Connecticut)
Consolidated Edison Company of New York, Inc. and Orange and Rockland Utilities, Inc. (ConEd and Orange and Rockland)
Dominion Resources, Inc. (Dominion)
Duke Energy Gas Transmission Corp. (Duke Transmission)
Duke Energy Trading and Marketing, L.L.C. (Duke Trading)
Dynergy Marketing and Trade (Dynergy)
Electric Power Supply Association (EPSA)
El Paso Corporation's Pipeline Group (El Paso)
EnCana Gas Storage Inc., EnCana Marketing (USA) Inc., and EnCana Energy Services Inc. (EnCana)
Gulf South Pipeline Company, LP (Gulf South)
Illinois Municipal Gas Agency (IMGA)
Independent Petroleum Association of America (IPAA)
Interstate Natural Gas Association of America (INGAA)
KeySpan Delivery Companies (KeySpan)
Louisville Gas and Electric Company (Louisville)
Maritimes & Northeast Pipeline, LLC (Maritimes)
Michigan Public Service Commission (Michigan PSC)
MidAmerican Energy Co. (MidAmerican)
Mirant Americas Energy Marketing, LP (Mirant)
National Association of State Utility Consumer Advocates (NASUCA)

Natural Gas Pipeline Company of America and Kinder Morgan Interstate Gas Transmission, LLC (jointly "KM Pipelines")
Natural Gas Supply Association (NGSA)
NEG Shippers (NEG)
NiSource Pipelines (NiSource)
Northern Natural Gas Company (Northern Natural)
Northwest Industrial Gas Users (NWIGU)
Oklahoma Corporation Commission (Oklahoma)
Peoples Gas Light and Coke Co., North Shore Gas Co., and Peoples Energy Resources Corp. (Peoples)
Process Gas Consumers Group, American Forest & Paper Association, American Iron and Steel Institute, Georgia Industrial Group, Industrial Gas Users of Florida, Florida Industrial Gas Users United States Gypsum Company (collectively, the "Industrials")
ProLiance Energy, LLC (ProLiance)
Public Service Commission of the state of New York (New York)
Public Utilities Commission of California (CPUC)
Sempra Energy Trading Corp. (Sempra)
TransColorado Gas Transmission Company (TransColorado)
Vector Pipeline L.P. (Vector)
The Williams Companies, Inc. (Williams)
Williston Basin Interstate Pipeline Company (Williston Basin)
Wisconsin Distributor Group (WDG)
Brownell, Commissioner, dissenting

1. In this order, the majority prohibits on a prospective basis the use of gas basis differentials to price negotiated rate transactions. The majority bases its determinations on the theory that such mechanisms provide pipelines with an incentive to withhold capacity in an attempt to widen the gas basis differential.

2. Gas basis differential pricing is a widely used tool for structuring competitive flexible transportation arrangements, demonstrating the appeal to both shippers and transporters alike. Many commenters argue that the Commission should assume that most shippers that negotiate rates are sophisticated market participants, and that gas basis differential pricing responds to the needs of shippers and consumers. These commenters conclude that the risk of manipulation is low while the potential benefits to shippers and pipelines are high and, therefore, the Commission should not preclude such transactions.

3. Gas basis differential pricing does not blur the role of the pipeline as a transporter with no direct interest in the commodity price because pipelines already use the gas basis differentials to value transportation. Whether or not a pipeline uses gas basis differential pricing in its negotiated rate transactions, pipelines determine the level of the discount that is necessary to maintain throughput on their systems by reference to the gas basis differentials. The Commission itself has recognized that the implicit price for transportation represents the most any shipper purchasing delivered gas at a downstream market would pay to move gas from the lower priced market to the higher priced market. Order No. 637 at 31.271.

4. The majority opinion ignores the Commission's existing regulations which prevent pipelines from withholding capacity. The order cites to no evidence that pipelines have the ability to withhold capacity or, in fact, have withheld capacity to increase the gas basis differentials. In Docket No. PL02-4-000, the Commission Staff presented data it had collected concerning capacity release transactions over a 22 month period. The data reflected that rates shippers received for their released transactions (above and below the recourse rate) tracked the applicable basis differentials. This finding further validates the Commission's determination in Order No. 637 that the "fact that prices for transportation rise during peak periods is not evidence of the exercise of market power but may be the appropriate market response to an increase in demand for capacity". Order No. 637 at 31.281.

5. The majority opinion seems to rely on *Transwestern Pipeline Co.*, 100 FERC ¶ 61,058 as a reason for prohibiting the use of gas basis differential pricing. In the *Transwestern case*, the pipeline was found to have violated its tariff by improperly giving prior notice of the capacity posting to two shippers that were awarded the capacity. Not complying with the open access tariff provisions is not a concern directed solely at negotiated rate transactions, but is a concern regardless of how the capacity is priced. I would further note that capacity was not being withheld in that proceeding, but unfairly directed.

6. Finally, the blanket prohibition of negotiated rate transactions that use gas basis differentials is overly prescriptive and an unnecessary intrusion in the marketplace, particularly when shippers have other choices. Most gas basis differential priced transactions are below the recourse rate. More importantly, shippers are protected because each negotiated rate transaction is noticed for comment and ultimately approved (or disapproved) by the Commission. The Commission has access to information about available pipeline capacity and daily gas basis differentials to monitor these types of transactions to determine if a pipeline is withholding capacity to increase the gas basis differential. With pipelines obligated to offer all available capacity, a viable recourse rate alternative, and our capability to monitor these transactions, the prohibition of gas basis differential pricing unnecessarily reduces flexibility and the value of the negotiated rate program.

7. For these reasons, I respectfully dissent.

Nora Mead Brownell,
Commissioner.

[FR Doc. 03-19882 Filed 8-4-03; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7539-9]

Investigator Initiated Grants: Request for Applications

AGENCY: Environmental Protection Agency.

ACTION: Notice of requests for applications.

SUMMARY: This notice provides information on the availability of fiscal year 2003 investigator initiated grants program announcements, in which the areas of research interest, eligibility and submission requirements, evaluation criteria, and implementation schedules are set forth. Grants will be competitively awarded following peer review.

DATES: Receipt dates vary depending on the specific research areas within the solicitations.

SUPPLEMENTARY INFORMATION: In its Requests for Applications (RFA) the U.S. Environmental Protection Agency invites research applications in the following areas of special interest to its mission: (1) Impacts of Manufactured Nanomaterials on Human Health and the Environment, (2) Market Mechanisms and Incentives for Environmental Management, (3) Environmental Statistics Research: Novel Analyses of Human Exposure Related Data (with ACC), (4) Computational Toxicology and Endocrine Disruptors: Use of Systems Biology in Hazard Identification and Risk Assessment, and (5) The Role of Air Pollutants in Cardiovascular Disease (with NIEHS)

Contacts: (1) Impacts of Manufactured Nanomaterials on Human Health and the Environment *karn.barbara@epa.gov*, (2) Market Mechanisms and Incentives for Environmental Management, *clark.matthew@epa.gov*, (3) Environmental Statistics Research: Novel Analyses of Human Exposure Related Data (with ACC), *saint.chris@epa.gov*, (4) Computational Toxicology and Endocrine Disruptors: Use of Systems Biology in Hazard Identification and Risk Assessment, *francis.elaine@epa.gov*, and (5) The Role of Air Pollutants in Cardiovascular Disease (with NIEHS), *katz.stacey@epa.gov*.

FOR FURTHER INFORMATION CONTACT: The complete program announcement can be accessed on the Internet at <http://www.epa.gov/ncer>, under "announcements." The required forms for applications with instructions are

accessible on the Internet at <http://es.epa.gov/ncer/rfa/forms/downlf.html>. Forms may be printed from this site.

Dated: July 24, 2003.

Approved for publication.

John C. Puzak,

Acting Director, National Center for Environmental Research.

[FR Doc. 03-19918 Filed 8-4-03; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION**Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission**

July 16, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 4, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments regarding this Paperwork Reduction Act (PRA) submission to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-B.Herman@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060-0936.

Title: Section 95.1215, Disclosure Policies and Section 95.1217, Labeling Requirements.

Form No: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents: 20.

Estimated Time Per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 20 hours.

Total Annual Cost: N/A.

Needs and Uses: The information collection requires manufacturers of transmitters for the Medical Implant Communications Service (MICS) to include with each transmitting device a statement regarding harmful interference and to label the device in a conspicuous location on the device. The requirements will allow use of potential life-saving medical technology without causing interference to other users of the 402-405 MHz band. This information collection has not changed and is being submitted to the OMB in order to obtain the full three year clearance.

OMB Control No.: 3060-XXXX.

Title: Request for Technical Support.

Form No: N/A.

Type of Review: New collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 31,500.

Estimated Time Per Response: 8 minutes (.13 hours).

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Total Annual Burden: 4,200 hours.

Total Annual Cost: \$336,000.

Needs and Uses: This electronic form will be used by the public to request technical support using Wireless Telecommunications Bureau (WTB) computer applications. This includes issues, problems, and questions about using software used for licensing, applying for licenses, participate in auctions for spectrum, and maintaining license information. Password reset requests for access to software used for these purposes is also a fundamental part of this package. This form will be submitted in lieu of free-form email requests for support and will facilitate

expedited processing of these requests by Commission staff, resulting in a faster turn-around for responses and corrected answers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03-19842 Filed 8-4-03; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

July 28, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 4, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments regarding this Paperwork Reduction Act submission to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., DC 20554; or via the Internet to Judith-B.Herman@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060-0233.

Title: Part 36—Separations.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents: 2,067 respondents; 5,433 responses.

Estimated Time Per Response: 5-22 hours.

Frequency of Response: On occasion, quarterly, and annual reporting requirements, third party disclosure requirements.

Total Annual Burden: 57,459 hours.

Total Annual Cost: N/A.

Needs and Uses: In order to allow determination of the study areas that are entitled to an expense adjustment, and the wire centers that are entitled to high-cost universal service support, each incumbent local exchange carrier must provide certain data to the National Exchange Carrier Association (NECA) annually and/or quarterly. Local telephone companies who want to participate in the federal universal service support program must make certain informational showings to demonstrate eligibility. With this submission, this information collection has been revised to eliminate 47 CFR Sections 36.701 through 36.741 which are no longer in effect. This modification was proposed in a *Notice of Proposed Rulemaking* in WC Docket No. 03-109, FCC 03-120. Additionally, the *Fourteenth Report and Order* in CC Docket No. 96-45, FCC 01-157, modified the requirement that only non-rural carriers are only required to file loop counts on a quarterly basis, this eliminating quarterly filing of loop cost data. This requirement was modified because it is no longer necessary for NECA to compute the national average cost per loop quarterly. The national average cost per loop is now frozen at \$240 per loop.

OMB Control No.: 3060-0817.

Title: Computer III Further Remand Proceedings: BOC Provision of Enhanced Services (ONA Requirements), CC Docket No. 95-20.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 5 respondents; 10 responses.

Estimated Time Per Response: 2-50 hours.

Frequency of Response: On occasion and semi-annual reporting requirements and third party disclosure requirement.

Total Annual Burden: 270 hours.

Total Annual Cost: N/A.

Needs and Uses: The Commission is seeking extension (no change) in this information collection. Bell Operating Companies (BOCs) are required to post their Comparably Efficient Interconnection (CEI) plans and amendments on their publicly accessible Internet sites. The requirement extends to CEI plans for new or modified telemessaging or alarm monitoring services and for new or amended payphone services. If the BOC receives a good faith request for a plan from someone who does not have Internet access, the BOC must notify that person where a paper copy of the plan is available for public inspection. The CEI plans will be used to ensure that BOCs comply with Commission policies and regulations safeguarding against potential anticompetitive behavior by the BOCs in the provision of information services.

OMB Control No.: 3060-0726.

Title: Quarterly Report of Interexchange Carriers Listing the Number of Dial-Around Calls for Which Compensation is Being Paid to Payphone Owners.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 261 respondents; 1,044 responses.

Estimated Time Per Response: 2 hours.

Frequency of Response: Quarterly reporting requirements and third party disclosure requirement.

Total Annual Burden: 522 hours.

Total Annual Cost: N/A.

Needs and Uses: The Commission is seeking extension (no change) in this information collection. Interexchange carriers responsible for paying per-call compensation to payphone providers must submit on a quarterly basis a list of dial-around calls to those payphone providers. The payphone providers need the list to calculate the compensation to be paid by the interexchange carriers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03-19843 Filed 8-4-03; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2617]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

July 22, 2003.

Petitions for Reconsideration and Clarification have been filed in the Commission's Rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR section 1.429(e). The full text of this document is available for viewing and copying in Room CY-A257, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Qualex International (202) 863-2893. Oppositions to these petitions must be filed by August 20, 2003. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions have expired.

Subject: In the Matter of the Commission's Rules to Create a Low Frequency Allocation for the Amateur Radio Service (ET Docket No. 02-98, RM-9404).

Number of Petitions Filed: 1.

Subject: In the Matter of Flexibility for Delivery of Communications by Mobile Satellite Service Providers in the 2 GHz Band, the L-Band, and the 1.6/2.4 GHz Bands (IB Docket No. 01-185).

Review of the Spectrum Sharing Plan Among Non-Geostationary Satellite Orbit Mobile Satellite Service Systems in the 1.6/2.4 GHz Bands (IB Docket No. 02-364).

Number of Petitions Filed: 7.

Marlene H. Dortch,

Secretary.

[FR Doc. 03-19804 Filed 8-4-03; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at <http://www.ffiec.gov/nic/>.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 29, 2003.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:

1. *East Penn Financial Corporation*, Emmaus, Pennsylvania; to acquire up to 24.9 percent of the voting shares of Berkshire Bank, Wyomissing, Pennsylvania.

B. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Mount Hope Bankshares, Inc.*, Mount Hope, West Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Mount Hope, Incorporated, Mount Hope, West Virginia.

C. Federal Reserve Bank of Kansas City (James Hunter, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Page Bancshares, Inc.*, Liberty, Missouri; to become a bank holding company by acquiring 100 percent of the voting shares of Griffin Bancshares, Inc., Cameron, Missouri, and thereby indirectly acquire Pony Express Bank, Braymer, Missouri.

Board of Governors of the Federal Reserve System, July 30, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03-19816 Filed 8-4-03; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary**

[Document Identifier: OS-0937-0025]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of Currently Approved collection.

Title of Information Collection: Application for Appointment as a Commissioned Officer in the U.S. Public Health Service Commissioned Corps and Supporting Regulations 42 CFR 21.22 through 42 CFR 21.34.

Form/OMB No.: OS-0937-0025.

Use: The PHS-50, Application for Appointment as a Commissioned Officer in the United States Public Health Service, is used to determine if an applicant is qualified for appointment in the Commissioned Corps of the Public Health Service (PHS). In addition, the information contained in PHS-50 establishes the basis for future assignments and benefits as a commissioned officer. The PHS-1813, Reference Request for Applicants to the U.S. Public Health Service Commissioned Corps, is used to obtain reference information concerning applicants for appointment in the Commissioned Corps of the PHS. Each applicant is required to provide four references.

Frequency: On occasion.

Affected Public: Individuals or households.

Annual Number of Respondents: 10,000 (PHS-50 2,000), (PHS-1813 8,000).

Total Annual Responses: 10,000.
Average Burden Per Response: 1 hour (PHS-50 1 hour), (PHS-1813 25 minutes).

Total Annual Hours: 4,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OS document identifier, to John.Burke@hhs.gov, or call the Reports Clearance Office on (202) 690-8356. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt (OMB #0937-0025), New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 24, 2003.

John P. Burke, III,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary, Department of Health and Human Services.

[FR Doc. 03-19827 Filed 8-4-03; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Tribal Child Support Direct Funding Regulation—Final.

OMB No.: 0970-0218.

Description: This final rule contains reporting requirements as proposed at 45 CFR part 309. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Administration for Children and Families submitted the requirements to the Office of Management and Budget (OMB) for its review.

Part 309 contains a regulatory requirement that, in order to receive funding for an independent Tribal IV-D program, a Tribe or Tribal organization must submit an application containing Standard Forms 424 and 424A and a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section

455(f) of the Act, including establishing paternity, establishing, modifying, and enforcing support orders, and locating noncustodial parents. Tribes and Tribal organizations must respond if they wish to operate a Federally funded program. In addition, any Tribe or Tribal organization participating in the program would be required to submit Standard Form 269A and form OCSE 34A and to submit statistical and narrative reports regarding its Tribal IV-D program.

Respondents: The potential respondents to these information collection requirements are approximately 10 Federally recognized Tribes and Tribal organizations, during year 1; 65 additional Federally recognized Tribes and Tribal organizations during Year 2; and 75 additional Federally recognized Tribes and Tribal organizations during Year 3; for a three-year total of 150 grantees. This information collection requirement will impose the estimated total annual burden on the Tribes and Tribal organizations described in the table below:

ANNUAL BURDEN ESTIMATES

Year 1—Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 309—Plan	10	1	480	4,800
Form OCSE 34A	10	4	8	320
Statistical Reporting	10	1	24	240
Total	10	6	512	5,360
Year 2—Information collection	Number of respondents	Responses per respondent	Average burden per response	Total annual burden
45 CFR 309—Plan	65	1	480	31,200
Form OCSE 34A	75	4	8	2,400
Statistical Reporting	75	1	24	1,800
Total	75	6	512	35,400
Year 3—Information collection	Number of respondents	Responses per respondent	Average burden per response	Total annual burden
45 CFR 309—Plan	75	1	480	36,000
Form OCSE 34A	150	4	8	4,800
Statistical Reporting	150	1	24	3,600
Total	150	6	512	44,400

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington,

DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: rsargis@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed

collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 29, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03-19908 Filed 8-4-03; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee State-of-Origin Report.

OMB No.: 0970-0043.

Description: The information collection of the ORR-11 (Refugee State-of-Origin-Report) is designed to satisfy the statutory requirements of the Immigration and Nationality Act (the Act). Section 412(a)(3) of the Act requires the Office of Refugee Resettlement (ORR) to compile and maintain data on the secondary migration of refugees within the United States (U.S.) after arrival.

In order to meet this legislative requirement, ORR requires each State to submit an annual count of the number of refugees who were initially resettled in another State. The State does this by counting the number of refugees with Social Security numbers indicating residence in another State at the time of arrival in the U.S. (The first three digits of the Social Security number indicate the State of residence of the applicant.)

Data submitted by the States are compiled and analyzed by the ORR statistician, who then prepares a summary report which is included in ORR's Annual Report to Congress. The primary use of data is to quantify and analyze refugee secondary migration among the 50 States. ORR uses these data to adjust its refugee arrival totals in order to calculate the ORR social services allocation.

Respondents: State, Local or Tribal.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-11	50	1	4.333	217
Estimated Total Annual Burden Hours				217

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 29, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03-19909 Filed 8-4-03; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[ACF-ADD-07-11-2003]

Developmental Disabilities: Notice of Availability of Financial Assistance and Request for Applications To Fund Training and Technical Assistance To Improve Voting Access for Individuals With Disabilities

AGENCY: Administration on Developmental Disabilities (ADD), ACF, DHHS.

ACTION: Announcement of availability of financial assistance and request for applications to fund training and technical assistance grants to establish/improve access to the voting process for

individuals with the full range of disabilities.

CFDA: Federal Catalog of Domestic Assistance Number 93.618 Developmental Disabilities.

SUMMARY: The Administration on Developmental Disabilities, Administration for Children and Families (ACF), is accepting applications for fiscal year 2003 Help America Vote Training and Technical Assistance Projects.

This Program Announcement No. ACF-ADD-07-11-2003 consists of five parts. Part I, the Introduction, discusses the goals and objectives of ACF and ADD. Part II provides background information on ADD for applicants. Part III describes the application review process. Part IV describes the priority area under which ADD requests applications for fiscal year 2003 funding of projects. Part V describes the process for preparing and submitting the application.

Grants will be awarded under this Program Announcement subject to the availability of funds for support of these activities.

DATES: The closing date for submittal of applications under this announcement is September 4, 2003.

Deadline*Applications Submitted by Mail*

Mailed applications shall be considered as meeting the announced deadline if they are received on or before the deadline date at the U.S. Department of Health and Human Services, ACF/Office of Grants Management, 370 L'Enfant Promenade SW., 8th Floor, Washington, DC 20447-0002, Attention: Lois B. Hodge. Applications received after 4:30 p.m. on the deadline date will not be considered for competition.

Application Submitted by Courier

Applications hand-carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., e.s.t., Monday through Friday (excluding Federal holidays), at the U.S. Department of Health and Human Services, ACF/Office of Grants Management, ACF Mailroom, 2nd Floor (near Loading Dock), Aerospace Center, 901 D Street, SW., Washington, DC 20024. Applicants using express/overnight services should allow two working days (Monday through Friday, excluding holidays) prior to the deadline date for receipt of applications. Note to applicants: Express/overnight mail services do not always deliver at the time to which they agreed.)

Receipt of Applications: Applications must either be hand delivered or mailed to the addresses listed above (under DEADLINE). ACF will acknowledge receipt of applications through a letter. ACF cannot accommodate transmission of applications by fax or through other electronic media. Applications transmitted electronically will not be accepted. Videotapes and cassette tapes may not be included as part of a grant application for panel review.

Additional material will not be accepted, or added to an application, unless it is received by the deadline date.

Closed Captioning for Audiovisual Efforts

Applicants must include closed captioning and audio description in the development of any audiovisual products.

Late Applications: Applications that do not meet the criteria above are considered late applications. ADD shall notify each late applicant that its application will not be considered in the current competition.

Extension of Deadlines: The Administration for Children and Families (ACF) may extend application deadlines when circumstances such as acts of God (e.g., floods, hurricanes) occur, or when there is widespread disruption of the mail service. Determinations to extend or waive deadline requirements rest with the Chief Grants Management Officer.

Notice of Intent To Submit Application: If you intend to submit an application, under this announcement, please contact, Carla R. Brown of ADD at (202) 690-8332 within 15 days of the date of this announcement. Please give your organization's name and address, and your contact person's name, phone and fax numbers, and e-mail address.

The information will be used to determine the number of expert reviewers needed and to update the mailing list for program announcements.

FOR FURTHER INFORMATION CONTACT: For information about the application process, program information and application materials contact, Administration for Children and Families (ACF), Carla R. Brown, Management Analyst, 370 L'Enfant Promenade, SW., Washington, DC 20447, (202) 690-8332, crbrown@acf.hhs.gov; or Lois Hodge, Grants Officer, 370 L'Enfant Promenade, SW., Washington, DC 20447, (202) 401-2344, lhodge@acf.hhs.gov. Copies of this program announcement and many of the required forms may be obtained electronically at the ADD World Wide Web page: <http://www.acf.dhhs.gov/programs/add/>.

Project Duration: The projects will be awarded for a project period of up to twelve (12) months.

Federal Share of Project Costs: The maximum Federal shares for applicants will be \$70,000 for the project period.

Number of Projects To Be Funded: Two projects will be funded not to exceed \$70,000 each.

SUPPLEMENTARY INFORMATION:**Part I. General Information***A. Goals of the Administration on Developmental Disabilities*

The Administration on Developmental Disabilities (ADD) is located within the Administration for Children and Families (ACF), Department of Health and Human Services (DHHS). ADD shares goals with other ACF programs that promote the economic and social well-being of families, children, individuals, and communities.

B. Purpose of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities (ADD) is the lead agency within ACF and DHHS responsible for planning and administering programs to promote the self-sufficiency and protect the rights of persons with developmental disabilities. ADD administers the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (the DD Act of 2000). The DD Act provides for funding to States to provide advocacy, promote consumer oriented systems change and capacity building activities, and facilitate network formations.

The four programs funded under the DD Act are:

(1) State Councils on Developmental Disabilities that engage in advocacy, capacity building and systematic change activities.

(2) Protection and Advocacy Systems (P&As) that protect the legal and human rights of individuals with developmental disabilities.

(3) The National Network of University Centers for Excellence in Developmental Disabilities, (UCEDD) that engages in training, outreach and dissemination activities.

(4) Projects of National Significance (PNS), including Family Support Grants that support the development of family-centered and directed systems for families of children with disabilities, including children with developmental disabilities.

(5) In addition to responsibilities under the DD Act, ADD, the Secretary of the U.S. Department of Health and Human Services has the responsibility for three grant programs authorized under the Help America Vote Act of 2002 (HAVA), Public Law 107-252.

C. Statutory Authorities Covered Under This Announcement

This announcement is covered under the Help America Vote Act of 2002, Public Law (P.L.) 107-252, title II subtitle D, part 2, section 291 (42 U.S.C. 15461). Provisions under this section provide for the award of grants for Training and Technical Assistance that support:

- Full participation in the electoral process for individuals with disabilities, including registering to vote, casting a vote, and accessing polling places;
- Training in the use of voting systems and technologies;
- Demonstration and evaluation of the use of such systems and technologies by individuals with disabilities (including blindness) in order to assess the availability and use

of such systems and technologies for such individuals; and

- At least one recipient must provide training and technical assistance for nonvisual access.

Part II. Background Information for Applicants

The Help America Vote Act (HAVA), signed into law by President George W. Bush on October 29, 2002, contains several provisions that will enable an applicant to establish, expand, and improve access to and participation in the election process by individuals with the full range of disabilities (e.g., disabilities such as blindness or visual impairment, deafness or hearing impairment, mobility-related, dexterity-related, emotional or intellectual) in the election process.

On February 20, 2003, "Division N—Consolidated Appropriations Resolution FY 2003, Public Law 108-7." Congress appropriated \$13 million for States to operate the Election Assistance for Individuals with Disabilities (EAID) grant program; \$2 million for payments for Protection and Advocacy systems, and \$140,000 (7 percent) for payments to provide training and technical assistance with respect to the activities carried out under Section 291 of the Help America Vote Act. HAVA assigned responsibility for the EAID to the Secretary of Health and Human Services (the Secretary), who has assigned responsibility for carrying out this program to the Administration for Children and Families (ACF). Within ACF, the Administration on Developmental Disabilities (ADD) is responsible for the administration of the EAID grant program.

Part III. The Application Review

A. Eligible Applicants

Eligible applicants include public or private non-profit organizations, including State and local governments, Federally recognized Indian tribes, faith-based and community organizations, and private nonprofit organizations including universities and other institutions of higher learning. An entity is eligible to receive a payment under subsection 291 if the entity is:

- A public or private non-profit entity with demonstrated experience in voting issues for individuals with disabilities;
- Governed by a board with respect to which the majority of its members are individuals with disabilities or family members of such individuals or individuals who are blind; and
- Submits to the Secretary an application at such time, in such manner, and containing such

information as the Secretary may require.

All applications that may be developed jointly by more than one agency or organization must identify only one organization as the lead organization and the official applicant. The other participating agencies and organizations can be included as co-participants, subgrantees, or subcontractors.

Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission. The non-profit agency can accomplish this by submitting any of the following that constitutes acceptable proof of status:

- a. A reference to the applicant organization's listing in the Internal Service's (IRS) most recent list of tax exempt organizations described in the IRS Code.
- b. A copy of a currently valid IRS tax exemption certificate.
- c. A statement from a State taxing body, State attorney general, or other appropriate State Official certifying that the applicant organization has a non-profit status and that none of the net earning accrue to any private shareholders or individuals.
- d. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.
- e. Any of the items in the paragraphs immediately above for a State of national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

ADD cannot fund a non-profit applicant without acceptable proof of its non-profit status.

Private, non-profit applicants are encouraged to fill out and submit the optional survey located at <http://www.acf.hhs.gov/programs/ofs/form/htm>.

Before applications under this Program Announcement are reviewed, each one will be screened to determine whether the applicant is eligible for funding. Applications from organizations that do not meet eligibility requirements will not be considered or reviewed in the competition, and the applicant will be so informed.

B. Review Process and Funding Decisions

Applications from eligible applicants received by the deadline date will be reviewed and scored by a panel of at least three (3) reviewers (primarily experts in the field from outside the

Federal Government). To facilitate this review, applicants should ensure that they address each minimum requirement in the program description under each section of the project Narrative Statement.

Reviewers will determine the strengths and weaknesses of each application in terms of the evaluation criteria listed in Part IV, provide comments, and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each applicant may receive per section in the review process. The results of this review are a primary factor in making funding decisions.

ADD reserves the option of discussing applications with, or referring them to, other Federal or non-Federal funding sources when this is determined to be in the best interest of the Federal Government or the applicant.

Grantees funded by ADD may be requested to cooperate in evaluation efforts funded by ADD. The purpose of these evaluation activities is to learn from the combined experience of multiple projects funded under a particular program description.

C. Available Funds

ADD intends to award new grants resulting from this announcement during the fourth quarter of fiscal year 2003. Up to \$140,000 in Federal funds will be available for support of these projects.

D. Matching Requirements and Non-Federal Share

There are no matching requirements.

E. General Instructions for the Uniform Project Description

The following ACF Uniform Project Description (UPD) has been approved under OMB Control Number 0970-0139.

Applicants are required to submit a full project description and should prepare the project description statement in accordance with the following instructions.

Project summary/abstract: Provide a summary of the project description (a page or less) with reference to the funding request.

Objectives and need for assistance: Clearly identify the physical, economic, social, financial, institutional, or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the

applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement. Applicant may include an assessment of the current voting accessibility within the area to be served.

Results or benefits expected: Identify the results and benefits to be derived. For example, extent to which the application is consistent with the objectives of the program announcement, and the extent to which the application indicates the anticipated contributions to policy practice, theory and research. Extent to which the proposed project cost is reasonable in view of the expected results.

Approach: Outline a plan of action that describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors that might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data are to be collected, maintained, and disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Organizational Profile: Provide information on the applicant organization(s) and cooperating partners such as with organizational charts,

financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission. Please see Part III, A-Eligible Applicants.

Budget and Budget Justification: Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF-424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

Part IV. Fiscal Year 2003—Applications to Fund Training and Technical Assistance Grants To Establish Access to the Voting Process for Individuals With Disabilities Requirements

Evaluation Criteria: Five (5) criteria will be used to review and evaluate each application under this announcement. Each criterion should be addressed in the project description section of the application. The point values indicate the maximum numerical weight possible for a criterion in the review process. The specific information to be included under each of these headings is described in Section E of Part III, General Instructions for the Uniform Project Description. Additional information that must be included is described below.

Criterion 1: Approach (Maximum 35 Points)

Discuss the criteria to be used to evaluate the results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. Applicants are expected to present a plan that (1) reflects an understanding of the characteristics, needs and services currently available to the targeted population; (2) provides

services that directly address the needs of the target population; (3) is evidence-based and grounded in theory and practice; (4) is appropriate and feasible; and (5) can be reliably evaluated.

The applicant must:

(1) Outline a plan of action pertaining to the scope and detail on how the proposed work will be accomplished for each project. Define goals and specific measurable objectives for the project (8 points);

(2) Identify the kinds of data to be collected and maintained, and discuss the criteria to be used to evaluate the results and success of the project. Describe how the proposed project will be evaluated to determine the extent to which it has achieved its stated goals and objectives; and whether the methods of evaluation include the use of performance measures that are clearly related to the intended outcome of the project (8 points);

(3) Describe any unusual features of the project, such as design or technological innovation, reductions in cost or time, or extraordinary social and community involvement (5 points);

(4) Provide for each assistance program quantitative projects of the accomplishments to be achieved, if possible. When accomplishments cannot be quantified, activities should be listed in chronological order to show the schedule of accomplishments and their target date (4 points);

(5) Describe the products to be developed during the implementation of the proposed project. This can include questionnaires, interview guides, data collection instruments, software, internet applications, reports, article outcomes and evaluation results. Also present a dissemination plan for conveying the information (4 points);

(6) Cite factors which might accelerate or decelerate the work and provide reasons for taking this approach as opposed to others (3 points); and

(7) List each organization, operator, consultant, or other key individual who will work on the project along with a short description of the nature of their effort of contribution (3 points).

Criterion 2: Objectives and Need for Assistance (Maximum 25 Points)

The application must describe the context of the proposed demonstration project, including the geographic location, environment, magnitude and severity of the problem(s) to be solved and the needs to be addressed.

The applicant must:

(1) Demonstrate the need for the assistance and state the principal and subordinate objectives for the project (10 points);

(2) Pinpoint any relevant physical, economic, social, financial, institutional, or other problems requiring a solution (5 points);

(3) Provide supporting documentation or other testimonies from concerned interests other than the applicant (5 points);

(4) Provide any relevant data based on planning studies (4 points); and

(5) Provide maps and other graphic aids (1 point).

Criterion 3: Results or Benefits Expected (Maximum 20 Points)

Identify results and benefits to be derived. The anticipated contribution to policy, practice, theory and research should be indicated.

The applicant must:

(1) Clearly describe project benefits and results as they relate to the objectives of the project (10 points); and

(2) Provide information as to the extent to which the project will build on current theory, research, evaluation and best practices to contribute to increased knowledge and understanding of the problems, issues or effective strategies and practices in family support (10 points).

Criterion 4: Organizational Profile (15 Points)

This section should consist of a brief (two to three pages) background description of how the applicant organization (or the unit within the organization that will have responsibility for the project) is structured, the types and quantity of services, and the research and management capabilities it possesses. Applicants need to demonstrate that they have the capacity to implement the proposed project. Capacity includes (1) experience with similar projects; (2) experience with the target population; (3) qualifications and experience of the project leadership; (4) commitment to developing sustaining work among key stakeholders; (5) experience and commitment of any proposed consultants and subcontractors; and (6) appropriateness of the organizational structure, including its management information system, to carry out the project.

The applicant must:

(1) Identify the background of the project director/principal investigator and key project staff (including name, address, and training, educational background and other qualifying experience) and the experience of the organization to demonstrate the applicant's ability to effectively and efficiently administer this project; present brief resumes (4 points);

(2) Provide a brief background description of how the applicant organization is organized, the types and quantity of services it provides, and the research and management capabilities it possesses (4 points);

(3) Describe the competence of the project team and its demonstrated ability to produce a final product that is readily comprehensible and usable (3 points); and

(4) Provide an organization chart showing the relationship of the project to the current organization (2 points).

Criterion 5: Budget and Budget Justification (5 Points)

Applicants are expected to present a budget with reasonable project costs, appropriately allocated across component areas, and sufficient to accomplish the objectives. The dollar amount requested must be fully justified and documented.

Applications must provide a narrative budget justification that describes how the categorical costs are derived and discuss the reasonableness and appropriateness of the proposed costs. Line item allocations and justifications are required for Federal funds.

Applicants have the option of omitting the Social Security Numbers and specific salary rates of the proposed project personnel from the two copies submitted with the original applications to ACF. For purposes of the outside review process, applicants may elect to summarize salary information on the copies of their application. All salary information must, however, appear on the signed original application for ACF.

The applicant must:

(1) Discuss and justify the costs of the proposed project which are reasonable and programmatically justified in view of the activities to be conducted and the anticipated results and benefits (3 points); and

(2) Describe the fiscal control and accounting procedures that will be used to ensure prudent use, proper disbursement, and accurate accounting of funds received under this program announcement (2 points).

Applicable Administrative Regulations

Applicable administrative regulations include 45 CFR part 74,—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments and 45 CFR part 92—Uniform Administrative Requirements

for Grants and Cooperative Agreements to State and Local Governments.

Part V. Instructions for the Development and Submission of Applications

This Part contains information and instructions for submitting applications in response to this announcement. Application forms and other materials can be obtained by any of the following methods: from Carla R. Brown, ADD, 370 L'Enfant Promenade SW., Washington, DC 20447. (202) 690-8332; <http://www.acf.dhhs.gov/programs/add/>; or from add@acf.dhhs.gov. Please copy and use these forms in submitting an application.

Potential applicants should read this section carefully in conjunction with the information contained in the program description in Part IV of this announcement.

A. Required Notification of the State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under this Order, States may design their own process for reviewing and commenting on proposed Federal assistance under covered programs. **Note:** State/Territory participation in the intergovernmental review process does not signify applicant eligibility for financial assistance under a program. A potential applicant must meet the eligibility requirements of the program for which it is applying prior to submitting an application to its single point of contact (SPOC), if applicable, or to ACF.

All States and Territories, except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington and Wyoming, have elected to participate in the Executive Order process and have established a State Single Point of Contact (SPOC). Applicants from these jurisdictions, or for projects administered by Federally recognized Indian Tribes, need not take any action regarding E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the potential applications and to receive any necessary instructions.

Applicants must submit all required materials to the SPOC as soon as possible. This will enable the program office to obtain and to review SPOC comments as part of the award process.

It is imperative that an applicant submits all required materials and indicate the date of the submittal (or date SPOC was contacted, if no submittal is required) on the SF 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application due date to comment on proposed new or competing continuation awards. These comments are reviewed as part of the award process. Failure to notify the SPOC can result in delays in awarding grants.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those Official State process recommendations that may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW., 8th Floor, Washington, DC 20447, Attn: 93.618. ADD—Training and Technical Assistance To Improve Voting Access for People with Disabilities.

Contact information for each State's SPOC is found at the ADD Web site (<http://www.acf.dhhs.gov/programs/add>) or by contacting Carla R. Brown, ADD, 370 L'Enfant Promenade SW., Washington, DC, 20447, (202) 690-8332.

B. Instructions for Preparing the Application and Completing Application Forms

The SF 424, SF 424A, SF 424A-Page 2 and Certifications/Assurances are contained in the application package that can be accessed as mentioned earlier in this announcement. *Please prepare your application in accordance with the following instructions:*

1. SF 424 Page 1, Application Cover Sheet

Please read the following instructions before completing the application cover sheet. An explanation of each item is included. Complete only the items specified.

Top of Page. Please indicate that you are applying for new or implementation funds.

Item 1. "Type of Submission"—Preprinted on the form.

Item 2. "Date Submitted" and *"Applicant Identifier"*—Date application is submitted to ACF and applicant's own internal control number, if applicable.

Item 3. "Date Received By State"—State use only (if applicable).

Item 4. "Date Received by Federal Agency"—Leave blank.

Item 5. "Applicant Information".
"Legal Name"—Enter the legal name of applicant organization. For applications developed jointly, enter the name of the lead organization only. There must be a single applicant for each application.

"Organizational Unit"—Enter the name of the primary unit within the applicant's organization that will actually carry out the project activity. Do not use the name of an individual as the applicant. If this is the same as the applicant organization, leave the organizational unit blank.

"Address"—Enter the complete address that the organization actually uses to receive mail, since this is the address to which all correspondence will be sent. Do not include both street address and P.O. Box number unless both must be used in mailing.

"Name and telephone number of the person to be contacted on matters involving this application (give area code)"—Enter the full name (including academic degree, if applicable) and telephone number of a person who can respond to questions about the application. This person should be accessible at the address given here and will receive all correspondence regarding the application.

Item 6. "Employer Identification Number (EIN)"—Enter the employer identification number of the applicant organization, as assigned by the Internal Revenue Service, including, if known, the Central Registry System suffix.

Item 7. "Type of Applicant"—Self-explanatory.

Item 8. "Type of Application"—Preprinted on the form.

Item 9. "Name of Federal Agency"—Preprinted on the form.

Item 10. "Catalog of Federal Domestic Assistance Number and Title"—Enter the Catalog of Federal Domestic Assistance (CFDA) number assigned to the program under which assistance is requested and its title.

Item 11. "Descriptive Title of Applicant's Project"—Enter the project title. The title is generally short and is descriptive of the project, not the priority area title.

Item 12. "Areas Affected by Project"—Enter the governmental unit where significant and meaningful impact could be observed. List only the largest unit or units affected, such as State, county, or city. If an entire unit is affected, list it rather than subunits.

Item 13. "Proposed Project"—Enter the desired start date for the project and projected completion date.

Item 14. "Congressional District of Applicant/Project"—Enter the number of the Congressional district where the applicant's principal office is located and the number of the Congressional district(s) where the project will be located. If Statewide, a multi-State effort, or nationwide, enter "00."

Item 15. Estimated Funding Levels.
In completing 15a through 15f, the dollar amounts entered should reflect, for a 12 month project period, the total amount requested.

Item 15a. Enter the amount of Federal funds requested in accordance with the preceding paragraph. This amount should be no greater than the maximum amount specified in the priority area description.

Items 15b-e. Enter the amount(s) of funds from non-Federal sources that will be contributed to the proposed project. Items b-e are considered cost sharing or "matching funds." The value of third party in-kind contributions should be included on appropriate lines as applicable. For more information regarding funding as well as exceptions to these rules, see Part III, Sections C and D.

Item 15f. Enter the estimated amount of program income, if any, expected to be generated from the proposed project. Do not add or subtract this amount from the total project amount entered under item 15g. Describe the nature, source and anticipated use of this program income in the Project Narrative Statement.

Item 15g. Enter the sum of items 15a-15e.

Item 16a. "Is Application Subject to Review By State Executive Order 12372 Process? Yes."—Enter the date the applicant contacted the SPOC regarding this application. Select the appropriate SPOC from the listing provided online at www.whitehouse.gov/omb/grants/spoc.html. The review of the application is at the discretion of the SPOC. The SPOC will verify the date noted on the application.

Item 16b. "Is Application Subject to Review By State Executive Order 12372 Process? No."—Check the appropriate box if the application is not covered by E.O. 12372 or if the program has not been selected by the State for review.

Item 17. "Is the Applicant Delinquent on any Federal Debt?"—Check the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include audit disallowances, loans and taxes.

Item 18. "To the best of my knowledge and belief, all data in this application/preapplication are true and correct. The document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded."—To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for signature of this application by this individual as the official representative must be on file in the applicant's office, and may be requested from the applicant.

Item 18a-c. "Typed Name of Authorized Representative, Title, Telephone Number"—Enter the name, title and telephone number of the authorized representative of the applicant organization.

Item 18d. "Signature of Authorized Representative"—Signature of the authorized representative named in Item 18a. At least one copy of the application must have an original signature. Use colored ink (not black) so that the original signature is easily identified.

Item 18e. "Date Signed"—Enter the date the application was signed by the authorized representative.

2. SF 424A—Budget Information—Non-Construction Programs

This is a form used by many Federal agencies. For this application, Sections A, B, C, E and F are to be completed. Section D does not need to be completed.

Sections A and B should include the Federal as well as the non-Federal funding for the proposed project covering (1) the total project period of 17 months or less or (2) the first year budget period, if the proposed project period exceeds 15 months.

Section A—Budget Summary. This section includes a summary of the budget. On line 5, enter total Federal costs in column (e) and total non-Federal costs (none for these projects), including third party in-kind contributions, but not program income, in column (f). Enter the total of (e) and (f) in column (g).

Section B—Budget Categories. This budget, which includes the Federal as well as non-Federal funding for the proposed project (none for these projects), covers the total project period of 12 months or less. It should relate to item 15g, total funding, on the SF 424. Under column (5), enter the total requirements for funds (Federal and non-Federal [none]) by object class category.

A separate budget justification should be included to fully explain and justify major items, as indicated below. The

types of information to be included in the justification are indicated under each category. For multiple year projects, it is desirable to provide this information for each year of the project. The budget justification should immediately follow the second page of the SF 424A.

Personnel—Line 6a. Enter the total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants; this should be included on line 6h, "Other."

Justification: Identify the principal investigator or project director, if known. Specify by title or name the percentage of time allocated to the project, the individual annual salaries, and the cost to the project (both Federal and non-Federal) of the organization's staff who will be working on the project.

Fringe Benefits—Line 6b. Enter the total costs of fringe benefits, unless treated as part of an approved indirect cost rate.

Justification: Provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Travel—6c. Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel or local transportation, which should be included on Line 6h, "Other."

Justification: Include the name(s) of traveler(s), total number of trips, destinations, length of stay, transportation costs and subsistence allowances.

Equipment—Line 6d. Enter the total costs of all equipment to be acquired by the project. For state and local governments, including Federally recognized Indian Tribes, "equipment" is tangible, non-expendable personal property having a useful life of more than one year and acquisition cost of \$5,000 or more per unit.

Justification: Equipment to be purchased with Federal funds must be justified. The equipment must be required to conduct the project, and the applicant organization or its subgrantees must not have the equipment or a reasonable facsimile available to the project. The justification also must contain plans for future use or disposal of the equipment after the project ends.

Supplies—Line 6e. Enter the total costs of all tangible expendable personal property (supplies) other than those included on Line 6d.

Justification: Specify general categories of supplies and their costs.

Contractual—Line 6f. Enter the total costs of all contracts, including (1) procurement contracts (except those

which belong on other lines such as equipment, supplies, etc.) and (2) contracts with secondary recipient organizations, including delegate agencies. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line. If the name of the contractor, scope of work, and estimated total costs are not available or have not been negotiated, include on Line 6h, "Other."

Justification: Attach a list of contractors, indicating the names of the organizations, the purposes of the contracts, and the estimated dollar amounts of the awards as part of the budget justification. Whenever the applicant/grantee intends to delegate part or the entire program to another agency, the applicant/grantee must complete this section (Section B, Budget Categories) for each delegate agency by agency title, along with the supporting information. The total cost of all such agencies will be part of the amount shown on Line 6f. Provide backup documentation identifying the name of contractor, purpose of contract, and major cost elements.

Construction—Line 6g. Not applicable. New construction is not allowable.

Other—Line 6h. Enter the total of all other costs. Where applicable, such costs may include, but are not limited to: Insurance; medical and dental costs; noncontractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); space and equipment rentals; printing and publication; computer use; training costs, including tuition and stipends; training service costs, including wage payments to individuals and supportive service payments; and staff development costs. Note that costs identified as "miscellaneous" and "honoraria" are not allowable.

Justification: Specify the costs included.

Total Direct Charges—Line 6i. Enter the total of Lines 6a through 6h.

Indirect Charges—6j. Enter the total amount of indirect charges (costs). If no indirect costs are requested, enter "none." Generally, this line should be used when the applicant (except local governments) has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency.

Local and State governments should enter the amount of indirect costs determined in accordance with DHHS requirements. When an indirect cost rate is requested, these costs are included in the indirect cost pool and

should not be charged again as direct costs to the grant.

In the case of training grants to other than State or local governments (as defined in title 45, Code of Federal Regulations, part 74), the Federal reimbursement of indirect costs will be limited to the lesser of the negotiated (or actual) indirect cost rate or 8 percent of the amount allowed for direct costs, exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

For training grant applications, the entry under line 6j should be the total indirect costs being charged to the project. The Federal share of indirect costs is calculated as shown above. The applicant's share is calculated as follows:

(a) Calculate total project indirect costs (a*) by applying the applicant's approved indirect cost rate to the total project (Federal and non-Federal) direct costs.

(b) Calculate the Federal share of indirect costs (b*) at 8 percent of the amount allowed for total project (Federal and non-Federal) direct costs exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

(c) Subtract (b*) from (a*). The remainder is what the applicant can claim as part of its matching cost contribution.

Justification: Enclose a copy of the indirect cost rate agreement. Applicants subject to the limitation on the Federal reimbursement of indirect costs for training grants should specify this.

Total—Line 6k. Enter the total amounts of lines 6i and 6j.

Program Income—Line 7. Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount.

Justification: Describe the nature, source, and anticipated use of program income in the Program Narrative Statement.

Section C—Non-Federal Resources.

This section summarizes the amounts of non-Federal resources that will be applied to the grant. Enter this information on line 12 entitled "Totals." In-kind contributions are defined in title 45 of the Code of Federal Regulations, Parts 74.51 and 92.24, as "property or services which benefit a grant-supported project or program and which are contributed by non-Federal third parties without charge to the grantee, the subgrantee, or a cost-type contractor under the grant or subgrant."

Justification: Describe third party in-kind contributions, if included.

Section D—Forecasted Cash Needs. Not applicable.

Section E—Budget Estimate of Federal Funds Needed for Balance of the Project. This section should only be completed if the total project period exceeds 17 months.

Totals—Line 20. For projects that will have more than one budget period, enter the estimated required Federal funds for the second budget period (months 13 through 24) under column "(b) First." If a third budget period will be necessary, enter the Federal funds needed for months 25 through 36 under "(c) Second." Columns (d) and (e) are not applicable in most instances, since ACF funding is almost always limited to a three-year maximum project period. They should remain blank.

Section F—Other Budget Information.

Direct Charges—Line 21. Not applicable.

Indirect Charges—Line 22. Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

3. Project Summary/Abstract

Clearly mark this separate page with the applicant name as shown in item 5 of the SF 424, the priority area number as shown at the top of the SF 424, and the title of the project as shown in item 11 of the SF 424. The summary description should not exceed 300 words. These 300 words become part of the computer database on each project.

Provide a summary description that accurately and concisely reflects the proposal. The summary should describe the objectives of the project, the approaches to be used and the expected outcomes. The description should also include a list of major products that will result from the proposed project, such as software packages, materials, management procedures, data collection instruments, training packages, or videos (please note that audiovisuals must be closed captioned and audio described). The project summary description, together with the information on the SF 424, will constitute the project "abstract." This is a major source of information about the proposed project and is usually the first part of the application that the reviewers read in evaluating the application.

4. Project Description

The Project Description is a very important part of an application. It should be clear, concise, and address the specific requirements mentioned

under the priority area description in Part IV. The narrative should also provide information concerning how the application meets the evaluation criteria, using the following headings:

- (a) *Objectives and Need for Assistance;*
- (b) *Results and Benefits Expected;*
- (c) *Approach;* and
- (d) *Organization Profile*
- (e) *Budget and Budget Justification*

The specific information to be included under each of these headings is described in Section E of Part III, General Instructions for the Uniform Project Description, and under Part IV, and Evaluation Criteria.

The narrative should be typed double-spaced on a single-side of an 8½" × 11" plain white paper, with 1" margins on all sides, using black print no smaller than 12 pitch or 12 point size. All pages of the narrative (including charts, references/footnotes, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with "Objectives and Need for Assistance" as page number one. Applicants should not submit reproductions of larger size paper, reduced to meet the size requirement.

The length of the application, including the application forms and all attachments, should not exceed 25 pages. This will be strictly enforced. A page is a single side of an 8½" × 11" sheet of paper. Applicants are requested not to send pamphlets, brochures or other printed material along with their application as these pose copying difficulties. These materials, if submitted, will not be included in the review process if they exceed the 25-page limit. Each page of the application will be counted to determine the total length.

5. Part V—Assurances/Certifications

Applicants must provide a certification concerning lobbying. Prior to receiving an award in excess of \$100,000, applicants should furnish an executed copy of the lobbying certification (approved by the Office of Management and Budget under control number 0348-0046). Applicants must sign and return the certification with their application.

Applicants must make the appropriate certification of their compliance with the Drug-Free Workplace Act of 1988. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must make the appropriate certification that they are not presently debarred, suspended or otherwise ineligible for the award. By signing and

submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicant must also understand that they will be held accountable for the smoking prohibition included within Pub. L. 103-227, Part C Environmental Tobacco Smoke (also known as the Pro-Children's Act of 1994). A copy of the Federal Register notice which implements the smoking prohibition is included with the forms. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application. Copies of these assurances/certifications can be obtained from the ADD Web site (<http://www.acf.dhhs.gov/programs/add>) or by contacting Carla R. Brown, ADD, 370 L'Enfant Promenade SW., Washington, DC 20447, (202) 690-8332. These forms can be reproduced, as necessary.

E. Checklist for a Complete Application

The checklist below is for your use to ensure that your application package has been properly prepared.

- One original, signed and dated application, plus two copies.
- Application is from an organization that is eligible under the eligibility requirements defined in Part IV under Program Description and Requirements.
- Application length does not exceed 25 pages, unless otherwise specified in the priority area description.
- A complete application consists of the following items in this order:
 - Application for Federal Assistance (SF 424, REV 4-92);
 - A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable.
 - Budget Information—Non-Construction Programs (SF 424A, REV 4-92);
 - Budget justification for Section B—Budget Categories;
 - Proof of designation as lead agency;
 - Table of Contents;
 - Letter from the Internal Revenue Service, etc. to prove non-profit status, if necessary;
 - Copy of the applicant's approved indirect cost rate agreement, if appropriate;
 - Project Description (See Part III, Section E);
 - Any appendices/attachments;
 - Assurances—Non-Construction Programs (Standard Form 424B, REV 4-92);
 - Certification Regarding Lobbying;
 - Certification of Protection of Human Subjects, if necessary; and

—Certification of the Pro-Children Act of 1994 (Environmental Tobacco Smoke), signature on the application represents certification.

F. The Application Package

Each application package must include an original and two copies of the complete application. Each copy should be stapled securely (front and back if necessary) in the upper left-hand corner. All pages of the narrative (including charts, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with page one. In order to facilitate handling, please do not use covers, binders or tabs. Do not include extraneous materials as attachments, such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

Applicants have the option of omitting from the application copies (not the original) of specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

Reporting Requirements

The Grantees are required to file the Financial Status Report (SF-269) semi-annually and the Program Performance Reports quarterly. Funds issued under these awards must be accounted for, and reported upon, separately from all other grant activities. The official receipt point for all reports and correspondence is the Grants Officer, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW., 8th Floor, Washington, DC 20447-0002, telephone: (202) 401-2344. An original and one copy of each report shall be submitted 30 days of the end of each reporting period directly to the Office of Grants Management.

A final Financial Status Report and Program Performance Report shall be due 90 days after the project expiration date or termination of Federal budget support.

G. Paperwork Reduction Act of 1995 (Pub. L. 104-13)

The Uniform Project Description information collection within this announcement is approved under the Uniform Project Description (0970-0139), Expiration Date 12/31/2003.

Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: July 25, 2003.

Patricia Morrissey,
Commissioner, Administration on
Developmental Disabilities.

[FR Doc. 03-19905 Filed 8-4-03; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N-0511]

Thomas Ronald Theodore; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarment Mr. Thomas Ronald Theodore from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Theodore was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and his opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Theodore failed to request a hearing. Mr. Theodore's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 5, 2003.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

On March 1, 2002, the U.S. District Court for the District of Massachusetts

entered judgment against Mr. Theodore for nine counts of mail fraud, Federal felony offenses under 18 U.S.C. 1341. Mr. Theodore devised a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses and representations. Mr. Theodore illegally arranged to ship an unapproved new drug identified as "LK-200" that had been manufactured in Woburn, MA, to the Bahamas, and then arranged to have the drug shipped from the Bahamas to pharmacists, physicians, and patients in the United States.

As a result of this conviction, FDA sent to Mr. Theodore by certified mail on December 17, 2002, a notice proposing to permanently debar Mr. Theodore from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. The proposal also offered Mr. Theodore an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) and (c)(2)(A)(ii) of the act (21 U.S.C. 335a(a)(2)(B) and (c)(2)(A)(ii)), that Mr. Theodore was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Theodore was provided 30 days to file objections and request a hearing. On January 3, 2003, FDA received from Mr. Theodore a response to the proposal to debar and notice of opportunity for hearing. Mr. Theodore did not request a hearing. Mr. Theodore argued that, although he was convicted of all felony counts, an appeal is pending. However, this argument fails under the applicability of conviction provision of section 306(l)(1)(A) of the act (21 U.S.C. 335a(l)(1)(A)). This law states that a person is considered to have been convicted of a criminal offense when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending. Therefore, Mr. Theodore's failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment. In the event that the convictions that served as the basis for Mr. Theodore's debarment are reversed on appeal, the order of debarment shall be withdrawn. (See section 306(d)(3)(B)(i) of the act (21 U.S.C. 335a(d)(3)(B)(i)).)

II. Findings and Order

Therefore, the Director, Center for Biologics Evaluation and Research, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), and under authority delegated to the Director (21

CFR 5.34(a)), finds that Mr. Theodore has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Theodore is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application. A drug product means a drug, including a biological product, subject to regulation under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Theodore, in any capacity, during Mr. Theodore's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Theodore, during his permanent debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, Mr. Theodore will be subject to civil money penalties (section 307(a)(7) of the act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Theodore during Mr. Theodore's permanent debarment.

Any application by Mr. Theodore for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2002N-0511 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in these submissions is governed by § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (§ 10.20(j)(1)).

Dated: July 23, 2003.

Mark Elengold,

Deputy Director for Operations, Center for Biologics Evaluation and Research.

[FR Doc. 03-19806 Filed 8-4-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P-0296]

Romano Cheese for Manufacturing Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kerry, Inc., Eau Galle Cheese Factory, and First District Association jointly to market test romano cheese for manufacturing that deviates from the U.S. standard of identity for romano cheese (21 CFR 133.183). The purpose of the temporary permit is to allow the co-applicants to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but not later than November 3, 2003.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued jointly to Kerry, Inc., 352 East Grand Ave., Beloit, WI 53511; Eau Galle Cheese Factory, N6765 State Hwy., Durand, WI 54736; and First District Association, 101 South Swift Ave., Litchfield, MN 55355.

The permit covers limited interstate marketing tests of products identified as "Romano cheese for manufacturing made from cow's milk." These products may deviate from the U.S. standard of identity for romano cheese (21 CFR 133.183) in two ways. First, the product is formulated using an enzyme technology that fully cures the cheese in 2 months rather than 5 months and, second, the product is intended only for further manufacturing into food ingredients. Except for these two deviations, the test product meets all the

requirements of the standard. The purpose of the temporary permit is to allow the co-applicants to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

The permit provides for the temporary marketing of a total of 9 million pounds (4.1 million kilograms) of the test product. The test product will be manufactured by Eau Galle Cheese Factory at N6765 State Hwy., Durand, WI 54736 and by First District Association at 101 South Swift Ave., Litchfield, MN 55355. The test product then will be shipped to Kerry, Inc., plants in Wisconsin and Minnesota, where it will be further manufactured into food ingredients. The food ingredients will be distributed by Kerry, Inc., throughout the United States. Each of the ingredients used in the test product must be declared on the labels of the test product as required by the applicable sections of 21 CFR part 101. The permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than November 3, 2003.

Dated: July 17, 2003.

Christine Taylor,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 03-19805 Filed 8-5-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD-

21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, e-mail at: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1 800-741-8138 (301-443-0572 in the Washington, DC area), code 12535. Please call the Information Line for up to date information on this meeting. Background materials for this meeting, when available, will be posted on the Web site 1 business day before the meeting at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

Agenda: The committee will discuss current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication errors resulting from look-alike and sound-alike names. This advisory committee meeting is in followup to FDA, Institute for Safe Medication Practices, and the Pharmaceutical Research and Manufacturers of America public meeting on the same subject, held on June 26, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 12, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-19807 Filed 8-4-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1991D-0425]

Guideline for the Clinical Evaluation of Analgesic Drugs; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled "Guideline for the Clinical Evaluation of Analgesic Drugs," which was issued on December 1, 1992. The guidance is outdated and no longer reflects FDA's current thinking on development of analgesic drugs. FDA is revising the guidance and will issue a draft for public comment in the future.

DATES: Comments on agency guidances are welcome at any time.

FOR FURTHER INFORMATION CONTACT:

Barbara J. Gould, Center for Drug Evaluation and Research (HFD-550), Food and Drug Administration, 5600 Rockville Pike, Rockville, MD 20850, 301-827-2504.

Dated: July 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-19802 Filed 8-4-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

New Annual "Low-Income" Levels for Various Health Professions and Nursing Programs Included in Titles VII and VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the new "low-income" levels for various programs included in titles VII and VIII of the Public Health Service (PHS) Act, which use the U.S. Census Bureau "low-

income" levels to determine eligibility for program participation. The Department periodically publishes in the **Federal Register** low-income levels used to determine eligibility for grants and cooperative agreements to institutions providing training for (1) disadvantaged individuals, (2) individuals from a disadvantaged background, or (3) individuals from "low-income" families.

SUPPLEMENTARY INFORMATION: This notice announces increase in income levels intended for use in determining eligibility for participation in the following programs:

- Advanced Education Nursing (section 811)
- Allied Health Special Projects (section 755)
- Nurse Education, Practice and Retention (section 831)
- Dental Public Health (section 768)
- Faculty Loan Repayment and Minority Faculty Fellowship Program (section 738)
- General and Pediatric Dentistry (section 747)
- Health Administration Traineeships and Special Projects (section 769)
- Health Careers Opportunity Program (section 739)
- Loans For Disadvantaged Students (section 724)
- Scholarships For Disadvantaged Students (section 737)
- Physician Assistant Training (section 747)
- Primary Care Residency Training (section 747)
- Public Health Traineeships (section 767)
- Quentin N. Burdick Program for Rural Interdisciplinary Training (section 754)
- Residency Training in Preventive Medicine (section 768)
- Public Health Training Centers (section 766)
- Nursing Workforce Diversity (section 821)

These programs generally award grants to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, chiropractic, public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

Low-Income Levels

The Department's poverty guidelines which were published in the **Federal Register** on Friday, February 7, 2003 (68 FR 6456), are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. HRSA is defining a "low-income family" as one with an annual income that is below 200 percent of the Department's poverty guidelines. The Secretary annually adjusts the low-income levels based on the Department's poverty guideline and makes them available to persons responsible for administering the applicable programs. The following income figures will be used for health professions and nursing grant programs funded in FY 2004.

Size of parent's family ¹	Income ² level
1	\$17,960
2	24,240
3	30,520
4	36,800
5	43,080
6	49,360
7	55,640
8	61,920

1. Includes only dependents on Federal income tax forms.

2. Adjusted gross income for calendar year 2002.

Dated: July 29, 2003.

Elizabeth M. Duke,
Administrator.

[FR Doc. 03-19799 Filed 8-4-03; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supporting Networks of HIV Care Project Cooperative Agreements (SNHC), Program Announcement HRSA 03-102, CFDA # 93.145B

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2003 Minority AIDS Initiative (MAI) funds allocated from the Department of Health and Human Services General Management Fund to continue the Supporting Networks of HIV Care (SNHC) Project. The total funding available for the SNHC Project is approximately \$2.3 million. HRSA will award two cooperative agreements

to two separate organizations to implement the SNHC Project in collaboration with the HRSA HIV/AIDS Bureau (HRSA/HAB). The purpose of this announcement is to request Letters of Intent to Apply and applications for these two cooperative agreements. HRSA is requesting Letters of Intent to Apply in order to estimate the number of applications it may receive and thereby plan appropriately for the timely award of these funds. Letters of Intent to Apply are not required to submit an application and they are not binding.

Background: The goal of the SNHC Project is to assist eligible organizations, including small to moderately sized non-profit organizations and faith- and community-based organizations (F/CBO), not currently directly funded by HRSA/HAB for HIV/AIDS service delivery in their efforts to develop, improve, and expand comprehensive HIV primary care, treatment and support service delivery in racial/ethnic minority communities most severely impacted by HIV/AIDS. For the purpose of this project, "communities" refer to both groups of people (*i.e.*, African Americans, substance abusers, men who have sex with men) and geographic areas (*i.e.*, Kansas City, MO; Navajo Territory; Appalachia). The term "severely impacted by HIV/AIDS" is defined as having HIV or AIDS incidence and prevalence rates above the national average within a particular group of people or geographic area. The desired outcome of the SNHC Project is to increase the availability, accessibility, and quality of HIV/AIDS-related services in communities most severely impacted by the disease.

Organizations funded to implement the SNHC Project will work with HRSA/HAB to achieve this goal and outcome by: (1) Identifying and outreaching to small to moderately sized non-profit organizations, including F/CBOs; (2) assessing each eligible organization's commitment and readiness to provide quality HIV primary care, treatment or support services to severely impacted communities; and (3) providing individualized long-term technical assistance designed to help each organization obtain the information, skills, and other resources needed to develop, improve or expand its infrastructure and capabilities. Organizations funded to implement the SNHC Project will respond to the needs of eligible organizations through the development and provision of on-site technical assistance, regional intensive skills building workshops, instructional documents, referrals to local

organizations providing similar assistance, and other resources.

Eligible organizations that will receive technical assistance and resources through the SNHC Project must: (1) Be small to moderately sized non-profit organizations, including F/CBOs in the United States and surrounding territories (does not include government or municipal agencies, such as health departments, schools, or public hospitals); (2) have a primary service delivery site that is physically located in or near a community whose residents at risk for or living with HIV are predominantly racial/ethnic minorities; (3) have at least a 3-year history of providing some primary health care or support service (e.g., HIV counseling and testing, substance abuse treatment, housing services, meals on wheels, clinical evaluation, spiritual counseling) to racial/ethnic minority residents in its surrounding community to demonstrate some initial organizational capacity for service delivery and a commitment to serving communities of color; (4) commit to accomplishing and reporting progress on the outcomes of the services received; (5) not be directly funded by the HRSA through the Ryan White CARE Act to provide primary health care or related support services; and (6) not have the financial resources (discretionary funding) to obtain this type of assistance independently.

HRSA will issue two cooperative agreements to two separate organizations to provide assistance and resources to eligible organizations. Funded organizations will work in collaboration with each other, HRSA/HAB staff, and other training, education and capacity building efforts. Specifically, the first cooperative agreement will serve as an *Assistance Coordinator* to: (1) identify and outreach to small to moderately sized non-profit organizations, including F/CBOs, in the United States and its surrounding territories; (2) review requests and select a number of eligible organizations to receive technical assistance; (3) arrange for assistance to be provided on-site through qualified staff, consultants, peers, mentors, or other local organizations; and (4) implement related activities. The second cooperative agreement will serve as a *Resource Coordinator* to: (1) Provide intensive regional skills building workshops and develop instructional materials addressing common challenges experienced by small to moderately sized non-profit organizations moving into HIV primary care service delivery; (2) identify, screen and make publicly available pertinent information on technical consultants with expertise in

HIV primary care programs; (3) collect and disseminate useful resources regarding HIV primary care service delivery; and (4) implement related activities.

To reduce the time and resources associated with project start-up, HRSA/HAB will encourage funded organizations to adopt and improve upon the outreach strategy, graphic elements, request for service materials, assessment protocols, information management systems, evaluation strategy and other items developed in the first year of the project. More information about the current activities SNHC Project is available at www.hivta.org.

Available Funding: The total amount available is \$2.3 million. It is estimated that approximately \$1.6 million to \$1.8 million will be available to support the Assistance Coordinator Cooperative Agreement, and that approximately \$500,000 to \$700,000 will be available to support the Resource Coordinator Cooperative Agreement. Awards will be made on or before September 29, 2003. Funding will be made available for 12 months, with a project period of up to three years. Funding levels will be determined annually during each year of the project period and are contingent upon the availability of funding and satisfactory performance. Funding for this project is provided through the Minority AIDS Initiative. Applicants are not required to match or share in project costs if an award is made. However, applicants must propose cost-effective and efficient plans to implement project activities with funds awarded.

Eligible Applicants: Statement of Eligibility for Minority AIDS Initiative Funds' Funding will be directed to activities designed to deliver services specifically targeting racial and ethnic minority populations impacted by HIV/AIDS. Applicants eligible to apply for the SNHC Project cooperative agreements include: not for profit community-based organizations, national organizations, colleges and universities, clinics and hospitals, research institutions, State and local government agencies and Tribal government and Tribal/urban Indian entities and organizations. Faith- and community-based organizations are eligible to apply for these cooperative agreements. This general statement is subject to program specific statutory and/or regulatory requirements.

Priority will be given to applicant organizations and their proposed project staff that have: (1) Experience working with small to moderately sized non-profit organizations, including F/CBOs, racial/ethnic minority-led organizations,

and organizations serving racial/ethnic minorities; (2) knowledge of the challenges faced by organizations providing care, treatment and support services to people living with HIV/AIDS; and (3) a commitment to addressing the needs of organizations that provide HIV-related services in communities severely impacted by HIV, as demonstrated by the applicant's organizational mission.

Organizations funded under the SNHC Project will be supported in the development of their own infrastructure and capabilities to continue similar work, consistent with their organizational mission, following the end of the of the project period.

Authorizing Legislation: The authority for these cooperative agreements is Title XXVI, Part F of the Public Health Service Act [Title 42, U.S.C., 300ff-111] as amended by Public Law 106-345, the Ryan White CARE Act Amendments of 2000, dated October 20, 2000.

Program Guidance & Application Kits: To prepare and submit an application, organizations must obtain: (1) The *Supporting Networks of HIV Care FY 2003 Project Guidance*—HRSA Program Announcement Number HRSA-03-102, Program Code SNHC, Catalogue of Federal Domestic Assistance (CFDA) # 93.145B; and (2) Federal grant application kit required for these cooperative agreements, Public Health Service (PHS) Form 5161-1. The Project Guidance is available on the HIV/AIDS Bureau Web site at the following Internet address: <http://www.hab.hrsa.gov/grant.htm>. The PHS Form 5161-1 is available at the following Internet address: <http://forms.psc.gov/forms/PHS-5161-1/phs-5161-1.html>. For those organizations who do not have access to the Internet, hard copies of the Project Guidance and PHS Form 5161-1 may be obtained from the HRSA Grants Application Center (GAC). You can reach the HRSA GAC toll-free by telephone: (877) 477-2123, fax: (877) 477-2345, or e-mail: hrsagac@hrsa.gov.

Letters of Intent To Apply Submission: Letters of Intent to Apply to this program should include the following information for the applicant: (1) The organization name and contact information, (2) a brief organizational capabilities statement, and (3) a brief description of the project model to be proposed. Letters of Intent to Apply should be mailed on or before August 20, 2003 to: Tanesha Burley, Public Health Analyst, HIV/AIDS Bureau, Parklawn Building Room 7-47, 5600 Fishers Lane, Rockville, MD 20857.

Application Submission: In order to be considered for competition,

applications to this cooperative agreement program must be received at the HRSA Grants Application Center by close of business on September 4, 2003. Applications shall be considered as meeting the deadline if they are: (1) Received on or before the deadline, or (2) postmarked on or before the deadline date and received in time for orderly processing. Private metered postmarks shall not be acceptable as proof of mailing. Applications received after the deadline will be returned to the applicant and not reviewed. Completed applications should be mailed or delivered to: HRSA Grants Management Center, Attn: Grants Management Officer, CFDA 93.145B, Program Announcement HRSA-03-102 (Code—SNHC), 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879. You will receive a Grant Application Receipt form from the HRSA Grants Application Center to confirm receipt of your application. You also can contact the center directly to confirm receipt.

For Additional Information: Additional information may be obtained from Tanesha Burley, HIV/AIDS Bureau, Parklawn Building Room 7-47, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443-4744, fax: (301) 594-2835, e-mail: tburley@hrsa.gov.

Paperwork Reduction Act: Should any data collection activities associated with the cooperative agreements fall under the purview of the Paperwork Reduction Act (PRA) of 1995, Office of Management and Budget (OMB) clearance will be sought.

Executive Order 12372: The Supporting Networks of HIV Care Project is not subject to Executive Order 12372—Intergovernmental Review of Federal Programs as implemented through 45 CFR, part 100. Executive Order 12372 allows States to review applications submitted to the Federal Government by organizations located in the State through a Singel Point of Contact (SPOC). For a list of States and Territories that participate in the SPOC review process, please go to the following Web site address: <http://www.whitehouse.gov/omb/grants/spoc.html>.

Dated: July 29, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03-19800 Filed 8-4-03; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its forty-fourth meeting:

Name: National Advisory Committee on Rural Health and Human Services
Dates and Times: September 7, 2003, 1 p.m.—5:30 p.m.; September 8, 2003, 8 a.m.—5 p.m.; September 9, 2003, 8 a.m.—10:30 a.m.

Place: Embassy Suites, 300 Court Street, Charleston, WV 25301, Telephone: 304-347-8700.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Sunday afternoon, September 7, at 1 p.m. the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. The first session will open with a discussion of the Committee business and a review of the 2004 workplan by the Honorable David Beasley and the Office of Rural Health Policy (ORHP) Acting Deputy Director, Mr. Tom Morris. This will be followed by a dialogue about the broad health and human services issues in West Virginia. The Committee will receive presentations on aging issues, oral health and the integration of primary care and behavioral health.

Monday morning, September 8, at 9 a.m., the Committee will break into Subcommittees and conduct site visits of local health and human services agencies. Transportation to these locations will not be provided to the public. The Committee will reconvene at 2 p.m. to discuss the site visits and draft the 2004 report.

The final session will be convened Tuesday morning, September 9, at 8 a.m. The Committee will review the site visits and the draft 2004 report. The meeting will conclude with a discussion of the February 2004 meeting. The meeting will be adjourned at 10:30 a.m.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding

the Committee should contact Tom Morris, MPA, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy, Telephone (301) 443-0835.

The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Dated: July 28, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03-19801 Filed 8-4-03; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219-9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 16C-17, Rockville, MD 20857; (301) 443-6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals

who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that the Secretary publish in the Federal Register a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 2, 2003, through March 31, 2003.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

(a) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by" one of the vaccines referred to in the Table, or

(b) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Table the first symptom or

manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading "For Further Information Contact"), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Office of Special Programs, 5600 Fishers Lane, Room 16C-17, Rockville, MD 20857. The Court's caption (*Petitioner's Name v. Secretary of Health and Human Services*) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Vincent L. Brown on behalf of Chance Michael V. Brown, Great Neck, New York, Court of Federal Claims Number 03-0001V
2. Kenneth W. Goss on behalf of Kendall L. Goss, Florence, South Carolina, Court of Federal Claims Number 03-0002V
3. Suzanne and Donald Jacques on behalf of Matthew Jacques, Altamont, New York, Court of Federal Claims Number 03-0003V
4. Cary Ann Bennett on behalf of Zachary Scraver, Houston, Texas, Court of Federal Claims Number 03-0004V
5. Carolyn and Marcelo Ferrari of Stefan Ferrari, Houston, Texas, Court of Federal Claims Number 03-0005V
6. Rebecca and Michael Hohe on behalf of Caroline Hohe, Houston, Texas, Court of Federal Claims Number 03-0006V
7. Ann and Keven Madsen on behalf of Nicholas Madsen, Houston, Texas, Court of Federal Claims Number 03-0007V
8. Rachel and Robert Ross on behalf of Benjamin Ross, Houston, Texas, Court of Federal Claims Number 03-0008V
9. Deborah and Charley West on behalf of Charley West, IV, Houston, Texas, Court of Federal Claims Number 03-0009V
10. Susan and James Wiles on behalf of Blake Wiles, Houston, Texas, Court of Federal Claims Number 03-0010V
11. Myra and Scott Robinson on behalf of William Robinson, Houston, Texas, Court of Federal Claims Number 03-0011V
12. Shawna and Rand Sarver on behalf of Ryan Sarver, Houston, Texas, Court of Federal Claims Number 03-0012V
13. Carmen Medina on behalf of Frank Mato, Phoenix, Arizona, Court of Federal Claims Number 03-0013V
14. Janice Thomas on behalf of Elijah Tavon Nathaniel Howell, New Albany, Mississippi, Court of Federal Claims Number 03-0014V
15. Denise Nason on behalf of Rachele Roxanne Nason, Massena, New York, Court of Federal Claims Number 03-0015V
16. Anita and William Anderson on behalf of Jack Dakota Anderson, Richmond, Virginia, Court of Federal Claims Number 03-0016V
17. Latonia Thomas on behalf of Brandon Thomas, Tyler, Texas, Court of Federal Claims Number 03-0017V
18. Christina Hess on behalf of William P. Hess, Jr., Schenectady, New York, Court of Federal Claims Number 03-0018V
19. Janeen Hollingsworth on behalf of Shakiem Hollingsworth, Monks Corner, South Carolina, Court of Federal Claims Number 03-0019V
20. Bambi Spooner and Shawn Price on behalf of Shawanna Price, Deceased, Lowell, Massachusetts, Court of Federal Claims Number 03-0020V
21. Lamekia Williams on behalf of Tevin James Williams, Tyler, Texas, Court of Federal Claims Number 03-0026V
22. Melanie and Michael Moore on behalf of Matthew Moore, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0027V
23. Michelle and Brandon Lyons on behalf of Brandon Lyons, Jr., Marrero, Louisiana, Court of Federal Claims Number 03-0028V
24. Mariece and Terry Metzger on behalf of Danielle Marie Metzger, Dallas, Texas, Court of Federal Claims Number 03-0029V
25. Pamela and Thomas Blake on behalf of William J. Blake, Baton Rouge, Louisiana, Court of Federal Claims Number 03-0031V
26. Josephine Gatto on behalf of Victoria Gatto, Tenafly, New Jersey, Court of Federal Claims Number 03-0032V
27. Crystal McClintock on behalf of Jonah Christopher Fox, Warren, Ohio, Court of Federal Claims Number 03-0033V
28. Theresa Stevens on behalf of Dalton Stevens, Berlin, New York, Court of Federal Claims Number 03-0034V
29. Martha and Stephen Andrews on behalf of Mackenzie Andrews, Schenectady, New York, Court of Federal Claims Number 03-0036V
30. Dorothy May on behalf of Williesia Williams, Houston, Texas, Court of Federal Claims Number 03-0039V
31. Dorothy May on behalf of Adrian Williams, Houston, Texas, Court of Federal Claims Number 03-0040V
32. Dorothy May on behalf of Devin Williams, Houston, Texas, Court of Federal Claims Number 03-0041V
33. Kimberly Smith on behalf of Tre'Shaud Smith, Houston, Texas, Court of Federal Claims Number 03-0042V
34. Emma Dawson on behalf of Sammie Peete, Houston, Texas, Court of Federal Claims Number 03-0043V
35. Carol Knox on behalf of Donovan Knox, Houston, Texas, Court of Federal Claims Number 03-0044V
36. Theresa Wilson on behalf of James Hicks, Houston, Texas, Court of Federal Claims Number 03-0045V
37. Rachel Harris on behalf of Douglas Harris, Houston, Texas, Court of Federal Claims Number 03-0046V

38. Torachel Craft on behalf of Alexis Craft, Houston, Texas, Court of Federal Claims Number 03-0047V
39. Laura and Calvin Willis on behalf of Jared Willis, Deatsville, Alabama, Court of Federal Claims Number 03-0048V
40. Kevin Dunphy on behalf of Yusuf Mustafa Dunphy, Great Neck, New York, Court of Federal Claims Number 03-0049V
41. Kelly Gatti on behalf of Philip Gatti, Jr., Centereach, New York, Court of Federal Claims Number 03-0050V
42. Kelly Gatti on behalf of Melissa Gatti, Centereach, New York, Court of Federal Claims Number 03-0051V
43. Angela A. Jones, Lubbock, Texas, Court of Federal Claims Number 03-0052V
44. Melanie Humphrey on behalf of Lee Humphrey, Dallas, Texas, Court of Federal Claims Number 03-0054V
45. Haven DeLay and Gerard Dziuba on behalf of Ethan Emerson Dragan Dziuba, Dallas, Texas, Court of Federal Claims Number 03-0055V
46. Cathy and Joseph Semens on behalf of Tyler Allen Semens, Dallas, Texas, Court of Federal Claims Number 03-0056V
47. Darlene M. Williams on behalf of Joshua D. Williams, Harrisburg, Pennsylvania, Court of Federal Claims Number 03-0057V
48. Linda C. Leavy on behalf of Jason P. Leavy, Harrisburg, Pennsylvania, Court of Federal Claims Number 03-0058V
49. Nery N. Ortiz-Mutilitis on behalf of Frankie Leigh Ann Mutilitis, Harrisburg, Pennsylvania, Court of Federal Claims Number 03-0059V
50. Monique and Luke Thometz on behalf of Tiffany Thometz, Deceased, Puyallup, Washington, Court of Federal Claims Number 03-0063V
51. Lori Abend on behalf of Michael Abend, Boston, Massachusetts, Court of Federal Claims Number 03-0064V
52. Lisa Lewis on behalf of Ethan Lewis, Boston, Massachusetts, Court of Federal Claims Number 03-0065V
53. Christine Bordi on behalf of Julea Bordi, Boston, Massachusetts, Court of Federal Claims Number 03-0066V
54. Monica Garcia on behalf of Odilon Murillo, Boston, Massachusetts, Court of Federal Claims Number 03-0067V
55. Sheila Ealey on behalf of Temple Ealey, Boston, Massachusetts, Court of Federal Claims Number 03-0068V
56. Kimberly Phillips on behalf of Erin Derieux, Boston, Massachusetts, Court of Federal Claims Number 03-0069V
57. Meredith Newnham on behalf of Allison Newnham, Boston, Massachusetts, Court of Federal Claims Number 03-0070V
58. Renee Compton on behalf of Lewis Aram Compton, Boston, Massachusetts, Court of Federal Claims Number 03-0071V
59. Michael Shepard on behalf of Jordan Shepard, Boston, Massachusetts, Court of Federal Claims Number 03-0072V
60. Georgia Mejias on behalf of Kelly Mejias, Boston, Massachusetts, Court of Federal Claims Number 03-0073V
61. Danielle Bates on behalf of Noelle Bates, Boston, Massachusetts, Court of Federal Claims Number 03-0074V
62. Donna Patterson on behalf of Mason Patterson, Boston, Massachusetts, Court of Federal Claims Number 03-0075V
63. Maria Villa on behalf of Cesar Javier Villa, Jr., Boston, Massachusetts, Court of Federal Claims Number 03-0076V
64. Sabbir Ahmed on behalf of Faraaz Ahmed, Boston, Massachusetts, Court of Federal Claims Number 03-0077V
65. Karol Hyland on behalf of Kory Deon Rollings, Chicago, Illinois, Court of Federal Claims Number 03-0078V
66. Larissa and Isaac Foster on behalf of Lacey Ann Foster, Chandler, Arizona, Court of Federal Claims Number 03-0079V
67. Alizabeth and Sultan Haddad on behalf of Kiyan Sultan Haddad, West Hills, California, Court of Federal Claims Number 03-0080V
68. Deidre Robinson on behalf of Tylor Herbert Robinson, Chicago, Illinois, Court of Federal Claims Number 03-0081V
69. Felicia and Harris Williams on behalf of Stephanie Renea Isom, Bensenville, Illinois, Court of Federal Claims Number 03-0082V
70. Marinka and Gregory Green on behalf of Scott Everett Green, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0085V
71. Sandra Adams, Irvine, California, Court of Federal Claims Number 03-0086V
72. Claudia Rodriguez on behalf of Mario Arturo Rodriguez, Kansas City, Missouri, Court of Federal Claims Number 03-0087V
73. Kathy and Jeffrey Greib on behalf of Travis Markel Greib, Dallas, Texas, Court of Federal Claims Number 03-0088V
74. Carmen and Craig Carley on behalf of Chloe Ann Carley, Dallas, Texas, Court of Federal Claims Number 03-0089V
75. Tonia and Gregory Wade on behalf of Kaliya Wade, Great Neck, New York, Court of Federal Claims Number 03-0093V
76. Diane and Frank Gagliardi on behalf of Amanda Gagliardi, Mount Kisco, New York, Court of Federal Claims Number 03-0094V
77. Carrie and Bradford Howard on behalf of Austyn Howard, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0095V
78. Barbara Paynter on behalf of Ian Paynter, Boston, Massachusetts, Court of Federal Claims Number 03-0096V
79. Nancy and John Gardella on behalf of Jonathan Alexander Gardella, New York, New York, Court of Federal Claims Number 03-0097V
80. Marcella Preble on behalf of Jakob Preble, Portland, Oregon, Court of Federal Claims Number 03-0098V
81. Kimberlee Sue Maelfeyt on behalf of Courtney Shriner, Portland, Oregon, Court of Federal Claims Number 03-0099V
82. Nancy Sitter on behalf of Paul Sitter, Portland, Oregon, Court of Federal Claims Number 03-0100V
83. Julia and Todd Simanski on behalf of Olivia Anne Simanski, Des Moines, Iowa, Court of Federal Claims Number 03-0103V
84. Sharon Bafetti on behalf of Connor Bafetti, Vienna, Virginia, Court of Federal Claims Number 03-0104V
85. John Brown on behalf of Chase Brown, Vienna, Virginia, Court of Federal Claims Number 03-0105V
86. Anna Duros on behalf of Andrew Duros, Vienna, Virginia, Court of Federal Claims Number 03-0106V
87. Stephanie Harzewski on behalf of Nicholas Harzewski, Vienna, Virginia, Court of Federal Claims Number 03-0107V
88. Pamela Parks and Paul Sandy on behalf of Trent Sandy, Vienna, Virginia, Court of Federal Claims Number 03-0108V
89. Holly Vanderdonck on behalf of Brooke Vanderdonck, Vienna, Virginia, Court of Federal Claims Number 03-0109V
90. Marie Louise and Terrence Augustine O'Grady on behalf of Timothy O'Grady, Richmond, Virginia, Court of Federal Claims Number 03-0111V
91. Stephanie and David Anderson on behalf of Jonathan Anderson, Suwanee, Georgia, Court of Federal Claims Number 03-0112V
92. Anne Wyman on behalf of Ryan Admirer-Wyman, Great Neck, New York, Court of Federal Claims Number 03-0113V
93. Robin and William Rickard on behalf of Michael Montgomery Rickard, Great Neck, New York, Court of Federal Claims Number 03-0114V
94. Elizabeth Pelletier on behalf of Jacob D. Pelletier, Portland, Oregon, Court of Federal Claims Number 03-0116V
95. Ronald Zemp on behalf of Casey Zemp, Portland, Oregon, Court of Federal Claims Number 03-0117V
96. Jennifer Worley on behalf of Samuel Linder, Portland, Oregon, Court of Federal Claims Number 03-0118V
97. James Holley on behalf of Michael Holley, Portland, Oregon, Court of Federal Claims Number 03-0119V
98. Joanne and Kevin McCarthy on behalf of Derek James McCarthy, Great Neck, New York, Court of Federal Claims Number 03-0120V
99. Lori and Chris Blount on behalf of Carrie K. Blount, Ridgeland, Mississippi, Court of Federal Claims Number 03-0121V
100. Allison and J. Michael Bertram on behalf of Andrew M. Bertram, Madison, Mississippi, Court of Federal Claims Number 03-0122V
101. Adele Livingston on behalf of Troy Livingston, Voorheesville, New York, Court of Federal Claims Number 03-0123V
102. Billie Jean Chalk on behalf of Christopher Chalk, Hamburg, Arkansas, Court of Federal Claims Number 03-0124V
103. Bonnie and Ted Calandra on behalf of Jesse A. Calandra, Madison, Mississippi, Court of Federal Claims Number 03-0125V
104. Susan and Dale Chukker on behalf of Lindsey M. Chukker, Melbourne, Florida, Court of Federal Claims Number 03-0126V
105. Susan and August Tomelleri on behalf of Jack A. Tomelleri, Kansas City, Missouri, Court of Federal Claims Number 03-0127V
106. Annie and Samuel Roberson on behalf of Travian Leander Roberson, Great Neck, New York, Court of Federal Claims Number 03-0128V
107. Rebecca and Jeffrey Brooks on behalf of Dawson Jeffrey Brooks, Great Neck, New York, Court of Federal Claims Number 03-0129V
108. Shilah and Jason Gould on behalf of Maisie Gould, Great Neck, New York, Court of Federal Claims Number 03-0130V
109. Adrienne Foster and Anthony Papandrea on behalf of Alyssa M. Papandrea, Great Neck, New York, Court of Federal Claims Number 03-0131V

110. Angelle and Anthony Comstock on behalf of Jack Comstock, Great Neck, New York, Court of Federal Claims Number 03-0132V
111. Brenda and Douglas Barnes on behalf of Virginia L. Barnes, Melbourne, Florida, Court of Federal Claims Number 03-0133V
112. Shelly and David Sulkoske on behalf of Nicholas A. Sulkoske, Canton, Georgia, Court of Federal Claims Number 03-0134V
113. Holly and Matt Hoskins on behalf of Sarah Hoskins, Melbourne, Florida, Court of Federal Claims Number 03-0135V
114. Elizabeth and G. Davis Peterson on behalf of Anne Wilson Peterson, Jackson, Mississippi, Court of Federal Claims Number 03-0136V
115. Myrna and Serge Mothee on behalf of Dwayne Mothee, Houston, Texas, Court of Federal Claims Number 03-0137V
116. Teresa and Mark Light on behalf of Romie Light, Houston, Texas, Court of Federal Claims Number 03-0138V
117. Carla and Joseph Manlapaz on behalf of Isabella Manlapaz, Houston, Texas, Court of Federal Claims Number 03-0139V
118. Julie Landon on behalf of Noah Landon, Houston, Texas, Court of Federal Claims Number 03-0140V
119. Elizabeth and Michael Morabito on behalf of Grant Morabito, Houston, Texas, Court of Federal Claims Number 03-0141V
120. Eileen and Lee Green on behalf of Evan Green, Houston, Texas, Court of Federal Claims Number 03-0142V
121. Eileen and Lee Green on behalf of Brooke Green, Houston, Texas, Court of Federal Claims Number 03-0143V
122. Lisa and Noah Leask on behalf of Brianna Leask, Houston, Texas, Court of Federal Claims Number 03-0144V
123. Shannon and Steven Johnson on behalf of Steven W. Johnson, Houston, Texas, Court of Federal Claims Number 03-0145V
124. Ellen Sweeney on behalf of Nicholas Sweeney, Houston, Texas, Court of Federal Claims Number 03-0146V
125. Nikki Belville on behalf of Tyler Belville, Summerville, South Carolina, Court of Federal Claims Number 03-0147V
126. Steven Thomason on behalf of Sabrina Thomason, Boston, Massachusetts, Court of Federal Claims Number 03-0148V
127. Laura Kiepert on behalf of Shaelyn Kiepert, Boston, Massachusetts, Court of Federal Claims Number 03-0149V
128. Melea Enzweiler on behalf of Luke Enzweiler, Boston, Massachusetts, Court of Federal Claims Number 03-0150V
129. Joan Rossi on behalf of Michaela Rossi, Boston, Massachusetts, Court of Federal Claims Number 03-0151V
130. Rita Whitney on behalf of Max Whitney, Boston, Massachusetts, Court of Federal Claims Number 03-0152V
131. Audrey Morrison on behalf of Enmitt Scott, Boston, Massachusetts, Court of Federal Claims Number 03-0153V
132. Cynthia Montgomery on behalf of Paul Montgomery, Boston, Massachusetts, Court of Federal Claims Number 03-0154V
133. Heather Nield on behalf of Karen Nield, Boston, Massachusetts, Court of Federal Claims Number 03-0155V
134. Jennifer Brehl on behalf of Elizabeth Brehl, Boston, Massachusetts, Court of Federal Claims Number 03-0156V
135. Karen Shuster on behalf of Glen Schuster, Boston, Massachusetts, Court of Federal Claims Number 03-0157V
136. Christina Porterfield on behalf of John Porterfield, Boston, Massachusetts, Court of Federal Claims Number 03-0158V
137. Jana Nebel on behalf of Cody Nebel, Boston, Massachusetts, Court of Federal Claims Number 03-0159V
138. Janelle Weaver on behalf of Liam Weaver, Boston, Massachusetts, Court of Federal Claims Number 03-0160V
139. Christine Miller on behalf of Jared Miller, Boston, Massachusetts, Court of Federal Claims Number 03-0161V
140. Jamie Brown on behalf of Preston Brown, Boston, Massachusetts, Court of Federal Claims Number 03-0162V
141. Pamela Beachum on behalf of Meshach Beachum, Boston, Massachusetts, Court of Federal Claims Number 03-0163V
142. Ronald Ostrow on behalf of John Ostrow, Boston, Massachusetts, Court of Federal Claims Number 03-0164V
143. Kelly Ratterree on behalf of Jordan Ratterree, Boston, Massachusetts, Court of Federal Claims Number 03-0165V
144. Tracy Snow on behalf of Kaitlyn Snow, Boston, Massachusetts, Court of Federal Claims Number 03-0166V
145. Cynthia Letsche on behalf of Jonathan Letsche, Boston, Massachusetts, Court of Federal Claims Number 03-0167V
146. Leighanne Collier on behalf of Ethan Collier, Boston, Massachusetts, Court of Federal Claims Number 03-0168V
147. Michele Sperduto on behalf of Michael Anthony Sperduto, Boston, Massachusetts, Court of Federal Claims Number 03-0169V
148. Carrie McDow on behalf of Autumn Skye Gardner, Anaheim, California, Court of Federal Claims Number 03-0170V
149. Wanda and Harold Shelton on behalf of Ryan Bradley Shelton, Birmingham, Alabama, Court of Federal Claims Number 03-0171V
150. Linda and Wayne Hollman on behalf of Madison Marie Hollman, Torrance, California, Court of Federal Claims Number 03-0172V
151. Ann and Gabriel Segovia on behalf of Gabriel James Segovia, Aransas Pass, Texas, Court of Federal Claims Number 03-0173V
152. Lynne and Steven Violett on behalf of Maxwell William Violett, Shakopee, Minnesota, Court of Federal Claims Number 03-0174V
153. Angel and Dereck Orihuela on behalf of Michael Anthony Dereck Orihuela, Houston, Texas, Court of Federal Claims Number 03-0175V
154. Julia Hornback on behalf of Kristi Hornback, Boston, Massachusetts, Court of Federal Claims Number 03-0179V
155. Michael Cox on behalf of Tyler Cox, Glenmont, New York, Court of Federal Claims Number 03-0180V
156. Jeffrey Van Horn on behalf of Logan Van Horn, Boston, Massachusetts, Court of Federal Claims Number 03-0181V
157. Shirley Nettles on behalf of William Nettles, Boston, Massachusetts, Court of Federal Claims Number 03-0182V
158. Vistoria Cronin on behalf of Christopher Cronin, Boston, Massachusetts, Court of Federal Claims Number 03-0183V
159. Sarah Ojo on behalf of Eli Ojo, Boston, Massachusetts, Court of Federal Claims Number 03-0184V
160. Kristen Cerenzia on behalf of Blake Cerenzia, Boston, Massachusetts, Court of Federal Claims Number 03-0185V
161. Jennifer Black on behalf of Hayden Black, Boston, Massachusetts, Court of Federal Claims Number 03-0186V
162. Janet Sheehan on behalf of Paul Sheehan, Boston, Massachusetts, Court of Federal Claims Number 03-0187V
163. Jennifer and Dan Hoffiz on behalf of Steven Hoffiz, Boston, Massachusetts, Court of Federal Claims Number 03-0188V
164. Laura and Stephen Pyburn on behalf of Bailey Pyburn, Dallas, Texas, Court of Federal Claims Number 03-0189V
165. Jeannine and Joseph Weiss on behalf of Christopher Weiss, Boca Raton, Florida, Court of Federal Claims Number 03-0190V
166. Laura Simonette on behalf of Michael Castellano, New York, New York, Court of Federal Claims Number 03-0194V
167. Carrie and Joseph Costa on behalf of Rebecca Costa, New York, New York, Court of Federal Claims Number 03-0195V
168. Phuong and Joseph O'Connor on behalf of Michael O'Connor, New York, New York, Court of Federal Claims Number 03-0196V
169. Jessica and Kevin Ellicott on behalf of Samuel Ellicott, New York, New York, Court of Federal Claims Number 03-0197V
170. Christine and Richard Van Dyke on behalf of Wyatt Van Dyke, Melbourne, Florida, Court of Federal Claims Number 03-0198V
171. Denise Minicozzi on behalf of Michael Walker, East Stroudsburg, Pennsylvania, Court of Federal Claims Number 03-0201V
172. Michelle and Peter Hill on behalf of Hamish Samuel McGregor, Dallas, Texas, Court of Federal Claims Number 03-0202V
173. Billie Dawn and Kyle Hightower on behalf of Cayde Wayne Hightower, Dallas, Texas, Court of Federal Claims Number 03-0203V
174. Marilyn Martinez on behalf of Benjamin Christian Figueroa, Dallas, Texas, Court of Federal Claims Number 03-0204V
175. Jessie O'Keefe on behalf of Molly O'Keefe, Deceased, Boston, Massachusetts, Court of Federal Claims Number 03-0205V
176. Gianna and Kim Carusillo on behalf of Mark Carusillo, Marlton, New Jersey, Court of Federal Claims Number 03-0206V
177. Barbara and Mark Epting on behalf of Nicholas Epting, Fonda, New York, Court of Federal Claims Number 03-0207V
178. Donald Hosler on behalf of Dominic Hosler, Boston, Massachusetts, Court of Federal Claims Number 03-0208V
179. Genett and Nathan Reed on behalf of Adam Reed, Dallas, Texas, Court of Federal Claims Number 03-0209V
180. Rudy Schutter on behalf of Jessica Schutter, Miami, Florida, Court of Federal Claims Number 03-0210V
181. Brandi and Jason Brown on behalf of Dugan Scott Brown, Tulsa, Oklahoma, Court of Federal Claims Number 03-0211V
182. Gabrielle and Thornton Floyd on behalf of Tino-Thornton Floyd, III, Ellicott City, Maryland, Court of Federal Claims Number 03-0212

183. Chandra Clark on behalf of Christopher Williams, Alexandria, Louisiana, Court of Federal Claims Number 03-0213V
184. Victoria and George Mead on behalf of William P. Mead, Portland, Oregon, Court of Federal Claims Number 03-0215V
185. Myrsa Montoya on behalf of Austin Brown, Portland, Oregon, Court of Federal Claims Number 03-0216V
186. Sheila Hadden on behalf of Abbey A. Carter, Portland, Oregon, Court of Federal Claims Number 03-0217V
187. Sherry and Ryan Haake on behalf of Chris Haake, Schenectady, New York, Court of Federal Claims Number 03-0218V
188. Te-Lin Huang on behalf of Kevin James Huang, Watervliet, New York, Court of Federal Claims Number 03-0219V
189. Pamela and Gabriel Karathomas on behalf of George Karathomas, Rexford, New York, Court of Federal Claims Number 03-0220V
190. Greer and Ernest Anderson on behalf of Gaston McKinley Julius Anderson, Stone Mountain, Georgia, Court of Federal Claims Number 03-0221V
191. Karen and Robert Kolacinski on behalf of Bailey Kolacinski, Vienna, Virginia, Court of Federal Claims Number 03-0222V
192. Jason Wang on behalf of Eric Wang, Boston, Massachusetts, Court of Federal Claims Number 03-0223V
193. Lori Custer on behalf of Dustin Custer, Boston, Massachusetts, Court of Federal Claims Number 03-0224V
194. Kara Travis on behalf of Colton James Travis, Boston, Massachusetts, Court of Federal Claims Number 03-0225V
195. Andrea Mays on behalf of Justin Mays, Boston, Massachusetts, Court of Federal Claims Number 03-0226V
196. James Stimpl on behalf of Michael Stimpl, Boston, Massachusetts, Court of Federal Claims Number 03-0227V
197. Melinda Robson on behalf of Blake Robson, Boston, Massachusetts, Court of Federal Claims Number 03-0228V
198. Betty Mingo on behalf of Derrien Mingo, Boston, Massachusetts, Court of Federal Claims Number 03-0229V
199. Raymond Laspada on behalf of Bianca Laspada, Boston, Massachusetts, Court of Federal Claims Number 03-0230V
200. Curtis Winn on behalf of Chase Winn, Boston, Massachusetts, Court of Federal Claims Number 03-0231V
201. Nassiby Carter-Desjardins on behalf of Danielle Desjardins, Boston, Massachusetts, Court of Federal Claims Number 03-0232V
202. Kathleen Skotnicki on behalf of Nathan Skotnicki, Boston, Massachusetts, Court of Federal Claims Number 03-0233V
203. Kathleen Stapleford on behalf of Devon Stapleford, Boston, Massachusetts, Court of Federal Claims Number 03-0234V
204. Cynthia Cano on behalf of Isaac Cano, Boston, Massachusetts, Court of Federal Claims Number 03-0235V
205. Maryanne Nugent on behalf of Andrew Nugent, Boston, Massachusetts, Court of Federal Claims Number 03-0236V
206. Laura Craig on behalf of Christian Cook, Boston, Massachusetts, Court of Federal Claims Number 03-0237V
207. Jennifer Kinne on behalf of Isaac Kinne, Boston, Massachusetts, Court of Federal Claims Number 03-0238V
208. Barbara and Franklin Bollettieri on behalf of Spencer Bollettieri, New York, New York, Court of Federal Claims Number 03-0239V
209. Elayne Carnegie on behalf of Ryan Scanlon, New York, New York, Court of Federal Claims Number 03-0240V
210. Shahran and Soosan Amiri on behalf of Mehrob Som Amiri, Melbourne, Florida, Court of Federal Claims Number 03-0241V
211. Shahran and Soosan Amiri on behalf of Shahzad Amiri, Melbourne, Florida, Court of Federal Claims Number 03-0242V
212. Kim and Dean Falsey on behalf of Chelsea Falsey, Miami, Florida, Court of Federal Claims Number 03-0243V
213. Paula and Ivor Levy on behalf of Matthew Levy, Miami, Florida, Court of Federal Claims Number 03-0244V
214. Kelly Johnson on behalf of Olivia Johnson, Boston, Massachusetts, Court of Federal Claims Number 03-0246V
215. Stacy and John Tollefson on behalf of Dakota Tollefson, Great Neck, New York, Court of Federal Claims Number 03-0247V
216. Toni and Pat Webb on behalf of Patrick Avery Webb, Dallas, Texas, Court of Federal Claims Number 03-0248V
217. Shannon Peoples on behalf of Stefvon L. Thomas, Dallas, Texas, Court of Federal Claims Number 03-0249V
218. Mary and Scott Finke on behalf of Nathaniel J. Finke, Melbourne, Florida, Court of Federal Claims Number 03-0250V
219. Cindy L. Wyant, Illiamna, Arkansas, Court of Federal Claims Number 03-0251V
220. Natasha Oligario on behalf of Elijah Carroll, Boston, Massachusetts, Court of Federal Claims Number 03-0253V
221. Shannon Taylor on behalf of Kaitlyn Taylor, Boston, Massachusetts, Court of Federal Claims Number 03-0254V
222. Lisa Courey on behalf of Michael Courey, Boston, Massachusetts, Court of Federal Claims Number 03-0255V
223. Dawn Moriarty on behalf of Matthew Moriarty, Boston, Massachusetts, Court of Federal Claims Number 03-0256V
224. Dawn Moriarty on behalf of Timothy Moriarty, Boston, Massachusetts, Court of Federal Claims Number 03-0257V
225. Assad Wahdat on behalf of Meelad Wahdat, Boston, Massachusetts, Court of Federal Claims Number 03-0258V
226. Kelli Lysz on behalf of Alexander Lysz, Boston, Massachusetts, Court of Federal Claims Number 03-0259V
227. Katrina Blanchard on behalf of Mackenzie Blanchard, Boston, Massachusetts, Court of Federal Claims Number 03-0260V
228. Shree and James Catapano on behalf of Allan Frazier Catapano, Dallas, Texas, Court of Federal Claims Number 03-0261V
229. Jill and Gonzalo Martinez on behalf of Sanitago Martinez, Dallas, Texas, Court of Federal Claims Number 03-0262V
230. Cherise and Walter Adams on behalf of Kayla Adams, Chicago, Illinois, Court of Federal Claims Number 03-0263V
231. Kelly Strzalkowski on behalf of Matthew Strzalkowski, Boston, Massachusetts, Court of Federal Claims Number 03-0266V
232. Staci and Michael Weaver on behalf of Joshua Weaver, Jacksonville, Florida, Court of Federal Claims Number 03-0267V
233. Joyce and Patrick Melker on behalf of Alexander Patrick Howard Melker, Fall River, Massachusetts, Court of Federal Claims Number 03-0268V
234. Sara and Christopher Bowen on behalf of Evan Christopher Bowen, Phoenix, Arizona, Court of Federal Claims Number 03-0269V
235. Elpida and Harry Karas on behalf of Paul Anthony Karas, Elgin, Illinois, Court of Federal Claims Number 03-0270V
236. Dawn Miller on behalf of Benjamin Miller, Glenmont, New York, Court of Federal Claims Number 03-0274V
237. Debora DelValle on behalf of Joshua N. DelValle, Tampa, Florida, Court of Federal Claims Number 03-0275V
238. Cecilia and Issac Lemon on behalf of Drake Issac Lemon, Houston, Texas, Court of Federal Claims Number 03-0276V
239. Debra and Raymond Ricci on behalf of Alexander James Ricci, Houston, Texas, Court of Federal Claims Number 03-0277V
240. Tammie Jenkins on behalf of Jeremiah James Jenkins, Houston, Texas, Court of Federal Claims Number 03-0278V
241. Barbara and Christopher Schmelzer on behalf of Samuel Schmelzer, Houston, Texas, Court of Federal Claims Number 03-0279V
242. Farida and Adib Yousofi on behalf of David Masseullah Yousofi, Houston, Texas, Court of Federal Claims Number 03-0280V
243. Misty and Jay Work on behalf of Anthony James Work, Dickson, Tennessee, Court of Federal Claims Number 03-0281V
244. Shannon Dennison and Darin Washington on behalf of Derron Ebon Washington, Bel Air, Maryland, Court of Federal Claims Number 03-0282V
245. Jami and Christopher Nelson on behalf of River Gene White, Denton, Texas, Court of Federal Claims Number 03-0283V
246. Maria and Garry Lund on behalf of Kyle Christopher Lund, Dallas, Texas, Court of Federal Claims Number 03-0284V
247. Amy and William Talley on behalf of Harrison Talley, Miami, Florida, Court of Federal Claims Number 03-0285V
248. Denise and John Gormley on behalf of Matthew Gormley, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0286V
249. Cindy and John Barkowski on behalf of John R. Barkowski, Schenectady, New York, Court of Federal Claims Number 03-0292V
250. Lisa and Todd Lippincott on behalf of Kevin Lippincott, New York, New York, Court of Federal Claims Number 03-0293V
251. Douglas White on behalf of Austin James White, Cape Girardeau, Missouri, Court of Federal Claims Number 03-0294V
252. Tonya L. Jarvis, Washington, DC, Court of Federal Claims Number 03-0295V
253. Debbie and Sam Schwartz on behalf of Haley Elizabeth Schwartz, Salisbury, North Carolina, Court of Federal Claims Number 03-0297V
254. James Bates on behalf of Jacob Bates, Tyler, Texas, Court of Federal Claims Number 03-0298V
255. Laura and Michael Brosfosky on behalf of Grace Brosfosky, Lawrenceville, Ga

- Georgia, Court of Federal Claims Number 03-0299V
256. Allison and James Gozzo on behalf of Isabella Gozzo, New York, New York, Court of Federal Claims Number 03-0300V
257. Robyn and Kevin Carter on behalf of Avery Quinn Carter, Florence, Alabama, Court of Federal Claims Number 03-0301V
258. Laurie Colabelli on behalf of Zachary W. Kilmer, Rensselaer, New York, Court of Federal Claims Number 03-0302V
259. Desiree and Troy Feliciano on behalf of Isaiah Feliciano, New York, New York, Court of Federal Claims Number 03-0303V
260. Christine and Thomas Prendergast on behalf of Dylan Prendergast, New York, New York, Court of Federal Claims Number 03-0304V
261. Ruth McCommon, Peachtree City, Georgia, Court of Federal Claims Number 03-0305V
262. Valerie and William Boergesson on behalf of Alexander Boergesson, Houston, Texas, Court of Federal Claims Number 03-0307V
263. Susan and Peter Pruyn on behalf of Thomas Pruyn, Houston, Texas, Court of Federal Claims Number 03-0308V
264. Ursula and John Zettlemoyer on behalf of Melanie Zettlemoyer, Houston, Texas, Court of Federal Claims Number 03-0309V
265. Cheryl and Clifford Bost on behalf of Roy Bost, Houston, Texas, Court of Federal Claims Number 03-0310V
266. Brenda and Bill Shepard on behalf of Gage Shepard, Houston, Texas, Court of Federal Claims Number 03-0311V
267. Judith and Kevan Braun on behalf of Kevin Braun, Houston, Texas, Court of Federal Claims Number 03-0312V
268. Melinda and Michael Hanna on behalf of Heather Hanna, Houston, Texas, Court of Federal Claims Number 03-0313V
269. Susan and Peter Pruyn on behalf of Samuel Pruyn, Houston, Texas, Court of Federal Claims Number 03-0314V
270. Donna and Douglas Bernard on behalf of Matthew Bernard, Houston, Texas, Court of Federal Claims Number 03-0315V
271. Lisa and Patrick Wayman on behalf of Noah Wayman, Houston, Texas, Court of Federal Claims Number 03-0316V
272. Alecia and Steven Schaller on behalf of Asher N. Travilian, Houston, Texas, Court of Federal Claims Number 03-0317V
273. Nancy and Lawrence Munoz on behalf of Nicholas Munoz, Alexandria, Virginia, Court of Federal Claims Number 03-0318V
274. Kristy Bergo on behalf of Kyle Bergo, Boston, Massachusetts, Court of Federal Claims Number 03-0319V
275. Teresa Tucker on behalf of Cameron Tucker, Boston, Massachusetts, Court of Federal Claims Number 03-0320V
276. Brenda Clark on behalf of Mason Clark, Boston, Massachusetts, Court of Federal Claims Number 03-0321V
277. Tanya Dethouars-Cosgrove on behalf of Kyle Cosgrove, Boston, Massachusetts, Court of Federal Claims Number 03-0322V
278. Christina Snow on behalf of Tamara Snow, Boston, Massachusetts, Court of Federal Claims Number 03-0323V
279. Sylvia Deanda on behalf of John Deanda, Boston, Massachusetts, Court of Federal Claims Number 03-0324V
280. Cheryl Lloyd on behalf of Aliyah Lloyd, Boston, Massachusetts, Court of Federal Claims Number 03-0325V
281. Leah Skinner on behalf of Shane Skinner, Boston, Massachusetts, Court of Federal Claims Number 03-0326V
282. Robyn Crompton on behalf of Hunter Crompton, Boston, Massachusetts, Court of Federal Claims Number 03-0327V
283. Tina Marascia on behalf of Robert Lewis, III, Boston, Massachusetts, Court of Federal Claims Number 03-0328V
284. Denise Ogle on behalf of Chance Ogle, Boston, Massachusetts, Court of Federal Claims Number 03-0329V
285. Nadine Winters on behalf of Charles Winters, Boston, Massachusetts, Court of Federal Claims Number 03-0330V
286. Carolann Zielinski on behalf of Michael Zielinski, Boston, Massachusetts, Court of Federal Claims Number 03-0331V
287. Susan Tellechea on behalf of Daniel Loney, Boston, Massachusetts, Court of Federal Claims Number 03-0332V
288. Shirley Baker on behalf of Caitlin Baker, Boston, Massachusetts, Court of Federal Claims Number 03-0333V
289. Kimberly Robinson on behalf of Hunter Robinson, Boston, Massachusetts, Court of Federal Claims Number 03-0334V
290. Richard Rex on behalf of Michael Rex, Boston, Massachusetts, Court of Federal Claims Number 03-0335V
291. Sonya Quaterman on behalf of De'Andre Quaterman, Boston, Massachusetts, Court of Federal Claims Number 03-0336V
292. Christina McDermott on behalf of Jacob Brown, Boston, Massachusetts, Court of Federal Claims Number 03-0337V
293. Dana Schoenfeld on behalf of Hunter Schoenfeld, Boston, Massachusetts, Court of Federal Claims Number 03-0338V
294. Tina Martin on behalf of Alexander Bonds, Boston, Massachusetts, Court of Federal Claims Number 03-0339V
295. Tara Rhetta on behalf of Ryan Rhetta, Boston, Massachusetts, Court of Federal Claims Number 03-0341V
296. Corey Williams on behalf of Victoria Williams, Boston, Massachusetts, Court of Federal Claims Number 03-0342V
297. Gina and Michael Giordano on behalf of Michael Giordano, New York, New York, Court of Federal Claims Number 03-0343V
298. Selena and James Yagey on behalf of Alec James Yagey, Melbourne, Florida, Court of Federal Claims Number 03-0344V
299. Brooke and Timothy Schwab on behalf of Atlee Schwab, Baltimore, Maryland, Court of Federal Claims Number 03-0345V
300. Wendy and Alan Tucker on behalf of Matthew Tucker, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0346V
301. Tammi Perricci Pinkley on behalf of Devin Perricci, Baltimore, Maryland, Court of Federal Claims Number 03-0347V
302. Angela and Scott Finet on behalf of Eric Shaw Finet, Vienna, Virginia, Court of Federal Claims Number 03-0348V
303. Nicole Shaffer, Meadville, Pennsylvania, Court of Federal Claims Number 03-0349V
304. Madeline Wilk, Vienna, Virginia, Court of Federal Claims Number 03-0350V
305. Howard Gordon on behalf of Elijah Gordon, Vienna, Virginia, Court of Federal Claims Number 03-0351V
306. Sharon Faulk on behalf of Ryan E. Faulk, Melbourne, Florida, Court of Federal Claims Number 03-0353V
307. Sharon Faulk on behalf of Andrew L. Faulk, Melbourne, Florida, Court of Federal Claims Number 03-0354V
308. Ramona and Peter Loutos on behalf of Peter A. Loutos, II, Melbourne, Florida, Court of Federal Claims Number 03-0355V
309. April and James Shearin on behalf of Charles Shearin, Great Neck, New York, Court of Federal Claims Number 03-0356V
310. Robin Cline on behalf of Aaron Michael Rothrock, Great Neck, New York, Court of Federal Claims Number 03-0357V
311. Suzanne Kosse on behalf of Ilexis Kosse, Great Neck, New York, Court of Federal Claims Number 03-0358V
312. Krystal and Christopher Davis on behalf of Gabrielle Davis, Great Neck, New York, Court of Federal Claims Number 03-0359V
313. Tonya and Shawn Goss on behalf of Chloe Goss, Great Neck, New York, Court of Federal Claims Number 03-0360V
314. Aimee Ward on behalf of Jayden Hardway, Great Neck, New York, Court of Federal Claims Number 03-0361V
315. Loretta and James Smith on behalf of Lancelot Smith, Great Neck, New York, Court of Federal Claims Number 03-0362V
316. Heather and Brooke Walton on behalf of Sara Walton, Great Neck, New York, Court of Federal Claims Number 03-0363V
317. Theresa and James Roberts on behalf of James Roberts, Jr., Great Neck, New York, Court of Federal Claims Number 03-0364V
318. Dionne Dunham on behalf of Devin Dunham, Great Neck, New York, Court of Federal Claims Number 03-0365V
319. Angela and Ken Riederman on behalf of Mary Beth Riederman, Great Neck, New York, Court of Federal Claims Number 03-0366V
320. Jamie and Antonio Bautista on behalf of Joshua Bautista, Great Neck, New York, Court of Federal Claims Number 03-0367V
321. Michelle and Melvin Nichols on behalf of Melvin Nichols, Great Neck, New York, Court of Federal Claims Number 03-0368V
322. Michelle Peterson and Thanh Guinan on behalf of Tyler Guinan, Great Neck, New York, Court of Federal Claims Number 03-0369V
323. Laura Simonetti on behalf of Michael Joseph Castellano, Great Neck, New York, Court of Federal Claims Number 03-0370V
324. Niladri and Ruma Chatterjee on behalf of Chris Chatterjee, Great Neck, New York, Court of Federal Claims Number 03-0371V
325. Joan and Shane Steckelberg on behalf of Lydia Steckelberg, Great Neck, New York, Court of Federal Claims Number 03-0372V
326. Vanessa Citriglia on behalf of Orion Citriglia, Boston, Massachusetts, Court of Federal Claims Number 03-0373V
327. Dawn Gregor on behalf of Noah Gregor, Boston, Massachusetts, Court of Federal Claims Number 03-0374V
328. Betsy Spaeth on behalf of Brandon Spaeth, Boston, Massachusetts, Court of Federal Claims Number 03-0375V
329. Julia Krumlauf on behalf of Ethan Krumlauf, Boston, Massachusetts, Court of Federal Claims Number 03-0376V

330. Lynn Wagner on behalf of Timothy Wagner, Boston, Massachusetts, Court of Federal Claims Number 03-0377V
331. Lynn Wagner on behalf of Ian Wagner, Boston, Massachusetts, Court of Federal Claims Number 03-0378V
332. John Poulin on behalf of Cameron Poulin, Boston, Massachusetts, Court of Federal Claims Number 03-0379V
333. Carole Hahn on behalf of Andrew Hahn, Boston, Massachusetts, Court of Federal Claims Number 03-0380V
334. Vincent Lovenduski on behalf of Austin Lovenduski, Boston, Massachusetts, Court of Federal Claims Number 03-0381V
335. Wendy Weitkemper on behalf of Quinn Weitkemper, Boston, Massachusetts, Court of Federal Claims Number 03-0382V
336. Yvonne Barrett-Furbee & James W. Furbee, Jr. on behalf of Nicholas James Barrett-Furbee, Winston-Salem, North Carolina, Court of Federal Claims Number 03-0383V
337. Karen Tribble on behalf of Zarek James Anthony, Gastonia, Georgia, Court of Federal Claims Number 03-0384V
338. Vanessa Fleming on behalf of Jamario Phipps, Houston, Texas, Court of Federal Claims Number 03-0385V
339. Yvonne Johnson on behalf of Da'Quida Patten, Houston, Texas, Court of Federal Claims Number 03-0386V
340. Paula Thompson and Graig Odems on behalf of Tawandelin Williams, Houston, Texas, Court of Federal Claims Number 03-0387V
341. Giselle Escobar on behalf of Kaivon Behbehani-Escobar, Portland, Oregon, Court of Federal Claims Number 03-0388V
342. Anthony Williams on behalf of Tyler Williams, Portland, Oregon, Court of Federal Claims Number 03-0389V
343. Andrea Schreiber on behalf of Macmilliam Schreiber, Portland, Oregon, Court of Federal Claims Number 03-0390V
344. Jody Ringman on behalf of Dion Moody, Portland, Oregon, Court of Federal Claims Number 03-0391V
345. Jamie Hahn on behalf of Page Novotny, Portland, Oregon, Court of Federal Claims Number 03-0392V
346. Lisa Crawford on behalf of Collin Crawford, Portland, Oregon, Court of Federal Claims Number 03-0393V
347. Kathleen and Joseph Buff on behalf of Kelly F. Buff, Altamont, New York, Court of Federal Claims Number 03-0394V
348. Jennifer and Michael Goodwin on behalf of Joshua Dale Goodwin, Dallas, Texas, Court of Federal Claims Number 03-0395V
349. Michelle and Donald Horst on behalf of Isaiah David Horst, New York, New York, Court of Federal Claims Number 03-0396V
350. Toan "Mike" Nguyen on behalf of Brian Nguyen, Houston, Texas, Court of Federal Claims Number 03-0397V
351. Rebecca Christoffer on behalf of Peyton Christoffer, Minneapolis, Minnesota, Court of Federal Claims Number 02-0398V
352. Christine and Steven Wiley on behalf of Jacob Wiley, Ferndale, Michigan, Court of Federal Claims Number 03-0399V
353. Melissa and Donald Bryant on behalf of Ryan A. Bryant, Alexandria, Virginia, Court of Federal Claims Number 03-0408V
354. Shadiya and Moulay Patton-Bey on behalf of Ilyas Patton-Bey, Alexandria, Virginia, Court of Federal Claims Number 03-0409V
355. Yvette and Kevin Ohree on behalf of Jordan P. Ohree, Alexandria, Virginia, Court of Federal Claims Number 03-0410V
356. Temeka and Antoine Moss on behalf of Antoine Moss, Jr., Alexandria, Virginia, Court of Federal Claims Number 03-0411V
357. Julie and Gary Mitchum on behalf of Douglas Edward Mitchum, Melbourne, Florida, Court of Federal Claims Number 03-0414V
358. Monique Leroux-Bice and Trevor Bice on behalf of John-Paul Leroux-Bice, Melbourne, Florida, Court of Federal Claims Number 03-0415V
359. Dorothy Owen Powell on behalf of Trevor Wyatt Powell, Falkville, Alabama, Court of Federal Claims Number 03-0416V
360. Dorothy Owen Powell on behalf of Matthew Drake Powell, Falkville, Alabama, Court of Federal Claims Number 03-0417V
361. Stephanie Pearson on behalf of Sydnie Grace Pearson, Fort Smith, Arkansas, Court of Federal Claims Number 03-0418V
362. Missy Smith on behalf of Tanya Smith, Vienna, Virginia, Court of Federal Claims Number 03-0423V
363. Joyce Dooley-Rodriguez and Pedro J. Rodriguez on behalf of John Brooks Rodriguez, Hallandale Beach, Florida, Court of Federal Claims Number 03-0424V
364. Carolyn and Joseph Thurmond on behalf of Sarah Rose Thurmond, Sarasota, Florida, Court of Federal Claims Number 03-0425V
365. Evelyn O'Neill-Torres and Jose Torres on behalf of Jonathan David Torres, Melbourne, Florida, Court of Federal Claims Number 03-0426V
366. Leslie and Ronald Giroux on behalf of Graham Giroux, Great Neck, New York, Court of Federal Claims Number 03-0427V
367. Lisa and Michael Bonsignore on behalf of Michael Bonsignore, Great Neck, New York, Court of Federal Claims Number 03-0428V
368. Heather and Bryan Cogan on behalf of Kurren Cogan, Great Neck, New York, Court of Federal Claims Number 03-0429V
369. Jennifer Nelson on behalf of Samuel Nelson, Portland, Oregon, Court of Federal Claims Number 03-0430V
370. Tracy Knight on behalf of Taylor M. Knight, Portland, Oregon, Court of Federal Claims Number 03-0431V
371. Terri Jefferies on behalf of Jared Jefferies, Portland, Oregon, Court of Federal Claims Number 03-0432V
372. Loretta Reagan on behalf of Kyleeah Reagan, Portland, Oregon, Court of Federal Claims Number 03-0433V
373. Marie Roarks on behalf of Anthony Roarks, Portland, Oregon, Court of Federal Claims Number 03-0434V
374. Tammy Cervenka on behalf of Thomas Webber, Portland, Oregon, Court of Federal Claims Number 03-0435V
375. Angela and Gary Fennern on behalf of Macayla Rose Herron, Pensacola, Florida, Court of Federal Claims Number 03-0436V
376. Maryann and Peter Panariello on behalf of Danny Panariello, New York, New York, Court of Federal Claims Number 03-0437V
377. Vanessa and Kevin Brink on behalf of Samuel A. Brink, Dallas, Texas, Court of Federal Claims Number 03-0438V
378. Bert Cox on behalf of Allison Cox, Concord, New Hampshire, Court of Federal Claims Number 03-0440V
379. Rosa and Thomas Jawski on behalf of Thomas Louis Jawski, New York, New York, Court of Federal Claims Number 03-0443V
380. Virginia Blair on behalf of Preston Blair, Boston, Massachusetts, Court of Federal Claims Number 03-0447V
381. Robin Hubbell on behalf of Aaron Rothrock, Boston, Massachusetts, Court of Federal Claims Number 03-0448V
382. Deena Licht on behalf of Jacob Licht, Boston, Massachusetts, Court of Federal Claims Number 03-0449V
383. Anne Pessetto on behalf of Amanda Pessetto, Boston, Massachusetts, Court of Federal Claims Number 03-0451V
384. Gordon Downie on behalf of Gordon Downie, Jr., Boston, Massachusetts, Court of Federal Claims Number 03-0452V
385. Joyce Tesaker on behalf of Sydnie Bordino, Boston, Massachusetts, Court of Federal Claims Number 03-0453V
386. Robyn Shepherd on behalf of Taylor Shepherd, Boston, Massachusetts, Court of Federal Claims Number 03-0454V
387. Lorenzo Brandon on behalf of Lloyd Brandon, Boston, Massachusetts, Court of Federal Claims Number 03-0455V
388. Tonya Haynes on behalf of Tyler Haynes, Boston, Massachusetts, Court of Federal Claims Number 03-0456V
389. Kimberly Wood on behalf of Jonathon Wood, Boston, Massachusetts, Court of Federal Claims Number 03-0457V
390. Maxine Denise Poole on behalf of Adam J. Poole, Alexandria, Virginia, Court of Federal Claims Number 03-0458V
391. Renee and Frederick Henderson on behalf of Nasya R. Henderson, Alexandria, Virginia, Court of Federal Claims Number 03-0459V
392. Teresa and Joseph Turowski on behalf of Kevin Turowski, Alexandria, Virginia, Court of Federal Claims Number 03-0460V
393. Nancy and Lawrence Munoz on behalf of Megan Munoz, Alexandria, Virginia, Court of Federal Claims Number 03-0461V
394. Anne Pessetto on behalf of Roger Pessetto, Boston, Massachusetts, Court of Federal Claims Number 03-0463V
395. Rosa and Gregory James on behalf of Gregory C.A. James, Jr., Eufaula, Alabama, Court of Federal Claims Number 03-0466V
396. Waira Berroa on behalf of Rodrigo Berroa, Boston, Massachusetts, Court of Federal Claims Number 03-0467V
397. Kerry and Robert Bloch on behalf of David Joseph Bloch, Jacksonville, Florida, Court of Federal Claims Number 03-0468V
398. Jolené Bevelacqua on behalf of James Charles Bevalacqua, New York, New York, Court of Federal Claims Number 03-0469V
399. Heather Wise on behalf of Connor Wilson, Boston, Massachusetts, Court of Federal Claims Number 03-0472V
400. Robert Smith on behalf of Andre Smith, Boston, Massachusetts, Court of Federal Claims Number 03-0473V
401. Tammy Meher on behalf of McGuire Maher, Boston, Massachusetts, Court of Federal Claims Number 03-0474V
402. Margaret Neelsen on behalf of Ryan Neelsen, Boston, Massachusetts, Court of Federal Claims Number 03-0475V

403. Chanta Howard on behalf of Alala Howard, Boston, Massachusetts, Court of Federal Claims Number 03-0476V
404. Twila Waters on behalf of Sean Waters, Boston, Massachusetts, Court of Federal Claims Number 03-0477V
405. Seth Ross on behalf of Dylan Ross, Boston, Massachusetts, Court of Federal Claims Number 03-0478V
406. Rachel Fulgencio on behalf of Drake Fulgencio, Boston, Massachusetts, Court of Federal Claims Number 03-0479V
407. Nikki Reavie on behalf of Wyatt Reavie, Boston, Massachusetts, Court of Federal Claims Number 03-0480V
408. Tyler Felix on behalf of Elizabeth Rodrigues, Deceased, Boston, Massachusetts, Court of Federal Claims Number 03-0481V
409. Mary Kay Carroll on behalf of Patrick Carroll, Boston, Massachusetts, Court of Federal Claims Number 03-0482V
410. Tracy Williams on behalf of Katrina Williams, Martinsville, Indiana, Court of Federal Claims Number 03-0485V
411. Jennifer and Dan Olson on behalf of George Olson, Minneapolis, Minnesota, Court of Federal Claims Number 03-0486V
412. Diana and Tilghman Turner on behalf of Tilghman Anderson Turner, Grant, Alabama, Court of Federal Claims Number 03-0487V
413. Cheryl and James Hoffman on behalf of Sara E. Hoffman, Oxford, Ohio, Court of Federal Claims Number 03-0488V
414. Kami and John Olmstead on behalf of Jonah M. Olmstead, Rock Island, Illinois, Court of Federal Claims Number 03-0491V
415. Esmeralda and Wilford Shriver on behalf of Nolan Bryce Shriver, Houston, Texas, Court of Federal Claims Number 03-0492V
416. Cheryl and Andrew Christopherson on behalf of Michael Christopherson, Alexandria, Virginia, Court of Federal Claims Number 03-0493V
417. Gladys Minor on behalf of Keiona Murray, Alexandria, Virginia, Court of Federal Claims Number 03-0494V
418. Lorraine Nutt on behalf of Thomas J. Nutt, Alexandria, Virginia, Court of Federal Claims Number 03-0495V
419. Kimberly and Thomas Blevins on behalf of Cody Blevins, Muncie, Indiana, Court of Federal Claims Number 03-0496V
420. Anissa and Robert Ryland on behalf of Nicholas Wilson Ryland, Dallas, Texas, Court of Federal Claims Number 03-0497V
421. Rachelle and Troy Potter on behalf of Trenton Dean Potter, Dallas, Texas, Court of Federal Claims Number 03-0498V
422. Charity and Dave Christman on behalf of Faith Ashley Christman, Dallas, Texas, Court of Federal Claims Number 03-0499V
423. Ernestina and Abel Gonzalez on behalf of Josue Gonzalez, Dallas, Texas, Court of Federal Claims Number 03-0500V
424. Linda and Johnny Black on behalf of Elizabeth Black, Dallas, Texas, Court of Federal Claims Number 03-0501V
425. Carla and Eric Blaha on behalf of Christopher Blaha, Dallas, Texas, Court of Federal Claims Number 03-0502V
426. Bridgette Donison on behalf of Nia Donison, Dallas, Texas, Court of Federal Claims Number 03-0503V
427. Risa and Charles Bently on behalf of John Harrison Bently, Dallas, Texas, Court of Federal Claims Number 03-0504V
428. Latisha Simpson Moore on behalf of Jasmine Moore, Portland, Oregon, Court of Federal Claims Number 03-0505V
429. Hans Rosenberg on behalf of Hans Rosenberg, Jr., Portland, Oregon, Court of Federal Claims Number 03-0506V
430. Lisa and Frank McKinney on behalf of Kennedy McKinney, Portland, Oregon, Court of Federal Claims Number 03-0507V
431. Carol and Charles Heinz on behalf of Brandon Heinz, Houston, Texas, Court of Federal Claims Number 03-0508V
432. Beverlee and Jeffrey Peters on behalf of Avery Peters, Houston, Texas, Court of Federal Claims Number 03-0509V
433. Annette Hubbs on behalf of Joseph Hubbs, Houston, Texas, Court of Federal Claims Number 03-0510V
434. Stormy Lester on behalf of Cameron Lester, Houston, Texas, Court of Federal Claims Number 03-0511V
435. Gina and Richard Mouser on behalf of Eric Mouser, Houston, Texas, Court of Federal Claims Number 03-0512V
436. Paula Sessing on behalf of Sean Sessing, Houston, Texas, Court of Federal Claims Number 03-0513V
437. William K. Stewart on behalf of William Stewart, Houston, Texas, Court of Federal Claims Number 03-0514V
438. Terri Reid on behalf of Joseph Willis, Houston, Texas, Court of Federal Claims Number 03-0515V
439. Alisha and Wilbert Gibson on behalf of Jabari Gibson, Houston, Texas, Court of Federal Claims Number 03-0516V
440. Julie and John Stackpole on behalf of John Stackpole, Jr., Houston, Texas, Court of Federal Claims Number 03-0517V
441. Kelley and Luis Tijero on behalf of Luis Tijero, Jr., Houston, Texas, Court of Federal Claims Number 03-0518V
442. Margaret and Daniel Kivumbi on behalf of Daniel Kivumbi, Jr., Houston, Texas, Court of Federal Claims Number 03-0519V
443. Heather and Lennox Carty on behalf of Stevyn Carty, Houston, Texas, Court of Federal Claims Number 03-0520V
444. Dianna and Monte Cunningham on behalf of Caryson Cunningham, Houston, Texas, Court of Federal Claims Number 03-0521V
445. David Adams on behalf of Michael Adams, Houston, Texas, Court of Federal Claims Number 03-0522V
446. Annette and Gerald Lichtenstein on behalf of Ivan Lichtenstein, Houston, Texas, Court of Federal Claims Number 03-0523V
447. Vickie and Brian Hilverding on behalf of Noah Hilverding, Houston, Texas, Court of Federal Claims Number 03-0524V
448. Maria and Robert Brock on behalf of Christopher Brock, Houston, Texas, Court of Federal Claims Number 03-0525V
449. Tina and Jamie Scarbro on behalf of Trevor Scarbro, Houston, Texas, Court of Federal Claims Number 03-0526V
450. Claire and Michael Mullen on behalf of William Mullen, Houston, Texas, Court of Federal Claims Number 03-0527V
451. Kimberly and Lance Erickson on behalf of Hunter T. Erickson, Houston, Texas, Court of Federal Claims Number 03-0528V
452. Jeffrey Wolfson on behalf of Richard M. Wolfson, Melbourne, Florida, Court of Federal Claims Number 03-0529V
453. Christina and Tim Beaudrie on behalf of Savannah Beaudrie, Great Neck, New York, Court of Federal Claims Number 03-0530V
454. Kerri and John Carney on behalf of John Carney, Great Neck, New York, Court of Federal Claims Number 03-0531V
455. Jennifer and Richard Volker on behalf of Scott Alexander Volker, Springfield, Massachusetts, Court of Federal Claims Number 03-0532V
456. Beth and James Mortl on behalf of Clayton Mortl, New Berlin, Wisconsin, Court of Federal Claims Number 03-0533V
457. Heather Cogan on behalf of Kurren Cogan, Boston, Massachusetts, Court of Federal Claims Number 03-0534V
458. Lisa Hnath on behalf of Joseph Hnath, Boston, Massachusetts, Court of Federal Claims Number 03-0535V
459. Patricia and Richard Gavigan on behalf of Kristen P. Gavigan, Schenectady, New York, Court of Federal Claims Number 03-0536V
460. Melissa and Shanin Seamons on behalf of Dylan C. Seamons, New Orleans, Louisiana, Court of Federal Claims Number 03-0537V
461. Theresa and Andrew Holloway on behalf of Elijah Holloway, Dallas, Texas, Court of Federal Claims Number 03-0539V
462. Kevin Dass on behalf of Dillon Jacob Dass, Kansas City, Missouri, Court of Federal Claims Number 03-0540V
463. Kevin Dass on behalf of Kyle Steven Dass, Kansas City, Missouri, Court of Federal Claims Number 03-0541V
464. Kimberly Yench on behalf of Nicolas Yench, Lisle, Illinois, Court of Federal Claims Number 03-0542V
465. Paige and Jay Ingram on behalf of Spencer Mitchell Ingram, Dallas, Texas, Court of Federal Claims Number 03-0544V
466. Lisa and Dale Willows on behalf of Jacob Willows, Dallas, Texas, Court of Federal Claims Number 03-0545V
467. Carla Lingenfelter on behalf of Cody Lingenfelter, Boston, Massachusetts, Court of Federal Claims Number 03-0546V
468. Glenda O'Dell on behalf of Patrick O'Dell, Boston, Massachusetts, Court of Federal Claims Number 03-0547V
469. Eugene Venable on behalf of Mark Venable, Boston, Massachusetts, Court of Federal Claims Number 03-0548V
470. Lisa Weydert on behalf of Clinton Weydert, Boston, Massachusetts, Court of Federal Claims Number 03-0549V
471. Coralee Howard on behalf of Sierra Howard, Boston, Massachusetts, Court of Federal Claims Number 03-0550V
472. Jackeline Novikov-Carles on behalf of Natasha Carles, Boston, Massachusetts, Court of Federal Claims Number 03-0551V
473. Roxana Lynn Pettit on behalf of Manny Lee Garza, Boston, Massachusetts, Court of Federal Claims Number 03-0552V
474. Maria and George Plunkett on behalf of Nicolas Plunkett, New York, New York, Court of Federal Claims Number 03-0553V
475. Kelly and Steve Flynn on behalf of Alexander Flynn, New York, New York, Court of Federal Claims Number 03-0554V

476. Theresa and Stephen Pirrelli on behalf of Joseph Pirrelli, New York, New York, Court of Federal Claims Number 03-0555V
477. Maryann and Peter Panariello on behalf of Danny Panariello, New York, New York, Court of Federal Claims Number 03-0556V
478. Lori and Mark Taliercio on behalf of Anthony Taliercio, New York, New York, Court of Federal Claims Number 03-0557V
479. Deborah and Thomas Anderson on behalf of Thomas Anderson, New York, New York, Court of Federal Claims Number 03-0558V
480. Julie Riley on behalf of Timothy Riley, Jr., Boston, Massachusetts, Court of Federal Claims Number 03-0561V
481. Dana Stone on behalf of Noah Stone, Boston, Massachusetts, Court of Federal Claims Number 03-0562V
482. Joan and Philip Correale on behalf of Nicholas Correale, New York, New York, Court of Federal Claims Number 03-0563V
483. Stephanie and Kevin McAree on behalf of Dylan McAree, New York, New York, Court of Federal Claims Number 03-0566V
484. Colleen and Bob Dillon on behalf of Cameron Dillon, New York, New York, Court of Federal Claims Number 03-0567V
485. Joie and Michael Lanza on behalf of Anthony Lanza, New York, New York, Court of Federal Claims Number 03-0568V
486. Abigail Turner on behalf of Patrick Turner, New York, New York, Court of Federal Claims Number 03-0569V
487. Stacy and Daniel Zollo on behalf of Daniel Zollo, New York, New York, Court of Federal Claims Number 03-0570V
488. Sharlene and Charles Bedard on behalf of Dylan Bedard, New York, New York, Court of Federal Claims Number 03-0571V
489. Rosanna and Leonard Scandaglia on behalf of Anthony Scandaglia, New York, New York, Court of Federal Claims Number 03-0572V
490. Barrie and Barry Usmana on behalf of Barrie Usmana, New York, New York, Court of Federal Claims Number 03-0573V
491. Renee and Gail Caron on behalf of Tyler J. Caron, Melbourne, Florida, Court of Federal Claims Number 03-0574V
492. Lisa Funderburk on behalf of Nicholas Funderburk, Boston, Massachusetts, Court of Federal Claims Number 03-0577V
493. Mary Brumbaugh on behalf of Dorothy Brumbaugh, Boston, Massachusetts, Court of Federal Claims Number 03-0578V
494. Louann Petrucci-Duane on behalf of Gregory Duane, Boston, Massachusetts, Court of Federal Claims Number 03-0579V
495. Frances and David Langum on behalf of David J. Langum, Jr., Birmingham, Alabama, Court of Federal Claims Number 03-0580V
496. Monica and Blake Sullivan on behalf of Conner Sullivan, Kokomo, Indiana, Court of Federal Claims Number 03-0581V
497. Kim and James Gordon on behalf of Olivia Gordon, Vienna, Virginia, Court of Federal Claims Number 03-0582V
498. Linda Pedraza on behalf of Michael Raphael Pedraza, Dallas, Texas, Court of Federal Claims Number 03-0583V
499. Mylinda and Fred King on behalf of Jordan King, Portland, Oregon, Court of Federal Claims Number 03-0584V
500. Lien Vu and Mark Lindsay on behalf of Lorenzo Lindsay, Portland, Oregon, Court of Federal Claims Number 03-0585V
501. Dianne Doggett and Gary Fagelman on behalf of Augie Fagelman, Portland, Oregon, Court of Federal Claims Number 03-0586V
502. Jacqueline Fowler on behalf of Steven Fowler, Portland, Oregon, Court of Federal Claims Number 03-0587V
503. Christina Emerson on behalf of Kristopher Emerson, Portland, Oregon, Court of Federal Claims Number 03-0588V
504. Diana Cornejo on behalf of Diego Cornejo, Boston, Massachusetts, Court of Federal Claims Number 03-0591V
505. Rohert Anderson on behalf of Charles Anderson, Boston, Massachusetts, Court of Federal Claims Number 03-0592V
506. Sabrina Lepre Leva on behalf of Lorenzo Leva, Boston, Massachusetts, Court of Federal Claims Number 03-0593V
507. Rebecca Gleeson on behalf of Anthony Gleeson, Boston, Massachusetts, Court of Federal Claims Number 03-0594V
508. Vallie Naylor on behalf of Jacob Naylor, Boston, Massachusetts, Court of Federal Claims Number 03-0595V
509. Linda Leavy on behalf of Jason Leavy, Boston, Massachusetts, Court of Federal Claims Number 03-0596V
510. Melissa and Michael Robinson on behalf of Martia Rochana Robinson, Richmond, Virginia, Court of Federal Claims Number 03-0597V
511. Kathleen and Richard Hybl on behalf of Patrick Ryan Hybl, Richmond, Virginia, Court of Federal Claims Number 03-0598V
512. Evelyn and Frances Yee on behalf of Jacqueline Frances Yee, Dallas, Texas, Court of Federal Claims Number 03-0599V
513. Karen and Robert Kolacinski on behalf of Taylor Kolacinski, Kennesaw, Georgia, Court of Federal Claims Number 03-0602V
514. Karen and Edward Hiney on behalf of Andrew Hiney, Great Neck, New York, Court of Federal Claims Number 03-0603V
515. Christine and Patrick Mazza on behalf of Anthony Mazza, Great Neck, New York, Court of Federal Claims Number 03-0604V
516. Tamera and Duffy Trotter on behalf of Christopher Ray Trotter, Great Neck, New York, Court of Federal Claims Number 03-0605V
517. Karrie Wallingford on behalf of Jesse Wallingford, Great Neck, New York, Court of Federal Claims Number 03-0606V
518. Andrea Adler on behalf of Shawn Garcia, Great Neck, New York, Court of Federal Claims Number 03-0607V
519. Shirley and Charles McDonald on behalf of Jonah McDonald, Great Neck, New York, Court of Federal Claims Number 03-0608V
520. Kathleen and Kurt O'Donnell on behalf of Conner O'Donnell, Great Neck, New York, Court of Federal Claims Number 03-0609V
521. Megann Reed on behalf of Dylan Richmond, Great Neck, New York, Court of Federal Claims Number 03-0610V
522. Shamecka Sweet on behalf of Nasir Lewis, Great Neck, New York, Court of Federal Claims Number 03-0611V
523. Brenda and Paul Bright on behalf of Zachary O'Neal Bright, Great Neck, New York, Court of Federal Claims Number 03-0612V
524. Margie and Michael Barres on behalf of Brandon Barres, Great Neck, New York, Court of Federal Claims Number 03-0613V
525. Kelly and William Milazzo on behalf of Robert Milazzo, Great Neck, New York, Court of Federal Claims Number 03-0614V
526. Heather and Ryan Smith on behalf of Trevon Smith, Great Neck, New York, Court of Federal Claims Number 03-0615V
527. Karen and Greg Sokolowski on behalf of Adam Sokolowski, Vienna, Virginia, Court of Federal Claims Number 03-0618V
528. Stephanie Sherman on behalf of Cody Hill, Reno, Nevada, Court of Federal Claims Number 03-0619V
529. Adele Quintana De Bazan, Alviso, California, Court of Federal Claims Number 03-0620V
530. Lynn and Wesley Avram on behalf of Paul Avram, New York, New York, Court of Federal Claims Number 03-0621V
531. Laura and Jose Turrubiates on behalf of Eric Turrubiates, San Antonio, Texas, Court of Federal Claims Number 03-0622V
532. Tina Gordon on behalf of Darris J. Gordon, Alexandria, Virginia, Court of Federal Claims Number 03-0624V
533. Morgan and Hugh Leggette on behalf of Kayleigh Hannah Leggette, Alexandria, Virginia, Court of Federal Claims Number 03-0625V
534. Cassandra Standley and Leon Vincente on behalf of Bailey Vicente, Miami, Florida, Court of Federal Claims Number 03-0627V
535. Raschelle and George Theoharris on behalf of Max Theoharris, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 03-0628V
536. Verna Lisa and Jay Schmel on behalf of Jayson Louis Schmel, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0629V
537. Abigail and Joseph Musser on behalf of Jacob Musser, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 03-0630V
538. Lynne and Alan Boro on behalf of Tyler Boro, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 03-0631V
539. Lori and Robert Krakow on behalf of Alexander Krakow, Lake Success, New York, Court of Federal Claims Number 03-0632V
540. Lisa and Arnold Schouten on behalf of Matthew Schouten, Lake Success, New York, Court of Federal Claims Number 03-0633V
541. Janice and Daniel Beahan on behalf of Nicky Beahan, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 03-0634V
542. Joanne Williams on behalf of James Blakeley, Ludowici, Georgia, Court of Federal Claims Number 03-0637V
543. Angelique and William Edelen on behalf of Benjamin Luke Edelen, Salisbury, North Carolina, Court of Federal Claims Number 03-0638V
544. Colleen Bennett on behalf of Preston Bennett, Boston, Massachusetts, Court of Federal Claims Number 03-0639V
545. Kristen Falenski on behalf of Zachary Falenski, Boston, Massachusetts, Court of Federal Claims Number 03-0640
546. Robert Snyder on behalf of Adam Snyder, Boston, Massachusetts, Court of Federal Claims Number 03-0641V

547. Kimberly Hipps on behalf of Branson Hipps, Boston, Massachusetts, Court of Federal Claims Number 03-0642V
548. Chadd Wickert on behalf of Chase Wickert, Boston, Massachusetts, Court of Federal Claims Number 03-0643V
549. Michelle and Anthony Spalla on behalf of Nicholas Rocco Spalla, Palos Heights, Illinois, Court of Federal Claims Number 03-0644V
550. Linda and Melville Jones on behalf of Tatyana Noel Jones, Philadelphia, Pennsylvania, Court of Federal Claims Number 03-0645V
551. Rosa and Peter Joseph Scala on behalf of Peter John Scala, Lake Success, New York, Court of Federal Claims Number 03-0648V
552. Linda and Bruce Gavin on behalf of Jacob Bruce Gavin, Houston, Texas, Court of Federal Claims Number 03-0649V
553. Dollie Smith on behalf of Miracle Dollie Smith, Houston, Texas, Court of Federal Claims Number 03-0650V
554. Penny and Neville Travillon on behalf of Kejoni Amari Singleton, Houston, Texas, Court of Federal Claims Number 03-0651V
555. Susan Jones on behalf of Joshua Gaylon Jones, Houston, Texas, Court of Federal Claims Number 03-0652V
556. Harriett Gibbons and Charles Hoover on behalf of Leonard Hoover, Miami, Florida, Court of Federal Claims Number 03-0653V
557. Angela and Rolf Hazelhurst on behalf of William Yates Hazelhurst, Twin Falls, Idaho, Court of Federal Claims Number 03-0654V
558. Rena Riccardi-Hurley and Paul Hurley on behalf of Stephanie Rose Hurley, New York, New York, Court of Federal Claims Number 03-0655V
559. Gerri and John McGaha on behalf of Zachary L. McGaha, Marbury, Alabama, Court of Federal Claims Number 03-0656V
560. Lisa Attenazio on behalf of Ajay Attenazio, Dover, New Hampshire, Court of Federal Claims Number 03-0657V
561. Catherine and Steven DiGuilio on behalf of Amanda DiGuilio, Pembroke Pines, Florida, Court of Federal Claims Number 03-0659V
562. Nancy and Raymond Pate on behalf of Marissa Elizabeth Pate, Indianapolis, Indiana, Court of Federal Claims Number 03-0660V
563. Victoria and Richard Emery on behalf of Jake Emery, Indianapolis, Indiana, Court of Federal Claims Number 03-0661V
564. Monica and Adam Singer on behalf of Spencer Paul Singer, Nanuet, New York, Court of Federal Claims Number 03-0662V
565. Tracy and Erle Murphy on behalf of Nehemiah Fredrick Murphy, Houston, Texas, Court of Federal Claims Number 03-0663V
566. Natalie and Anthony Richard on behalf of Emily Mikaela Richard, Houston, Texas, Court of Federal Claims Number 03-0664V
567. Jennifer and Willard Bradley on behalf of Sean Ryan Bradley, Houston, Texas, Court of Federal Claims Number 03-0665V
568. Torrie Smith on behalf of Tyshawn Maliek Smith, Houston, Texas, Court of Federal Claims Number 03-0666V
569. Shannon Grafenstine on behalf of Michael Patrick Smith, Philadelphia,

Pennsylvania, Court of Federal Claims Number 03-0667V

570. Rochelle and Justin Newton on behalf of Joseph Newton, Tampa, Florida, Court of Federal Claims Number 03-0670V
571. Gail Cahill and Alberto Velez on behalf of Christian D. Velez, Houston, Texas, Court of Federal Claims Number 03-0671V
572. Deanna and Lee Parker on behalf of Lee Thomas Parker, Houston, Texas, Court of Federal Claims Number 03-0672V
573. Amy Tuorila on behalf of Jayden Tappor Tuorila, Houston, Texas, Court of Federal Claims Number 03-0673V
574. Vicky and Scott Truett on behalf of Chance Scott Truett, Houston, Texas, Court of Federal Claims Number 03-0674V
575. Angelia January on behalf of Jazzlyn January, Houston, Texas, Court of Federal Claims Number 03-0675V
576. Doreen Mandy on behalf of Raymond Calamito, Jr., Great Neck, New York, Court of Federal Claims Number 03-0676V
577. Linda Carzoli on behalf of Thomas Carzoli, Great Neck, New York, Court of Federal Claims Number 03-0677V
578. Theresa and James Roberts on behalf of Calen Mae Roberts, Great Neck, New York, Court of Federal Claims Number 03-0678V
579. Florence and Steven Cataneo on behalf of Taylor Rae Cataneo, Great Neck, New York, Court of Federal Claims Number 03-0679V
580. Rita and Marc Safian on behalf of Daniel Safian, Great Neck, New York, Court of Federal Claims Number 03-0680V
581. Carla and John Fitzsimons on behalf of John Fitzsimons, Jr., Great Neck, New York, Court of Federal Claims Number 03-0681V

Dated: July 29, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03-19798 Filed 8-4-03; 8:45 am]

BILLING CODE 4165-15-U

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Submission for OMB Emergency Review; Comment Request

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Information collection request; comments solicited.

SUMMARY: The Department of Homeland Security has submitted the following information collection request (ICR), utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). OMB approval has been requested by August 5, 2003. A copy of this ICR, with applicable

supporting documentation, may be obtained by calling the Agency Clearance Officer at the Bureau of Customs and Border Protection, Room 3.2.C, 1300 Pennsylvania Avenue NW., Washington, DC 20229, Tel. (202) 927-1429. Comments and questions about the ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Bureau of Customs and Border Protection, Office of Management and Budget, Room 10235, Washington, DC 20503.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Agency: Bureau of Customs and Border Protection.

Title: Application—Alternative Inspection Services/FAST Commercial Driver Application.

OMB Number: 1653-0010.

Type of Review: Emergency Revision.

Affected Public: Commercial Truck Drivers.

Number of Respondents: 25,000.

Estimated Time Per Respondent: 30 minutes.

Total Burden Hours: 12,500.

Total Burden Cost: \$750,000.

Description: A new form has been developed for commercial truck drivers, known as the FAST Commercial Driver Application—Mexico, CBP 823F. FAST is a clearance process for known low risk shipments. This program seeks to expedite clearance of low risk trans-border shipments by reducing CBP information requirements, and by dedicating lanes at major crossing points to FAST participants. It is an expansion of the Free and Secure Trade Initiative to the U.S. southern border.

FAST membership will help companies satisfy the security requirements of their customers and service providers. This program has been operating on the northern border using a Canadian/U.S. form, administered and collected by the Canadian Government.

Dated: July 22, 2003.

Tracey Denning,

Agency Clearance Officer, Information Services Branch.

[FR Doc. 03-19797 Filed 8-4-03; 8:45 am]

BILLING CODE 4820-02-P

Department of Housing and Urban Development

[Docket No. FR-4815-N-53]

Notice of Submission of Proposed Information Collection to OMB: Energy Conservation for PHA-Owned or Leased Projects—Audits, Utility Allowances

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act.

Public Housing Agencies (PHAs) are required to establish allowances for PHA-furnished utilities and for resident-purchased utilities. PHAs document, and provide for resident inspection, the basis upon which allowances and scheduled surcharges (and revisions thereof) are established. PHAs complete

energy audits, benefit/cost analyses for individual vs. mastermeters. PHAs review tenant utility allowances. HUD is seeking reinstatement of the approval to collect this information.

The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 4, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577-0062) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; E-mail Lauren.Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the

description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Energy Conservation for PHA-Owned or Leased Projects—Audits, Utility Allowances.

OMB Approval Number: 2577-0062.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: In support of national energy conservation goals, Public Housing Agencies (PHAs) establish allowances for PHA-furnished utilities and for resident-purchased utilities. PHAs document, and provide for resident inspection, the basis upon which allowances and scheduled surcharges (and revisions thereof) are established. PHAs complete energy audits, benefit/cost analyses for individual vs. mastermeters. PHAs review tenant utility allowances.

Respondents: PHAs with PHA-owned or Leased Projects.

Frequency of Submission: Annually.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting burden	3400	3400		3.9		13,268

Total Estimated Burden Hours: 13,268.

Status: Reinstatement, without change, of a previously approved collection for which approval expired.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 31, 2003.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 03-19941 Filed 8-4-03; 8:45 am]

BILLING CODE 4210-72-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4815-N-52]

Notice of Submission of Proposed Information Collection to OMB: Real Estate Settlement Procedures Act (RESPA) Disclosures

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork

Reduction Act. The Real Estate Settlement Procedures Act of 1974 requires settlement providers to disclose to homebuyers certain information at or before settlement and pursuant to the servicing of the loan and escrow account. This includes a Special Information Booklet, a Good Faith Estimate, an Initial Servicing Disclosure, a Settlement Statement (the Form HUD-1 or Form HUD-1A), and, when applicable, an Initial Escrow Account Statement, an Annual Escrow Account Statement, an Escrow Account Disbursement Disclosure, an Affiliated Business Arrangement Disclosure, and a Servicing Transfer Disclosure. The

Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 4, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0265) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; e-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as

required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Real Estate Settlement Procedures Act (RESPA) Disclosures.

OMB Approval Number: 2502-0265.

Form Numbers: HUD-1, HUD-1A.

Description of the Need for the Information and its Proposed Use: The Real Estate Settlement Procedures Act of 1974 requires settlement providers to disclose to homebuyers certain information at or before settlement and pursuant to the servicing of the loan and escrow account. This includes a Special Information Booklet, a Good Faith Estimate, an Initial Servicing Disclosure, a Settlement Statement (the Form HUD-1 or Form HUD-1A), and when applicable an Initial Escrow Account Statement, an Annual Escrow Account Statement, an Escrow Account Disbursement Disclosure, an Affiliated Business Arrangement Disclosure, and a Servicing Transfer/Disclosure.

HUD is requesting an extension of the currently approved information collection while considering changes that would be implemented in a later publication of a rule.

Respondents: Business or other for-profit.

Frequency of Submission: On occasion and annually.

	Number of respondents	Annual responses	Hours per response	Burden hours
Reporting burden	20,000	129,980,000	0.07	9,672,400

Total Estimated Burden Hours: 9,672,400.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 30, 2003.

Wayne Eddins,
*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 03-19942 Filed 8-4-03; 8:45 am]

BILLING CODE 4210-72-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4815-N-51]

Notice of Submission of Proposed Information Collection to OMB: Low-Income Public Housing Operating Budget, Supporting Schedules and Board Resolution

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Information will ensure that Public Housing Authorities (PHAs) follow sound financial practices and that Federal funds are used for eligible expenditures. PHAs use the information as a financial summary and analysis of immediate and long-term operating programs and plans to provide control over operations and achieve objectives.

DATES: *Comments Due Date:* September 4, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577-0026) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number

(202) 395-6974; e-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how

frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Low-Income Public Housing Operating Budget, Supporting Schedules and Board Resolution.

OMB Approval Number: 2577-0026.
Form Numbers: HUD-52564, HUD-52566, HUD-25267, HUD-52571, HUD-52573, HUD-52574.

Description of the Need for the Information and its Proposed Use: Information will ensure that Public

Housing Authorities (PHAs) follow sound financial practices and that Federal Funds are used for eligible expenditures. PHAs use the information as a financial summary and analysis of immediate and long-term operating programs and plans to provide control over operations and achieve objectives.

Respondents: Not-for-profit institutions, State, Local or Tribal Government.

Frequency of Submission: Annually.

	Number of respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting burden	3,500	3,500		120		420,000

Total Estimated Burden Hours: 420,000.

Status: Reinstatement, without change, of previously approved collection for which approval has expired.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 30, 2003.

Wayne Eddins,

*Departmental Reports Management Officer,
 Office of the Chief Information Officer.*

[FR Doc. 03-19943 Filed 8-4-03; 8:45 am]

BILLING CODE 4210-72-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4463-N-14]

Mortgage and Loan Insurance Programs Under the National Housing Act "Debenture Interest Rates"

AGENCY: Office of the Assistant Secretary for Housing "Federal Housing Commissioner, (HUD).

ACTION: Notice of change in debenture interest rates.

SUMMARY: This notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Commissioner under the provisions of the National Housing Act (the "Act"). The interest rate for debentures issued under Section 221(g)(4) of the Act during the 6-month

period beginning July 1, 2003, is 5 percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the 6-month period beginning July 1, 2003, is 4½ percent.

FOR FURTHER INFORMATION CONTACT:

James B. Mitchell, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Room 6164, Washington, DC 20410. Telephone (202) 708-3944, extension 2612, or TDD (202) 708-4594 for hearing- or speech-impaired callers. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: Section 224 of the National Housing Act (12 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to Section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at

24 CFR 203.405, 203.479, 207.259(e)(6), and 220.830. These regulatory provisions state that the applicable rates of interest will be published twice each year as a notice in the **Federal Register**.

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the annual interest rate determined by the Secretary of the Treasury pursuant to a statutory formula based on the average yield of all outstanding marketable Treasury obligations of maturities of 15 or more years.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of Section 224, that the statutory maximum interest rate for the period beginning July 1, 2003, is 4½ percent; and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 4½ percent for the 6-month period beginning July 1, 2003. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to Section 221(g)(4)) with insurance commitment or endorsement date (as applicable) within the last 6 months of 2003.

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1980:

Effective interest rate—	On or after—	Prior to—
9½	Jan. 1, 1980	July 1, 1980.
9⅞	July 1, 1980	Jan. 1, 1981.
11¼	Jan. 1, 1981	July 1, 1981.
12⅞	July 1, 1981	Jan. 1, 1982.
12¾	Jan. 1, 1982	Jan. 1, 1983.
10¼	Jan. 1, 1983	July 1, 1983.
10⅞	July 1, 1983	Jan. 1, 1984.

Effective interest rate—	On or after—	Prior to—
11½	Jan. 1, 1984	July 1, 1984.
13⅞	July 1, 1984	Jan. 1, 1985.
11⅝	Jan. 1, 1985	July 1, 1985.
11¼	July 1, 1985	Jan. 1, 1986.
10¾	Jan. 1, 1986	July 1, 1986.
8¾	July 1, 1986	Jan. 1, 1987.
8	Jan. 1, 1987	July 1, 1987.
9	July 1, 1987	Jan. 1, 1988.
9⅞	Jan. 1, 1988	July 1, 1988.
9⅝	July 1, 1988	Jan. 1, 1989.
9¼	Jan. 1, 1989	July 1, 1989.
9	July 1, 1989	Jan. 1, 1990.
8⅞	Jan. 1, 1990	July 1, 1990.
9	July 1, 1990	Jan. 1, 1991.
8¾	Jan. 1, 1991	July 1, 1991.
8½	July 1, 1991	Jan. 1, 1992.
8	Jan. 1, 1992	July 1, 1992.
8	July 1, 1992	Jan. 1, 1993.
7¾	Jan. 1, 1993	July 1, 1993.
7	July 1, 1993	Jan. 1, 1994.
6⅝	Jan. 1, 1994	July 1, 1994.
7¾	July 1, 1994	Jan. 1, 1995.
8⅞	Jan. 1, 1995	July 1, 1995.
7¼	July 1, 1995	Jan. 1, 1996.
6½	Jan. 1, 1996	July 1, 1996.
7¼	July 1, 1996	Jan. 1, 1997.
6¾	Jan. 1, 1997	July 1, 1997.
7⅞	July 1, 1997	Jan. 1, 1998.
6⅞	Jan. 1, 1998	July 1, 1998.
6⅞	July 1, 1998	Jan. 1, 1999.
5½	Jan. 1, 1999	July 1, 1999.
6⅞	July 1, 1999	Jan. 1, 2000.
6½	Jan. 1, 2000	July 1, 2000.
6½	July 1, 2000	Jan. 1, 2001.
6	Jan. 1, 2001	July 1, 2001.
5⅞	July 1, 2001	Jan. 1, 2002.
5¼	Jan. 1, 2002	July 1, 2002.
5¾	July 1, 2002	Jan. 1, 2003.
5	Jan. 1, 2003	July 1, 2003.
4½	July 1, 2003	Jan. 1, 2004.

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the "going Federal rate" in effect at the time the debentures are issued. The term "going Federal rate" is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a statutory formula based on the average yield on all outstanding marketable Treasury obligations of 8- to 12-year maturities, for the 6-month periods of January through June and July through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.255 and 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to Section 221(g)(4) during the 6-month period beginning July 1, 2003, is 5 percent.

HUD expects to publish its next notice of change in debenture interest rates in January 2004.

The subject matter of this notice falls within the categorical exemption from HUD's environmental clearance procedures set forth in 24 CFR 50.19(c)(6). For that reason, no environmental finding has been prepared for this notice.

(Sections 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 1715l, 1715o; Section 7(d), Department of HUD Act, 42 U.S.C. 3535(d)).

Dated: July 23, 2003.

John C. Weicher,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 03-19939 Filed 8-4-03; 8:45 am]

BILLING CODE 4210-27-P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments

regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;
2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The utility, quality, and clarity of the information to be collected; and,
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Industrial Minerals Surveys.

Current OMB approval number: 1028-0062.

Abstract: Respondents supply the U.S. Geological Survey with domestic production and consumption data on nonfuel mineral commodities. This information will be published as monthly, quarterly, semiannual, and annual reports for use by Government agencies, industry, and the general public.

Bureau form number: Various (41 forms).

Frequency: Monthly, quarterly, semiannual, and annual.

Description of respondents: Producers and consumers of industrial minerals.

Annual responses: 18,437.

Annual burden hours: 12,782.

Bureau clearance officer: John E. Cordyack, Jr., 703-648-7313.

John H. DeYoung, Jr.,

Chief Scientist, Minerals Information Team.

[FR Doc. 03-19897 Filed 8-04-03; 8:45 am]

BILLING CODE 4310-Y7-M

DEPARTMENT OF INTERIOR

Geological Survey

Patent, Trademark & Copyright Acts

AGENCY: Geological Survey

ACTION: Notice of prospective intent to award exclusive license.

SUMMARY: The United States Geological Survey (USGS) is contemplating the award of an exclusive license to: Besst, Inc., of Larkspur, CA, on U.S. Patent Nos. 6,131,451 and 6,164,127, both entitled "Well Flowmeter and Down-Hole Sample."

INQUIRIES: If other parties are interested in similar activities, or have comments relating to the prospective award, please contact Neil Mark, USGS, 12201 Sunrise Valley Drive, MS 500, Reston, VA

20192, phone (703) 648-4344, fax (703) 648-4706, or email nmark@usgs.gov.

SUPPLEMENTARY INFORMATION: This notice is submitted to meet the requirements of 35 U.S.C. 208 *et seq.*

Dated: June 10, 2003.

Glenn G. Patterson,

Staff Assistant to Associate Director for Water.

[FR Doc. 03-19896 Filed 8-4-03; 8:45 am]

BILLING CODE 4310-Y7-M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submitted for Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of an extension of a currently approved information collection (OMB Control Number 1010-0087).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements in the regulations under 30 CFR Part 228—Cooperative Activities with States and Indian Tribes. This notice also provides the public a second opportunity to comment on the paperwork burden of these regulatory requirements. The ICR is titled "30 CFR Part 228 Cooperative Activities with States and Indian Tribes."

DATES: Submit written comments on or before September 4, 2003.

ADDRESSES: Submit written comments either by fax (202) 395-5806 or e-mail (Ruth_Solomon@omb.eop.gov) directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (OMB Control Number 1010-0087). Mail or hand-carry a copy of your comments to Sharron L. Gebhardt, Regulatory Specialist, Minerals Management Service, Minerals Revenue Management, P.O. Box 25165, MS 320B2, Denver, Colorado 80225. If you use an overnight courier service, our courier address is Building 85, Room A-614, Denver Federal Center, Denver, Colorado 80225.

FOR FURTHER INFORMATION CONTACT: Sharron L. Gebhardt by telephone (303) 231-3211 or fax (303) 231-3781. You may also contact Sharron Gebhardt to obtain a copy at no cost of the

regulations that require the subject collection of information.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR Part 228—Cooperative Activities with States and Indian Tribes.

OMB Control Number: 1010-0087.

Bureau Form Number: None.

Abstract: The Department of the Interior (DOI) is responsible for matters relevant to mineral resource development on Federal and Indian lands and the Outer Continental Shelf (OCS). The Secretary of the Interior (Secretary) under the Mineral Leasing Act (30 U.S.C. 1923) and the Outer Continental Shelf Lands Act (43 U.S.C. 1353) is responsible for managing the production of minerals from Federal and Indian lands and the OCS, collecting royalties from lessees who produce minerals, and distributing the funds collected in accordance with applicable laws. The Secretary has an Indian trust responsibility to manage Indian lands and seek advice and information from Indian beneficiaries. MMS performs the royalty management functions and assists the Secretary in carrying out DOI's Indian trust responsibility.

The Secretary of the Interior is authorized by Public Law 97-451, the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA), 30 U.S.C. 1732, and 30 U.S.C. 1701 *et seq.* to enter into cooperative agreements using the capabilities of tribes to carry out royalty audits and related investigation and enforcement activities. The Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA), Public Law 104-185, as corrected by Public Law 104-200, amended FOGRMA and essentially limited 30 CFR Part 228 to Indian tribes. As noted under 30 CFR Part 228.3, this part does not apply to Federal lands. Federal lands are audited by States under the provisions of 30 CFR Part 227, Delegation to States. Cooperative agreements benefit both MMS and Indian tribes by helping to ensure proper product valuation, correct and timely production reporting, and correct and timely royalty payment through the application of an aggressive and comprehensive audit program. To be considered for a cooperative agreement, Indian tribes must comply with the regulations at 30 CFR Part 228 by submitting a written request to the Director, MMS, and preparing a proposal that details the work to be done.

Currently, eight Indian tribes have cooperative audit agreements to perform audits and investigations. When an Indian tribe performs any of the

delegated functions under the 30 CFR Part 228 regulations, the Indian tribe also assumes the burden of providing various types of information to MMS. This information, provided to MMS in the course of performing cooperative agreements, is the focus of this information collection. We have changed the title of this ICR from "Cooperative Agreements" to "30 CFR Part 228, Cooperative Activities with States and Indian Tribes" for consistency with the regulatory language we are covering under 30 CFR Part 228.

We are also revising this ICR to include reporting requirements that were inadvertently overlooked when the

final rule was published. See the chart below for these requirements and associated burden hours.

MMS is requesting OMB's approval to continue to collect this information. Not collecting this information would limit the Secretary's ability to discharge his/her duties and may also result in loss of royalty payments to the Indian lessor due to royalties not being collected. Proprietary information submitted is protected, and there are no questions of a sensitive nature included in this information collection. The requirement to respond is voluntary.

Frequency: Quarterly, annually, or when deemed necessary.

Estimated Number and Description of Respondents: Eight Indian tribes currently have cooperative audit agreements.

Estimated Annual Reporting and Recordkeeping "Hour" Burden: 1,912 hours.

The following chart details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. Therefore, we consider these to be usual and customary and took that into account in estimating the burden.

TRIBAL RESPONDENT ANNUAL BURDEN HOUR CHART

30 CFR Section	Reporting requirement	Burden hours per response	Annual number of responses	Annual burden Phours
228.100 (a) and (b)(1), (2), (3), and (4); 228.101(a), (c); 228.107(b).	* * * Indian tribe may request the Department to enter into a cooperative agreement by sending a letter from the * * * tribal chairman * * * to the Director of MMS. The request for an agreement shall be in a format prescribed by MMS * * * Agreements * * * shall be valid for * * * 3 years and shall be renewable * * * upon request of the * * * Indian tribe * * * Indian tribe may unilaterally terminate an agreement by giving a 120-day written notice of intent to terminate. Each cooperative agreement shall contain detailed schedules identifying those activities and costs which qualify for funding and the procedures, timing, and mechanics for implementing Federal funding.	200	1	200
228.101(d)	* * * Indian tribe will be given 60-days to respond to the notice of deficiencies and to provide a plan for correction of those deficiencies.	80	1	80
228.103 (a) and (b)	The * * * Indian tribe entering into a cooperative agreement * * * must retain all records, reports, working papers, and any backup materials * * * The * * * Indian tribe shall maintain all books and records * * *.	120	8	960
228.105(a) (1) and (2)	The Department may * * * reimburse the * * * Indian tribe up to 100 percent of the costs of eligible activities. Eligible activities will be agreed upon annually upon the submission and approval of a workplan and funding requirement. A cooperative agreement may be entered into with * * * Indian tribe, upon request, without a requirement for reimbursement of costs by the Department.	60	8	480
228.105(c)	The * * * Indian tribe shall submit a voucher for reimbursement of eligible costs incurred within 30-days of the end of each calendar quarter. The * * * Indian tribe must provide the Department a summary of costs incurred, for which the * * * Indian tribe is seeking reimbursement, with the voucher.	4	48	192
Total	66	1,912

Estimated Annual Reporting and Recordkeeping "Non-hour" Cost Burden: We have identified no "non-hour" cost burdens.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor, and a person is not required to respond to,

a collection of information unless it displays a currently valid OMB Control Number.

Comments: Section 3506(c)(2)(A) of the PRA requires each agency " * * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each

proposed collection of information * * *." Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate

the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

To comply with the public consultation process, we published a notice in the **Federal Register** on May 5, 2003 (68 FR 23759), announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. We received no comments in response to this notice.

If you wish to comment in response to this notice, you may send your comments to the offices listed under the **ADDRESSES** section of this notice. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, to ensure maximum consideration, OMB should receive public comments by September 4, 2003.

Public Comment Policy: We will post all comments in response to this notice on our Web site at http://www.mrm.mms.gov/Laws_R_D/InfoColl/InfoColCom.htm. We will also make copies of the comments available for public review, including names and addresses of respondents, during regular business hours at our offices in Lakewood, Colorado. Individual respondents may request that we withhold their home address from the public record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you request that we withhold your name and/or address, state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

MMS Information Collection Clearance Officer: Jo Ann Lauterbach. (202) 208-7744.

Dated: July 25, 2003.

Lucy Querques Denett,

Associate Director for Minerals Revenue Management.

[FR Doc. 03-19914 Filed 8-4-03; 8:45 am]

BILLING CODE 4310-MR-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Klamath Project, Oregon

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of order establishing prohibitions in areas of Bureau of Reclamation Lands and Projects.

PURPOSE: To provide for the safety of the public and protection of government property.

SUMMARY: Pursuant to 43 CFR part 423, Public Conduct on Bureau of Reclamation Lands and Projects, the Bureau of Reclamation is issuing a Closure Order for certain lands and waters of the Klamath Project in the State of Oregon.

In accordance with 43 CFR part 423, Public Conduct on Bureau of Reclamation Lands, Reclamation is publishing the Closure Order in the **Federal Register**.

DATES: immediately and indefinitely.

ADDRESSES: Klamath Basin Area Office, 6600 Washburn Way, Klamath Falls, Oregon 97603.

FOR FURTHER INFORMATION CONTACT: Dave Sabo, Area Manager, (541) 883-6935.

SUPPLEMENTARY INFORMATION: This action is being taken under 43 CFR 423, to protect Reclamation facilities and property and to improve public safety. The Order prohibits trespassing, entering, or remaining in or upon the closure areas as described; tampering or attempting to tamper with the facilities, structures or other property located within the closure areas or moving, manipulating, or setting in motion any parts thereof; vandalism or destroying, injuring, defacing, or damaging property or real property that is not under one's lawful control or possession. The following areas are closed to public access:

A Canal Headgate Area—The closure area includes all lands, waters and facilities within 100 feet of either side of the centerline of the A Canal which lies between the Highway 97 onramp and the canal's confluence with Upper Klamath Lake. This closure area includes the entire A Canal headgate facility and related structures and buildings, walkways, gate operating mechanisms and all lands surrounding such structures within the described area.

Link River—The closure area includes the entire dam structure and surrounding lands and water 100 feet downstream and 50 feet upstream of the

dam and 50 feet from the right and left abutments.

Station 48 Drop—The closure area includes the land, water and facilities within and including the existing fence surrounding the headgate structure.

Klamath Basin Area Office Headquarters Area—The closure area includes the land and facilities immediately adjacent to and south of the KBAO office building and lying within and including the existing chain link fence which is bounded on the north by Joe Wright Road and on the east by Washburn Way and excludes the formal offices of the Fish and Wildlife Service and the Bureau of Reclamation.

The following acts are prohibited on the facilities, lands and waters in the above described closure areas:

1. Trespassing, entering, or remaining in or upon the closure areas described above. Exceptions: Operations and Maintenance personnel that have express authorization from Reclamation, law enforcement officers and Reclamation employees acting within the scope of their employment, and any others who have received express written authorization from Reclamation to enter the closure areas.

2. Tampering or attempting to tamper with the facilities, structures or other property located within the closure areas or moving, manipulating, or setting in motion any of the parts thereof. Exceptions: see 1 above.

3. Vandalism or destroying, injuring, defacing, or damaging property within the closure areas or real property that is not under one's lawful control or possession. This order is posted at the Klamath Basin Area Office, and at closed areas in Klamath Falls, Oregon, in accordance with 43 CFR Part 423.3(b).

Dated: July 29, 2003.

Christine D. Karas,

Acting Area Manager, Klamath Basin Area Office.

[FR Doc. 03-19837 Filed 8-4-03; 8:45 am]

BILLING CODE 4310-MN-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Sacramento Valley Water Management Program—Implementation of Short-term Projects

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent to prepare a programmatic environmental impact statement/environmental impact report (EIS/EIR) and hold public scoping meetings.

SUMMARY: The Department of the Interior, Bureau of Reclamation (Reclamation) and the California Department of Water Resources (CDWR) propose to prepare a Programmatic EIS/EIR to analyze the potential effects of the short-term phase of the Sacramento Valley Water Management Program (Short-term Program). The Short-term Program would include implementation of multiple short-term water management projects and other actions. The short-term projects would be implemented by Reclamation, CDWR, and Sacramento Valley water-users, and each project would operate for 10 years after implementation. The programmatic analysis in this EIS/EIR would include, but is not limited to, projects described in the "Sacramento Valley Water Management Agreement Short-term Workplan, October 2001" ("Short-term Workplan"). The purpose of implementing the Short-term Program is to promote better water management in the Sacramento Valley and develop additional water supplies through a cooperative water management partnership. The Short-term Program was developed to resolve water quality and water rights issues as an alternative to determining responsibility for flow-related water quality objectives of the 1995 Sacramento/San Joaquin Bay-Delta Water Quality Control Plan through a State Water Resources Control Board water rights hearing.

The environmental effects of some short-term projects would also be analyzed at a site-specific level of detail in the Programmatic EIS/EIR, and would constitute the final CEQA or NEPA document for those projects. As many short-term projects as possible would be analyzed at a site-specific level; however, the specific projects to be analyzed at that level are unknown at this time. Specific alternatives have not been identified at this time, and will be developed following scoping. Public scoping meetings regarding the preparation of the Programmatic EIS/EIR will be conducted as described below.

This notice is published in accordance with the National Environmental Policy Act regulations

found in 40 CFR 1501.7. The purpose of this notice is to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the Programmatic EIS/EIR. A similar notice is being published by the CDWR in accordance with the California Environmental Quality Act. Comments and participation in this scoping process are encouraged.

DATES: Two public scoping meetings will be held:

- Wednesday, August 20, 2003, 3–5 p.m., Sacramento, CA
- Thursday, August 21, 2003, 3–5 p.m., Colusa, CA

ADDRESSES: Scoping meetings will be held at:

- Sacramento at the Expo Inn, 1413 Howe Avenue (just south of Arden Way), The Expo Room.
- Colusa at the Colusa Industrial Properties, 100 Sunrise Boulevard (off Highway 45/20), The Conference Room.

Written comments on the scope of the Short-term Program or issues to be addressed in the EIS/EIR should be sent to the California Department of Water Resources, Attention: John Fielden, Project Manager, P.O. Box 942836, Sacramento, CA 94236-0001 by September 5, 2003.

FOR FURTHER INFORMATION CONTACT: John Fielden with CDWR via e-mail at jfielden@water.ca.gov or by calling (916) 651-7053 or Robert Eckart with Reclamation via e-mail at reckart@mp.usbr.gov or by calling (916) 978-5051. Additional information may also be found on the CDWR Web site at www.water.ca.gov.

SUPPLEMENTARY INFORMATION: As an alternative to participating in the State Water Resources Control Board's Phase 8 Bay-Delta Water Rights Hearings, Reclamation, CDWR, and numerous Sacramento Valley and export water interests entered into the "Short-term Agreement to Guide Implementation of the Short-term Water Management Actions to Meet Local Water Supply Needs and to Make Water Available to the SWP and CVP to Assist In Meeting the Requirements of the 1995 Water Quality Control Plan and to Resolve Phase 8 Issues" (the Short-term Settlement Agreement). The Short-term

Settlement Agreement established a process by which parties collaborate in the development and implementation of a variety of projects and actions to help meet flow-related water quality objectives established for the Sacramento/San Joaquin Bay-Delta, meet local water needs, and improve water supplies throughout the State.

Five categories of short-term projects and actions will be considered in the Short-term Program EIS/EIR:

- *Water Management*—includes groundwater substitution in lieu of surface water supplies, conjunctive use of groundwater and surface water, refurbish existing groundwater extraction wells, install groundwater monitoring stations, and install new groundwater extraction wells (some actions include construction of facilities)
- *Reservoir Re-operation*—includes changes in the operational diagrams and schedules for reservoirs in the Sacramento River watershed
- *System Improvement*—includes canal lining, tailwater recovery, and improved operations (some actions include construction of facilities)
- *Surface Water and Groundwater Planning*—includes studies, modeling, monitoring, and area wide inventory or assessment (actions could include minor construction of facilities for monitoring and testing purposes)
- *Other Actions*—includes potential water transfer actions and/or actions with substantial regulatory/institutional requirements (does not involve construction of facilities).

The effects of implementing the Short-term Program (short-term projects and actions) will be evaluated at the programmatic level. The known short-term projects proposed throughout the Sacramento Valley are presented in Table 1. In addition to the programmatic analysis, some proposed projects would also be analyzed at a site-specific level to allow for their immediate implementation. As many projects as possible would be analyzed at a site-specific level of review; however, the specific projects to be analyzed at that level are unknown at this time.

TABLE 1.—PROPOSED SHORT-TERM WATER MANAGEMENT PROJECTS TO BE ANALYZED IN THE PROGRAMMATIC EIS/EIR *

Project name (type)	Proponent	County	Description
Redding Sub-basin: Conjunctive Use Program (Water Management)	Anderson-Cottonwood Irrigation District.	Shasta County	Construct monitoring and extraction wells.

TABLE 1.—PROPOSED SHORT-TERM WATER MANAGEMENT PROJECTS TO BE ANALYZED IN THE PROGRAMMATIC EIS/
EIR*—Continued

Project name (type)	Proponent	County	Description
Churn Creek Lateral Improvements (System Improvement).	Anderson-Cottonwood Irrigation District.	Shasta County	Replace leaky canal lateral with pipeline in the reach east of the Sacramento River to eliminate seepage and spills.
Main Canal Modernization Project (System Improvement).	Anderson-Cottonwood Irrigation District.	Shasta County	Construct canal improvements to eliminate spills and reduce diversions.
Redding Basin Water Resources Management Plan (Surface Water/Groundwater Planning).	Anderson-Cottonwood Irrigation District.	Shasta County	Complete Phase 2C—Water Supply and Management Alternatives, part of multi-step planning process.
Feather/Butte Sub-basin:			
Integrated Watershed and Resource Conservation Program (Surface Water/Groundwater Planning).	Butte County	Butte County	Integrated watershed and resource conservation, groundwater monitoring and modeling, forecast water use.
Groundwater Monitoring Program (Surface Water/Groundwater Planning).	Butte County	Butte County	Install additional monitoring wells and extensometers, monitoring.
Groundwater Modeling Program (Surface Water/Groundwater Planning).	Butte County	Butte County	Update existing model to support decision-making about groundwater resources, as well as overall water resources management in the County.
Sutter-Butte Main Canal Lining Project (System Improvement).	Sutter Extension Water District, Gridley Water District, Richvale Irrigation District.	Butte and Sutter Counties	Conduct field study, obtain environmental permits, develop final construction drawings, construct.
Concow Dam (Reservoir Reoperation)	Thermalito Irrigation District.	Butte County	Feasibility study for raising existing concrete dam.
Water Management Project (Water Management) ...	RD 1004	Colusa County	Install extraction wells.
Colusa Sub-basin:			
Development of Conjunctive Water Management Facilities (Water Management).	Glenn-Colusa Irrigation District.	Glenn and Colusa Counties.	Fully use private land-owner wells.
Conjunctive Use Project (Water Management)	Maxwell Irrigation District ..	Colusa County	Test-hole drilling, evaluation and production well construction and testing, groundwater monitoring.
Stony Creek Fan Conjunctive Water Management Program (Water Management).	Orland-Artois Water District, Orland Unit Water Users' Association, Glenn-Colusa Irrigation District.	Glenn County	Feasibility study, groundwater production investigation, groundwater monitoring program, integrated groundwater/surface water model, and outreach plan.
Pilot Well Development/Conjunctive Management Project (Water Management).	RD 108	Colusa and Yolo Counties	Development of production well and analysis of basin expenses.
Tehama-Colusa Canal Extension (Water Management and System Improvement).	Tehama-Colusa Canal Authority Yolo-Zamora Water District.	Colusa and Yolo Counties	Prepare hydrologic and concept reports, conduct preliminary design, and collect information for project-specific environmental analysis.
Glen County Groundwater Monitoring Program and Model Development (Surface Water/Groundwater Planning).	Glenn-Colusa Irrigation District.	Glenn County	Develop groundwater data clearinghouse, analyze existing data, design monitoring program, install new monitoring wells, develop groundwater model.
Water Inventory and Analysis (Surface Water/Groundwater Planning).	Tehama County	Tehama County	Information gathering process and analysis.

TABLE 1.—PROPOSED SHORT-TERM WATER MANAGEMENT PROJECTS TO BE ANALYZED IN THE PROGRAMMATIC EIS/EIR*—Continued

Project name (type)	Proponent	County	Description
Feasibility Study: Regulatory Reservoirs and Off-canal Storage (Surface Water/Groundwater Planning).	Glenn-Colusa Irrigation District.	Glenn and Colusa Counties.	Feasibility study.
Flow Measurement Devices in Main Canal, Lateral System, and Drain Outflow Points/Existing Automation Program (System Improvement).	Glenn-Colusa Irrigation District.	Glenn and Colusa Counties.	Permitting, design, and construction of 12 flow measurement devices at previously identified system outflow points/permitting, design, and construction of 5 Main Canal check structures.
Regional Water Use Efficiency Project (System Improvement).	Orland Unit Water Users Association and Tehama-Colusa Canal Authority.	Glenn County	Conduct feasibility studies, build pilot projects, and begin conceptual design of regional pipeline.
Development of Conveyance Alternatives for TCCA Emergency Water Supplies (System Improvement).	Tehama-Colusa Canal Authority.	Colusa County	Feasibility study for Stony Creek Conveyance options; investigate an interim solution to operate a constant head orifice; agency coordination and permit planning.
Tehama-Colusa Canal Conveyance of Water to Sites Reservoir (System Improvement).	Tehama-Colusa Canal Authority.	Glenn and Colusa Counties.	Feasibility study, review ability of Tehama-Colusa Canal to convey potential water to a Sites Reservoir.
Antelope Creek Retention Basin Feasibility Study (Surface Water/Groundwater Planning).	Tehama County Flood Control and Water Conservation District.	Tehama County	Feasibility study for construction of a retention basin.
Water Management Project (Water Management) ...	Princeton-Codora-Glenn Irrigation District.	Glenn and Colusa Counties.	Construct one groundwater extraction well.
Water Management Project (Water Management) ...	Provident Irrigation District	Glenn and Colusa Counties.	Construct one groundwater extraction well.
Water Management Project (Water Management) ...	River Garden Farms	Yolo County	Construct three groundwater extraction wells.
Yuba Sub-basin: Coordinated Operations Project (Surface Water/Groundwater Planning).	Yuba County Water Agency.	Yuba County	Feasibility investigation of water supply benefits for out-of-county use, environmental and Endangered Species Act assessment and potential increased flood control benefits.
Conjunctive Use and Water Management Project (Water Management).	Brown's Valley Irrigation District.	Yuba County	Development of four groundwater production wells in lower portion of district and a lift pump and conveyance pipe to supply water to upper end of district.
Conjunctive Use Project (Water Management)	Yuba County Water Agency.	Yuba County	Installation of extraction wells.
Sutter Sub-basin: Groundwater Monitoring Program (Surface Water/Groundwater Planning).	Sutter Mutual Water Company.	Sutter County	Additional monitoring well, monitoring and data collection.
Watershed Assessment and Monitoring Program (Surface Water/Groundwater Planning).	Sutter County	Sutter County	Information gathering process and analysis.
Groundwater Management Plan (Surface Water/Groundwater Planning).	Sutter County	Sutter County	Information gathering process and analysis.
Irrigation Recycle Project (System Improvement) ...	Sutter Mutual Water Company, RD 1500.	Sutter County	Feasibility analysis of a tailwater recovery system.
Canal Lining (System Improvement)	Sutter Mutual Water Company.	Sutter County	Canal lining to reduce diversions, eliminate spills.
Ground Water Development (Water Management) ..	Pelger Mutual Water Company.	Sutter County	Construct two groundwater extraction wells.

TABLE 1.—PROPOSED SHORT-TERM WATER MANAGEMENT PROJECTS TO BE ANALYZED IN THE PROGRAMMATIC EIS/EIR *—Continued

Project name (type)	Proponent	County	Description
Water Management Project (Water Management) ...	Meridian Farms	Sutter County	Installation of extraction wells.
American Sub-basin: Conjunctive Use Project (Water Management)	Natomas Central Mutual Water Company.	Sacramento and Sutter Counties.	Pump existing wells, monitoring and analyzing results after one season.
Water Management Project (Water Management) ...	Pleasant Grove Verona Mutual Water Company.	Sutter County	Installation of extraction wells.
Re-operation of the Middle Fork Project (Reservoir Re-operation).	Placer County Water Agency.	Placer County	Re-operate primary storage reservoirs.
Yolo Sub-basin: Conjunctive Use Project Feasibility Study for Expanding Surface Water Supplies to the Yolo-Zamora Water District (Surface Water/Groundwater Planning and System Improvement).	Yolo County Flood Control and Water Conservation District.	Yolo County	Feasibility study for expanding surface water supplies to Yolo Zamora.
Conjunctive Use Project Feasibility Study for Expanding Surface Water Supplies to Agricultural Water Users in Areas (Surface Water/Groundwater Planning and System Improvement).	Yolo County Flood Control and Water Conservation District.	Yolo County	Feasibility study for expanding surface water supplies to Agricultural areas northwest of Woodland.
Groundwater Quality Monitoring Program (Surface Water/Groundwater Planning).	Yolo County Flood Control and Water Conservation District.	Yolo County	Development of a groundwater-quality monitoring program.
Delta Sub-basin: Conjunctive Use Proposal (Water Management)	RD 2068	Yolo County	Develop a single production well to determine conjunctive use potential.
Sacramento Valley: Sub-basin-level Water Measurement (Surface Water/Groundwater Planning).	Participants in the Basin-wide Management Plan.	Sacramento Valley—Various Counties.	Feasibility study, design and construction of water measurement facilities.

* The effects analysis in the Programmatic EIS/EIR would not be limited to these projects, and would include all short-term projects and actions that could be proposed under the Sacramento Valley Water Management Program.

This Programmatic EIS/EIR is expected to analyze the adverse and beneficial effects of implementing the Short-term Program on these environmental resources: surface water, water quality, fisheries, wildlife, vegetation, special-status species, land-use, cultural resources, air quality, noise, recreation, energy, visual impacts, and socioeconomic conditions. Analysis presented in the Programmatic EIS/EIR will also determine if environmental justice issues are associated with the Short-term Program. Although there are Indian Trust Assets (ITAs) in the counties where these projects are proposed, any association between these ITAs and the proposed projects and actions is unknown at this time. The following is a list of tribal trust land, per county where these projects are proposed:

- Shasta County—Redding Rancheria
- Butte County—Berry Creek Rancheria, Enterprise Rancheria, Mooretown Rancheria
- Glenn County—Grindstone Rancheria
- Colusa County—Colusa Rancheria, Cortina Rancheria

It is Reclamation's practice to make comments on a Notice of Intent, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There may also be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

Dated: July 30, 2003.

Robert Eckart,

Chief, Environmental Compliance Branch, Mid-Pacific Region.

[FR Doc. 03-19841 Filed 8-4-03; 8:45 am]

BILLING CODE 4310-MN-P

INTERNATIONAL TRADE COMMISSION

[Investigation 332-454]

Remediation and Nature and Landscape Protection Services: An Overview of U.S. and Foreign Markets

AGENCY: United States International Trade Commission.

ACTION: Institution of Investigation and scheduling of public hearing.

EFFECTIVE DATE: July 22, 2003.

SUMMARY: Following receipt of a request on July 1, 2003 from the United States Trade Representative (USTR), the Commission instituted Investigation No. 332-454, Remediation and Nature and Landscape Protection Services: An Examination of U.S. and Foreign Markets, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

FOR FURTHER INFORMATION CONTACT: Information specific to this investigation may be obtained from Jennifer Baumert, Project Leader (202-502-3450; jbaumert@usitc.gov), or Richard Brown, Chief, Services and Investment Division

(202-205-3438; rbrown@usitc.gov), Office of Industries, U.S. International Trade Commission, Washington, DC, 20436. For information on the legal aspects of this investigation, contact William Gearhart of the Office of the General Counsel (202-205-3091; wgearhart@usitc.gov). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202) 205-1810.

Background: As requested by the USTR, the Commission's report will, to the extent possible, (1) Provide an overview of foreign and domestic markets for remediation and nature and landscape protection services; (2) examine trade and investment in remediation and nature and landscape protection services markets, including barriers affecting such trade and investment, if any; and (3) if possible, discuss existing regulatory practices. USTR has requested that the Commission's study include examples from both developed and developing country markets. As requested by USTR, the range of services to be investigated in this study will be determined upon further consultation between USTR and ITC staff. The USTR asked that the Commission furnish its report by October 1, 2004, and that the Commission make the report available to the public in its entirety.

The USTR letter also requests an investigation on solid and hazardous waste services. In response, the Commission has instituted Investigation No. 332-455, Solid and Hazardous Waste Services: An Examination of U.S. and Foreign Markets, which is due to the USTR on April 1, 2004.

Public Hearing: A public hearing in connection with the investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on March 17, 2004. All persons shall have the right to appear, by counsel or in person, to present information and to be heard. Requests to appear at the public hearing should be filed with the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436, no later than 5:15 p.m., March 3, 2004. Any prehearing briefs (original and 14 copies) should be filed not later than 5:15 p.m., March 5, 2004; the deadline for filing post-hearing briefs or statements is 5:15 p.m., March 31, 2004. In the event that, as of the close of business on March 3, 2004, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or non-

participant may call the Secretary of the Commission (202-205-1816) after March 3, 2004, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements (original and 14 copies) concerning the matters to be addressed by the Commission in its report on this investigation. Commercial or financial information that a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties. The Commission will not include any confidential business information in the report it sends to the USTR. To be assured of consideration by the Commission, written statements relating to the Commission's report should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on March 31, 2004. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by 201.8 of the Commission's Rules (19 CFR 201.18) (see Handbook for Electronic Filing Procedures, ftp://ftp.usitc.gov/pub/reports/electronic_filing_handbook.pdf).

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>).

List of Subjects

WTO, GATS, remediation and nature and landscape protection services.

Issued: July 30, 2003.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03-19818 Filed 8-4-03; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation 332-455]

Solid and Hazardous Waste Services: An Overview of U.S. and Foreign Markets

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of public hearing.

EFFECTIVE DATE: July 29, 2003.

SUMMARY: Following receipt of a request on July 1, 2003 from the United States Trade Representative (USTR), the Commission instituted investigation No. 332-455, Solid and Hazardous Waste Services: An Examination of U.S. and Foreign Markets, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

FOR FURTHER INFORMATION CONTACT:

Information specific to this investigation may be obtained from Jennifer Baumert, Project Leader (202-205-3450; jbaumert@usitc.gov), or Richard Brown, Chief, Services and Investment Division (202-205-3438; rbrown@usitc.gov), Office of Industries, U.S. International Trade Commission, Washington, DC, 20436. For information on the legal aspects of this investigation, contact William Gearhart of the Office of the General Counsel (202-205-3091; wgearhart@usitc.gov). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202) 205-1810.

Background: As requested by the USTR, the Commission's report will, to the extent possible, (1) Provide an overview of foreign and domestic markets for solid and hazardous waste services; (2) examine trade and investment in solid and hazardous waste services markets, including barriers affecting such trade and investment, if any; and (3) if possible, discuss existing regulatory practices. USTR has requested that the Commission's study include examples from both developed- and developing-country markets. For the purpose of this study, solid and hazardous waste management services are defined to include the collection of solid and hazardous waste from households and industry; the treatment and disposal of solid and hazardous waste by various means; the collection, separation, and sorting of recyclable materials; waste compacting; waste reduction services; and incidental services.

The USTR asked that the Commission furnish its report by April 1, 2004, and

that the Commission make the report available to the public in its entirety.

The USTR letter also requests an investigation on remediation and nature and landscape protection services. In response, the Commission has instituted Investigation No. 332-454, Remediation and Nature and Landscape Protection Services: An Examination of U.S. and Foreign Markets, which is due to the USTR on October 1, 2004.

Public Hearing: A public hearing in connection with the investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, beginning at 9:30 a.m. on October 21, 2003. All persons shall have the right to appear, by counsel or in person, to present information and to be heard. Requests to appear at the public hearing should be filed with the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436, no later than 5:15 p.m., October 7, 2003. Any prehearing briefs (original and 14 copies) should be filed not later than 5:15 p.m., October 9, 2003; the deadline for filing post-hearing briefs or statements is 5:15 p.m., November 5, 2003. In the event that, as of the close of business on October 7, 2003, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or non-participant may call the Secretary of the Commission (202-205-1816) after October 7, 2003, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements (original and 14 copies) concerning the matters to be addressed by the Commission in its report on this investigation. Commercial or financial information that a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties. The Commission will not include any confidential business information in the report it sends to the USTR. To be assured of consideration by the Commission, written statements relating to the Commission's report should be

submitted to the Commission at the earliest practical date and should be received no later than the close of business on November 5, 2003. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's Rules, as amended, 67 FR 68036 (Nov. 8, 2002).

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>).

List of Subjects

WTO, GATS, solid and hazardous waste services.

Issued: July 30, 2003.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03-19817 Filed 8-4-03; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: National Tracing Center Trace Request and NTC Obliterated Serial Number Trace Request.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until October 6, 2003. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with

instructions or additional information, please contact Ben Hayes, ATF National Tracing Center, 244 Needy Road, Martinsburg, WV 25401.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection

(2) *Title of the Form/Collection:* National Tracing Center Trace Request and Obliterated Serial Number Trace Request.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 3312.1 and ATF F 3312.2. Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal Government. Other: State, Local, or Tribal Government. The forms are used by the Federal, State, Local, and International law enforcement community to request that ATF trace firearms used, or suspected to have been used, in crimes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 112,123 respondents will complete each form within 6 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 22,425 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Deputy Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW, Washington, DC 20530.

Dated: July 31, 2003.

Brenda E. Dyer,
Deputy Clearance Officer, Department of Justice.
[FR Doc. 03-19852 Filed 8-4-03; 8:45 am]
BILLING CODE 4410-FB-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 25, 2002, and published in the **Federal Register** on November 7, 2002, (67 FR 67870), Aldrich Chemical Company Inc., dba Isotec, 3858 Benner Road, Miamisburg, Ohio 45342-4304, made application to the Drug Enforcement Administration for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Aminorex (1585)	I
Gamma hydroxybutyric acid (2010)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxyamphetamine (7400)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxy-methamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
N-Ethyl-1-phenylcyclohexylamine (7455)	I
Dihydromorphine (9145)	I
Normorphine (9313)	I
Acetylmethadol (9601)	I
Alphacetylmethadol Except Levo-Alphacetylmethadol (9603)	I
Normethadone (9635)	I
3-Methylfentanyl (9813)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II

Drug	Schedule
Secobarbital (2315)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
1-Piperidinocyclohexanecarbonitrile (8603)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylcogonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk, (non-dosage forms) (9273)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The firm plans to manufacture small quantities of the listed controlled substances to produce standards for analytical laboratories.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Aldrich Chemical Company Inc., dba Isotec, to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Aldrich Chemical Company Inc., dba Isotec, to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: July 22, 2003.

Laura M. Nagel,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-19813 Filed 8-4-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 21, 2003, and published in the **Federal Register** on April 9, 2003, (68 FR 17402), Boehringer Ingelheim Chemicals, Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances sited below:

Drug	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Levo-alphacetylmethadol (9648)	II
Fentanyl (9801)	II

The firm plans to manufacture the listed controlled substances for formulation into finished pharmaceuticals.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Boehringer Ingelheim Chemicals, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Boehringer Ingelheim Chemicals, Inc. to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: July 22, 2003.

Laura M. Nagel,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-19811 Filed 8-4-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 3, 2003, and published in the **Federal Register** on April 15, 2003, (68 FR 18261), Chatterm Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
N-Ethylamphetamine (1475)	I
4-Methoxyamphetamine (7411) ..	I
2, 5-Dimethoxyamphetamine (7396).	I
Difenoxin (9168)	II
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Codeine (9050)	II
Oxycodone (9143)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Dextropropoxyphene, bulk, (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The firm plans to manufacturer the listed controlled substances to produce products for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Chatterm Chemicals, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Chatterm Chemicals, Inc. to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: July 22, 2003.
 Laura M. Nagel,
 Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.
 [FR Doc. 03-19815 Filed 8-04-03; 8:45 am]
 BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 14, 2003, and published in the **Federal Register** on April 2, 2003, (68 FR 16089), Mallinckrodt, Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Nicomorphine (9312)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine HCL (9059)	II
Dihydrocodeine (9120)	II
Hydromorphone (9150)	II
Oxycodone (9143)	II
Diphenoxylate (9170)	II
Benzoylcegonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Metopon (9260)	II
Dextropropoxyphene, bulk (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Levo-alphaacetylmethadol (9648)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The above cited Notice of Application contained an error in that the drug code

for Oxycodone was listed as 9160 rather than 9143.

The firm plans to manufacture the listed controlled substances for internal use and for sale to other companies.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Mallinckrodt, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Mallinckrodt, Inc. to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: July 22, 2003.
 Laura M. Nagel,
 Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.
 [FR Doc. 03-19814 Filed 8-4-03; 8:45 am]
 BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on April 2, 2003, Penick, Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II

The firm plans to manufacture bulk controlled substances and non-controlled flavor extracts.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than October 6, 2003.

Dated: July 22, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-19809 Filed 8-4-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturers of Controlled Substances; Notice of Registration

By Notice dated March 14, 2003, and published in the **Federal Register** on April 2, 2003, (68 FR 16091) Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of Schedule I and II controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Dihydrocodeine (9102)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Thebaine (9333)	II
Noroxymorphone (9668)	II
Fentanyl (9801)	II

The firm plans to produce bulk products for conversion and distribution to its customers.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Rhodes Technologies to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Rhodes Technologies to

ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: July 22, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-19812 Filed 8-4-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 23, 2003, Wildlife Laboratories, Inc., 1401 Duff Drive, Suite 600, Fort Collins, Colorado 80524, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of Carfentanil (9743), a basic class of controlled substance listed in Schedule II.

The firm plans to manufacture the listed controlled substance for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the deputy Assistance Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than October 6, 2003.

Dated: July 22, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03-19810 Filed 8-4-03; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Federal Bureau of Investigations

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: FBI Questionnaire for National Security Positions.

The Department of Justice (DOJ), Federal Bureau of Investigations (FBI), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until October 6, 2003. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ms. Gari L. Carter, Supervisory Applicant Case Specialist, Bureau Applicant Employment Unit, Applicant Processing Section, Administrative Services Division, Federal Bureau of Investigation, Washington, DC 20535, (202) 324-0801.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

- (1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* FBI Questionnaire for National Security Positions.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: FD-957, Federal Bureau of Investigation, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal Government. Other: Individuals. In accordance with the FBI's efforts to re-engineer the hiring process for FBI employment and in accordance with the Paperwork Reduction Act of 1995, Public Law 104.13.109 Stat.163, the FBI has determined that suitability determinations and the granting/denying of security clearances can be made based on information provided by applicants on the SF-86, Questionnaire for National Security Positions in addition to a supplemental FBI form to collect collateral information. This form has been designated as FD-957, FBI Questionnaire for National Security Positions.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 50,000 respondents with an average response rate of one-half hour to complete each form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 25,000 total annual burden hours associated with this collection.

FOR FURTHER INFORMATION CONTACT: Brenda E. Dyer, Deputy Clearance

Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW, Washington, DC 20530.

Dated: July 30, 2003.
Brenda E. Dyer,
Deputy Clearance Officer, Department of Justice.
 [FR Doc. 03-19851 Filed 8-4-03; 8:45 am]
BILLING CODE 4410-02-P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

July 24, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation, contact Vanessa Reeves on 202-693-4124 (this is not a toll-free number) or e-Mail: reeves.vanessa2@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Office for the Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503 (202-395-7316/

this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension of currently approved collection.

Title: Statement of Expenditures and Adjustments of Federal Funds for Unemployment Compensation for Federal Employees and Ex-Servicemembers.

OMB Number: 1205-0162.

Affected Public: State, Local, or Tribal govt.

Frequency: Quarterly.

Type of Response: Recordkeeping and Reporting.

Number of Respondent: 53.

Information collection requirements	Annual responses	Average response time (hours)	Annual burden hours
ETA 191	53	24.00	1,272
Total			1,272

Total Annualized capital/startup costs: \$0.

Total annual costs (operating/maintaining systems or purchasing services): \$0.

Description: Federal and military agencies must reimburse the Federal Employees Compensation Account for the amount expended for benefits to former Federal (civilian) employees (UCFE) and ex-servicemembers (UCX).

The report informs ETA of the amount to bill each such agency.

Ira L. Mills,
Department Clearance Officer.
 [FR Doc. 03-19846 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

July 30, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of this

ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation, contact Vanessa Reeves on 202-693-4124 (this is not a toll-free number) or e-Mail: reeves.vanessa2@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503 (202-395-7316/ this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Revision of a currently approved collection.

Title: Trade Adjustment Assistance/NAFTA Financial Status/Request for Funds Report.

OMB Number: 1205-0275.

Affected Public: State, Local, or Tribal govt.

Frequency: Quarterly.

Type of Response: Reporting.

Number of Respondents: 52.

Information collection requirements	Annual responses	Average response time (hours)	Annual burden hours
TAA (ETA 9023)	52	10.00	520
NAFTA (ETA 9023)	52	10.00	520
Total			1,040

Information collection requirements	Annual responses	Average response time (hours)	269 burden hours
TAA (SF 269)	52	2.50	130
NAFTA (SF 269)	52	2.50	130
Total			260

Total Annualized capital/startup costs: \$0.

Total annual costs (operating/maintaining systems or purchasing services): \$33,946.

Description: The Department of Labor requires financial data for the Trade Adjustment Assistance (TAA) program administered by States which is currently used from the Standard Form 424 and 424A. The required data are necessary in order to meet statutory requirements prescribed in Pub. L. 100-418, the Omnibus Trade and Competitiveness Act of 1988 and the North American Free Trade Agreement Implementation Act (Pub. L. 103-182) in accordance with section 250(a) Subchapter D, Chapter 2, Title II of the Trade Act of 1974.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 03-19847 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

July 30, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation, contact Vanessa Reeves on 202-693-4124 (this is not a toll-free number) or e-mail: reeves.vanessa2@dol.gov.

Comments should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk for the Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503 (202-395-7316 / this is not a toll-free number), within 30

days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension of a currently approved collection.

Title: Reporting and Performance Standards System for Indian and Native American Programs Under Title I, Section 166 of the Workforce Investment Act (WIA).

OMB Number: 1205-0422.
Affected Public: Not-for-profit institutions and State, Local, or Tribal govt.

Frequency: Semi-annually and Annually.
Type of Response: Recordkeeping and Reporting.
Number of Respondents: 145.

Required section 166 activity (comprehensive services)	DINAP form No.	Number of respondents	Responses per year	Total responses	Hours per response	Total burden hours
Plan Narrative	145	1	145	12.00	1,740
Recordkeeping	145	17,000	3	51,000
Participant Reporting	ETA 9084	145	2	290	9.67	2,804
Total	145	3	17,435	24.67	55,544

Required section 166 activity (supplemental youth services)	DINAP form No.	Number of respondents	Responses per year	Total responses	Hours per response	Total burden hours
Plan Narrative	105	1	105	6	630
Recordkeeping	105	8,000	2	16,000
Participant Reporting	ETA 9085	105	2	210	9.67	2,031
Total	3	8,315	17.67	18,661

Total Annualized capital/startup costs: \$0.

Total annual costs (operating/maintaining systems or purchasing services): \$0.

Description: This is an extension of a currently-approved collection of participant information relating to the operation of employment and training programs for Indians and Native Americans under title I, section 166 of the Workforce Investment Act (WIA). It also contains the basis of the new performance standards system for WIA section 166 grantees. The burden estimates for this collection include the Supplemental Youth Services Program as well as the Comprehensive Services Program authorized under section 166. Burden estimates do not include those tribes currently participating in the demonstration under Pub. L. 102-477.

Ira L. Mills,
Departmental Clearance Officer.
[FR Doc. 03-19848 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA-W) issued during the period of July 2003.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated; and

(2) That sales or production, or both, of the firm or sub-division have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production of such firm or subdivision.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

None.

In the following case, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

The investigation revealed that criterion (a)(2)(A)(I.C.) (Increased imports) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

- TA-W-52,169; Allsteel, Inc., a div. of Hon Industries, Inc., Milan, TN
- TA-W-52,039; Heraeus Electro-Nite Co., Philadelphia, PA
- TA-W-52,066; SWR Sound Corp., Sun Valley, CA
- TA-W-52,116; SPI Polyols, Inc., New Castle, DE

The workers firm does not produce an article as required for certification under section 222 of the Trade Act of 1974.

- TA-W-52,270; LM Services LLC, Cumberland, MD
- TA-W-52,006; America Online, Inc., Oklahoma City, OK
- TA-W-52,124; New England Joint Board, UNITE, Willimantic, CT

The investigation revealed that criteria (a)(2)(A)(I.A) (no employment declines) have not been met.

- TA-W-52,207; Fishing Vessel (F/V) Selah, Haines, AK
- TA-W-52,261; Cummings Fisheries, Dillingham, AK
- TA-W-52,283; Fishing Vessel (F/V) Peregrine's Catch, Haines, AK

The investigation revealed that criteria (a)(2)(A)(I.C) (increased imports) and (a)(2)(B) (II.C) (has shifted production to country not under the free trade agreement with U.S.) have not been met.

- TA-W-52,216; Scope Molding, LLC, Almena, WI

The investigation revealed that criteria (2) has not been met. The workers firm (or subdivision) is not a supplier or downstream producer to trade-affected companies.

- TA-W-51,889; Sommer Products Co., Bartonville, IL

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of (a)(2)(A) (increased imports) of Section 222 have been met.

- TA-W-51,928 & A; *Joan Fabrics Corp., Newton Finishing Plant, Newton, NC and Weaving and Support Operation, Hickory, NC*: June 2, 2002.
- TA-W-51,964; *American Glass Co. d/b/a L.E. Smith Glass Co., Mount Pleasant, PA*: May 28, 2002.
- TA-W-52,105; *Johnson Hosiery Mills, Inc., Hickory, NC*: June 19, 2002.
- TA-W-52,151; *Portland General Electric, Trojan Nuclear Plant, Rainier, OR*: June 20, 2002.
- TA-W-52,155; *SFO Apparel, San Francisco, CA*: June 13, 2002.
- TA-W-52,190; *Stearns, Inc., Grey Eagle Div., Grey Eagle, MN*: June 24, 2002.
- TA-W-51,526; *Yofi Textile Printing Co., Passaic, NJ*: February 26, 2002.
- TA-W-51,986; *Amyx Industries, Inc., a div. of Walsh and Simmons Seating, West Plains, MO*: June 2, 2002.
- TA-W-52,041; *Trigen Biopower, Inc., St. Mary's, GA*: June 10, 2002.
- TA-W-52,074; *Wellmade Industries, Inc., New York, NY*: June 5, 2002.
- TA-W-52,099; *Sony Semiconductor Co. including leased workers from Manpower Professionals, San Antonio, TX*: June 18, 2002.
- The following certifications have been issued. The requirements of (a)(2)(B) (shift in production) of Section 222 have been met.
- TA-W-51,937; *Magnequench UG, Valparaiso, IN*: May 30, 2002. TA-W-51,975 & A; *Walstenburg Apparel Corp., Walstenburg, NC and Vanceboro, NC*: May 30, 2002.
- TA-W-52,025; *Dynamco, Roper Pump Co., McKinney, TX*: June 11, 2002.
- TA-W-52,130; *The Sherwin-Williams Co., Chemical Coatings Div., Harrisburg, PA*: June 23, 2002.
- TA-W-52,140; *North American Battery Co. including leased workers from Remedy Staffing, San Diego, CA*: June 17, 2002.
- TA-W-52,144; *Homecrest Industries, Inc., Wadena, MN*: June 25, 2002.
- TA-W-52,244; *Schneider Electric—Square D, Cedar Rapids, IA*: July 2, 2002.
- TA-W-52,214; *ITT Industries, Searcy, AR*: June 22, 2002.

- TA-W-52,163; *General Electric Co., Industrial Systems Div., Mebane, NC*: June 26, 2002.
- TA-W-52,150; *Honeywell International, Sensing and Control Div., including leased workers of Manpower and Atech, Milpitas, CA*: June 12, 2002.
- TA-W-51,984; *Martinrea Industries, Inc., Pilot Industries, Inc., Manchester Div., Manchester, MI*: June 9, 2002.
- TA-W-52,224; *VF Imagewear, Inc., Brownsville, TX*: July 2, 2002.
- TA-W-52,247; *Mackie Designs, Inc., including leased workers of Adecco, Express Personnel, Onsite and Remedy, Woodinville, WA*: July 2, 2002.
- The following certification has been issued. The requirement of upstream supplier to a trade certified primary firm has been met.
- TA-W-52,282; *Fishing Vessel (F/V) Njord, Elfin Cove, AK*: July 8, 2002.
- TA-W-52,205; *Kimball Electronics, d/b/a Kimball Manufacturing, Boise, ID*: June 26, 2002.

I hereby certify that the aforementioned determinations were issued during the month of July 2003. Copies of these determinations are available for inspection in Room C-5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, during normal business hours or will be mailed to persons who write to the above address.

Dated: July 21, 2003.

Timothy Sullivan,
Director, Division of Trade Adjustment Assistance.
[FR Doc. 03-19861 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-50,366]

Agere Systems, Inc., Optoelectronics Division, Formerly Lucent Technologies, Inc.'s Microelectronics Business, Breinigsville, Pennsylvania; Notice of Revised Determination on Reconsideration

On May 12, 2003, the Department issued an Affirmative Determination Regarding Application on Reconsideration applicable to workers and former workers of the subject firm. The notice was published in the **Federal Register** on May 29, 2003 (68 FR 32124).

On January 27, 2003 the Department initially denied TAA to workers of Agere Systems, Inc., Optoelectronics

Division, formerly Lucent Technologies, Inc.'s Microelectronics Division, Breinigsville, Pennsylvania producing optoelectronic devices because the "contributed importantly" group eligibility requirement of Section 222 of the Trade Act of 1974, was not met.

On reconsideration, the department surveyed additional customers of the subject plant regarding their purchases of optoelectronic devices during the 2001 and 2002 period. The survey revealed that major declining customer(s) increased their reliance on imports of optoelectronic devices in the relevant period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with optoelectronic devices, contributed importantly to the declines in sales or production and to the total or partial separation of workers of Agere Systems, Inc., Optoelectronics Division, formerly Lucent Technologies, Inc.'s Microelectronics Division, Breinigsville, Pennsylvania. In accordance with the provisions of the Act, I make the following certification:

All workers of Agere Systems, Inc., Optoelectronics Division, formerly Lucent Technologies, Inc., Microelectronics Division, Breinigsville, Pennsylvania who became totally or partially separated from employment on or after December 9, 2001 through two years of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC this 18th day of July 2003.

Elliott S. Kushner,
Certifying Officer, Division of Trade Adjustment Assistance.
[FR Doc. 03-19856 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-52,138]

Agere Systems, Inc., Optoelectronics Division, Formerly Lucent Technologies, Inc., Microelectronics Business, Breinigsville, PA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 25, 2003 in response to a petition filed on behalf of workers at Agere Systems, Inc., formerly Lucent Technologies, Inc.,

Microelectronics business, Breinigsville, Pennsylvania.

The petitioning group of workers is covered by an active certification issued on July 18, 2003 and which remains in effect (TA-W-50,366). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 25th day of July, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19869 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,065]

State of Alaska Commercial Fisheries Entry Commission Permit #S1SB578390, Fairbanks, AK; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 17, 2003, in response to a petition filed by a company official on behalf of workers covered by the State of Alaska Commercial Fisheries Entry Commission Permit #S1SB578390, Fairbanks, Alaska.

The Department has been unable to locate the company official for the subject group to obtain the information necessary to reach a determination on worker group eligibility. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 21st day of July, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19860 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,049]

American Leather, LP, Dallas, TX; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on June 17, 2003, in response to a worker petition which was filed by

a company official on behalf of workers at American Leather, LP, Dallas, Texas (TA-W-52,049).

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 25th day of July, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19870 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-50,330]

Bardon Rubber Company, Inc., Union Grove, Wisconsin; Notice of Revised Determination

By letter dated March 31, 2003, the International Union, United Automobile, Aerospace & Agricultural Implement Workers of America-UAW, requested administrative reconsideration regarding the Department's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to the workers of the subject firm.

The initial investigation resulted in a negative determination issued on February 10, 2003. The Department initially denied TAA to workers of Bardon Rubber Company, Inc., Union Grove, Wisconsin producing rubber products (such as "O" rings, gaskets, and seals) because the "contributed importantly" group eligibility requirement of Section 222 of the Trade Act of 1974, as amended, was not met. The notice was published in the *Federal Register* on March 26, 2003 (68 FR 14708).

In the request for reconsideration, the union indicated that the subject firm should be considered on the basis of secondary upstream supplier impact, and provided the names of customers that were under existing trade certifications. Upon further review, it was revealed that the Department erred in its initial investigation, as secondary impact was indicated on the petition.

Having conducted an investigation of subject firm workers on the basis of secondary impact, it was revealed that Bardon Rubber Company, Inc., Union Grove, Wisconsin supplies component parts for clamps, valves and pump products, and at least 20 percent of its

production or sales is supplied to a manufacturer whose workers were certified eligible to apply for adjustment assistance.

Conclusion

After careful review of the facts obtained in the investigation, I determine that workers of Bardon Rubber Company, Inc., Union Grove, Wisconsin qualify as adversely affected secondary workers under Section 222 of the Trade Act of 1974, as amended. In accordance with the provisions of the Act, I make the following certification:

All workers of Bardon Rubber Company, Inc., Union Grove, Wisconsin who became totally or partially separated from employment on or after December 11, 2001 through two years from the date of certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 11th day of July 2003.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19855 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,278]

Brandt, a Varco Company, Oklahoma City, Oklahoma; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 10, 2003, in response to a petition filed on behalf of workers at Brandt, a Varco Company, Oklahoma City Oklahoma.

The petition regarding the investigation has been deemed invalid. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 25th day of July, 2003.

Linda G. Poole.

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19866 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-50,314]

Electroglas, Inc. Including Leased Workers of Advanced Technical Resources San Jose, CA; Notice of Revised Determination on Reconsideration—Business Confidential

By application of March 25, 2003, a petitioner requested administrative reconsideration regarding the Department's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to the workers of the subject firm.

The initial investigation resulted in a negative determination issued on January 31, 2003, based on the finding that imports of wafer probers did not contribute importantly to worker separations at the San Jose plant. The denial notice was published in the **Federal Register** on February 24, 2003 (68 FR 8619).

To support the request for reconsideration, the petitioner supplied additional information to supplement that which was gathered during the initial investigation. Upon further review and contact with the company, it was revealed that the company increased their imports of wafer probers, contributing significantly to the layoffs during the relevant period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with those produced at Electroglas, Inc., San Jose, California, contributed importantly to the declines in sales or production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Electroglas, Inc., including leased workers of Advanced Technical Resources, San Jose, California, who became totally or partially separated from employment on or after December 9, 2001 through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC this 14th day of July 2003.

Elliott S. Kushner,*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 03-19854 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-52,361]

EXFO Burleigh Products Group, Inc., Victor, NY; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 21, 2003, in response to a petition filed by a company official on behalf of workers at EXFO Burleigh Products Group, Inc., Victor, New York.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 25th day of July, 2003.

Linda G. Poole,*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 03-19863 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-52,265]

Gasboy International, LLC, Lansdale, PA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 10, 2003, in response to a worker petition filed by a company official on behalf of workers at Gasboy International, LLC, Lansdale, Pennsylvania.

The company official has withdrawn the petition; thus, further investigation would serve no purpose and the investigation under this petition has been terminated.

Signed at Washington, DC, this 25th day of July, 2003.

Linda G. Poole,*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. 03-19867 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration**

[TA-W-50,514].

General Electric Company, Industrial Systems, Mebane, NC; Dimissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at General Electric Company, Industrial Systems, Mebane, North Carolina. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA-W-50,514; General Electric Company, Industrial Systems Mebane, North Carolina (July 17, 2003).

Signed at Washington, DC this 22nd day of July 2003.

Timothy F. Sullivan,*Director, Division of Trade Adjustment Assistance.*

[FR Doc. 03-19857 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR**Employment and Training Administration****Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance**

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the

Director, Division of Trade Adjustment Assistance, at the address shown below, not later than August 15, 2003.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address

shown below, not later than August 15, 2003.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C-5311, 200

Constitution Avenue, NW, Washington, DC 20210.

Signed at Washington, DC this 21st day of July 2003.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted Between 07/14/03 and 07/18/03]

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
52,297	Internet (Comp)	Radford, VA	07/14/03	06/23/03
52,298	Harriet and Henderson Yarns, Inc. (Comp)	Henderson, NC	07/14/03	07/11/03
52,299	Gerber Plumbing Fixtures, LLC (Wkrs)	Delphi, IN	07/14/03	07/11/03
52,300	A.O. Smith Corporation (Comp)	McBee, SC	07/14/03	07/08/03
52,301	Edgcomb Metals (USWA)	Roseville, MI	07/14/03	07/01/03
52,302	Grayson Properties Corporation (Comp)	Galax, VA	07/14/03	07/14/03
52,303	DOW Chemical Company (USWA)	Ludington, MI	07/14/03	07/07/03
52,304	Standard Register Company (Wkrs)	Kirkville, MO	07/14/03	07/07/03
52,305	National Steel Corp. (Wkrs)	Trenton, MI	07/14/03	07/03/03
52,306	York International Corporation (Comp)	York, PA	07/15/03	07/11/03
52,307	Ovalstrapping, Inc. (Wkrs)	Fort Payne, AL	07/15/03	07/14/03
52,308	Cal Quality Electronics (Comp)	Santa Ana, CA	07/15/03	07/11/03
52,309	B.A.G. Corporation (Comp)	Pennington Gap, VA	07/15/03	07/10/03
52,310	Stopfill, Inc. (Comp)	Mt. Pleasant, PA	07/15/03	07/02/03
52,311	Ceodeux, Inc. (Comp)	Mt. Pleasant, PA	07/15/03	07/02/03
52,312	Rotarex Inc., N.A. (Comp)	Mt. Pleasant, PA	07/15/03	07/02/03
52,313	Convergys (Wkrs)	Orem, UT	07/15/03	07/14/03
52,314	Presstek, Inc. (Wkrs)	Hudson, NH	07/15/03	07/07/03
52,315	Murphy's Custom Canvas (Comp)	Central Point, OR	07/15/03	07/14/03
52,316	Louisiana Pacific (Wkrs)	Bonnars Ferry, ID	07/15/03	06/26/03
52,317	Onamac Industries, Inc. (WA)	Everett, WA	07/15/03	07/14/03
52,318	GE Osmonics (Wkrs)	Minnetonka, MN	07/15/03	07/10/03
52,319	Akron Porcelain and Plastics (USWA)	Akron, OH	07/15/03	06/20/03
52,320	Computer Sciences Corp. (Wkrs)	Newark, DE	07/15/03	06/19/03
52,321	Anvil International Inc. (Wkrs)	S. Kearny, NJ	07/15/03	07/14/03
52,322	DeMarco California Fabrics (NY)	New York, NY	07/16/03	07/15/03
52,323	Stanek Tool Corporation (Comp)	New Berlin, WI	07/16/03	07/15/03
52,324	Medite Division of Sierra Pine, Ltd. (AWPPW)	Medford, OR	07/16/03	07/10/03
52,325	Solelectron (Wkrs)	Beaverton, OR	07/16/03	06/30/03
52,326	Bojud Knitting Mills, Inc. (Comp)	Amsterdam, NY	07/16/03	07/08/03
52,327	NIBCO (USWA)	Elkhart, IN	07/16/03	07/15/03
52,328	Photocircuits (GA)	Peachtree, GA	07/16/03	07/16/03
52,329	ASML (Wkrs)	Austin, TX	07/16/03	07/14/03
52,330	Computer Sciences Corporation (Wkrs)	Dallas, TX	07/16/03	07/15/03
52,331	Advanced Micro Device (Wkrs)	Austin, TX	07/16/03	04/15/03
52,332	Aircraft Precision Products, Inc. (Comp)	Ithaca, MI	07/16/03	07/15/03
52,333	Kline Iron and Steel Co., Inc. (Comp)	W. Columbia, SC	07/16/03	07/15/03
52,334	TNS Mills, Inc. (Wkrs)	Gaffney, SC	07/16/03	07/16/03
52,335	American Bag (Comp)	Sterns, KY	07/17/03	07/17/03
52,336	Consolidated Diesel Co. (NC)	Whitakers, NC	07/17/03	07/16/03
52,337	Kaba High Security Locks Corp. (Comp)	Southington, CT	07/17/03	07/16/03
52,338	Takata Petri Inc. (Comp)	Port Huron, MI	07/17/03	07/16/03
52,339	Metal FX (Wkrs)	Willits, CA	07/17/03	07/16/03
52,340	RST and B Curtain and Drapery (Comp)	Florence, SC	07/17/03	07/17/03
52,341	Firestone Tube Company (USWA)	Russellville, AR	07/18/03	07/16/03
52,342	Citation (Comp)	Browtown, WI	07/18/03	07/16/03
52,343	Control Devices (Comp)	Stadish, ME	07/18/03	07/16/03
52,344	Green Bay Packaging (PACE)	Green Bay, WI	07/18/03	07/03/03
52,345	SPX Dock Products (Comp)	Milwaukee, WI	07/18/03	07/17/03
52,346	George F. Adams Co., Inc. (Comp)	Moscow, VT	07/18/03	07/18/03
52,347	Astaris LLC (Comp)	Soda Springs, ID	07/18/03	07/15/03
52,348	Labinal Snecma Group (Comp)	Corinth, TX	07/18/03	07/16/03

[FR Doc. 03-19850 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,289]

Phillips Plastics Corporation, Medical Molding and Assembly, Menomonie, WI; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 11, 2003, in response to a worker petition filed on behalf of workers at Plastics Corporation, Medical Molding and Assembly, Menomonie, Wisconsin.

The petitioning group of workers is covered by an earlier petition filed on June 20, 2003 (TA-W-52,107), that is the subject of an ongoing investigation for which a determination has not yet been issued. Further investigation in this case would duplicate efforts and serve no purpose; therefore the investigation under this petition has been terminated.

Signed at Washington, DC, this 23rd day of July, 2003

Elliott S. Kushner,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19862 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,260]

Rockwell Automation, Inc., Mequon, WI; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 10, 2003, in response to a petition filed by a company official on behalf of workers at Rockwell Automation, Inc., Mequon, Wisconsin.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 25th day of July, 2003.

Linda G. Poole,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19868 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-51,861]

Rosewood Manufacturing Company, A Division of Blauer Manufacturing Company, Inc., Charleston, MS; Notice of Revised Determination on Reconsideration

By letter of June 25, 2003, a company official requested administrative reconsideration regarding the Department's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to the workers of the subject firm.

The initial investigation resulted in a negative determination issued on June 13, 2003, based on the finding that imports of public safety sweaters and jackets did not contribute importantly to worker separations at the subject plant. The denial notice was published in the *Federal Register* on July 3, 2003 (68 FR 39976).

To support the request for reconsideration, the company supplied additional information to supplement that which was gathered during the initial investigation. Upon further review, it was revealed that sales and production figures provided in the initial investigation combined subject firm sales and production with import data. Subsequently, it was revealed that in fact sales and production declines did occur, and also that company imports increased in the relevant period, contributing to layoffs at the subject firm.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with those produced at Rosewood Manufacturing Company, Inc., A Division of Blauer Manufacturing Company, Inc., Charleston, Mississippi, contributed importantly to the declines in sales or production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Rosewood Manufacturing Company, Inc., A Division of Blauer Manufacturing Company, Inc., Charleston, Mississippi, who became totally or partially separated from employment on or after May 16, 2002, through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 11th day of July, 2003.

Elliott S. Kushner,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19859 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-51,523]

Stimson Lumber Company, Arden, WA; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Stimson Lumber Company, Arden, Washington. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA-W-51,523; Stimson Lumber Company, Arden, Washington (July 17, 2003).

Signed at Washington, DC this 22nd day of July 2003.

Timothy F. Sullivan,
Director, Division of Trade Adjustment Assistance.

[FR Doc. 03-19858 Filed 8-4-03; 8:45 am]
BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,305]

National Steel Corporation/United States Steel C.P.A.D. Division, a.k.a United States Steel Corporation, Technical Center, Trenton, MI; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 14, 2003, in response to a worker petition filed on behalf of workers at United States Steel, Technical Center, Trenton, Michigan.

The petitioning group of workers is covered by an active certification issued on July 9, 2003, and which remains in effect (TA-W-51,611E). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 22nd day of July, 2003.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19865 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-52,334]

Wellstone Mills, LLC, Formerly TNS Mills, Inc., Gaffney Weaving Division, Gaffney, SC; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 16, 2003, in response to a petition filed on behalf of workers of Wellstone Mills, LLC, formerly TNS Mills, Inc., Gaffney Weaving Division, Gaffney, South Carolina.

The petitioning group of workers is covered by an active certification (TA-W-41,658), which was amended to reflect the new ownership and remains in effect through October 10, 2004. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 25th day of July, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03-19864 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection; Comment Request; Correction

ACTION: Correction.

SUMMARY: In the notice document 03-19218 beginning on page 44547 in the issue of Tuesday, July 29, 2003, make the following correction:

On page 44547 in the first column in the 2nd paragraph, the comment due date is omitted. The comment due date should be September 29, 2003.

Dated: July 29, 2003.

Maria K. Flynn,

Acting Administrator, Office of Policy Development, Evaluation and Research, Employment and Training Administration.

[FR Doc. 03-19849 Filed 8-4-03; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL SCIENCE FOUNDATION

Notice of Meeting; NSB Education and Human Resources Subcommittee

AGENCY HOLDING MEETING: National Science Foundation, National Science Board.

DATE AND TIME: August 5, 2003; 11 a.m.—12 a.m.—Open Session.

PLACE: The National Science Foundation, 4201 Wilson Boulevard—Room 130, Arlington, VA 22230, www.nsf.gov.

FOR FURTHER INFORMATION CONTACT: Robert Webber, (703) 292-7000.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Tuesday, August 5, 2003

Open

NSB Subcommittee on Education and Human Resources, Graduate Working Group, Teleconference, Room 130.

1. Overview of Graduate Working Group objectives

a. Should the Graduate Working Group review the performance and evaluation reports for the GK-12, IGERT, and other programs?

2. Strategies for achieving Working Group objectives

3. Research on student decision-making regarding graduate education in STEM fields—

4. Impacts of increases in NSF stipend levels.

5. Coordination with other Federal Agencies.

6. Comments and requests related to the May 2003 Three-Groups Background Book

7. Schedule for Graduate Working Group activities

Robert Webber,

Policy Analyst, NSBO.

[FR Doc. 03-19803 Filed 8-4-03; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-285]

Omaha Public Power District, Fort Calhoun Station, Unit 1; Exemption

1.0 Background

The Omaha Public Power District (the licensee) is the holder of Facility Operating License No. DPR-40 which authorizes operation of the Fort Calhoun Station, Unit 1 (FCS). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of a pressurized water reactor located in Washington County in Nebraska.

2.0 Request/Action

Title 10 of the Code of Federal Regulations (10 CFR), part 50, appendix G, which is invoked by 10 CFR 50.60, requires that pressure-temperature (P-T) limits be established for reactor pressure vessels (RPVs) during normal operating and hydrostatic or leak rate testing conditions. Specifically, appendix G to 10 CFR part 50 states that “[t]he appropriate requirements on * * * the pressure-temperature limits and minimum permissible temperature must be met for all conditions,” and “[t]he pressure-temperature limits identified as ‘ASME [American Society for Mechanical Engineers] Appendix G limits’ * * * require that the limits must be at least as conservative as limits obtained by following the methods of analysis and the margins of safety of Appendix G of Section XI of the ASME [Boiler and Pressure Vessel] Code.” Appendix G of 10 CFR part 50 also specifies that the Editions and Addenda of the ASME Code which are incorporated by reference in 10 CFR 50.55a apply to the requirements in appendix G to 10 CFR part 50. In the 2003 Edition of the Code of Federal Regulations, the NRC endorsed Editions and Addenda of the ASME Code through the 1998 Edition and 2000 Addenda. However, the licensee has currently incorporated the 1989 Edition of the ASME Code into the FCS licensing basis for defining the ASME Code requirements which apply to the plant’s ASME Code, Section XI program. Hence, with respect to the statements from appendix G to 10 CFR part 50 referenced above, it is the 1989 Edition of ASME Code, Section XI, Appendix G, which continues to apply for FCS. Finally, 10 CFR 50.60(b) states that,

"[p]roposed alternatives to the requirements in [Appendix G] of this part or portions thereof may be used when an exemption is granted by the Commission under [10 CFR 50.12]."

In the licensee's October 8, 2002, license amendment request to implement a pressure-temperature limits report (PTLR) for FCS, the licensee identified Topical Report Combustion Engineering (CE) NPSD-683-A, Revision 6, as part of the PTLR methodology that would be cited in the FCS Technical Specifications (TS). The NRC staff approved CE NPSD-683-A, Revision 6, by letter dated March 16, 2001, with specified limitations or additional licensee actions which are necessary to support a licensee's adoption of CE NPSD-683-A, Revision 6. One of the specified licensing actions stated that if a licensee proposed to utilize the methodology in CE NPSD-683-A, Revision 6, for the calculation of flaw stress intensity factors due to thermal stress loadings (K_{It}), an exemption was required since the methodology for the calculation of K_{It} values in CE NPSD-683-A, Revision 6, could not be shown to be conservative with respect to the methodology for the determination of K_{It} provided in Editions and Addenda of ASME Code, Section XI, Appendix G, through the 1995 Edition and 1996 Addenda (the latest Edition and Addenda of the ASME Code which had been incorporated into 10 CFR 50.55a at the time of the staff's review of CE NPSD-683-A, Revision 6). Therefore, in conjunction with the licensee's October 8, 2002, license amendment request, the licensee also submitted an exemption request, consistent with the requirements of 10 CFR 50.60, to apply the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, as part of the FCS PTLR methodology.

During the NRC staff's review of CE NPSD-683-A, Revision 6, the staff evaluated the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, versus the methodologies for K_{It} calculation given in Appendix G to Section XI of the ASME Code. In the staff's March 16, 2001, safety evaluation (SE), the staff noted, "[i]n the [CE methodology], the K_{It} is calculated using thermal [stress] influence coefficients developed from 2-dimensional (2-D) FEM [finite element] models with linear, quadratic, and cubic vessel temperature profiles. These thermal influence coefficients are then corrected for the 3-D elliptical crack geometry using the procedures of Appendix A to Section XI of the ASME Code. Theoretically, using CE's thermal influence coefficients is equivalent to

using the [thermal] stress influence coefficients of the current [1995 Edition through 1996 Addenda] Appendix G methodology.... Thus, the alternative methodology in [the CE NPSD-683-A, Revision 6] for calculating K_{It} factors is similar to that in the most recent edition of Appendix G to the Code endorsed by the NRC." In addition, work done by Mr. J. A. Keeney and Mr. T. L. Dickson of Oak Ridge National Laboratory has demonstrated that a 3-dimensional FEM approach gives thermal influence coefficients that are very similar to those incorporated in the CE NPSD-683-A, Revision 6, methodology. In summary, the staff concluded in its March 16, 2001, SE that the methodology in CE NPSD-683-A, Revision 6, including that for the calculation of K_{It} , would lead to the development of P-T limit curves which are only slightly non-conservative with respect to those which would be calculated using the 1989 Edition of Appendix G to Section XI of the ASME Code (the Edition of record for FCS). The staff stated in the SE that P-T limit curves developed using the methodology of CE NPSD-683-A, Revision 6, are adequate to protect the RPV against brittle fracture under all normal operating and hydrostatic/leak test conditions and licensees applying for PTLRs could apply the methods of CE NPSD-683-A, Revision 6, to the P-T limit calculations provided an exemption to use the methodology would be reviewed and granted by the staff in accordance with the provisions of 10 CFR 50.60(b).

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present.

Special circumstances, pursuant to 10 CFR 50.12(a)(2)(ii), are present in that continued operation of FCS with P-T limit curves developed in accordance with ASME Section XI, Appendix G without the relief provided by utilizing the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, is not necessary to achieve the underlying purpose of Appendix G to 10 CFR part 50. Application of the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, in lieu of the calculational methodology specified in ASME Code Section XI, Appendix G, provides an acceptable alternative evaluational

procedure which will continue to meet the underlying purpose of appendix G to 10 CFR part 50. The underlying purpose of the regulations in appendix G to 10 CFR part 50 is to provide an acceptable margin of safety against brittle failure of the RCS during any condition of normal operation to which the pressure boundary may be subjected over its service lifetime.

Based on the staff's March 16, 2001, SE regarding CE NPSD-683-A, Revision 6, and the licensee's exemption request, the staff accepts the licensee's determination that an exemption would be required to approve the use of the K_{It} calculational methodology of CE NPSD-683-A, Revision 6. The staff concludes that the application by FCS of the technical provisions of the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, provide sufficient margin in the development of RPV P-T limit curves such that the underlying purpose of the regulations (appendix G to 10 CFR part 50) continues to be met. Therefore, the NRC staff concludes that the exemption requested by the licensee meets the special circumstances of 10 CFR 50(a)(2)(ii), "[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule," and is therefore justified and may be granted.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants Omaha Public Power District an exemption from the requirements of 10 CFR part 50, appendix G, to allow application of the K_{It} calculational methodology of CE NPSD-683-A, Revision 6, in establishing PTLR methodology for FCS.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (68 FR 44110).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th day of July 2003.

For The Nuclear Regulatory Commission.

Ledyard B. Marsh,

Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03-19887 Filed 8-4-03; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-328]

Tennessee Valley Authority, Sequoyah Nuclear Plant, Unit 2; Exemption

1.0 Background

Tennessee Valley Authority (TVA, the licensee) is the holder of Facility Operating License No. DRP-79 which authorizes operation of Sequoyah Nuclear Power Station, Unit 2 (SQN2). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of a pressurized water-reactor located on TVA's Sequoyah site, which is located in Hamilton County, Tennessee.

2.0 Request/Action

Title 10 of the Code of Federal Regulations (10 CFR), part 50, appendix G, which is invoked by 10 CFR 50.60, requires that pressure-temperature (P-T) limits be established for reactor pressure vessels (RPVs) during normal operating and hydrostatic or leak rate testing conditions. Specifically, appendix G to 10 CFR part 50 states that "[t]he appropriate requirements on . . . the pressure-temperature limits and minimum permissible temperature must be met for all conditions," and "[t]he pressure-temperature limits identified as 'ASME Appendix G limits' . . . require that the limits must be at least as conservative as limits obtained by following the methods of analysis and the margins of safety of Appendix G of Section XI of the ASME Code." Appendix G of 10 CFR part 50 also specifies that the Editions and Addenda of the ASME Boiler and Pressure Vessel (B&PV) Code which are incorporated by reference in 10 CFR 50.55a apply to the requirements in appendix G to 10 CFR part 50. The NRC endorsed Editions and Addenda of the ASME B&PV Code through the 1998 Edition and 2000 Addenda. However, TVA has currently incorporated the 1995 Edition through the 1996 Addenda of the ASME B&PV Code into the SQN2 licensing basis for defining the ASME B&PV Code requirements which apply to the unit's ASME B&PV Code, Section XI program. Hence, with respect to the statements from appendix G to 10 CFR part 50 referenced above, it is the 1995 Edition through 1996 Addenda of ASME B&PV Code, Section XI, Appendix G which apply for SQN2. Finally, 10 CFR 50.60(b) states that, "[p]roposed

alternatives to the described requirements in [Appendix G] of this part or portions thereof may be used when an exemption is granted by the Commission under [10 CFR 50.12]."

TVA requested in its submittal dated September 6, 2002, as supplemented by letters dated December 19, 2002, and June 24, 2003, that the staff exempt SQN2 from application of specific requirements of appendix G to 10 CFR part 50, and substitute use of ASME B&PV Code Case N-640. ASME B&PV Code Case N-640 permits the use of an alternate reference fracture toughness curve for RPV materials for use in determining the P-T limits. The exemption request is consistent with, and needed to support, a SQN2 license amendment request that was submitted on June 5, 2003, to modify the P-T limit curves in the facility's Technical Specifications (TS). The SQN2 license amendment request will revise the P-T limits for heatup, cooldown, and inservice test limitations for the reactor coolant system (RCS) to 32 effective full power years of operation.

Code Case N-640

The licensee has proposed an exemption to allow use of ASME Code Case N-640 in conjunction with ASME Section XI, Appendix G, 10 CFR 50.60(a) and 10 CFR part 50, appendix G, to establish P-T limits for the SQN2 RPV. The revised P-T limits have been developed using the lower bound K_{IC} fracture toughness curve shown in ASME Section XI, Appendix A, Figure A-2200-1, in lieu of the lower bound K_{IA} fracture toughness curve of ASME Section XI, Appendix G, Figure G-2210-1, as the basis fracture toughness curve for defining the SQN2 P-T limits. The other margins involved with the ASME Section XI, Appendix G process of determining P-T limit curves remain unchanged.

Use of the K_{IC} curve as the basis fracture toughness curve for the development of P-T operating limits is more technically correct than use of the K_{IA} curve. The K_{IC} curve appropriately implements the use of a relationship based on static initiation fracture toughness behavior to evaluate the controlled heatup and cooldown process of an RPV, whereas the K_{IA} fracture toughness curve codified into Appendix G to Section XI of the ASME Code was developed from more conservative crack arrest and dynamic fracture toughness test data. The application of the K_{IA} fracture toughness curve was initially codified in Appendix G to Section XI of the ASME Code in 1974 to provide a conservative representation of RPV material fracture

toughness. This initial conservatism was necessary due to the limited knowledge of RPV material behavior in 1974. However, additional knowledge has been gained about RPV materials which demonstrates that the lower bound on fracture toughness provided by the K_{IA} fracture toughness curve is well beyond the margin of safety required to protect the public health and safety from potential RPV brittle failure. Application of the provisions of ASME Code Case N-640 will result in the implementation of P-T limit curves having sufficient margin to ensure that, when stressed, the reactor pressure vessel will behave in a nonbrittle manner and that the probability of rapidly propagating brittle fracture is extremely low.

In addition, P-T limit curves based on the K_{IC} fracture toughness curve will enhance overall plant safety by opening the P-T operating window with the greatest safety benefit in the region of low temperature operations. The operating window through which the operator heats up and cools down the RCS is determined by the difference between the maximum allowable pressure determined by Appendix G of ASME Section XI, and the minimum required pressure for the reactor coolant pump seals adjusted for instrument uncertainties. A narrow operating window could potentially have an adverse safety impact by increasing the possibility of inadvertent overpressure protection system actuation due to pressure surges associated with normal plant evolutions such as RCS pump starts or swapping operating charging pumps with the RCS in a water-solid condition.

Therefore, the licensee concluded that these considerations were special circumstances pursuant to 10 CFR 50.12(a)(2)(ii), and supported the requested exemption to utilize the provisions of ASME B&PV Code Case N-640 in the development of SQN2 RPV P-T limit curves.

The NRC staff has reviewed the exemption request submitted by TVA and has concluded that an exemption should be granted to permit the licensee to utilize the provisions of ASME B&PV Code Case N-640 for the purpose of developing SQN2 RPV P-T limit curves. The NRC staff agrees that special circumstances pursuant to 10 CFR 50.12(a)(2)(ii), "[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule," exist. The NRC staff concurs that the licensee may acceptably apply the provisions of

ASME Code Case N-640 to relax the requirements found in the 1995 Edition through 1996 Addenda of the ASME B&PV Code, Section XI, Appendix G, while maintaining, pursuant to 10 CFR 50.12(a)(2)(ii), the underlying purpose of the ASME B&PV Code and the NRC regulations to ensure that adequate margins of safety exist to protect the RCS from the potential for brittle failure.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, when (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security, and (2) when special circumstances are present. The NRC staff accepts the licensee's determination that an exemption would be required to approve the use of ASME B&PV Code Case N-640. The NRC staff concluded that the use of ASME B&PV Code Case N-640 would meet the underlying intent of appendix G to 10 CFR part 50. Based upon a consideration of the conservatism that is explicitly incorporated into the methodologies of appendix G to 10 CFR part 50, the staff concluded that application of ASME Code Case N-640 as described would provide an adequate margin of safety against brittle failure of the RPV. This is also consistent with the determination that the staff has reached for other licensees under similar conditions based on the same considerations. Therefore, the staff concludes that requesting the exemption under the special circumstances of 10 CFR 50.12(a)(2)(ii) is appropriate and that the methodology of Code Case N-640 may be used to revise the P-T limits for the SQN2 RPV.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not endanger life or property or common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants Tennessee Valley Authority an exemption from the requirements of appendix G to 10 CFR part 50 for the development of P-T limit curves for the SQN2 RPV.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not result in any significant effect on the

quality of the human environment (68 FR 44550).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th Day of July 2003.

For The Nuclear Regulatory Commission.

Ledyard B. Marsh,

Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03-19886 Filed 8-4-03; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of August 4, 11, 18, 25, September 1, 8, 2003.

PLACE: Commissioners Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of August 4, 2003

There are no meetings scheduled for the Week of August 4, 2003.

Week of August 11, 2003—Tentative,

There are no meetings scheduled for the Week of August 11, 2003.

Week of August 18, 2003—Tentative

There are no meetings scheduled for the Week of August 18, 2003.

Week of August 25, 2003—Tentative

Monday, August 25, 2003

9:30 a.m.—Discussion in Investigatory and Enforcement Issued (Closed—Ex. 7 & 5).

Week of September 1, 2003—Tentative

There are no meetings scheduled for the Week of September 1, 2003.

Week of September 8, 2003—Tentative

Wednesday, September 10, 2003

1 p.m.—Meeting with Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD) (Public Meeting) (Contact: John Zabko, 301-415-2308).

This meeting will be Webcast live at the Web address—<http://www.nrc.gov>
3 p.m.—Discussion of Security Issues (Closed—Ex. 1).

Thursday, September 11, 2003

1:30 p.m.—Discussion of Security Issues (Closed—Ex. 1).

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415-1292. Contact person for more information: David Louis Gamberoni (301) 415-1651.

* * * * *
Additional Information: "Briefing on License Renewal Program, Power Uprate Activities, and High Priority Activities," previously scheduled for August 27th, 2003 has been postponed.

* * * * *
The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/what-we-do/policy-making/schedule.html>

* * * * *
This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301-415-1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to dkw@nrc.gov.

Dated: July 31, 2003.

D.L. Gamberoni,
Technical Coordinator, Office of the Secretary.

[FR Doc. 03-19985 Filed 8-1-03; 8:45 am]

BILLING CODE 7590-01-M

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

Background

Pursuant to Pub. L. 97-415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Pub. L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or

proposed to be issued from, July 11, 2003, through July 24, 2003. The last biweekly notice was published on July 22, 2003 (68 FR 43382).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards; Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville

Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By September 4, 2003, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene.

Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any

hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff, or may be delivered to the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland, by the above date. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that petitions for leave to intervene and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to hearingdocket@nrc.gov. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and because of continuing disruptions in delivery of mail to United States Government offices, it is requested that copies be transmitted either by means of facsimile transmission to 301-415-3725 or by e-mail to OGCMailCenter@nrc.gov. A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdrc@nrc.gov.

Carolina Power & Light Company, Docket Nos. 50-325 and 50-324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of amendments request: July 21, 2003.

Description of amendments request: The proposed license amendment requests approval to revise the Updated Final Safety Analysis Report, Section 9.4.5, "Turbine Building Ventilation System," and supporting information in Section 6.4.4.1, "Radiological Protection," and Section 15.6.3, "Main Steam Line Break Accident," to allow the system to be operated in a once-through versus recirculation configuration in support of outage activities.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The accident of concern for the proposed modification is a Main Steam Line Break (MSLB). The probability of this event is not impacted by the change to the turbine building ventilation system configuration. The consequences of the event have been re-evaluated to determine the impact on control room operator doses and offsite doses. The re-evaluation was performed consistent with the analysis done in support of the adoption of Alternative Source Term (AST) which was approved for use at BSEP (Brunswick Steam Electric Plant) in Amendments 221 and 246 for Units 1 and 2, respectively. The results of the re-evaluation demonstrate that control room doses remain well below regulatory limits and [that] there is no significant impact on offsite doses. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The turbine building ventilation system is non-safety related and its purpose is to provide an acceptable environment for equipment and personnel within the turbine building as well as treat the gaseous effluent prior to release. As such, modification of this system cannot (1) Alter any design basis accident initiators, (2) create new types of accident precursors, or (3) introduce new failure modes of safety related equipment. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The margin of safety for this modification is considered to be that provided by meeting the applicable regulatory limits. Operation of the turbine building ventilation system in a once-through versus recirculation configuration does not impact the ability to ensure that the doses at the exclusion area and low population zone boundaries, as well as the control room, remain well within corresponding regulatory limits with respect to a MSLB event (*i.e.*, the only event whose consequences can be impacted by the proposed modification). This was confirmed through re-evaluation of the consequences of a MSLB event, consistent with the analysis done in support of the adoption of AST. Since the proposed changes continue to ensure that the doses at the exclusion area and low population zone boundaries, as well as the control room are within corresponding regulatory limits, the proposed license amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Steven R. Carr, Associate General Counsel—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Section Chief: Allen G. Howe.

Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: April 25, 2003, as supplemented on May 21 and June 11, 2003.

Description of amendment request: The proposed changes to the Technical Specifications (TSs) consists of revisions to protective instrumentation specifications. These changes are made to resolve non-conservative TS issues, relax overly restrictive requirements, and to provide consistency between TS and design and licensing bases. These changes also involve reformatting data, as well as relocation of some data to plant-controlled documents.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff's review is presented below:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not significantly affect the design or fundamental operation and maintenance of the plant. Accident initiators or the frequency of analyzed accident events are not significantly affected as a result of the proposed changes; therefore, there will be no significant change to the probabilities of accidents previously evaluated.

The proposed changes do not significantly alter assumptions or initial conditions relative to the mitigation of an accident previously evaluated. The proposed changes continue to ensure process variables, structures, systems, and components (SSCs) are maintained consistent with the safety analyses and licensing basis. The revised TSs continue to require that SSCs are properly maintained to ensure operability and performance of safety functions as assumed in the safety analyses. The design basis events analyzed in the safety analyses will not change significantly as a result of the proposed changes to the TSs.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not involve any physical alteration of the plant (no new or different type of equipment being installed) and do not involve a significant change in the design, normal configuration or basic operation of the plant. The proposed changes do not introduce any new accident initiators. In some cases, the proposed changes impose different requirements; however, these new requirements are consistent with the assumptions in the safety analyses and current licensing basis. Where requirements are relocated to other licensee-controlled documents, adequate controls exist to ensure their proper maintenance.

Therefore, the proposed TS changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Involve a significant reduction in a margin of safety.

Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident situation. The proposed changes do not significantly affect any of the assumptions, initial conditions or inputs to the safety analyses. Plant design is unaffected by these proposed changes and will continue to provide adequate defense-in-depth and diversity

of safety functions as assumed in the safety analyses.

There is no proposed change to Safety Limits and only administrative and more restrictive changes to Limiting Safety System Setting requirements. The proposed changes maintain requirements consistent with safety analyses assumptions and the licensing basis. Fission product barriers will continue to meet their design capabilities without significant impact to their ability to maintain parameters within acceptable limits. The safety functions are maintained within acceptable limits without any significant decrease in margin.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. David R. Lewis, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037-1128.
NRC Section Chief: James W. Clifford.

Exelon Generation Company, LLC, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois

Date of amendment request: February 27, 2003. By a letter dated July 17, 2003, the licensee revised its analysis about the issue of no significant hazards consideration.

Description of amendment request: The proposed amendments would revise the Technical Specifications (TS) Section 3.4.9, Reactor Coolant System Pressure and Temperature (P/T) Limits, and delete the license conditions specified in Facility Operating License Sections 2.C(8) and 3.P, Pressure-Temperature Limit Curves, for Dresden Nuclear Power Station, Units 2 and 3 respectively. The P/T limit curves are proposed to be replaced with ones that are applicable to the remainder of the licensed life of the plant.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed TS changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The P/T limits are prescribed during all operational conditions to avoid encountering pressure, temperature, and temperature rate

of change conditions that might cause undetected flaws to propagate, resulting in non-ductile failure of the reactor coolant pressure boundary, which is an unanalyzed condition. The methodology used to determine the P/T limits has been approved by the NRC and thus is an acceptable method for determining these limits. Therefore, the proposed changes do not affect the probability of an accident previously evaluated.

There is no specific accident that postulates a non-ductile failure of the reactor coolant pressure boundary. The loss of coolant accident analyzed for the plant assumes a complete break of the reactor coolant pressure boundary. The revision to the P/T limits does not change this assumption. Thus, the radiological consequences of any accident previously evaluated are not increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed TS changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not change the response of plant equipment to transient conditions. The proposed changes do not introduce any new equipment, modes of system operation, or failure mechanisms.

Non-ductile failure of the reactor coolant pressure boundary is not an analyzed accident. The proposed changes to the P/T limits were developed using an NRC-approved methodology, and thus the revised limits will continue to provide protection against non-ductile failure of the reactor coolant pressure boundary.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed TS changes do not involve a significant reduction in a margin of safety.

The margin of safety related to the proposed changes is the margin between the proposed P/T limits and the pressures and temperatures that would produce non-ductile failure of the reactor coolant pressure boundary. The use of an NRC-approved methodology together with conservatively-chosen plant-specific input parameters provides an acceptable margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Edward J. Cullen, Deputy General Counsel, Exelon BSC—Legal, 2301 Market Street, Philadelphia, PA 19101.

NRC Section Chief: Anthony J. Mendiola.

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket No. 50-278, Peach Bottom Atomic Power Station, Unit 3, York County and Lancaster County, Pennsylvania

Date of amendment request: June 23, 2003.

Description of amendment request: Exelon Generation Company, LLC, the licensee, is proposing a change to the Peach Bottom Atomic Power Station (PBAPS), Unit 3, Technical Specifications (TSs) contained in Appendix A to the Operating License. This proposed change will revise the TS section on safety limits to incorporate revised safety limit minimum critical power ratios (SLMCPRs) based on the cycle-specific analysis performed by Global Nuclear Fuel for PBAPS, Unit 3, Cycle 15.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Changing the SLMCPRs does not require any physical plant modifications, physically affect any plant components, or involve changes in plant operation. Therefore, the probability of an accident previously evaluated remains unchanged.

The operability of plant systems designed to mitigate any consequences of accidents has not changed, therefore, the consequences of an accident previously evaluated are not expected to increase.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed change does not involve any modifications of the plant configuration for allowable modes of operation. The SLMCPRs are not accident initiators, and their revision will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

The proposed SLMCPRs provide a margin of safety by ensuring that no more than 0.1% of the rods are in a boiling transition if the operating limit minimum critical power ratios are

violated during all modes of operation. The change in the SLMCPRs continues to ensure that during normal operation and during abnormal operational transients, at least 99.9% of all fuel rods in the core do not experience transition boiling if the limit is not violated when all uncertainties are considered, thereby preserving the fuel cladding integrity. Therefore, the proposed TS change will not involve a significant reduction in a margin of safety.

Based on the NRC staff's review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Edward Cullen, Vice President & General Counsel, Exelon Generation Company, LLC, 300 Exelon Way, Kennett Square, PA 19348.

NRC Section Chief: James W. Clifford.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50-334, Beaver Valley Power Station, Unit No. 1 (BVPS-1), Beaver County, Pennsylvania

Date of amendment request: June 24, 2003.

Description of amendment request: The proposed amendments would change the Technical Specification (TS) steam generator tube inspection definition such that the definition of tube inspection would exclude the portion of the tube within the tubesheet below the W^* distance and would change the tube plugging criteria to indicate that the plugging or repair criteria does not apply to service-induced degradation identified in the W^* distance. Service-induced degradation identified in the W^* distance would be repaired upon detection. The W^* distance is defined in Westinghouse Topical Report, WCAP-14797, Revision 1, and is the distance from the top of the tubesheet to the bottom of the W^* length including the distance to the bottom of the WEXTEX transition (approximately 0.25 inches from the top of the tubesheet) plus uncertainties. This equals approximately 7.12 inches on the hot leg side plus the distance to the bottom of the WEXTEX transition and 7.62 inches on the cold leg side plus the distance to the bottom of the WEXTEX transition.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change modifies the BVPS Unit 1 TSs to incorporate [an] SG [steam generator] tube inspection scope based on WCAP-14797, Revision 1. The proposed change only clarifies the current process which has been utilized in the past. The W^* analysis takes into account the reinforcing effect that the tubesheet has on the external surface of an expanded SG tube. Tube-bundle integrity will not be adversely affected by the implementation of the W^* tube inspection scope. SG tube burst or collapse cannot occur within the confines of the tubesheet; therefore, the tube burst and collapse criteria of Regulatory Guide (RG) 1.121 are inherently met. Any degradation below the W^* distance is shown by analysis and test results to be acceptable, and therefore does not result in an increase in probability of a tube rupture or an increase in the consequences of a tube rupture.

Tube burst is precluded for cracks within the tubesheet by the constraint provided by the tubesheet. However, in the unlikely event of a complete circumferential separation of a tube occurring below the W^* distance, SG tube pullout is precluded, tube integrity is maintained and leakage is predicted to be maintained within the Updated Final Safety Analysis Report limits during all plant conditions.

In conclusion, the incorporation of the W^* inspection scope into BVPS Unit 1 TS[s] maintains existing design limits and does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed change modifies the BVPS Unit 1 TSs to incorporate SG tube inspection scope based on WCAP-14797, Revision 1. Tube-bundle integrity will be maintained during all plant conditions upon implementation of the proposed tube inspection scope. Use of this scope does not induce a new mechanism that would result in a different kind of accident from those previously analyzed. Even with the limiting circumstances of a complete circumferential separation of a tube occurring below the W^* distance, SG tube pullout is precluded and leakage is predicted to be maintained within the design limits during all plant conditions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. WCAP-14797, Revision 1 describes the testing that was performed to define the length of non-degraded tubing that is sufficient to compensate for the axial forces on the tube and thus prevent pullout. The operating conditions utilized in WCAP-14797, Revision 1, bound BVPS Unit 1 operating conditions. Upon implementation of the W^* inspection scope, operation with potential cracking below the W^* distance in

the WESTEX expansion region of the SG tubing meets the margin of safety as defined in RG 1.121 and RG 1.83 and the requirements of General Design Criteria 14, 15, 16, 31, and 32.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for Licensee: Mary O'Reilly, FirstEnergy Nuclear Operating Company, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Section Chief: Richard J. Laufer.

Florida Power Corporation, et al., Docket No. 50-302, Crystal River Unit 3 Nuclear Generating Plant, Citrus County, Florida.

Date of amendment request: July 14, 2003.

Description of amendment request: The proposed license amendment would revise Technical Specification 3.7.9 by adding a note to allow a one-time 10-day completion time for restoring an inoperable nuclear services seawater system train to operable status. The proposed change would allow the refurbishment of one nuclear services seawater system emergency pump (RWP-2A or RWP-2B) online. The note would specify that the one-time 10-day completion time will expire on December 30, 2004.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed license amendment extends, on a one-time basis, the Completion Time for restoring an inoperable Nuclear Services Seawater System train to Operable status. The Nuclear Services Seawater System is designed to provide cooling for components essential to the mitigation of plant transients and accidents. The system is not an initiator of design basis accidents. During the requested extended time period of ten days, the redundant Emergency Nuclear Services Seawater pump will be available and capable of providing cooling for containment heat loads and essential equipment during emergency conditions. RWP-1 is the CR-3 [Crystal River Unit 3] normal duty Nuclear Closed Cycle Cooling Water pump. Although RWP-1 is non-safety related and its motor is non-seismic, has a lower flow capability than

either RWP-2B or RWP-2A and is not connected to an emergency power source, it will also be available and capable of removing emergency heat loads from essential equipment from all design basis events. Informal calculations performed show that below a Ultimate Heat Sink (UHS) temperature of approximately 90°F, RWP-1 can maintain adequate heat removal under accident conditions.

A Probabilistic Safety Assessment (PSA) has been performed to assess the risk impact of an increase in Completion Time. Although the proposed one-time change results in an increase in Core Damage Frequency (CDF) and Large Early Release Frequency (LERF), the value of these increases are considered as very small in the current regulatory guidance.

Therefore, granting this LAR [License Amendment Request] does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does not create the possibility of a new or different type of accident from any accident previously evaluated.

The proposed license amendment extends, on a one-time basis, the Completion Time for restoring an inoperable Nuclear Services Seawater System train to Operable status.

The proposed LAR will not result in changes to the design, physical configuration of the plant or the assumptions made in the safety analysis. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does not involve a significant reduction in the margin of safety.

The proposed license amendment extends, on a one-time basis, the Completion Time for restoring an inoperable Nuclear Services Seawater System train to Operable status. The proposed change will allow online repair of one of the Emergency Nuclear Services Seawater pumps to improve its reliability and useful lifetime, thus increasing the long term margin of safety of the system.

The proposed LAR will reduce the probability (and associated risk) of a plant shutdown to repair an Emergency Nuclear Services Seawater pump. To ensure defense in depth capabilities and the assumptions in the risk assessment are maintained during the proposed one-time extended Completion Time, CR-3 will continue the performance of 10 CFR 50.65(a)(4) assessments before performing maintenance or surveillance activities and no maintenance activities of other risk sensitive equipment beyond that required for the refurbishment activity will be scheduled concurrent with the repair activity. Other compensatory actions that may be implemented, include: Use of pre-job briefings and periodic operator walkdowns to assess status of risk sensitive equipment in the redundant train, selection of beneficial Makeup Pump configurations and redundant off-site power feeds to the remaining Emergency Nuclear Services Seawater System pump, no elective maintenance to be scheduled in the switchyard, and the establishment of fire watches in fire areas identified in [PSA Risk Assessment of RWP-2A/2B Extended AOT (Allowed Outage Time)].

As described above in Item 1, a PSA has been performed to assess the risk impact of an increase in Completion Time. Although the proposed one-time change results in an increase in Core Damage Frequency (CDF), and Large Early Release Frequency, the value of these increases are considered as very small in the current regulatory guidance.

Therefore, granting this LAR does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Steven R. Carr, Associate General Counsel—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Section Chief: Allen G. Howe.

Nuclear Management Company, LLC, Docket No. 50-305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin.

Date of amendment request: July 7, 2003.

Description of amendment request: The proposed amendment would revise the Kewaunee Nuclear Power Plant Technical Specification (TS) Section 3.3.e, "Service Water System," to add requirements for the turbine building service water header isolation logic.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The service water system and specifically the supply to the turbine building, does not initiate any accidents previously evaluated. This change will provide an automatic feature to a function that was previously available to operators, to ensure Emergency Safety Features (ESF) loads will receive adequate service water flow. Flow is provided to ESF components that are cooled by service water without relying on the operator to identify and take action to provide isolation. Diesel loading and sequencing will not be adversely affected by this change. The components supplied by the service water system will continue to be supplied in a timely manner. The valve logic will be properly calibrated and tested consistent with other valves associated with safety significant structures, systems and components.

Therefore, the proposed change will not increase the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

This change will not affect the service water system function or any components that are accident initiators. The ability to isolate the turbine building load in the event of a system malfunction has been previously evaluated.

Therefore, any change to the system would not affect the probability of an accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

This change will ensure that Engineered Safety Features (ESF) components receiving service water-cooling are not negatively impacted by turbine building load. There are no components served by the turbine building header that are safety systems, structures, or components.

Therefore, NMC concludes that there is not a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bradley D. Jackson, Esq., Foley and Lardner, P.O. Box 1497, Madison, WI 53701-1497.

NRC Section Chief: L. Raghavan.

PPL Susquehanna, LLC, Docket No. 50-387, Susquehanna Steam Electric Station, Unit 1, Luzerne County, Pennsylvania

Date of amendment request: July 1, 2003.

Description of amendment request: The proposed amendment would change the Unit 1 Technical Specifications (TSs) by including the Unit 1 Cycle 14 (U1C14) Minimum Critical Power Ratio (MCPR) Safety Limits in Section 2.1.1.2, changing the references listed in Section 5.6.5.b, and changing the design features in Section 4.2.1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated?

Response: No.

The proposed change to the MCPR Safety Limits does not directly or indirectly affect any plant system, equipment, component, or change the processes used to operate the plant. Further, the U1C14 MCPR Safety Limits are generated using NRC approved

methodology and meet the applicable acceptance criteria. Thus, this proposed amendment does not involve a significant increase in the probability of occurrence of an accident previously evaluated.

Prior to the startup of U1C14, licensing analyses are performed (using NRC approved methodology referenced in Technical Specification Section 5.6.5.b) to determine changes in the critical power ratio as a result of anticipated operational occurrences. These results are added to the MCPR Safety Limit values proposed herein to generate the MCPR operating limits in the U1C14 COLR [Core Operating Limits Report]. These limits could be different from those specified for the U1C13 COLR. The COLR operating limits thus assure that the MCPR Safety Limit will not be exceeded during normal operation or anticipated operational occurrences. Postulated accidents are also analyzed prior to startup of U1C14 and the results shown to be within the NRC approved criteria.

The U1C14 reload fuel bundles will utilize a small amount of depleted uranium in certain fuel rods, in addition to natural and slightly enriched uranium. There is no change to the composition of the fuel pellets containing depleted uranium material (*i.e.*, UO_2) except a slight decrease in the amount of Uranium-235. Therefore, the use of depleted uranium in the fuel rods does not affect the mechanical performance of the fuel rods. The depleted uranium was modeled in the approved design and licensing methodology.

The changes to the references in Section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C14 core operating limits. The use of this approved methodology does not increase the probability of occurrence or consequences of an accident previously evaluated.

Therefore, this proposed amendment does not involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The change to the MCPR Safety Limits does not directly or indirectly affect any plant system, equipment, or component and therefore does not affect the failure modes of any of these items. Thus, the proposed changes do not create the possibility of a previously unevaluated operator error or a new single failure.

The use of depleted uranium in the fuel rods does not affect the mechanical performance of the fuel rods.

The changes to the references in Section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C14 core operating limits. The use of this approved methodology does not create the possibility of a new or different kind of accident.

Therefore, the proposed amendment does not involve the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Since the proposed changes do not alter any plant system, equipment, component, or the processes used to operate the plant, the proposed change will not jeopardize or degrade the function or operation of any plant system or component governed by Technical Specifications. The proposed MCPR Safety Limits do not involve a significant reduction in the margin of safety as currently defined in the Bases of the applicable Technical Specification sections, because the MCPR Safety Limits calculated for U1C14 preserve the required margin of safety.

The use of depleted uranium in the fuel rods does not affect the mechanical performance of the fuel rods.

The changes to the references in Section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C14 core operating limits. This approved methodology is used to demonstrate that all applicable criteria are met, thus, demonstrating that there is no reduction in the margin of safety.

Therefore, these proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bryan A. Snapp, Esquire, Assoc. General Counsel, PPL Services Corporation, 2 North Ninth St., GENTW3, Allentown, PA 18101-1179.

NRC Section Chief: Richard J. Laufer.

PSEG Nuclear, LLC, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: July 9, 2003.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 3.7.2, to increase the allowed outage time (AOT) for one train of the control room emergency filtration (CREF) system from 7 days to 30 days. The proposed AOT change would only apply when one CREF train is inoperable due to an inoperable chiller during Modes 1, 2, or 3.

Basis for proposed no significant hazards consideration determination: As required by Title 10 of the Code of Federal Regulations (10 CFR) section 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS change does not affect the design, operational characteristics, function or reliability of the control room emergency filtration (CREF) system. The CREF is not an initiator of any previously evaluated accident. The proposed change will increase the allowed outage time for the chiller from seven days to 30 days for the chiller in OPERATIONAL CONDITIONS 1, 2, AND 3. The 30-day AOT is based on the low probability of an event requiring control room isolation concurrent with failure of the redundant train. Therefore, one train will always be available to remove the normal and accident heat loads and provide control room isolation.

Increasing the AOT will allow for completion of maintenance activities requiring extended down time to perform and result in significant improvements to the overall reliability of control room chillers. Improving reliability will provide additional assurance that chillers will be capable of performing their design basis accident function.

Therefore, this proposed amendment does not involve a significant increase in the probability of occurrence or radiological consequences of an accident previously analyzed.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change will increase the AOT for the control room chiller from seven to thirty days in modes 1 through 3. During the time one chiller is inoperable, the redundant train is capable of handling the heat loads during normal operation and accident conditions. The proposed change does not involve a change in the design, configuration, or method of operation of the plant that could create the possibility of a new or different kind of accident. The proposed change would not introduce new failure modes or effects and would not, in the absence of other unrelated failures, create a new or different accident from any accidents previously evaluated.

Therefore, the proposed changes would not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the change involve a significant reduction in the margin of safety?

Response: No.

The basis for technical specification 3/4.7.2 is to ensure that the temperature in the control room does not exceed the maximum allowable for the equipment and instrumentation located therein. The system also limits radiation exposure to control room personnel following an accident to below GDC-19 [General Design Criterion 19] limits. Either of the two redundant trains can perform these functions. Although one chiller may be inoperable for longer than seven days, the redundant train can perform all normal and accident functions. The length of time for the chiller AOT is sufficiently short to assure that an event requiring control room isolation concurrent with the failure of the redundant train is not credible.

Therefore, these changes do not involve a significant reduction in [a] margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Section Chief: James W. Clifford.

PSEG Nuclear, LLC, Docket Nos. 50-272 and 50-311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: June 6, 2003.

Description of amendment request: The proposed amendment would revise the Salem Nuclear Generating Station, Unit Nos. 1 and 2, Technical Specification (TS) 3/4.11.2.5, "Explosive Gas Mixture." The proposed changes would: (1) Add a footnote to Limiting Condition for Operation (LCO) 3.11.2.5, to allow maintenance on the waste gas system; (2) revise Surveillance Requirement 4.11.2.5, to delete reference to hydrogen which is not limited by the LCO; and (3) incorporate changes to the appropriate TS Bases pages.

Basis for proposed no significant hazards consideration determination: As required by Title 10 of the Code of Federal Regulations (10 CFR) section 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to the Technical Specifications (TS) 3/4.11.2.5, Explosive Gas Mixtures, would correct inconsistencies while continuing to preclude the combination of explosive concentrations of oxygen and hydrogen in the Salem Generating Station (SGS) Unit 1 and 2 waste gas system. The changes eliminate the potential for misinterpretation and achieve internal consistency between TS sections. No changes to the design of structures, systems, or components (SSC) are made and there are no effects on accident mitigation.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Section 15.3.6 of the SGS Updated Final Safety Analysis Report (UFSAR) summarizes the results of a postulated non-mechanistic rupture of a waste gas decay tank. This postulated accident scenario is not affected by the proposed amendment, nor is any new accident scenario introduced by the proposed changes. The proposed administrative and editorial changes to the TS do not change the design function of or operation of any SSCs. The TS, as amended, would continue to limit explosive and flammable gas concentrations to prevent an uncontrolled release from the waste gas system.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes [] do not affect the ability of plant SSCs to perform their design basis accident functions. In addition, the [proposed TS license amendment] does not change the margin of safety since no SSCs are changed and the [current] limits on explosive gas mixtures are maintained.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Section Chief: James W. Clifford.

TXU Generation Company LP, Docket Nos. 50-445 and 50-446, Comanche Peak Steam Electric Station, Units 1 and 2, Somervell County, Texas.

Date of amendment request: July 10, 2003.

Brief description of amendments: The proposed amendments would provide for a one-time change for each unit to revise Technical Specification 3.7.10, entitled "Control Room Emergency Filtration/Pressurization System (CREFS)," to extend the COMPLETION TIME for ACTION B from 24 hours to 14 days.

Basis for proposed no significant hazards consideration determination: As required by Section 50.91(a) of Title 10 of the Code of Federal Regulations (10 CFR), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

This is a revision to the Technical Specifications for the control room emergency/filtration system which is a mitigation system designed to minimize in leakage and to filter the control room atmosphere to protect the operator following accidents previously analyzed. An important part of the system is the control room boundary. The control room boundary integrity is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. The analysis of the consequences of analyzed accident scenarios under the control room breach conditions along with the compensatory actions for restoration of control room integrity demonstrate that the consequences of any accident previously evaluated are not increased. Therefore, it is concluded that this change does not significantly increase the probability of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes will not impact the accident analysis. The changes will not alter the requirements of the control room emergency/filtration system or its function during accident conditions. The administrative controls and compensatory actions will ensure the control room emergency/filtration system will perform its safety function. [Sentence deleted] The changes do not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory actions and administrative controls. The proposed changes do not affect systems that respond to safely shutdown the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: George L. Edgar, Esq., Morgan, Lewis and Bockius, 1800 M Street, NW., Washington, DC 20036.

NRC Section Chief: Robert A. Gramm.

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia.

Date of amendment request: September 5, 2002, as supplemented April 16, June 9, and July 7, 2003.

Description of amendment request: The proposed technical specification (TS) amendment will add provisions to permit inspection and related repair of a buried fuel oil storage tank during plant operation.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

This proposed TS change does not alter the assumptions of the accident analyses or the TS Basis. The inclusion of provisions to permit inspection and related repair of a buried fuel oil storage tank during plant operation does not impact the availability of the EDGs [emergency diesel generators] to perform their required function, which is to provide an emergency source of power to vital equipment when a normal power source is not available. Furthermore, while a buried tank is out of service, the proposed change includes requirements to verify the availability of onsite and offsite fuel oil sources to ensure that an adequate supply of fuel oil remains available. Therefore, the proposed change does not result in a significant increase in either the probability or consequences of an accident previously evaluated.

2. Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

This proposed TS change does not involve a physical change to the plant, nor does it alter the assumptions of the accident analyses. Inclusion of provisions to permit inspection and related repair of a buried fuel oil storage tank does not introduce any new failure modes. Therefore, the proposed change does not create the possibility of a new or different kind of accident from those previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

This proposed TS change alters the method of operation of the Fuel Oil System. However, the availability of the EDGs to perform their required function is not impacted, and the assumptions of the accident analyses are not altered. Furthermore, a plant specific risk evaluation of the acceptability of the provisions was

performed. The risk evaluation concluded that the risk impact is acceptable (*i.e.*, is characterized as "very small" by Regulatory Guide 1.174 criteria and is within the acceptance criteria of Regulatory Guide 1.177). Therefore, the proposed change does not significantly reduce the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Lillian M. Cuoco, Esq., Senior Counsel, Dominion Resources Services, Inc., Millstone Power Station, Building 475, 5th Floor, Rope Ferry Road, Rt. 156, Waterford, Connecticut 06385.

NRC Section Chief: John A. Nakoski.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the *Federal Register* as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) The applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection

at the Commission's Public Document Room, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Unit Nos. 1, 2, and 3, Maricopa County, Arizona.

Date of application for amendments: August 28, 2002.

Brief description of amendments: The amendments extend the expiration date of the operating licenses from December 31, 2024, to June 1, 2025, for Unit 1, December 9, 2025, to April 24, 2026, for Unit 2, and March 25, 2027, to November 25, 2027, for Unit 3 of Palo Verde Nuclear Generating Station.

Date of Issuance: July 15, 2003.

Effective date: July 15, 2003, and shall be implemented within 60 days of the date of issuance.

Amendment Nos.: Unit 1-147, Unit 2-147, Unit 3-147.

Facility Operating License Nos. NPF-41, NPF-51, and NPF-74: The amendments revised the Operating Licenses.

Date of initial notice in Federal Register: October 15, 2002 (67 FR 63688). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 15, 2003.

No significant hazards consideration comments received: No.

Calvert Cliffs Nuclear Power Plant, Inc., Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 (CCNPP), Calvert County, Maryland.

Date of application for amendments: June 11, 2002, as supplemented May 2, 2003, and June 23, 2003.

Brief description of amendments: These amendments revise the CCNPP Technical Specification Administrative Controls Section to incorporate six changes previously approved for the Improved Standard Technical Specifications and one administrative change in renumbering pages.

Date of issuance: July 16, 2003.

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment Nos.: 259 and 236.

Renewed Facility Operating License Nos. DPR-53 and DPR-69: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: September 3, 2002 (67 FR 56318). The May 9, 2003, letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the initial proposed no significant hazards consideration determination as published in the *Federal Register* on September 3, 2002 (67 FR 56318). The June 23, 2003, letter withdrew the requested change dealing with clarifying references to 10 CFR part 20 in the Technical Specifications and did not change the initial proposed no significant hazards consideration determination as published in the *Federal Register* on September 3, 2002 (67 FR 56318). The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated July 16, 2003.

No significant hazards consideration comments received: No.

Detroit Edison Company, Docket No. 50-341, Fermi 2, Monroe County, Michigan

Date of application for amendment: February 13, 2003.

Brief description of amendment: The amendment revises Technical Specification (TS) 5.5.10, "Technical Specifications (TS) Bases Control Program," to provide consistency with the changes to 10 CFR 50.59, which were published in the *Federal Register* (64 FR 53582) on October 4, 1999, and became effective March 13, 2001. Specifically, TS 5.5.10 has been revised to remove the phrase "unreviewed safety question."

Date of issuance: July 22, 2003.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 156.

Facility Operating License No. NPF-43: The amendment revises the Technical Specifications.

Date of initial notice in Federal Register: May 27, 2003 (68 FR 28848). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 22, 2003.

No significant hazards consideration comments received: No.

Entergy Gulf States, Inc., and Entergy Operations, Inc., Docket No. 50-458, River Bend Station, Unit 1, West Feliciana Parish, Louisiana

Date of amendment request: March 20, 2002, as supplemented by letter dated May 28, 2003.

Brief description of amendment: The amendment revises the reporting requirements specified in Section 2.E of the Facility Operating License and Technical Specification Section 5.6.4 by eliminating requirements that provide the U.S. Nuclear Regulatory Commission with information that is not risk significant, and change the reporting time period to be consistent with Section 50.73 of Title 10 of the Code of Federal Regulations.

Date of issuance: July 16, 2003.

Effective date: As of the date of issuance and shall be implemented 30 days from the date of issuance.

Amendment No.: 135.

Facility Operating License No. NPF-47: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in Federal Register: April 30, 2002 (67 FR 21286). The May 28, 2003, supplemental letter withdrew a portion of the original amendment request, but did not expand the scope of the original *Federal Register* notice or change the proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 16, 2003.

No significant hazards consideration comments received: No.

Entergy Gulf States, Inc., and Entergy Operations, Inc., Docket No. 50-458, River Bend Station, Unit 1, West Feliciana Parish, Louisiana

Date of amendment request: August 15, 2002, as supplemented by letter dated May 9, 2003.

Brief description of amendment: The amendment revises the reactor vessel surveillance program required by Title 10 of the Code of Federal Regulations, part 50, appendix H, section IIIB.3, allowing River Bend Station to incorporate the Boiling Water Reactor Vessel Internals Project Integrated Surveillance Program into the licensing basis.

Date of issuance: July 24, 2003.

Effective date: As of the date of issuance and shall be implemented 60 days from the date of issuance.

Amendment No.: 136.

Facility Operating License No. NPF-47: The amendment consists of NRC staff approval of changes to the Updated Safety Analysis Report.

Date of initial notice in Federal Register: October 1, 2002 (67 FR 61679). The May 9, 2003, supplemental letter provided clarifying information that did not change the scope of the original **Federal Register** notice or the original no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 24, 2003.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50-293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: July 5, 2002, as supplemented August 13, 2002.

Brief description of amendment: The amendment relocates portions of Technical Specification (TS) 3/4.6.B, "Primary System Boundary—Coolant Chemistry," from the TSs to the Updated Final Safety Analysis Report (UFSAR). The portions of the TSs relocated to the UFSAR are the reactor coolant chemistry requirements for conductivity and chloride concentration. Specifically, TSs 3/4.6.B.2, 3/4.6.B.3, and 3.6.B.4 are relocated to the UFSAR.

Date of issuance: July 21, 2003.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 202.

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 27, 2003 (68 FR 28850). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 21, 2003.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket Nos. 50-334 and 50-412, Beaver Valley Power Station, Unit Nos. 1 and 2 (BVPS-1 and 2), Beaver County, Pennsylvania

Date of application for amendments: October 31, 2001, as supplemented by letters dated December 21, 2001, and February 4, May 31, and December 2, 2002.

Brief description of amendments: The changes relocated the pressure temperature (P/T) limit curves and low temperature overpressure protection system limits to the Pressure and Temperature Limits Report (PTLR) in the BVPS-1 and 2 Licensing Requirements Manual and the reference that report in the affected TS limiting

conditions for operation and Bases. The changes also included the addition of the PTLR to the Definitions Section of the TSs and added a new section to the reporting requirements in the Administrative Controls Section of the TSs delineating the necessary reports. The proposed changes were based on Generic Letter 96-03, "Relocation of the Pressure Temperature Limit Curves and Low Temperature Overpressure Protection System Limits," dated January 31, 1996, and the Nuclear Regulatory Commission (NRC) staff's approval of the BVPS-1 and 2 plant-specific P/T limits methodology documented in the letter from Richard J. Laufer, NRC, to Mark B. Bezilla, FENOC, dated October 8, 2002.

Date of issuance: July 15, 2003.

Effective date: Effective as of the date of issuance and shall be implemented within 60 days.

Amendment Nos.: 256 and 138.

Facility Operating License Nos. DPR-66 and NPF-73: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: December 26, 2001 (66 FR 66465). The supplements dated December 21, 2001, and February 4, May 31, and December 2, 2002, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 15, 2003.

No significant hazards consideration comments received: No.

Florida Power Corporation, et al., Docket No. 50-302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida

Date of application for amendment: October 11, 2002, as supplemented March 4, 2003.

Brief description of amendment: The amendment revises Crystal River Unit 3 Improved Technical Specifications (ITS) 3.3.15, "Reactor Building Purge Isolation-High Radiation"; ITS Bases 3.7.15, "Spent Fuel Assembly Storage"; ITS 3.9.3, "Containment Penetrations"; and ITS 3.9.6, "Refueling Canal Water Level" to account for the handling of irradiated fuel within containment that has not occupied part of a critical reactor core within the previous 72 hours.

Date of issuance: July 14, 2003.

Effective date: As of the date of issuance, and shall be implemented prior to entering Mode 6 for the Cycle 13 refueling outage.

Amendment No.: 208.

Facility Operating License No. DPR-72: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: February 4, 2003 (68 FR 5676). The March 4, 2003, supplement contained clarifying information only and did not change the initial no significant hazards consideration determination or expand the scope of the initial application. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2003.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket No. 50-315, Donald C. Cook Nuclear Plant, Unit 1, Berrien County, Michigan

Date of application for amendment: December 10, 2002.

Brief description of amendment: The amendment consists of changes to the Donald C. Cook Nuclear Plant (D. C. Cook) Unit 1 Technical Specifications related to the reactor pressure vessel (RPV) operating limits at low temperatures. The amendment approves revised pressure-temperature limits for the RPV to be applicable for a maximum of 32 effective full-power years of facility operation. These changes were based, in part, on the use of American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code) Case N-641.

Date of issuance: July 18, 2003.

Effective date: As of the date of issuance and shall be implemented prior to startup from Unit 1 refueling outage 19.

Amendment No.: 278.

Facility Operating License No. DPR-58: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: April 1, 2003 (68 FR 15762). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 18, 2003.

No significant hazards consideration comments received: No.

Maine Yankee Atomic Power Company, Docket No. 50-309, Maine Yankee Atomic Power Station, Lincoln County, Maine

Date of application for amendment: April 24, 2003.

Brief description of amendment: The amendment revises the Technical Specifications to eliminate the requirement for at least one person qualified to stand watch being present in the control room when irradiated fuel is stored in the fuel storage pool.

Date of issuance: July 02, 2003.

Effective date: Date of issuance to be implemented within [30] days from the date of issuance.

Amendment No.: 169.

Facility Operating License No. DPR-36: The amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 27, 2003 (68 FR 28854). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 02, 2003.

No significant hazards consideration comments received: No.

Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: October 8, 2002.

Brief description of amendment: The amendment changes the title of Shift Supervisor to Shift Manager. This amendment also replaces plant-specific titles with generic titles consistent with Industry/Technical Specification Task Force (TSTF) Standard Technical Specification Change Traveler TSTF-65, Rev. 1.

Date of issuance: July 15, 2003.

Effective date: As of the date of issuance and shall be implemented 60 days from the date of issuance.

Amendment No.: 200.

Facility Operating License No. DPR-46: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 27, 2003 (68 FR 28854). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 15, 2003.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of application for amendments: March 19, 2003.

Brief description of amendments: The amendments revise Technical Specification (TS) Section 5.3, "Plant Staff Qualifications." The amendments update requirements that have been outdated based on licensed operator training programs being accredited by the National Academy for Nuclear Training and promulgation of the revised Title 10 of the Code of Federal Regulations, part 55, "Operators' Licenses."

Date of issuance: July 22, 2003.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment Nos.: 159 and 150.

Facility Operating License Nos. DPR-42 and DPR-60: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: April 15, 2003 (68 FR 18281). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 22, 2003.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: April 10, 2002.

Brief description of amendments: The license amendments revised several required actions in the Diablo Canyon Nuclear Power Plant (DCPP) Technical Specifications (TSs) that require suspension of operations involving positive reactivity additions or suspension of operations involving reactor coolant system (RCS) boron concentration reductions. In addition, the amendments revised several Limiting Condition for Operation notes that preclude reductions in RCS boron concentration when a reactor coolant pump(s) and/or a residual heat removal pump(s) are removed from operation. The changes allow small, controlled, safe insertions of positive reactivity, but limit the introduction of positive reactivity to ensure that compliance with the required shutdown margin or refueling boron concentration limits are satisfied.

Date of issuance: July 10, 2003.

Effective date: July 10, 2003, and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: Unit 1-158; Unit 2-159.

Facility Operating License Nos. DPR-80 and DPR-82: The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: June 11, 2002 (67 FR 40024). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 10, 2003.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: February 28, 2003, as supplemented by letter dated June 26, 2003.

Brief description of amendments: The amendments revise Technical Specification (TS) Section 3.5.2,

"ECCS—Operating," Action A to allow a one-time increase in the allowed outage time for centrifugal charging pump (CCP) 1-1, for the purpose of seal replacement during Unit 1's Cycle 12 from 72 hours to 7 days. Additionally, the amendments delete a similar one-time TS change for Unit 2's CCP 2-1 that has expired.

Date of issuance: July 15, 2003.

Effective date: July 15, 2003, and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: Unit 1-159; Unit 2-160.

Facility Operating License Nos. DPR-80 and DPR-82: The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: April 29, 2003 (68 FR 22753). The June 26, 2003, supplemental letter provided additional clarifying information that did not expand the scope of the application as originally noticed and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 15, 2003.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket No. 50-364, Joseph M. Farley Nuclear Plant, Unit 2, Houston County, Alabama

Date of amendments request: February 11, 2003.

Brief Description of amendment: The amendment modifies Technical Specifications (TS) to allow a 40-month inspection interval for Farley, Unit 2 after the completion of the first post-replacement in-service inspection, rather than the completion of two consecutive inspections resulting in a classification of C-1.

Date of issuance: July 14, 2003.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment No.: 153.

Facility Operating License No. NPF-8: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: May 13, 2003 (68 FR 25657). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2003.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendments request: March 21, 2003.

Brief description of amendments: The proposed Technical specifications (TS) amendments revise TS Section 5.5.1 "Offsite Dose Calculation Manual (ODCM)." The proposed change will remove reference to the Plant Operations Review Committee review and acceptance of licensee initiated changes to the ODCM.

Date of issuance: July 14, 2003.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 160 & 152.

Facility Operating License Nos. NPF-2 and NPF-8: Amendments revise the Technical Specifications.

Date of initial notice in Federal Register: May 27, 2003 (68 FR 28857). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 14, 2003.

No significant hazards consideration comments received: No.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: September 24, 2002, as supplemented April 8, 2003.

Brief description of amendment: This amendment revises the Technical Specification (TS) Surveillance Requirement 4.0.3, to incorporate the approved consolidated line item improvement program change associated with the TS Task Force traveler TSTF-358, "Change to Surveillance Requirement 3.0.3 Regarding Missed Surveillances." Additionally, a change to the administrative controls section, Section 6.8, is included, to incorporate a new TS requirement for a Bases control program, consistent with the Bases control program presented in Section 5.5 NUREG 1431, "Improved Standard Technical Specifications for Westinghouse Plants," Revision 2.

Date of issuance: July 11, 2003.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 163.

Facility Operating License No. NPF-12: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: November 26, 2002 (67 FR 70768). The April 8, 2003, letter provided clarifying information that did not change the initial proposed no significant hazards consideration determination or expand the scope of the application. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 11, 2003.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 25th day of July 2003.

For The Nuclear Regulatory Commission.

Cornelius F. Holden,

Acting Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03-19487 Filed 8-4-03; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request; Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549

Extension:

Form T-1, OMB Control No. 3235-0110, SEC File No. 270-121
Form T-2, OMB Control No. 3235-0111, SEC File No. 270-122
Form T-3, OMB Control No. 3235-0105, SEC File No. 270-123
Form T-4, OMB Control No. 3235-0107, SEC File No. 270-124

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for approval.

Form T-1 (OMB 3235-0110; SEC File No. 270-121) is a statement of eligibility and qualification under the Trust Indenture Act of 1939 of a corporation designated to act as a trustee. The information is used to determine whether the trustee is qualified to serve under the indenture. Form T-1 takes approximately 15 hours to prepare and is filed by 13 respondents. It is estimated that 25% of the 195 total burden hours (49 hours) is prepared by the company. The remaining 75% of the

burden hours is attributed to outside cost.

Form T-2 (OMB 3235-0111; SEC File No. 270-122) is a statement of eligibility of an individual trustee to serve under an indenture relating to debt securities offered publicly. The information is used to determine whether the trustee is qualified to serve under the indenture. Form T-2 takes approximately 9 hours to prepare and is filed by 36 respondents. It is estimated that 25% of the 324 total burden hours (81 hours) is prepared by the filer. The remaining 75% of the burden hours is attributed to outside cost.

Form T-3 (OMB 3235-0105; SEC File No. 270-123) is an application for qualification of an indenture under the Trust Indenture Act of 1939. The information provided by Form T-3 is used by the staff to decide whether to qualify an indenture relating to securities offered to the public in an offering registered under the Securities Act of 1933. Form T-3 takes approximately 43 hours to prepare and is filed by 78 respondents. It is estimated that 25% of the 3,354 total burden hours (838.5 hours) is prepared by the filer. The remaining 75% of the burden hours is attributed to outside cost.

Form T-4 (OMB 3235-0107; SEC File No. 270-124) is used to apply for an exemption pursuant to Section 304(c) of the Trust Indenture Act of 1939 and is transmitted to shareholders. Form T-4 takes approximately 5 hours to prepare and is filed by 3 respondents. It is estimated that 25% of the 15 burden hours (4 hours) is prepared by the filer. The remaining 75% of the burden hours is attributed to outside cost.

Written comments are invited on: (a) Whether these proposed collections of information are necessary for the performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comment to Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549.

Dated: July 30, 2003.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 03-19891 Filed 8-4-03; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35-27703; International Series
Release No. 1270]

Filings Under the Public Utility Holding Company Act of 1935, as Amended ("Act")

July 30, 2003.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by August 25, 2003, to the Secretary, Securities and Exchange Commission, Washington, DC 20549-0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After August 25, 2003, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Hydro-Québec, et al. (70-10083)

Hydro-Québec ("HQ"), 75 René-Lévesque Blvd. West, Montréal, Québec H2Z 1A4 Canada, a corporation wholly owned by the government of Québec and a public-utility holding company that claims exemption under the Act under rule 10, and its subsidiaries, TransEnergie HQ, Inc. ("TEI"), 740 rue Notre-Dame Ouest, Bureau 800, Montréal, Québec, H3C 3X6 Canada, a Canadian corporation, TransEnergie U.S. Ltd. ("TEUS"), a Delaware corporation and Cross-Sound Cable Company (New York), LLC ("CSC NY"),

a New York limited liability company, both located at 110 Turnpike Road, Westborough, MA 01581 (collectively, "Applicants") have filed an application under sections 3(a)(1), 3(a)(5), 9(a)(2) and 10 of the Act in connection with a proposed acquisition of interests in CSC NY (the "Transaction").

Applicants request an order under sections 9(a)(2) and 10 of the Act authorizing HQ, through TEI and TEUS to acquire interests in CSC NY;¹ an order exempting TEUS from registration under section 3(a)(1); and an order exempting HQ from registration under section 3(a)(5).

I. Background

HQ is a large electric utility operating in eastern Canada. HQ owns both gas and electric systems. The company's overall international strategy is to become a multi-service electric and gas utility in the areas where it operates.

HQ was created in 1944 by the Hydro-Québec Act of the Parliament of Québec. HQ's common stock is held entirely by the Government of Québec ("GOQ"). Applicants state that the GOQ plays no role in day-to-day management of HQ, but it appoints the 18-member board of directors of the company. Of these eighteen, two are representatives of the GOQ, one is also the chief executive officer of HQ, and the remaining fifteen directors, including the Chairman of the Board, are independent directors. The daily affairs of HQ are managed by the Executive Committee, which consists of seven members appointed by the Board of Directors. Of those seven, five are drawn from the ranks of the independent directors. The Executive Committee, in turn, appoints the senior corporate officers.

Pursuant to the Hydro-Québec Act, HQ must provide quality electric service to all Québec customers and manage its affairs to create value for its sole shareholder, the GOQ. To that end, every two years, HQ submits a strategic plan to the GOQ for approval. This plan discusses whether the generation will be built or developed, financial targets for profitability of the major business segments (generation, transmission and distribution) and the nature and amount of investments for each segment. Upon GOQ approval of the plan, the utility's officers (selected by the Board of Directors) will execute the plan. Applicants note that, although HQ is wholly owned by the GOQ, it is required by the *Act respecting the Régie de l'énergie* to be subject to the regulatory jurisdiction of the Québec

Energy Board, an independent agency established pursuant to the *Act respecting the Régie de l'énergie* with respect to certain matters primarily related to transmission and distribution.

HQ has six functionally, but not legally, separate business segments: Transmission; Distribution; Generation; Construction; Oil and Gas; and Corporate and Other Activities (which includes research and development and corporate and financial services). HQ is organized along these functional lines, but, as a result of its statutory mandate, it does not conduct business outside of Québec. Instead, all of its non-Québec activities are conducted through intermediate companies, such as TEI.

HQ's Generation segment activities include the sale of surplus electricity outside of Québec through a subsidiary, H.Q. Energy Marketing, Inc. ("HQEM"), and energy trading operations. HQ exports electrical power subject to the *National Energy Board Act (Canada)*, which requires that a permit or license be obtained from the National Energy Board of Canada (the "National Board") for such exports. HQ holds two permits, which were granted by the National Board in December 1994 and which authorize HQ to export annually, for a continuous period of no more than five years for any single contract, up to 30 gigawatts ("TWh") of interruptible energy and up to 20 TWh of firm energy to the United States. The permits cover a 16-year period from December 1, 1994 to December 31, 2010, and allow HQ to take advantage of the spot market in the United States. Longer-term export contracts (more than five years) remain subject to the prior issuance of specific permits or licenses by the National Board.

On April 8, 1999, HQEM, a Québec corporation wholly owned by HQ, obtained two permits from the National Board to enable HQEM, as a power marketer outside Québec, to export firm and interruptible energy up to 30 TWh annually to the United States from interconnections located in other provinces, under contracts with a term of five years or less. The permits cover a 10-year period from April 8, 1999 to April 7, 2009. HQEM buys, sells and trades power in Canada and the United States. On March 5, 2003, HQEM obtained a renewal of its permit to export natural gas to the United States. This permit covers a 2-year period through March 4, 2005.

HQ is a holding company under the Act by reason of its indirect ownership interest in Gaz Métropolitain, Inc. ("GMI"), a Canadian corporation and a public-utility holding company exempt from registration by order under section

¹ When CSC NY commences operations, it will be a public-utility company under the Act.

3(a)(5) of the Act.² GMI is the general partner of Gaz Métropolitain and Company, Limited Partnership ("GMCLP"), in which it holds a 77.4% interest. Through Northern New England Gas Corporation, a public-utility holding company exempt from registration under section 3(a)(1) of the Act, GMCLP owns a 100% ownership interest in Vermont Gas Systems, Inc., a Vermont gas utility company. By order of the Commission dated November 23, 1994, GMI is exempt from registration under section 3(a)(5) of the Act.³ The holding companies over GMI rely upon rule 10(a)(2) for exemption from registration.⁴

Noverco also owns 9.8% of Enbridge Inc. ("Enbridge"), a Canadian gas public-utility company that wholly owns St. Lawrence Gas Company, Inc. ("St. Lawrence Gas"), a New York public-utility company. HQ thus holds an indirect, economic interest in St. Lawrence Gas of less than 5%.

HQ's subsidiaries also have an active presence in the United States gas and electric markets.⁵ HQ Energy Services (U.S.) Inc. ("HQUS") is a power marketing subsidiary of HQ that was authorized by the Federal Energy Regulatory Commission (the "FERC") in November 1997 to sell electricity at wholesale within the United States at market-based rates. HQUS does not own any electric generation or transmission facilities within the meaning of the Act in North America. HQUS buys electricity from HQ for resale in the United States and is an active trader of power in the New York Independent System Operator ("New York ISO"), the New England Independent System Operator ("New England ISO") and the PJM Interconnection, organizations in which HQUS is a member.⁶

² HQ owns 41.2% of the share capital of Noverco Inc., a Canadian corporation that holds a 100% ownership interest in GMI.

³ Holding Co. Act Release No. 26170.

⁴ Rule 10(a) in pertinent part provides an exemption for a holding company that is such "solely by reason of such company having as a subsidiary any company which, insofar as it is * * * a holding company, is: (2) A company exempted as a holding company * * * under subparagraph [3(a)(5) of the Act.]"

⁵ HQ is a voluntary foreign government registrant of the Commission. HQ has debt securities registered under section 12(b) of the Securities Exchange Act of 1934 and files an Annual Report on Form 18-K.

⁶ HQ also holds an indirect ownership interest in Bucksport Energy LLC ("Bucksport Energy"), which owns 72.2% of a qualifying cogeneration facility located in Bucksport, Maine. Energy Holding, Inc., a wholly owned subsidiary of HQ, owns 38.88% of Bucksport Energy's membership interests. MEG Holding US Corporation owns the remaining 61.12% interest. MEG Holding US Corporation is wholly owned by Multinational Electricity and Gas Corporation, which, in turn, is 50% owned by HQ.

HQ's transmission activities in the United States are held through an intermediate entity, TEL. TEL, a Canadian corporation, is a wholly owned subsidiary of HQ, with which TEL is fully consolidated.⁷ At present, TEL has no utility or non-utility businesses in the United States except its indirect interest in the Project described below.

TEUS, currently a Delaware corporation, is owned by TEL.⁸ Applicants state that, by holding TEUS through a conduit such as TEL, HQ can satisfy its legal mandate of conducting operations solely within the province of Québec.

II. The Transaction

A. The Project

TEUS and UIL Holdings Corporation ("UIL"), a Connecticut public-utility holding company exempt from registration under section 3(a)(1) of the Act by rule 2, have formed a joint venture for the construction, financing and ownership of a new merchant transmission facility between Connecticut and New York (the "Project").⁹ The Project consists of a 26-mile high-voltage direct-current transmission cable system underneath the Long Island Sound that will connect the electric transmission grids of Connecticut and Long Island, New York, and provide additional power transfer capability of up to 330 megawatts in both directions between New Haven, Connecticut and Brookhaven/Shoreham, New York.

TEUS has obtained approval from the FERC to sell transmission service at negotiated rates that reflect the difference between generation prices in Connecticut and Long Island. The Project will not have any retail customers. It will sell only rights to transmission capacity, and will not take title to, or sell, electricity. Its sole customer will be the Long Island Lighting Company, doing business as

HQ therefore owns 49.9968% of the Bucksport facility, which commenced operations in January 2001.

⁷ TEL does not publish financial statements separate from those of HQ.

⁸ At present, TEUS is a Delaware corporation. A New York corporation, TransEnergie Newco, Inc. ("TEUS-NY") has been authorized to be formed as a wholly owned subsidiary of TEL. Applicants state that all necessary corporate approvals have been obtained to merge TEUS into TEUS-NY with the latter being the surviving corporation. Applicants state that upon receipt of the Commission's approval and following the filing of the various certificates of merger, TEUS-NY, a New York corporation will hold 100% of the Class A membership interest in CSC-NY and 75% of the Class B membership interest in CSC-NY.

⁹ The sole public-utility subsidiary company of UIL is The United Illuminating Company.

LIPA. LIPA is a wholly owned subsidiary of the Long Island Power Authority, which is a corporate municipal instrumentality of the State of New York. LIPA provides retail electric service to Long Island residents and has entered into a twenty-year contract for all of the Project's available transmission capacity rights.

B. Ownership of CSC NY

CSC NY has undertaken the construction, financing and ownership of the Project, and holds all of the Project's assets. As noted above, upon the commencement of operations, CSC NY will be an electric utility company within the meaning of section 2(a)(3) of the Act.

There are two classes of membership interests in CSC NY. A Class A membership interest entitles the holder to 100% of the voting rights. A Class B membership interest entitles the holder to a percentage of the economic benefits from the Project and no voting rights. "Economic benefits" consist of the right to income, losses and any gains or losses on the sale of the project.

TEUS owns all of the Class A membership interests in CSC NY (and thus has 100% of the voting interests) and 75% of the Class B membership interests (which entitle TEUS to 75% of the economic benefits). United Capital Investments, Inc. ("UCI"), a wholly owned subsidiary of United Resources, Inc., a non-regulated business unit of UIL, holds the remaining 25% of the Class B membership interest in CSC NY and is therefore entitled to 25% of the economic benefits in the Project. As of February 28, 2003, TEUS and UCI had made capital contributions of \$29,250,750 and \$9,750,250, respectively, for their respective membership interests in the Project.

C. Operating and Financing Agreements

Applicants state that, upon commercial operation of the Project, both day-to-day and long-term administration of the Project will be exercised according to the following contracts and arrangements: (i) The Firm Transmission Capacity Purchase Agreement dated August 2, 2000 and as amended from time to time between TEUS, as seller, and LIPA, as buyer (the "LIPA Off-Take Agreement"), and the Assignment and Assumption Agreement between TEUS, as assignor and CSC NY, as assignee, under which CSC NY assumes all of the rights and obligations of TEUS under the LIPA Off-take Agreement; (ii) the Transmission System Operation and Maintenance Agreement dated October 13, 2000 and as amended from time to time between

CSC NY, as owner of the Project's assets, and TEUS, as operator; (iii) the Limited Liability Company Agreement of CSC NY, effective October 13, 2000 and as amended from time to time, and (iv) the Project's financing documents.

III. Requested Orders and Other Requests

As noted above, Applicants request an order under sections 9(a)(2) and 10 of the Act authorizing HQ, through TEI and TEUS to acquire interests in CSC NY. In addition, Applicants request an order exempting TEUS from registration under section 3(a)(1) of the Act. TEUS states that, following the Transaction, both it and CSC NY will be predominantly intrastate in character and carry on their business substantially in New York, the state in which both will be organized. HQ requests an order under section 3(a)(5) of the Act exempting it from registration. HQ states that, following the Transaction, it will continue to be a holding company that is not, and derives no material part of its income, directly or indirectly, from any one or more subsidiary companies which are, a company or companies the principal business of which within the United States is that of a public-utility company.

Applicants further request that the Commission look through TEI, an intermediate holding company, for purposes of the analysis under section 11(b)(2) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,
Deputy Secretary,

[FR Doc. 03-19889 Filed 8-4-03; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-48244; File No. SR-Amex-2003-47]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange LLC To Amend Commentary .02 of Amex Rule 126(g) to Restrict the Crossing of Agency Orders of 5,000 Shares or More To Orders for the Accounts of Persons Who Are Not Brokers or Dealers

July 29, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,²

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

notice is hereby given that on May 19, 2003, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .02 to Amex Rule 126(g) ("Special Rules" under "Precedence of Bids and Offers")³ to restrict the crossing of agency orders of 5,000 shares or more to orders for the accounts of persons who are not brokers or dealers. The text of the proposed rule change is below. Text in brackets indicates material to be deleted, and text in italics indicates material to be added.

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Rule 126(g)

Commentary

.02 When a member has an order to buy and an order to sell an equivalent amount of the same security, and both orders are of 5,000 shares or more and are for the accounts of persons who are not [members or member organizations] *brokers or dealers (including, all U.S. registered and foreign registered brokers or dealers)*, the member may "cross" those orders at a price at or within the prevailing quotation. The member's bid or offer shall be entitled to priority at such cross price, irrespective of pre-existing bids or offers at that price. The member shall follow the crossing procedures of Rule 151, and another member may trade with either the bid or offer side of the cross transaction only to provide a price which is better than the cross price as to all or part of such bid or offer. A member who is providing a better price to one side of the cross transaction must trade with all other market interest having priority at that price before trading with any part of the cross transaction. No member may break up the proposed cross transaction, in whole or in part, at the cross price. No specialist or registered trader may effect a proprietary transaction to provide price improvement to one side or the other of

³ The Exchange made a typographical correction to the reference of Amex Rule 126. Telephone conversation between Michael Cavalier, Associate General Counsel, Amex, and Andy Shipe, Special Counsel, Division of Market Regulation, Commission, on July 16, 2003.

a cross transaction effected pursuant to this Commentary .02. A transaction effected at the cross price in reliance on this Commentary .02 shall be printed as "stopped stock".

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Amex Rule 126(g), Commentary .02 provides that a member may cross an order to buy and an order to sell an equivalent amount of the same security at or within the prevailing quotation if both orders are for 5,000 shares or more, and if they are for the accounts of non-members or member organizations. These are referred to as "clean agency crosses" or "agency cross transactions." A member is not permitted to break up a proposed clean agency cross at the cross price, but may trade with the bid or offer side to provide price improvement to all or part of the bid or offer. The purpose of the rule is to permit more crosses to take place on the Exchange without risk of being "broken up" at the cross price and to reduce the amount of crossing activity lost to regional exchanges or the third market.

In addition, because these crosses are required under Amex Rule 151 to be effected at the minimum price variation, since the advent of decimal pricing, it is possible for members to interfere with a cross while providing price improvement of only \$.01 to a portion of the cross. The Commission approved an amendment to Amex Rule 126(g), Commentary .02 to provide that orders of 5,000 shares or more for the account of a non-member organization may be crossed at a price at or within the bid or offer without being broken up by a specialist or Registered Trader acting as

principal.⁴ However, the Exchange believes that this recent change to Commentary .02 of Amex Rule 126(g) continues to put orders for the accounts of non-member brokers and dealers in a more advantageous position than Amex specialists and Registered Traders, but, more importantly, continues to put orders for the accounts of non-member brokers and dealers in a more advantageous position than public customer orders represented in the trading crowd and on the specialist's book at the clean agency cross price. This is because such non-member broker-dealer orders always have priority over public customer (non-broker or dealer) orders at the clean agency cross price. In addition, such orders can participate in a clean agency cross even though an Amex specialist or Registered Trader is prohibited from interacting with a clean agency cross to provide price improvement.

The Exchange believes it is appropriate to amend Amex Rule 126(g), Commentary .02 to limit the advantages offered by this rule to public customer orders only, and not to orders for the accounts of brokers or dealers. This change will prohibit orders for the accounts of brokers and dealers (including all U.S. and foreign registered brokers or dealers) from having priority over existing bids and offers and from engaging in crosses without risk of being broken up by a specialist and/or Registered Trader who wishes to trade at an improved price with one side or the other of the cross. The Exchange believes this change will facilitate the efficient crossing of public customer orders by placing non-member brokers and dealers in the same position as member brokers and dealers with respect to crossing procedures under Commentary .02 of Amex Rule 126(g).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act⁶ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in

general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will impose no burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

- (A) By order approve such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, as amended, that are filed with the Commission, and all written communications relating to the proposed rule change, as amended, between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to file number SR-Amex-2003-47 and should be submitted by August 26, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁷

Margaret H. McFarland,
Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-48253; File No. SR-NASD-2003-115]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Listing and Trading of Industrial 15 Notes

July 29, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 29, 2003, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to approve the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Substance of the Proposed Rule Change

Nasdaq proposes to list and trade Strategic Return Notes' linked to the Industrial 15 Index ("Notes") issued by Merrill Lynch & Co., Inc. ("Merrill Lynch").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. Nasdaq has prepared summaries, set forth in Sections A, B,

⁴ See Securities Exchange Act Release No. 47345 (February 11, 2003), 68 FR 8316 (February 20, 2003).

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to list and trade notes, the return on which is based upon the fifteen highest dividend yielding stocks from a group of certain stocks in Standard & Poor's ("S&P") Industrial Index³ from year to year that meet the additional criteria set forth below ("Industrial 15 Index" or "Index").⁴

Under NASD Rule 4420(f), Nasdaq may approve for listing and trading innovative securities which cannot be readily categorized under traditional listing guidelines.⁵ Nasdaq proposes to list for trading the Notes under NASD Rule 4420(f). Nasdaq represents that the Industrial 15 Index is to be determined, calculated and maintained solely by the American Stock Exchange LLC ("Amex").⁶

The Notes will initially be subject to Nasdaq's listing criteria for other securities under NASD Rule 4420(f). Specifically, under NASD Rule 4420(f)(1):⁷

(A) The issuer shall have assets in excess of \$100 million and stockholders' equity of at least \$10 million. In the case of an issuer which is unable to satisfy the income criteria set forth in paragraph (a)(1), Nasdaq generally

will require the issuer to have the following: (i) Assets in excess of \$200 million and stockholders' equity of at least \$10 million; or (ii) assets in excess of \$100 million and stockholders' equity of at least \$20 million;

(B) There must be a minimum of 400 holders of the security, provided, however, that if the instrument is traded in \$1,000 denominations, there must be a minimum of 100 holders;

(C) For equity securities designated pursuant to this paragraph, there must be a minimum public distribution of 1,000,000 trading units;

(D) The aggregate market value/principal amount of the security will be at least \$4 million.

In addition, Nasdaq represents that Merrill Lynch satisfies the listed marketplace requirement set forth in NASD Rule 4420(f)(2).⁸ Lastly, pursuant to NASD Rule 4420(f)(3), prior to the commencement of trading of the Notes, Nasdaq will distribute a circular to members providing guidance regarding compliance responsibilities and requirements, including suitability recommendations, and highlighting the special risks and characteristics of the Notes. In particular, Nasdaq will advise members recommending a transaction in the Notes to: (1) Determine that such transaction is suitable for the customer; and (2) have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, such transaction.

The Notes will be subject to Nasdaq's continued listing criterion for other securities pursuant to NASD Rule 4450(c). Under this criterion, the aggregate market value or principal amount of publicly-held units must be at least \$1 million. The Notes also must have at least two registered and active market makers as required by NASD Rule 4310(c)(1). Nasdaq will also prohibit the continued listing of the Notes if Merrill Lynch is not able to meet its obligations on the Notes.⁹

The Notes are a series of senior non-convertible debt securities of Merrill Lynch that provide for a single payment at maturity. The Notes will have a term of not less than one, nor more than ten, years. The Notes will entitle the owner at maturity to receive an amount based

upon the percentage change between the "Starting Index Value" and the "Ending Index Value" (the "Redemption Amount"). The "Starting Index Value" is the value of the Industrial 15 Index on the date on which Merrill Lynch prices the Notes for the initial sale to the public. The "Ending Index Value" is the value of the Industrial 15 Index over a period shortly prior to the expiration of the Notes. The Ending Index Value will be used in calculating the amount owners will receive upon maturity. The Notes may not have a minimum principal amount that will be repaid and, accordingly, payments on the Notes prior to or at maturity may be less than the original issue price of the Notes. During the designated month each year, the investors may have the right to require Merrill Lynch to repurchase the Notes at a redemption amount based on the value of the Industrial 15 Index at such repurchase date. The Notes are not callable by Merrill Lynch.

The Notes are cash-settled in U.S. dollars and do not give the holder any right to receive a portfolio security or any other ownership right or interest in the portfolio securities, although the return on the investment is based on the aggregate portfolio value of the Industrial 15 Index securities.

The Industrial 15 Index will consist of the a portfolio of the fifteen qualifying stocks ("Qualifying Stocks") with the highest dividend yields at the time of initial composition or any reconstitution of the Industrial 15 Index. Qualifying Stocks are those stocks from the S&P Industrial Index that are (1) In the top 75% of the Index, as measured by market capitalization after elimination of stocks included in the Dow Jones Industrial Average ("DJIA"), and (2) have an S&P Common Stock Ranking of A or A+.

Components of the Industrial 15 Index approved pursuant to this filing will meet the following criteria: (1) A minimum market value of at least \$75 million, except that up to 10% of the component securities in the Industrial 15 Index may have a minimum market value of \$50 million; (2) average monthly trading volume in the last six months of not less than 1,000,000 shares, except that up to 10% of the component securities in the Industrial 15 Index may have an average monthly trading volume of 500,000 shares or more in the last six months; (3) 90% of the Industrial 15 Index's numerical value and at least 80% of the total number of component securities will meet the then current criteria for standardized option trading set forth in Amex Rule 915; and (4) all component

³ The S&P Industrial Index is a subset of the S&P 500 Index consisting of the largest 400 industrial stocks of the S&P 500. The S&P Industrial Index is calculated by starting with the S&P 500 Index and then excluding financial, utility and transportation stocks.

⁴ As of June 24, 2003, the portfolio of securities comprising the Industrial 15 Index are as follows: Abbott Laboratories; Albertson's, Inc.; Anheuser-Busch Companies Inc.; Bristol-Myers Squibb Company; The Clorox Company; ConAgra Foods, Inc.; Colgate-Palmolive Company; Emerson Electric Co.; Ingersoll-Rand Company Limited; Johnson Controls, Inc.; Paychex, Inc.; Pfizer, Inc.; Rohm and Haas Company; Schering-Plough Corporation; and Wm. Wrigley Jr. Company.

The portfolio of securities will include the fifteen highest dividend yielding stocks from a group of certain stocks in the S&P Industrial Index for that year and Nasdaq represents that the Amex will not have any discretion in the selection process.

⁵ See Securities Exchange Act Release No. 32988 (September 29, 1993); 58 FR 52124 (October 6, 1993).

⁶ Subject to the criteria in the prospectus supplement regarding the construction of the Index, Nasdaq represents that the Amex has sole discretion regarding changes to the Index due to annual reconstitutions and adjustments to the Index and the multipliers of the individual components.

⁷ Nasdaq represents that Merrill Lynch and the Notes satisfy these listing criteria. Telephone call between Sapna C. Patel, Attorney, Division of Market Regulation, Commission, and John Nachmann, Senior Attorney, Office of the General Counsel, Nasdaq, on July 29, 2003.

⁸ NASD Rule 4420(f)(2) requires issuers of securities designated pursuant to this paragraph to be listed on Nasdaq or the New York Stock Exchange ("NYSE") or be an affiliate of a company listed on The Nasdaq National Market or the NYSE; provided, however, that the provisions of Rule 4450 will be applied to sovereign issuers of "other" securities on a case-by-case basis.

⁹ Telephone call between Sapna C. Patel, Attorney, Division of Market Regulation, Commission, and John Nachmann, Senior Attorney, Office of the General Counsel, Nasdaq, on July 29, 2003.

stocks will either be listed on the Amex, the NYSE, or traded through the facilities of Nasdaq and reported National Market System securities.

As of July 9, 2003, Nasdaq represents that the market capitalization of the portfolio of securities representing the Industrial 15 Index ranged from a high of \$258.6 billion to a low of \$6.7 billion. The average monthly trading volume for the last six months, as of the same date, ranged from a high of 20.2 million shares to a low of 0.6 million shares. Moreover, as of July 29, 2003, Nasdaq represents that all of the components comprising the portfolio of securities representing the Industrial 15 Index were eligible for standardized options trading pursuant to Amex Rule 915.

The value of the Industrial 15 Index at any time will equal: (1) The sum of the products of the current market price for each stock underlying the Industrial 15 Index and the applicable share multiplier,¹⁰ plus (2) an amount reflecting current calendar quarter dividends, and less (3) a pro rata portion of the annual index adjustment factor.¹¹ Nasdaq represents that current quarter dividends for any day will be determined by the Amex and will equal the sum of each dividend paid by the issuer on one share of stock underlying the Industrial 15 Index during the current calendar quarter multiplied by the share multiplier applicable to such stock on the ex-dividend date.

Nasdaq represents that, as of the first day of the start of each calendar quarter, the Amex will allocate the current quarter dividends as of the end of the immediately preceding calendar quarter to each then outstanding component of the Industrial 15 Index. The amount of the current quarter dividends allocated to each stock will equal the percentage of the value of such stock contained in the portfolio of securities comprising the Industrial 15 Index relative to the value of the entire portfolio based on the closing market price of such stock on the last day in the immediately preceding calendar quarter. The share multiplier of each stock will be increased to reflect the number of shares, or portion of a share, that the

amount of the current quarter dividend allocated to each stock can purchase of each stock based on the closing market price on the last day in the immediate preceding calendar quarter.

Nasdaq represents that, as of the close of business on each anniversary date (June 26th of each year, which is the anniversary of the date the Industrial 15 Index was originally calculated and disseminated) through the applicable anniversary date in the year preceding the maturity of the Notes, the portfolio of securities comprising the Industrial 15 Index will be reconstituted by the Amex so as to include the fifteen Qualifying Stocks in the S&P Industrial Index having the highest dividend yield on the second scheduled index business day prior to the applicable anniversary date. Nasdaq also represents that the Amex will announce such changes to investors at least one day prior to the anniversary date.¹²

The portfolio will be reconstituted and rebalanced on the anniversary date so that each stock in the Industrial 15 Index will represent 6.67% of the value of the Industrial 15 Index. To effectuate this, Nasdaq represents that the share multiplier for each new stock will be determined by the Amex and will indicate the number of shares or fractional portion thereof of each new stock, given the closing market price of such new stock on the anniversary date, so that each new stock represents an equal percentage of the Industrial 15 Index value at the close of business on such anniversary date. For example, if the Industrial 15 Index value at the close of business on an anniversary date was 150, then each of the fifteen new stocks comprising the Industrial 15 Index would be allocated a portion of the value of the Index equal to 10, and if the closing market price of one such new stock on the anniversary date was 20, the applicable share multiplier would be 0.5. Conversely, if the Industrial 15 Index value was 60, then each of the fifteen new stocks comprising the Industrial 15 Index would be allocated a portion of the value of the Industrial 15 Index equal to 4, and if the closing market price of one such new stock on the anniversary was 20, the applicable share multiplier would be 0.2. The last anniversary date on which such reconstitution will occur will be the anniversary date in the year preceding the maturity of the Notes. As noted above, investors will receive information on the new portfolio of

¹² Nasdaq represents that the Amex will publish a notice to advise investors of changes to the securities underlying the Industrial 15 Index if any such changes are made following an annual reconstitution.

securities comprising the Industrial 15 Index at least one day prior to each anniversary date.

The multiplier of each component stock in the Industrial 15 Index will remain fixed unless adjusted for quarterly dividend adjustments, annual reconstitutions or certain corporate events, such as payment of a dividend other than an ordinary cash dividend, a distribution of stock of another issuer to its shareholders,¹³ stock split, reverse stock split, and reorganization.

The multiplier of each component stock may be adjusted, if necessary, in the event of a merger, consolidation, dissolution or liquidation of an issuer or in certain other events such as the distribution of property by an issuer to shareholders. If the issuer of a stock included in the Industrial 15 Index were to no longer exist, whether by reason of a merger, acquisition or similar type of corporate transaction, a value equal to the stock's final value will be assigned to the stock for the purpose of calculating the Industrial 15 Index value prior to the subsequent anniversary date. For example, if a company included in the Industrial 15 Index were acquired by another company, a value will be assigned to the company's stock equal to the value per share at the time the acquisition occurred. If the issuer of stock included in the Industrial 15 Index is in the process of liquidation or subject to a bankruptcy proceeding, insolvency, or other similar adjudication, such security will continue to be included in the Industrial 15 Index so long as a market price for such security is available or until the subsequent anniversary date. If a market price is no longer available for an Industrial 15 Index stock due to circumstances including but not limited to, liquidation, bankruptcy, insolvency, or any other similar proceeding, then the security will be assigned a value of zero when calculating the Industrial 15 Index for so long as no market price exists for that security or until the subsequent anniversary date. If the stock remains in the Industrial 15 Index, the multiplier of that security in the Industrial 15 Index may be adjusted to maintain the component's relative weight in the Industrial 15 Index at the level immediately prior to the corporate action. In all cases, the multiplier will

¹³ If the issuer of a component security in the Industrial 15 Index issues to all of its shareholders publicly traded stock of another issuer, such new securities will be added to the portfolio comprising the Industrial 15 Index until the subsequent anniversary date. The multiplier for the new component will equal the product of the original issuer's multiplier and the number of shares of the new component issued with respect to one share of the original issuer.

¹⁰ The multiplier indicates the number of shares (or fraction of one share) of a security, given its market price on an exchange or Nasdaq, to be included in the calculation of the portfolio.

¹¹ At the end of each day, the Industrial 15 Index will be reduced by a pro rata portion of the annual index adjustment factor, 1.5% (i.e., 1.5%/365 days = 0.0041% daily). This reduction to the value of the Index will reduce the total return to investors upon redeeming the Notes at maturity. An explanation of this deduction will be included in any marketing materials, fact sheets, or any other materials circulated to investors regarding the trading of this product.

be adjusted, if necessary, to ensure Industrial 15 Index continuity.

Nasdaq represents that the Amex will calculate the Industrial 15 Index and, similar to other stock index values published by the Amex, the value of the Index will be calculated continuously and disseminated every fifteen seconds over the Consolidated Tape Association's Network B.¹⁴ The Index value will equal the sum of the products of the most recently available market prices and the applicable multipliers for the component securities.

Since the Notes will be deemed equity securities for the purpose of Rule 4420(f), the NASD and Nasdaq's existing equity trading rules will apply to the Notes. First, pursuant to Rule 2310 and IM-2310-2, members must have reasonable grounds for believing that a recommendation to a customer regarding the purchase, sale or exchange of any security is suitable for such customer upon the basis of the facts, if any, disclosed by such customer as to his other security holdings and as to his financial situation and needs.¹⁵ In addition, Nasdaq will distribute a circular to advise members recommending a transaction in the Notes to, among other things, have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, such transaction. Furthermore, the Notes will be subject to the equity margin rules. Lastly, the regular equity trading hours of 9:30 am to 4:00 pm will apply to transactions in the Notes.

Nasdaq represents that NASD's surveillance procedures are adequate to properly monitor the trading of the Notes. Specifically, NASD will rely on its current surveillance procedures governing equity securities, and will include additional monitoring on key pricing dates.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the

¹⁴ Nasdaq will prohibit the continued listing of the Notes if the Amex discontinues publication of the Industrial 15 Index and a successor index or index value is not disseminated every 15 seconds during calculation days. Telephone call between Sapna C. Patel, Attorney, Division of Market Regulation, Commission, and John Nachmann, Senior Attorney, Office of the General Counsel, Nasdaq, on July 29, 2003.

¹⁵ Rule 2310(b) requires members to make reasonable efforts to obtain information concerning a customer's financial status, a customer's tax status, the customer's investment objectives, and such other information used or considered to be reasonable by such member or registered representative in making recommendations to the customer.

provisions of Section 15A of the Act,¹⁶ in general, and with Section 15A(b)(6) of the Act,¹⁷ in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. Specifically, the proposed rule change will provide investors with another investment vehicle based on an index of the fifteen highest dividend yielding stocks from a group of certain stocks in the S&P Industrial Index.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR-NASD-2003-115 and should be submitted by August 26, 2003.

¹⁶ 15 U.S.C. 78o-3.

¹⁷ 15 U.S.C. 78o-3(b)(6).

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 15A(b)(6) of the Act.¹⁸ The Commission notes that it has previously approved the listing of Industrial 15 Index notes on the Amex.¹⁹ Furthermore, the Commission finds that this proposal is similar to several other approved instruments currently listed and traded on the Amex and the NYSE.²⁰ Accordingly, the Commission finds that the listing and trading of the Notes on Nasdaq is consistent with the Act and will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and, in general, protect investors and the public interest consistent with Section 15A(b)(6) of the Act.²¹

The Notes are not leveraged instruments; however, their price will still be derived and based upon the

¹⁸ 15 U.S.C. 78o-3(b)(6).

¹⁹ See Securities Exchange Act Release No. 44437 (June 18, 2001) 66 FR 33585 (June 22, 2001) (accelerated approval for listing and trading of Industrial 15 Index on the Amex).

²⁰ See Securities Exchange Act Release Nos. 44342 (May 23, 2001), 66 FR 29613 (May 31, 2001) (accelerated approval order for the listing and trading of Select Ten Notes); 42582 (March 27, 2000), 65 FR 17685 (April 4, 2000) (accelerated approval order for the listing and trading of notes linked to a basket of no more than twenty equity securities) (File No. SR-Amex-99-42); 41546 (June 22, 1999), 64 FR 35222 (June 30, 1999) (accelerated approval order for the listing and trading of notes linked to a narrow based index with a non-principal protected put option) (File No. SR-Amex-99-15); 39402 (December 4, 1997), 62 FR 65459 (December 12, 1997) (notice of immediate effectiveness for the listing and trading non-principal protected commodity preferred securities linked to certain commodities indices) (File No. SR-Amex-97-47); 37533 (August 7, 1996), 61 FR 42075 (August 13, 1996) (accelerated approval order for the listing and trading of the Top Ten Yield Market Index Target Term Securities ("MITTS")) (File No. SR-Amex-96-28); 33495 (January 19, 1994), 59 FR 3883 (January 27, 1994) (accelerated approval order for the listing and trading of Stock Upside Note Securities) (File No. SR-Amex-93-40); 32840 (September 2, 1993), 58 FR 47485 (September 9, 1993) (accelerated approval order for the listing and trading of MITTS on the NYSE) (File No. SR-NYSE-93-31); and 32343 (May 20, 1993), 58 FR 30833 (May 27, 1993) (accelerated approval order for the listing and trading of non-principal protected notes linked to a single equity security) (File No. SR-Amex-92-42).

²¹ 15 U.S.C. 78o-3(b)(6). In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

underlying linked security. Accordingly, the level of risk involved in the purchase or sale of the Notes is similar to the risk involved in the purchase or sale of traditional common stock. Nonetheless, because the final rate of return of the Notes is derivatively priced, based on the performance of a portfolio of securities, and the components of the Industrial 15 Index are more likely to change each year, over the term of the Notes, than products previously issued, there are several issues regarding the trading of this type of product.

The Commission notes that Nasdaq's rules and procedures that address the special concerns attendant to the trading of hybrid securities will be applicable to the Notes. In particular, by imposing the hybrid listing standards and the suitability, disclosure, and compliance requirements noted above, the Commission believes that Nasdaq has addressed adequately the potential problems that could arise from the hybrid nature of the Notes. Moreover, Nasdaq will distribute a circular to its membership calling attention to the specific risks associated with the Notes.

In approving the product, the Commission recognizes that the components are likely to change each year over the life of the product. Nevertheless, the Commission believes that this is acceptable because the Amex has clearly stated the guidelines and formula for replacing components from a specific group of well-known and highly capitalized securities. Each year, as noted above, the portfolio of securities comprising the Industrial 15 Index will represent the fifteen highest dividend yielding Qualifying Stocks in the S&P Industrial Index. Nasdaq represents that the Amex will do the calculation for replacements based on a set formula to determine which of the S&P Industrial Index securities will be in the Index for the following year. The Commission believes that within these confines the potential frequent changes in the components of the Industrial 15 Index are reasonable and will meet the expectation of investors.

In addition, the Commission notes that the Notes are non-principal protected. The Notes may not have a minimum principal amount that will be repaid, and payments on the Notes prior to or at maturity may be less than their original issue price. The Commission also recognizes that during the designated month, investors may require the issuer to repurchase the Notes at a redemption amount based on the value of the Industrial 15 Index at such repurchase date.

The Commission notes that the Notes are dependent upon the individual credit of the issuer, Merrill Lynch. To some extent, this credit risk is minimized by Nasdaq's listing standards in NASD Rules 4420(f)(1) and 4420(f)(2), which provide that only issuers satisfying substantial asset and equity requirements may issue securities such as the Notes. In addition, Nasdaq's hybrid listing standards further require that the Notes have at least \$4 million in market value.²² In any event, financial information regarding Merrill Lynch, in addition to the information on the issuers of the underlying securities comprising the Industrial 15 Index, will be publicly available.²³

The Commission also has a systemic concern, however, that a broker-dealer, such as Merrill Lynch, or a subsidiary providing a hedge for the issuer will incur position exposure. As discussed in the prior approval orders for similar instruments (e.g., the Select Ten Notes and the Industrial 15 Notes for the Amex), the Commission believes this concern is minimal given the size of the Notes issuance in relation to the net worth of Merrill Lynch.

The Commission also believes that the listing and trading of the Notes should not unduly impact the market for the underlying securities comprising the Industrial 15 Index. First, the underlying securities comprising the S&P Industrial Index, from which the Industrial 15 Index components are selected, are well-capitalized, highly liquid stocks. Second, because all of the components of the Industrial 15 Index will be equally weighted, initially and immediately following each annual reconstitution of the Industrial 15 Index, no single stock or group of stocks will likely dominate the Industrial 15 Index. Finally, the issuers of the underlying securities comprising the Industrial 15 Index are subject to reporting requirements under the Act, and all of the portfolio securities are either listed or traded on, or traded through the facilities of, U.S. securities markets. Additionally, Nasdaq's surveillance procedures will serve to deter as well as detect any potential manipulation.

Finally, the Commission notes that the value of the Industrial 15 Index will be disseminated at least once every fifteen seconds throughout the trading day. The Commission believes that providing access to the value of the Industrial 15 Index at least once every fifteen seconds throughout the trading day is extremely important and will

provide benefits to investors in the product.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. In determining to grant the accelerated approval for good cause, the Commission notes that the Industrial 15 Index is a portfolio of highly capitalized and actively traded securities similar to hybrid securities products that have been approved by the Commission for U.S. exchange trading and is also similar to several other instruments currently listed and traded on the Amex and the NYSE, including the Industrial 15 Notes on the Amex.²⁴ Additionally, the Notes will be listed pursuant to existing hybrid security listing standards as described above. Based on the above, the Commission finds, consistent with Section 15A(b) of the Act,²⁵ that there is good cause for accelerated approval of the product.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²⁶ that the proposed rule change (SR-NASD-2003-115), is hereby approved on an accelerated

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.²⁷

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 03-19824 Filed 8-4-03; 8:45 am]
BILLING CODE 8010-01-P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3528]

State of Ohio; (Amendment #2)

In accordance with the notice received from the Department of Homeland Security—Federal Emergency Management Agency, effective July 29, 2003, the above numbered declaration is hereby amended to include Crawford and Pike counties as disaster areas due to damages caused by severe storms and flooding occurring on July 4, 2003 and continuing through July 11, 2003.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Adams, Highland, Huron, Jackson, Marion, Morrow, Richland, Ross, Scioto, Seneca and Wyandot in the State of

²⁴ See *supra* notes 19-20.

²⁵ 15 U.S.C. 78o-3(b).

²⁶ 15 U.S.C. 78s(b)(2).

²⁷ 17 CFR 200.30-3(a)(12).

²² See NASD Rule 4420(f)(1)(D).

²³ The companies that comprise the Industrial 15 Index are reporting companies under the Act.

Ohio may be filed until the specified date at the previously designated location. All other counties contiguous to the above named primary counties have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is September 15, 2003, and for economic injury the deadline is April 15, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: July 30, 2003.

Cheri L. Cannon,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 03-19885 Filed 8-4-03; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3533]

State of Tennessee

As a result of the President's major disaster declaration on July 29, 2003, I find that Shelby County in the State of Tennessee constitutes a disaster area due to damages caused by severe storms, high winds and heavy rain occurring on July 21 through July 22, 2003. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on September 29, 2003 and for economic injury until the close of business on April 29, 2004 at the address listed below or other locally announced locations:

U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Fayette and Tipton in the State of Tennessee; Crittenden County in the State of Arkansas; and DeSoto and Marshall counties in the State of Mississippi.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.625
Homeowners without credit available elsewhere	2.812
Businesses with credit available elsewhere	5.906
Businesses and non-profit organizations without credit available elsewhere	2.953
Others (including non-profit organizations) with credit available elsewhere	5.500

	Percent
Economic Injury: Businesses and small agricultural cooperatives without credit available elsewhere	2.953

The number assigned to this disaster for physical damage is 353311. For economic injury the number is 9W6000 for Tennessee; 9W6100 for Arkansas; and 9W6200 for Mississippi.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: July 30, 2003.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 03-19883 Filed 8-4-03; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3531]

State of Texas (Amendment #2)

In accordance with notices received from the Department of Homeland Security—Federal Emergency Management Agency, effective July 28, 2003, the above numbered declaration is hereby amended to establish the incident period for this disaster as beginning on July 15, 2003 and continuing through July 28, 2003. This declaration is also amended to include DeWitt, Frio, Karnes, Live Oak and San Patricio counties as disaster areas due to damages caused by Hurricane Claudette occurring on July 15, 2003 and continuing through July 28, 2003.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Atascosa, Dimmit, Duval, Gonzales, Jim Wells, LaSalle, McMullen, Medina, Nueces, Uvalde, Wilson and Zavala in the State of Texas may be filed until the specified date at the previously designated location. All other counties contiguous to the above named primary counties have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is September 16, 2003, and for economic injury the deadline is April 19, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: July 30, 2003.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 03-19884 Filed 8-4-03; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF STATE

[Public Notice 4431]

Office of Visa Services; 60-Day Notice of Proposed Information Collection: Form DS-3032, Choice of Address and Agent for Immigrant Visa Applicants; OMB Control Number 1405-0126

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. This process is conducted in accordance with the Paperwork Reduction Act of 1995.

The following summarizes the information collection proposal to be submitted to OMB:

Type of Request: Extension of currently approved collection.

Originating Office: Bureau of Consular Affairs, Department of State (CA/VO).

Title of Information Collection: Choice of Address and Agent For Immigrant Visa Applicants.

Frequency: Once per respondent.

Form Number: DS-3032.

Respondents: All persons applying for Immigrant Visas whose petitions have been approved in U.S.

Estimated Number of Respondents: 330,000 per year.

Average Hours Per Response: 10 minutes.

Total Estimated Burden: 55,000 hours per year.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed information collection is necessary for the proper performance of the functions of the agency.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including through the use of automated collection techniques or other forms of technology.

FOR FURTHER INFORMATION CONTACT:

Public comments, or requests for additional information regarding the collection listed in this notice should be directed to Brendan Mullarkey of the Office of Visa Services, U.S. Department of State, 2401 E St. NW, RM L-703,

Washington, DC 20520, who may be reached at 202-663-1163.

Dated: July 25, 2003.

Janice L. Jacobs,
Deputy Assistant Secretary of State for Visa Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 03-19903 Filed 8-4-03; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF STATE

[Public Notice 4430]

30-Day Notice of Proposed Information Collection: Form DS-1998, Registration for the Foreign Service Officer Written Examination; OMB Control Number 1405-0008

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995. Comments should be submitted to OMB within 30 days of the publication of this notice.

The following summarizes the information collection proposal submitted to OMB:

Type of Request: Extension of currently approved collection.

Originating Office: HR/REE.

Title of Information Collection: Registration for the Foreign Service Officer Written Examination.

Frequency: One application period per year.

Form Number: DS-1998.

Respondents: Registrants for the Foreign Service Officer Written Examination.

Estimated Number of Respondents: 27,585 per year.

Average Hours Per Response: 20 minutes.

Total Estimated Burden: 9,195 hrs.

Public comments are being solicited to permit the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of burden of the collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including

through the use of automated collection techniques or other forms of technology.

FOR FURTHER INFORMATION CONTACT:

Copies of the proposed information collection and supporting documents may be obtained from Beatrice E. Smotherman, Bureau of Personnel, Examination Division, Foreign Service Written Officer Examination (202) 261-8883, U.S. Department of State, Washington, DC 20522. Public comments and questions should be directed to the State Department Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20530, who may be reached on (202) 395-3897.

Dated: June 24, 2003.

Ruben Torres,

Executive Director, Bureau of Human Resources, Department of State.

[FR Doc. 03-19904 Filed 8-4-03; 8:45 am]

BILLING CODE 4710-15-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST-2003-14525]

Application of Reliant Airlines, Inc. and Kalitta Charters II, LLC, for Transfer of Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of order to show cause (Order 2003-7-37).

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Kalitta Charters II, LLC, fit, willing, and able, and transferring to it the all-cargo authority contained in the interstate and foreign cargo charter certificates currently issued to Reliant Airlines, Inc.

DATES: Persons wishing to file objections should do so no later than August 13, 2003.

ADDRESSES: Objections and answers to objections should be filed in Docket OST-2003-14525 and addressed to the Department of Transportation Dockets (M-30, Room PL-401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Ms. Delores King, Air Carrier Fitness Division (X-56, Room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366-2343.

Dated: July 30, 2003.

Michael W. Reynolds,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 03-19899 Filed 8-4-03; 8:45 am]

BILLING CODE 4910-62-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2003-15209; Notice 2]

Public Meeting on Electronic Reporting Procedures Under the Early Warning Reporting Regulations

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of public meeting.

SUMMARY: Prior to the first electronic submission of early warning reporting (EWR) data, NHTSA will hold a final series of public meetings with interested members of the public to discuss the manner in which EWR information is to be submitted by motor vehicle and motor vehicle equipment manufacturers to NHTSA's Office of Defects Investigation (ODI) pursuant to 49 CFR part 579, subpart C. NHTSA will hold two separate public meetings for the following types of manufacturers:

- (1) Manufacturers of tires, child restraint systems, and equipment
- (2) Manufacturers of motor vehicles, including light, medium-heavy vehicles and buses, trailers, and motorcycles.

NHTSA will discuss the procedures by which EWR information must be submitted, security measures involving the EWR information, NHTSA's acknowledgment of the EWR information, and other technical aspects associated with manufacturers' electronic submissions. NHTSA will also answer questions on these issues raised at the meetings.

DATES: NHTSA will conduct these meetings on the following dates and times:

August 27, 2003 at 9:30 a.m. to 12:30 p.m. for manufacturers of tires, child restraint systems and equipment.

August 28, 2003 at 9:30 a.m. to 12:30 p.m. for manufacturers of motor vehicles.

All meetings will be held in Room 2230 of the United States Department of Transportation (Nassif Building), 400 Seventh Street, SW. Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Lorena Villa, Office of Defects Investigation, National Highway Traffic Safety Administration, 400 Seventh

Street; SW., Room 5319, Washington, DC 20590; (202) 366-0699 or at bvilla@nhtsa.dot.gov.

SUPPLEMENTARY INFORMATION: NHTSA recommends that all visitors arrive at least 45 minutes early in order to sign in with security. Visitors to the building should enter through the Southwest Lobby to sign in with security and to be escorted to the meeting room.

NHTSA will provide auxiliary aids to participants as necessary. Any person desiring such auxiliary aids (sign language interpreter, telecommunications devices for deaf persons (TDDs), readers, taped tests, brailled materials, or large print materials, and magnifying devices) should contact Julia Goldson at (202) 366-9944, by Wednesday, August 13, 2003.

Issued on: July 30, 2003.

Kenneth N. Weinstein,

Associate Administrator for Enforcement.

[FR Doc. 03-19902 Filed 8-4-03; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2003-14620]

Safety Belt Use Integrated Project Team (IPT) Plan

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of availability of document.

SUMMARY: This notice announces the availability of NHTSA's third of four high priority safety reports describing the agency's current and planned activities to address safety belt use. The report is available from the Docket Management System, U.S. Department of Transportation, at <http://dms.dot.gov> or on NHTSA's Web site at <http://www.nhtsa.dot.gov/people/ipreports.html>. While the document is final, the agency is offering the public the opportunity to comment on the agency's planned safety belt use activities. The comments will be considered for future agency efforts.

DATES: Comments must be received no later than September 19, 2003.

ADDRESSES: You may submit comments identified by Safety Belt Use DOT DMS Docket Number [NHTSA-2003-14620] by any of the following methods:

- Web site: <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1-202-493-2251.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001.
- Hand Delivery: Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Instructions: All submissions must include the agency name and docket number. Note that all comments received will be posted without change to <http://dms.dot.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://dms.dot.gov>, at any time or to Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Barbara Sauers, National Highway Traffic Safety Administration, Room 6240, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202-366-0144 or Dee Williams, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202-366-0498.

SUPPLEMENTARY INFORMATION: Safety belt use is the single most effective strategy a person can employ to prevent deaths and injuries and reduce the costs associated with motor vehicle crashes. Despite over 30 years of efforts and the expenditure of substantial resources, safety belt use in the United States is currently 75 percent. Although safety belt use has risen dramatically and has saved more than 100,000 lives in the past twenty years (13,000 in 2002 alone), the current level of nonuse in the U.S. still results in thousands of lives lost, over 100,000 serious injuries and billions of dollars in economic losses each year. NHTSA has made finding solutions to increase safety belt use one of the agency's highest priorities. Initiatives the agency plans to pursue include:

- (1) Behavioral Strategies
 - a. Upgrade Existing Safety Belt Laws
 - b. High Visibility Enforcement
 - c. National Communications Plan
 - d. Employer Policies and Regulation
 - e. Insurance Industry Collaboration
- (2) Vehicle Strategies
 - a. Safety Belt Reminders, Voluntary Installation of In-Vehicle Devices and Evidence of Safety Belt Use

b. Improvements to Safety Belt Comfort and Convenience

NHTSA believes the initiatives described in this report will lead to both near-term and longer-term solutions to increase safety belt use among the United States population.

In September 2002, NHTSA assembled integrated project teams (IPTs) to address four highway safety programs of special interest: safety belt use; impaired driving; vehicle compatibility; and vehicle rollover. The reports associated with vehicle compatibility and vehicle rollover were released in June 2003 and can be found on NHTSA's Web site at <http://www.nhtsa.dot.gov/people/ipreports.html> and also on DOT's docket management system (DMS) at <http://dms.dot.gov/>. Once completed, the fourth report addressing impaired driving will also be found in these locations. The docket numbers for each of the respective draft reports are as follows:

- Safety Belt Use: NHTSA-2003-14620;
- Impaired Driving: NHTSA-2003-14621;
- Rollover Mitigation: NHTSA-2003-14622; and
- Vehicle Compatibility: NHTSA-2003-14623.

Each document describes the safety problem and provides strategies the agency plans to pursue in addressing vehicle compatibility; increasing safety belt use, reducing impaired driving and mitigating rollover. Comments received will be evaluated and incorporated, as appropriate, into planned agency activities.

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA-2003-14620) in your comments.

Please send two paper copies of your comments to Docket Management or submit them electronically. The mailing address is U. S. Department of Transportation Docket Management, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590. If you submit your comments electronically, log onto the Docket Management System website at <http://dms.dot.gov> and click on "Help & Information" or "Help/Info" to obtain instructions.

How Can I Be Sure That My Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your

comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, send three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NCC-110, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street, SW., Washington, DC 20590. Include a cover letter supplying the information specified in our confidential business information regulation (49 CFR part 512).

In addition, send two copies from which you have deleted the claimed confidential business information to Docket Management, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590.

Will the Agency Consider Late Comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

How Can I Read the Comments Submitted by Other People?

You may read the comments by visiting Docket Management in person at Room PL-401, 400 Seventh Street, SW., Washington, DC from 10 a.m. to 5 p.m., Monday through Friday.

You may also see the comments on the Internet by taking the following steps:

- Go to the Docket Management System (DMS) Web page of the Department of Transportation (<http://dms.dot.gov>).
- On that page, click on "search."
- On the next page (<http://dms.dot.gov/search/>) type in the four-digit Docket number shown at the beginning of this document (14620). Click on "search."

• On the next page, which contains Docket summary information for the Docket you selected, click on the desired comments. You may also download the comments.

Authority: 49 U.S.C. 30111, 30117, 30168; delegation of authority at 49 CFR 1.50 and 501.8.

Dated:

Rose A. McMurray,
Associate Administrator for Planning,
Evaluation & Budget.
[FR Doc. 03-19878 Filed 8-4-03; 8:45 am]
BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB-308 (Sub-No. 3X)]

Central Michigan Railway Company- Abandonment Exemption-in Saginaw County, MI

On July 16, 2003, Central Michigan Railway Company (CMR) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon an approximately 1.77-mile line of railroad, extending from milepost 2.83 at the western end of CMR's railroad bridge over Interstate 75 to milepost 4.60 in Saginaw County, MI.¹ The line traverses United States Postal Service Zip Code 48601.

The line does not contain federally granted rights-of-way. Any documentation in CMR's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.-Abandonment-Goshen*, 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 3, 2003.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer must be accompanied by a \$1,100 filing fee. See 49 CFR 1002.2(f)(25).

¹ CMR indicates that the above-described mileposts are sometimes referred to by their former designations as milepost 17.21 and milepost 15.46, totaling approximately 1.75-miles of rail line and differing from the current designations by .02-mile. CMR points out that this discrepancy is just a measurement error in the milepost labeling, a fairly common occurrence in railroad milepost designations.

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than August 25, 2003. Each trail use request must be accompanied by a \$150 filing fee. See 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB-308 (Sub-No. 3X) and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423-0001; and (2) William A. Mullins, 915 15th Street, NW., Suite 1000, Washington, DC 20005-2318. Replies to the CMR petition are due on or before August 25, 2003.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565-1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565-1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: July 23, 2003.

By the Board, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,
Secretary.

[FR Doc. 03-19333 Filed 8-4-03; 8:45 am]

BILLING CODE 4915-00-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB-33 (Sub-No. 206X)]

**Union Pacific Railroad Company—
Abandonment Exemption—in Polk and
Story Counties, IA**

Union Pacific Railroad Company (UP) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon a 14.0-mile line of railroad, known as the Ankeny Subdivision, extending from milepost 10.7 near Ankeny to milepost 341.1 (Equation: 23.20 = 339.60) near Slater, in Polk and Story Counties, IA. The line traverses United States Postal Service Zip Codes 50015, 50021, 50244.

UP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 4, 2003, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,¹ formal expressions of intent to file an OFA

¹ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

under 49 CFR 1152.27(c)(2),² and trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 15, 2003. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 25, 2003, with: Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423-0001.

A copy of any petition filed with the Board should be sent to UP's representative: Mack H. Shumate, Jr., Senior General Attorney, Union Pacific Railroad Company, 101 North Wacker Drive, Room 1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

UP has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. SEA will issue an environmental assessment (EA) by August 8, 2003. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423-0001) or by calling SEA, at (202) 565-1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by UP's filing of a notice of consummation by August 5, 2004, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: July 29, 2003.

By the Board, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,
Secretary.

[FR Doc. 03-19779 Filed 8-4-03; 8:45 am]

BILLING CODE 4915-00-P

² Each OFA must be accompanied by the filing fee, which currently is set at \$1,100. See 49 CFR 1002.2(f)(25).

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the
Currency

[Docket No. 03-17]

Preemption Determination and Order

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice.

SUMMARY: The Office of the Comptroller of the Currency (OCC) is issuing this Determination and Order, attached as an appendix to this Notice, in response to a request from National City Bank, National City Bank of Indiana, and their operating subsidiaries, National City Mortgage Company and First Franklin Financial Company (referred to collectively herein as National City). The request asks the OCC to determine whether the Georgia Fair Lending Act (GFLA)¹ applies to the banks and their operating subsidiaries, and to issue an appropriate order. National City asserts that the GFLA is preempted under various provisions of Federal law and that, accordingly, the OCC should conclude that the Georgia law does not apply to it. For the reasons summarized here and described in detail in the appendix, the OCC has concluded that the provisions of the GFLA affecting national banks' real estate lending are preempted by Federal law. Therefore, we are issuing an order providing that the GFLA does not apply to National City or to any other national bank or national bank operating subsidiary that engages in real estate lending activities in Georgia.

FOR FURTHER INFORMATION CONTACT: Michele Meyer, Counsel, or Mark Tenhundfeld, Assistant Director, Legislative and Regulatory Activities Division, (202) 874-5090.

SUPPLEMENTARY INFORMATION: In brief, the reasons supporting our Determination and Order are as follows:

- National banks' authority to engage in real estate lending activities derives exclusively from Federal law. Under applicable Federal preemption principles, based on the Supremacy Clause of the U.S. Constitution and articulated by the U.S. Supreme Court, a state law may not modify a Congressional grant of power to national banks by limiting, conditioning, or otherwise impermissibly affecting a national bank's exercise of that power.
- The Federal statute that authorizes national banks' real estate lending activities, 12 U.S.C. 371, precludes

¹ The GFLA codified at GA Code, Ann §§ 7-6A-1 et seq.

application of many provisions of the GFLA to national banks. First, by its terms, the statute grants real estate lending power unconditioned by the application of any state's law. As it said in *Barnett Bank of Marion County, N.A. v. Nelson*,² the Supreme Court ordinarily finds that state law conditions on the exercise of national bank powers are preempted if Congress has not expressly directed the application of state law. Second, the text of the statute specifically gives the OCC authority to determine the "restrictions and requirements" that apply to national banks' real estate lending activities. The exclusion of state authority in this regard is consistent with the history of the statute, which has, since its inception, imposed only Federal limits and conditions on national banks' real estate lending activities.

- National banks' real estate lending standards are subject to a comprehensive Federal regulatory framework that addresses the types of abusive and predatory practices that the GFLA seeks to prohibit. In addition, the OCC has recently issued detailed guidance applicable to national banks' mortgage originations, use of mortgage brokers, and purchases of loans from others. This guidance targets abusive and predatory practices and will be administered by the OCC as part of its comprehensive supervision of national banks, in addition to the already-applicable Federal restrictions on high-cost real estate lending, Federal consumer protections and disclosure requirements that apply to all home mortgage lending, and Federal standards that require national banks to base lending decisions on the borrower's ability to repay and not the foreclosure value of the collateral.

- The OCC regulations implementing 12 U.S.C. 371 currently provide that certain types of state laws do not apply to national banks. For instance, part 34 of our rules says expressly that state laws concerning the schedule for the repayment of principal and interest and state laws concerning the term to maturity of a loan do not apply to national banks. Thus, Federal law, comprised of the statute and OCC regulations, already preempts the GFLA provisions that modify a national bank's real estate lending authority by imposing limits or restrictions that concern the schedule for repayment of principal and interest or the term to maturity of a loan.

- Section 371 and our rules also preempt the GFLA provisions that,

pursuant to the *Barnett* standards and the growing body of lower Federal court case law applying those standards, impose conditions on, or otherwise impermissibly affect, a national bank's exercise of its real estate lending powers. Thus, provisions of the GFLA that prescriptively prohibit or limit practices that are lawful under Federal law (but, in many cases, subject to Federal standards directed at eliminating abusive or predatory practices) also do not apply to national banks.

- Some provisions of the GFLA purport to limit the interest a national bank may charge for certain types of loans. As the Supreme Court has recently reaffirmed, the rate of interest that is permissible for national banks is determined exclusively by Federal law, at 12 U.S.C. 85. Section 85 permits national banks to charge the most favorable rate permitted by the laws of the state in which the bank is located, regardless of where the borrower is located. Under this standard, National City uses the most favored lender rates of Indiana, not Georgia, and thus is not subject to limits on the rates of interest imposed by the GFLA. (Moreover, national banks located in Georgia are not subject to the GFLA provisions concerning interest. The Office of Thrift Supervision has previously determined that the GFLA does not apply to Federal savings associations. By virtue of the parity provision in the GFLA, that law also would not apply to a Georgia state savings association. Thus, for purposes of section 85, a Georgia state savings association is the most favored lender with respect to the types of loans covered by the GFLA, and, accordingly, a national bank located in Georgia is similarly not subject to limits on the rate of interest it may charge for loans within the scope of the GFLA.)

- Other provisions of the GFLA purport to limit the non-interest fees a national bank may charge in connection with certain types of loans. These provisions are preempted because they are inconsistent with national banks' well recognized authority to establish non-interest fees pursuant to the national bank powers provisions of 12 U.S.C. 24(Seventh) and the OCC's rules that govern national bank fees.

- The GFLA is also preempted with respect to national bank operating subsidiaries. Federal law authorizes national banks to conduct through operating subsidiaries activities that are permissible for the bank itself. Activities conducted through operating subsidiaries are subject to the same terms and conditions as apply to the parent bank and, pursuant to OCC

regulations, are subject to state law only to the extent that the parent bank is subject to state law.

This Determination and Order provides that the GFLA does not apply to National City. Because our conclusions rest on an analysis of the legal effects of the GFLA under Constitutional preemption principles, they would not differ with respect to any other national bank or national bank operating subsidiary engaged in real estate lending activities in Georgia. The scope of our Order providing that the GFLA is preempted therefore includes any national bank or national bank operating subsidiary that is engaged in real estate lending activities in Georgia.

Finally, although National City has asked us to address whether Federal law occupies the field of real estate lending regulation, such that no state real estate lending law applies to national banks or their operating subsidiaries, our Determination and Order does not take up that issue. National City's request asked us to review only one state's law, the GFLA. A conclusion that Federal law occupies the field of real estate lending regulation would have implications beyond the applicability of the Georgia law. For that reason, we believe it is appropriate to consider the question of occupation of the field, as that theory may apply in the case of real estate lending, in a rulemaking. Contemporaneously with the issuance of this Determination and Order, therefore, we are initiating a rulemaking that addresses that issue.

Dated: July 30, 2003.

John D. Hawke, Jr.,
Comptroller of the Currency.

Appendix—Determination and Order; In the Matter of National City Bank, National City Bank of Indiana, and Their Operating Subsidiaries; Introduction and Summary Conclusions

The Office of the Comptroller of the Currency (OCC) is issuing this Determination and Order in response to a request from National City Bank, National City Bank of Indiana, and their operating subsidiaries, National City Mortgage Company and First Franklin Financial Company (referred to collectively herein as National City). The request asks the OCC to determine whether the Georgia Fair Lending Act (GFLA)¹ applies to the banks and their operating subsidiaries, and to issue an appropriate order. National City asserts that the GFLA is preempted under various provisions of Federal law and

¹ The GFLA is codified at GA Code Ann. §§7-6A-1 *et seq.*

² 517 U.S. 25 (1996).

that, accordingly, the OCC should conclude that the Georgia law does not apply to it. For the reasons summarized here and described in detail later in this Determination and Order, the OCC has concluded that the provisions of the GFLA affecting national banks' real estate lending are preempted by Federal law. Therefore, we are issuing an order providing that the GFLA does not apply to National City or to any other national bank or national bank operating subsidiary that engages in real estate lending activities in Georgia.

In brief, the reasons supporting our Determination and Order are as follows:

- National banks' authority to engage in real estate lending activities derives exclusively from Federal law. Under applicable Federal preemption principles, based on the Supremacy Clause of the U.S. Constitution and articulated by the U.S. Supreme Court, a state law may not modify a Congressional grant of power to national banks by limiting, conditioning, or otherwise impermissibly affecting a national bank's exercise of that power.

- The Federal statute that authorizes national banks' real estate lending activities, 12 U.S.C. 371, precludes application of many provisions of the GFLA to national banks. First, by its terms, the statute grants real estate lending power unconditioned by the application of any state's law. As it said in *Barnett Bank of Marion County, N.A. v. Nelson*,² the Supreme Court ordinarily finds that state law conditions on the exercise of national bank powers are preempted if Congress has not expressly directed the application of state law. Second, the text of the statute specifically gives the OCC authority to determine the "restrictions and requirements" that apply to national banks' real estate lending activities. The exclusion of state authority in this regard is consistent with the history of the statute, which has, since its inception, imposed only Federal limits and conditions on national banks' real estate lending activities.

- National banks' real estate lending standards are subject to a comprehensive Federal regulatory framework that addresses the types of abusive and predatory practices that the GFLA seeks to prohibit. In addition, the OCC has recently issued detailed guidance applicable to national banks' mortgage originations, use of mortgage brokers, and purchases of loans from others. This guidance targets abusive and predatory practices and will be administered by the OCC as part of its

comprehensive supervision of national banks, in addition to the already-applicable Federal restrictions on high-cost real estate lending, Federal consumer protections and disclosure requirements that apply to all home mortgage lending, and Federal standards that require national banks to base lending decisions on the borrower's ability to repay and not the foreclosure value of the collateral.

- The OCC regulations implementing 12 U.S.C. 371 currently provide that certain types of state laws do not apply to national banks. For instance, part 34 of our rules says expressly that state laws concerning the schedule for the repayment of principal and interest and state laws concerning the term to maturity of a loan do not apply to national banks. Thus, Federal law, comprised of the statute and OCC regulations, already preempts the GFLA provisions that modify a national bank's real estate lending authority by imposing limits or restrictions that concern the schedule for repayment of principal and interest or the term to maturity of a loan.

- Section 371 and our rules also preempt the GFLA provisions that, pursuant to the *Barnett* standards and the growing body of lower Federal court case law applying those standards, impose conditions on, or otherwise impermissibly affect, a national bank's exercise of its real estate lending powers. Thus, provisions of the GFLA that prescriptively prohibit or limit practices that are lawful under Federal law (but, in many cases, subject to Federal standards directed at eliminating abusive or predatory practices) also do not apply to national banks.

- Some provisions of the GFLA purport to limit the interest a national bank may charge for certain types of loans. As the Supreme Court has recently reaffirmed, the rate of interest that is permissible for national banks is determined exclusively by Federal law, at 12 U.S.C. 85. Section 85 permits national banks to charge the most favorable rate permitted by the laws of the state in which the bank is located, regardless of where the borrower is located. Under this standard, National City uses the most favored lender rates of *Indiana*, not Georgia, and thus is not subject to limits on the rates of interest imposed by the GFLA. (Moreover, national banks located in Georgia are not subject to the GFLA provisions concerning interest. The Office of Thrift Supervision (OTS) has previously determined that the GFLA does not apply to Federal savings associations. By virtue of the parity provision in the

GFLA, that law also would not apply to a Georgia state savings association. Thus, for purposes of section 85, a Georgia state savings association is the most favored lender with respect to the types of loans covered by the GFLA, and, accordingly, a national bank located in Georgia is similarly not subject to limits on the rate of interest it may charge for loans within the scope of the GFLA.)

- Other provisions of the GFLA purport to limit the non-interest fees a national bank may charge in connection with certain types of loans. These provisions are preempted because they are inconsistent with national banks' well recognized authority to establish non-interest fees pursuant to the national bank powers provisions of 12 U.S.C. 24(Seventh) and the OCC's rules that govern national bank fees.

- The GFLA is also preempted with respect to national bank operating subsidiaries. Federal law authorizes national banks to conduct through operating subsidiaries activities that are permissible for the bank itself. Activities conducted through operating subsidiaries are subject to the same terms and conditions as apply to the parent bank and, pursuant to OCC regulations, are subject to state law only to the extent that the parent bank is subject to state law.

This Determination and Order provides that the GFLA does not apply to National City. Because our conclusions rest on an analysis of the legal effects of the GFLA under Constitutional preemption principles, they would not differ with respect to any other national bank or national bank operating subsidiary engaged in real estate lending activities in Georgia. The scope of our Order providing that the GFLA is preempted therefore includes any national bank or national bank operating subsidiary that is engaged in real estate lending activities in Georgia.

Finally, although National City has asked us to address whether Federal law occupies the field of real estate lending regulation, such that no state real estate lending law applies to national banks or their operating subsidiaries, our Determination and Order does not take up that issue. National City's request asked us to review only one state's law, the GFLA. A conclusion that Federal law occupies the field of real estate lending regulation would have implications beyond the applicability of the Georgia law. For that reason, we believe it is appropriate to consider the question of occupation of the field, as that theory may apply in the case of real estate lending, in a rulemaking. Contemporaneously with the issuance

² 517 U.S. 25 (1996).

of this Determination and Order, therefore, we are initiating a rulemaking that addresses that issue.

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I. Background

A. Relevant Provisions of State and Federal Law and Regulations

1. The Georgia Fair Lending Act

The GFLA became effective October 1, 2002. As originally enacted, the GFLA restricted the ability of creditors or servicers to charge certain fees and engage in certain practices for three categories that it defined: "home loans,"

"covered home loans," and "high-cost home loans." Whether a loan was covered by one of these categories depended on the annual percentage rate and the amount of points and fees charged.³ All "home loans" were subject to certain restrictions on the terms of credit and loan-related fees, including prohibitions on the financing of credit insurance, debt cancellation or suspension coverage, and limitations on late fees and payoff statement fees.

In addition to the restrictions on "home loans," "covered home loans" were subject to restrictions on the number of times a loan could be refinanced and the circumstances in which a refinancing could occur. For example, the GFLA prohibited a creditor from refinancing an existing home loan that was less than five years old with a "covered home loan" that did not provide a reasonable "tangible net benefit" to the borrower, considering all the circumstances.

"High-cost home loans" were subject to the restrictions on "home loans" and "covered home loans," as well as numerous disclosure requirements and restrictions on the terms of credit and loan-related fees. Creditors were required to disclose to borrowers that the loan is high-cost, and borrowers were required to be provided with certain loan counseling before the creditor could make the loan. In addition, the GFLA prohibited certain pre-payment penalties; balloon payments; negative amortization; increases in interest rates after default; advance payments from loan proceeds; fees to modify, renew, extend, amend, or defer a payment; and accelerating payments at the creditor's or servicer's sole discretion.

The original GFLA provided a private right of action for borrowers against lenders and mortgage brokers for injunctive and declaratory relief as well as for actual, statutory, and punitive damages, and permitted recovery of a plaintiff's attorney's fees. In addition, the Georgia Attorney General, district attorneys, the Commissioner of Banking and Finance and, with respect to the insurance provisions, the Commissioner of Insurance were given the jurisdiction to enforce the GFLA through their general regulatory powers and civil processes permitted under state law.

The original GFLA also provided that any purchaser or assignee of a high-cost home loan would be subject to all affirmative claims and defenses that the borrower could assert against the original lender. This extension of lender liability to assignees and purchasers had

the potential to seriously impede the secondary market for Georgia mortgage loans and, following the enactment of the original GFLA, Moody's Investors Service concluded that including GFLA-covered loans in securitizations was too risky, causing lenders to scale back loans in the state and leading issuers to remove Georgia loans from securitizations. Standard and Poor's also announced that it would no longer rate mortgage-backed securities that included Georgia mortgage loans.

On March 7, 2003, the Georgia legislature amended the GFLA. The amendments eliminated the "covered home loan" category, but all of the original GFLA restrictions on "high-cost home loans" remain in effect under the current version of the law. The amendments did not change the civil liability provisions applicable to loan originators and mortgage brokers. The amendments did, however, limit purchaser or assignee liability by providing a due diligence defense in the event of a borrower claim and by capping the amount of the purchaser's or assignee's potential liability. However, Moody's and Standard and Poor's still apply significant limits on their willingness to rate mortgage-backed securities that include Georgia high-cost home loans.

As amended, the GFLA provides that if the GFLA has been determined to be preempted by Federal law for Federally-chartered institutions, the comparable state-chartered institutions (e.g. state banks, thrifts, trust companies, or their subsidiaries) will likewise not be subject to the GFLA.⁴ Under this parity law, most of the provisions in the GFLA are already inapplicable to state-chartered savings and loan associations because the OTS has determined that most of the GFLA is inapplicable to Federally-chartered thrifts.⁵

⁴ The statute provides that "[t]he provisions of this chapter shall not apply to any bank, trust company, savings and loan, savings bank, credit union, or subsidiary thereof, respectively, that is chartered under the laws of this state or any other state only to the extent federal law precludes or preempts or has been determined to preclude or preempt the application of the provisions of this chapter to any federally chartered bank, trust company, savings and loan, savings bank, credit union, or subsidiary thereof, respectively, and such federal preclusion or preemption shall apply only to the same type of state chartered entity as the federally chartered entity affected; provided, however, the provisions of this chapter . . . shall be applicable to an independent mortgage broker for any loan originated or brokered by the broker that is initially funded by any state or federally chartered bank, trust company, savings and loan, savings bank, or credit union." GFLA § 7-6A-12.

⁵ See OTS Op. Chief Counsel, P-2003-1 (Jan. 21, 2003), available at <http://www.ots.treas.gov/docs/56301.pdf>.

³ See GFLA § 7-6A-2.

2. Federal Law and Regulations

The real estate lending activities covered by the GFLA are authorized for national banks by Federal law and regulated under Federal standards.

a. National banks' real estate lending authority. Federal law authorizes national banks to engage in real estate lending activities and vests in the OCC comprehensive authority to regulate and supervise those activities:

[a]ny national banking association may make, arrange, purchase or sell loans or extensions of credit secured by liens on interests in real estate, subject to section 1828(o) of this title and such restrictions and requirements as the Comptroller of the Currency may prescribe by regulation or order.⁶ The exercise of the powers granted by section 371 is not conditioned on compliance with any state requirement, but subject only to a Federal law and such rules and regulations as the Comptroller may prescribe.⁷

The OCC has implemented section 371 in regulations set forth at 12 CFR part 34.⁸ Twelve CFR 34.3 establishes the general rule that a national bank and its operating subsidiaries may engage in real estate lending, and qualifies this rule by reference only to the "terms, conditions, and limitations prescribed by the Comptroller of the Currency by regulation or order." Twelve CFR 34.4(a) expressly provides that five types of state law limitations are not applicable to real estate loans made by national banks and their operating subsidiaries:

(a) *Specific preemption.* A national bank may make real estate loans under 12 U.S.C. 371 and § 34.3 without regard to State law limitations concerning:

- (1) The amount of a loan in relation to the appraised value of the real estate;
- (2) The schedule for the repayment of principal and interest;

⁶ 12 U.S.C. 371(a). The cross-reference in this provision is to the Federal requirement for safety and soundness standards that apply to real estate lending. The standards for national banks and their operating subsidiaries are set forth in 12 CFR part 34, Subpart D, Appendix A.

⁷ Federal legislation occasionally provides that national banks shall conduct certain activities subject to state law standards. For example, national banks conduct insurance sales, solicitation, and cross-marketing activities subject to certain types of state restrictions expressly set out in the Gramm-Leach-Bliley Act (GLBA). See 15 U.S.C. 6701(d)(2)(B). There is no similar Federal legislation subjecting national banks' real estate lending activities to state law standards.

⁸ Some of the OCC's regulations, such as part 34, apply by their terms to national bank operating subsidiaries. See 12 CFR 34.1(b). As explained below, however, a national bank operating subsidiary is treated the same as its parent bank and, thus, is also subject to OCC regulations that do not expressly refer to national bank operating subsidiaries.

(3) The term to maturity of the loan;
(4) The aggregate amount of funds that may be loaned upon the security of real estate; and

(5) The covenants and restrictions that must be contained in a lease to qualify the leasehold as acceptable security for a real estate loan. Twelve CFR 34.4(b) states:

The OCC will apply recognized principles of Federal preemption in considering whether State laws apply to other aspects of real estate lending by national banks.

b. Permissible rate of interest for national banks. The limitations on charges that comprise rates of interest on loans by national banks are determined exclusively by Federal law.⁹ Under 12 U.S.C. 85, a national bank is authorized to charge interest based on the laws of the state in which the bank is located.¹⁰ OCC regulations further provide that:

A national bank located in a state may charge interest at the maximum rate permitted to any state-chartered or licensed lending institution by the law of that state.¹¹

This "most favored" lender status permits a national bank to contract with borrowers in *any state* for interest at the maximum rate permitted for any state-chartered or licensed lending institution by the law of the state in which the national bank is located.

c. *National banks' authority to charge fees.* Twelve U.S.C. 24(Seventh) authorizes a national bank to engage in activities that are part of, or incidental to, the business of banking¹² as well as to engage in certain specified activities listed in the statute. Mortgage lending is expressly authorized for national banks and is thus inarguably part of the business of banking. Moreover, "negotiating * * * promissory notes" is one of the activities specified in section 24(Seventh). A bank's authority to provide these products or services to its customers necessarily encompasses the ability to charge a fee for the product or service.¹³

⁹ See *Beneficial Nat'l Bank v. Anderson*, 123 S.Ct. 2058 (2003).

¹⁰ See *Marquette Nat'l Bank of Minneapolis v. First of Omaha Service Corp.*, 439 U.S. 299 (1978).

¹¹ 12 CFR 7.4001(b); see also *Northway Lanes v. Hackley Union Nat'l Bank & Trust Co.*, 464 F.2d 855 (6th Cir. 1972).

¹² The powers clause of section 24(Seventh) provides that a national bank may "exercise by its board of directors or duly authorized officers or agents, subject to law, all such incidental powers as shall be necessary to carry on the business of banking." 12 U.S.C. 24(Seventh). See *NationsBank v. Variable Annuity Life Ins. Corp.*, 513 U.S. 251 (1995) (the "business of banking" is not limited to the list of powers enumerated in section 24(Seventh)).

¹³ Cf. *Franklin Nat'l Bank v. New York*, 347 U.S. 373, 377 (1954) (stating, in the context of bank

The authority to charge fees for the bank's services is expressly set out in 12 CFR 7.4002(a), which provides:

(a) Authority to impose charges and fees. A national bank may charge its customers non-interest charges and fees, including deposit account service charges.¹⁴

d. *Standards applicable to national bank operating subsidiaries.* Pursuant to their authority under 12 U.S.C. 24(Seventh) to exercise "all such incidental powers as shall be necessary to carry on the business of banking," national banks may use separately incorporated entities to engage in activities that the bank itself is authorized to conduct. The OCC's Operating Subsidiary Rule, codified at 12 CFR 5.34, specifies the licensing requirements when national banks seek permission from the OCC to conduct business through an operating subsidiary.¹⁵ Pursuant to this licensing process, the OCC licenses the operating subsidiary as a means through which a national bank is authorized to conduct activities permissible for the bank itself. Under this regulation, "[a] national bank may conduct in an operating subsidiary activities that are permissible for a national bank to engage in directly either as part of, or incidental to, the business of banking, as determined by the OCC, or otherwise under other statutory authority."¹⁶

The regulation further clarifies that in conducting permissible activities on behalf of its parent bank, the operating subsidiary is acting "pursuant to the same authorization, terms and conditions that apply to the conduct of such activities by its parent national bank."¹⁷ When established in

advertising, "[w]e cannot believe that the incidental powers granted to national banks should be construed so narrowly as to preclude the use of advertising in any branch of their authorized business.").

¹⁴ A bank's authority in this, as in all other, areas must be exercised in a manner that is consistent with safe and sound banking practices. Paragraph (b) of section 7.4002 sets out the factors that the bank should consider to ensure that its process for setting its fees and charges is consistent with safety and soundness. If a bank uses a decisionmaking process that takes these factors into consideration, then there is no supervisory impediment to the bank exercising its discretionary authority to charge non-interest fees and charges pursuant to § 7.4002(a). National City has not sought, nor provided information to support, a determination by the OCC that its processes in deciding to charge the fees at issue here are consistent with safe and sound banking. However, as we have pointed out in other contexts, national banks are not required to obtain a determination from the OCC that their fees comport with § 7.4002 in order to be able to exercise the federal power to charge fees. See, e.g., OCC Interpretive Letter No. 934 (Aug. 20, 2001).

¹⁵ See 12 CFR 5.34(b).

¹⁶ 12 CFR 5.34(e)(1).

¹⁷ 12 CFR 5.34(e)(3).

accordance with the procedures mandated by the OCC's Operating Subsidiary Rule and approved by the OCC, the operating subsidiary is a Federally-authorized means by which a national bank may conduct Federally-authorized activities.

e. Anti-predatory lending standards applicable to national banks. Recently, the OCC issued comprehensive supervisory standards to address predatory and abusive lending practices.¹⁸ The OCC standards on predatory lending make clear that national banks should adopt—and vigorously adhere to—policies and procedures to prevent predatory lending practices in direct lending and in transactions involving brokered and purchase loans.

Significantly, AL 2003-2 provides that bank policies and procedures on direct lending should reflect the degree of care that is appropriate to the risk of a particular transaction. In some cases, this will entail making the determination that a loan is reasonably likely to meet the borrower's individual financial circumstances and needs. AL 2003-2 also emphasizes that if the OCC has evidence that a national bank has engaged in abusive lending practices, we will review those practices to determine whether they violate specific provisions of the Federal laws, including the Homeowners Equity Protection Act of 1994 (HOEPA), the Fair Housing Act, or the Equal Credit Opportunity Act. The OCC also will evaluate whether such practices involve unfair or deceptive practices in violation of the Federal Trade Commission Act (FTC Act). Indeed, several practices cited in AL 2003-2, such as equity stripping, loan flipping, and the re-financing of special subsidized mortgage loans that originally contained terms favorable to the borrower, can be found to be unfair practices that violate the FTC Act.

The OCC's second advisory, AL 2003-3, addresses concerns that have been raised about the link between predatory lending and non-regulated lending intermediaries, and the risk that a national bank could indirectly and inadvertently facilitate predatory lending through the purchase of loans and mortgage-backed securities and in connection with broker transactions. Pursuant to our standards, a national bank needs to perform adequate due

diligence prior to entering into any relationships with loan brokers, third party loan originators, and the issuers of mortgage-backed securities, to ensure that the bank does not do business with companies that fail to employ appropriate safeguards against predatory lending in connection with loans they arrange, sell, or pool for securitization. AL 2003-3 also advises national banks to take specific steps to address the risk of fraud and deception in brokered loan transactions relating to broker-imposed fees and other broker compensation vehicles.

B. National City's Preemption Request

On January 29, 2003, National City submitted to the OCC a request for a determination or order under 12 U.S.C. 24(Seventh), 12 U.S.C. 371, 12 U.S.C. 85, and the OCC's implementing regulations, that the GFLA does not apply to National City.¹⁹ National City originates and funds home equity loans and lines of credit on a nationwide basis. It also originates and funds first and second mortgage loans throughout the United States for the purpose of financing and refinancing the acquisition and construction of real property containing one to four family residential dwellings. National City receives loan applications from third party mortgage brokers, and those mortgage brokers perform many services resulting in the origination of the loans and lines of credit issued by National City.

In its request, National City asked the OCC to determine that 12 U.S.C. 24(Seventh) and 12 U.S.C. 371 preempt the GFLA with respect to the bank and its operating subsidiaries. National City asserts that the structure of section 371 and § 34.3, together with the express preemption delineated in § 34.4(a), evidence a presumption that state law does not apply to the real estate lending activities of national banks and their operating subsidiaries unless the OCC determines under § 34.4(b) that a particular state law is not preempted. In other words, in "considering whether state laws apply" for purposes of issuing an order under section 371, National City asserted that the OCC could either issue an order confirming that the law is not applicable or providing that it will be applicable after applying the "recognized principles of preemption" referred to in § 34.4(b). Thus, National City argued that section 371, in effect, authorizes the OCC to "occupy the field" of real estate lending regulation

for national banks, and that, through its regulations, including § 34.4(a) and (b), the OCC has done so.

For purposes of determining whether any of the GFLA provisions not otherwise preempted under § 34.4(a) apply to National City, National City analyzed the degree to which the GFLA, in the words of *Barnett*, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."²⁰ In this regard, National City asserted that various GFLA provisions place impermissible limits on the exercise of national banks' real estate lending powers under 12 U.S.C. 371.

In addition to its arguments under section 371 and the OCC's implementing regulations, National City asserts that the GFLA places impermissible limits on the exercise of national banks' authority to lend money generally under 12 U.S.C. 24(Seventh) and to charge fees for lending products or services pursuant to 12 CFR 7.4002.

Finally, National City contends that the GFLA has the effect of restricting its ability to use third party mortgage brokers and compensate them for the services they provide.

C. Notice of, and Comments on, National City's Request

On February 26, 2003, the OCC published for comment a Notice of National City's request (the Notice).²¹ The OCC received 76 comments on the Notice. National banks, financial services providers, and trade associations submitted comments in support of the issuance of a preemption determination or order in this matter. Consumer organizations, state officials (including the Governor of Georgia and the Acting Commissioner of the Georgia Department of Banking and Finance), the Conference of State Bank Supervisors, the National Association of Attorneys General, certain members of the Committee on Financial Services of the United States House of Representatives, and one member of the Senate Committee on Banking, Housing, and Urban Affairs submitted comments in opposition.

As an initial matter, several commenters assert that National City's request is moot in light of the recent amendments to the GFLA. Others urged the OCC to rescind its notice until such time as it receives a revised request for preemption that reflects these amendments. Still others assert that, despite the amendments, the

¹⁸ See OCC Advisory Letter 2003-2, "Guidelines for National Banks to Guard Against Predatory and Abusive Lending Practices" (Feb. 21, 2003) (AL 2003-2) and OCC Advisory Letter 2003-3, "Avoiding Predatory and Abusive Lending Practices in Brokered and Purchased Loans" (Feb. 21, 2003) (AL 2003-3).

¹⁹ Following the amendments to the GFLA, National City reaffirmed its interest in obtaining such a determination or order.

²⁰ *Barnett*, 517 U.S. at 31 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

²¹ 68 FR 8959 (Feb. 26, 2003).

fundamental issues raised in National City's request remain unchanged.

We have reviewed the law as amended and, as discussed in greater detail below, conclude that the issue of whether Georgia may determine how national banks conduct real estate lending activities is not rendered moot, or fundamentally altered, by the changes adopted by the Georgia legislature. In addition, National City continues to assert that the GFLA remains impermissibly burdensome. Thus, we have proceeded with our consideration of National City's request.

National City's assertion that section 371 authorizes the OCC to "occupy the field" of national bank real estate lending generated considerable debate among the commenters over which preemption theory applies to National City's request. As explained further below, "occupation of the field" is one of the three ways in which Congress can preempt state law. In addition to field occupation, Congress can expressly provide in a Federal statute that the statute preempts state law or can adopt a statute that is in irreconcilable conflict with state law.²²

Many commenters favoring preemption argue that the OCC should adopt an "occupation of the field" analysis. Those commenters assert that Congress's intent that Federal law would "occupy the field" of national bank real estate lending is evident in the express language of section 371, its legislative history, and other Federal statutes. Many of these commenters suggest, however, that the OCC apply, either as an addition or alternative to the "occupation of the field" analysis, a "conflicts" analysis under *Barnett*. These commenters assert that the GFLA conflicts with the Federal grant of power to a national bank to engage in real estate lending activities.

Opponents of preemption argue that the statute, its legislative history, and Federal case law provide no support for field preemption. Several of these commenters also cite the preamble of an earlier version of the OCC's regulations implementing section 371, in which the OCC stated that it was clarifying "the limited scope" of the regulation's preemption. Because they believe that field preemption theory is inapplicable here, the opposing commenters assert that the OCC should apply only a *Barnett* "conflicts" analysis to National City's request to determine the extent to which each provision of the GFLA interferes with the exercise of national banks' authority to engage in real estate lending. Under this analysis, the

commenters argue that the GFLA does not prevent or significantly interfere with the exercise of national banks' real estate lending powers.

As discussed in detail below, our construction of section 371 and the results of a *Barnett* conflicts analysis of the GFLA provisions, both demonstrate that the GFLA places impermissible limits on national banks' real estate lending activities and, therefore, is preempted by Federal law. National City's request raises issues about only the laws in one state, however, and, in our view, is therefore not the appropriate vehicle to consider whether Federal law occupies the field of national bank real estate lending because that legal conclusion would have implications for other types of real estate lending laws and for real estate lending laws in all states. Accordingly, this Determination and Order does not address whether Federal law occupies the field of national banks' real estate lending activities. That issue will be considered, however, in a notice of proposed rulemaking that we are releasing simultaneously with this Determination and Order, to amend, among other parts of our rules, the rules in part 34 governing the applicability of state law to national banks' real estate lending activities.

In addition, the commenters debate the meaning of the considerable body of case law that has developed around the application of state law to the exercise of national banks powers. Commenters in favor of preemption note a long line of Supreme Court and lower Federal court precedent "interpreting grants of both enumerated and incidental 'powers' to national banks as grants of authority not normally limited by, but rather ordinarily pre-empting, contrary state law."²³ Commenters opposed to preemption argue that the courts have avoided finding preemption in areas of law, such as consumer protection, traditionally occupied by the states. These commenters assert that Congress specifically endorsed this presumptive application of state laws to national banks in the Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994 (Riegle-Neal Act).²⁴

As discussed in greater detail below, the presumption against preemption of state law is inapplicable when the states attempt to regulate in an area, such as national banking, where there is a history of significant Federal presence.²⁵ Moreover, the Riegle-Neal

Act applies the laws of the host state regarding community reinvestment, consumer protection, and fair lending to branches of an out-of-state national bank located in the host state only to the extent those laws are not otherwise preempted by Federal law.

Many of the comments concerned potential harm to consumers. Commenters opposed to preemption recite a host of abusive and predatory lending practices perpetrated against vulnerable borrowers, including minorities, the elderly, and the poor. These commenters believe such practices demonstrate the necessity of state predatory lending laws such as the GFLA. Commenters supportive of preemption argue that Federal law already prohibits these types of practices and that multiple, and often conflicting, state and local predatory lending laws will raise the cost of consumer credit, limit access to credit for borrowers with impaired credit histories, and restrict banks' ability to develop and implement new products or product features and customize services to meet consumers' needs.

The OCC shares the view of the commenters that predatory and abusive lending practices are inconsistent with national objectives of encouraging home ownership and community revitalization, and can be devastating to individuals, families, and communities. This does not lead, however, to the conclusion suggested by some commenters that the OCC should have no objection to state predatory lending laws being made applicable to national banks.

First, laws such as the GFLA apply to loans with rates of interest and other features typical of risk-based pricing of subprime loans. These laws generally prohibit certain mortgage loan terms and impose extra compliance obligations when other loan terms and conditions are present. These laws introduce new standards for subprime lending that are untested, sometimes vague, often complex, and, in many cases, different from established and well-understood Federal requirements. They also create new potential liabilities and penalties for any lender that missteps in its efforts to comply with those new standards and restrictions. Thus, these laws materially increase a bank's costs and compliance risks in connection with subprime lending. Given the already generally higher credit risk of lending to subprime borrowers, bank lenders will conclude—

²³ *Barnett*, 517 U.S. at 32.

²⁴ Pub. L. 103-328, 108 Stat. 2338 (1994).

²⁵ See *Bank of America v. City & County of San Francisco*, 309 F.3d 551, 559 (9th Cir. 2002); see

also *American Bankers Ass'n. v. Lockyer*, 239 F. Supp. 2d 1000, 1016 (E.D. Cal., 2002); *United States v. Locke*, 529 U.S. 89, 108 (2000).

²² See *infra* notes 40-45 and accompanying text.

and have concluded—that they simply are unable to effectively cover these increased costs and risks. Accordingly, they reduce their product offerings to avoid subprime mortgage lending, in order to concentrate on making loans for which they can receive acceptable compensation for the risks they undertake. The practical result of these laws, therefore, is to obstruct, or for practical purposes, prevent, national banks from making certain types of real estate loans, causing an overall reduction in credit available to subprime borrowers. This means that non-predatory, risk-priced credit will become more limited, or unavailable, to creditworthy subprime borrowers.²⁶

²⁶ For a more detailed discussion of the reasons why anti-predatory lending laws may impede the flow of legitimate credit to homebuyers and for other economic analysis relevant to evaluating state anti-predatory lending laws, see Office of the Comptroller of the Currency, Global Banking and Financial Analysis Department, "OCC Working Paper: Economic Issues in Predatory Lending" (July 30, 2003) (OCC Paper).

As noted in the OCC Paper, a growing body of evidence indicates that state anti-predatory lending laws are likely to restrict the availability of credit to subprime borrowers. For example, studies of subprime lending activity in North Carolina before and after enactment of that state's anti-predatory lending law have shown a post-enactment decline in subprime mortgage originations of about 15%. See Keith Harvey & Peter Nigro, "Do Predatory Lending Laws Influence Mortgage Lending? An Analysis of the North Carolina Predatory Lending Law," Paper Presented at the Credit Research Conference on Subprime Lending, September 2002 (publication forthcoming in 2003 in a conference volume of the *Journal of Real Estate Research*); Gregory Elliehausen & Michael Staten, "Regulation of Subprime Mortgage Products: An Analysis of North Carolina's Predatory Lending Law," Credit Research Center Working Paper #66, November 2002.

Other studies also have documented that an unfortunate and unintended consequence of legislation similar to the GFLA adopted in other jurisdictions has been the overall reduction in subprime loans being originated. See Robert E. Litan, "Unintended Consequences: The Risks of Premature State Regulation of Predatory Lending," available at <http://www.aba.com/NR/rdonlyres/000070c7qvaumpwesqzozjnk/PredReport20095.pdf>, and studies discussed therein. One study also documented that the impact of this reduction was greater for minority and low-income applicants. See Keith Harvey & Peter Nigro, "How Do Predatory Lending Laws Influence Mortgage Lending in Urban Areas? A Tale of Two Cities," 26 *J. Real Est. Res.* No. 2 (forthcoming in 2003).

Some proponents of state anti-predatory lending laws have nonetheless argued that these laws inhibit predatory and abusive lending practices without reducing the availability of credit to subprime borrowers. A recently released study concludes that the North Carolina law worked, as intended, to reduce loans with predatory terms without a reduction in access to credit for high-risk borrowers. See Roberto G. Quercia, Michael A. Stegman, & Walter R. Davis, "The Impact of North Carolina's Anti-Predatory Lending Law: A Descriptive Assessment," Center for Community Capitalism, The Frank Hawkins Kenan Institute for Private Enterprise, University of North Carolina at Chapel Hill (June 25, 2003) (the Stegman Study), available at <http://www.kenan-flagler.unc.edu/>

Second, evidence that national banks are engaged in predatory lending practices is scant to non-existent. Based on the absence of such information—from third parties, our consumer complaint database, and our supervisory process—we have no reason to believe that national banks are engaged in such practices to any discernible degree. This observation is consistent with an extensive study of predatory lending conducted by HUD and the Treasury Department,²⁷ and with comments submitted in connection with an OTS rulemaking concerning preemption of state lending standards by 46 State Attorneys General.²⁸

More recently, a coalition of State Attorneys General repeated the same view in a brief filed earlier this year in connection with a challenge to that OTS rulemaking. The case involves a revised regulation issued by the OTS to implement the Alternative Mortgage Transaction Parity Act (AMTPA). The revised regulation seeks to distinguish between federally supervised thrift institutions and non-bank mortgage lenders and makes non-bank mortgage lenders subject to state law restrictions on prepayment penalties and late fees. In supporting the OTS's decision to distinguish between supervised depository institutions and unsupervised housing creditors and to

News/DetailsNewsPage.cfm?id=466&menu=ki. However, the data presented in this Study contain variables and uncertainties that may limit the Study's utility for evaluating the effects of state anti-predatory lending laws on the availability of credit to the full range of subprime borrowers. See OCC Paper.

²⁷ A Treasury-HUD joint report issued in 2000 found that predatory lending practices in the subprime market are less likely to occur in lending by—

Banks, thrifts, and credit unions that are subject to extensive oversight and regulation * * *. The subprime mortgage and finance companies that dominate mortgage lending in many low-income and minority communities, while subject to the same consumer protection laws, are not subject to as much federal oversight as their prime market counterparts—who are largely federally-supervised banks, thrifts, and credit unions. The absence of such accountability may create an environment where predatory practices flourish because they are unlikely to be detected.

Departments of Housing and Urban Development and the Treasury, "Curbing Predatory Home Mortgage Lending: A Joint Report" 17-18 (June 2000) (Treasury-HUD Joint Report), available at <http://www.treas.gov/press/releases/report3076.htm>.

In addition, the report found that a significant source of abusive lending practices is non-regulated mortgage brokers and similar intermediaries who, because they "do not actually take on the credit risk of making the loan, * * * may be less concerned about the loan's ultimate repayment, and more concerned with the fee income they earn from the transaction." *Id.* at 40.

²⁸ Cited in *Nat'l Home Equity Mortgage Ass'n v. OTS*, Civil Action No. 02-2506 (GK) (D.D.C. 2003) at 26.

retain preemption of state laws with respect to the former, but not for the latter, the State Attorneys General stated:

Based on consumer complaints received, as well as investigations and enforcement actions undertaken by the Attorneys General, predatory lending abuses are largely confined to the subprime mortgage lending market and to non-depository institutions. Almost all of the leading subprime lenders are mortgage companies and finance companies, not banks or direct bank subsidiaries.²⁹

According to the State Attorneys General, "OTS looked to where the problems were and was well justified in addressing prepayment penalties and late fee regulation for state housing creditors only, not for supervised thrifts."³⁰ By not addressing supervised thrifts in its rule change, the OTS was retaining for those institutions preemption of state laws under its existing regulations. In practical effect, the State Attorneys General agreed that in matters of preemption, supervised depository institutions are distinguishable from other housing lenders, and did not take issue with OTS's preemption of state laws where the entity that benefits from the preemption is subject to substantial federal regulation and supervision, which effectively addresses the risk of abusive or predatory practices by those entities.

Against this background, the OCC's approach to predatory lending, embodied in the anti-predatory lending standards discussed above, implemented through the OCC's comprehensive supervision of national banks, minimizes the potential for harm from predatory or abusive lending without reducing the credit available to subprime borrowers. We recognize that certain loan terms and conditions are more likely to be used unfairly or abusively, but that does not mean that all risk-priced loans with those features are, necessarily, predatory. Thus, it is generally necessary to consider the totality of the circumstances to assess whether a loan is predatory and likely to lead to practices such as equity stripping. The OCC's supervisory approach, implemented by trained examiners reviewing on-site the lending practices of national banks, allows for this type of consideration.³¹ By focusing

²⁹ Brief for Amicus Curiae State Attorneys General, *Nat'l Home Equity Mortgage Ass'n*, Civil Action No. 02-2506 (GK) (D.D.C.) at 10-11 (emphasis added).

³⁰ *Id.* at 11.

³¹ Our supervisory track record also demonstrates that where we find abuse, or the potential for abuse, we will take strong action. See, e.g., *In the Matter*

on lending practices rather than banning specific lending products, this approach reduces the likelihood of predatory lending rather than the availability of credit to subprime borrowers.

Numerous commenters also raised issues concerning the scope of the Determination or Order requested by National City and the appropriate procedure for the OCC to follow in responding to the request. Many of the commenters supporting preemption urge that the determination or order apply to all national banks, not just National City, and to their operating subsidiaries. These commenters note that national banks have long used separately incorporated entities to engage in activities that the bank itself is authorized to conduct and that courts have consistently treated the operating subsidiary and the national bank as equivalents. Thus, these commenters argue that the preemption order or determination requested by National City should apply to operating subsidiaries consistent with the OCC's regulations set forth at 12 CFR 7.4006 providing that "[u]nless otherwise provided by Federal law or OCC regulation, State laws apply to national bank operating subsidiaries to the same extent that those laws apply to the parent national bank." Commenters in favor of preemption who assume that the preemption order or determination would apply only to National City's activities in Georgia urge the OCC to issue a rule in conjunction with the determination or order that would apply to all national banks and national bank operating subsidiaries and conclude that all state and local predatory lending laws are preempted.

A number of the commenters opposed to preemption argue that the OCC's response to National City's request should be narrowly tailored and not apply to operating subsidiaries. These commenters believe that the OCC has no legal authority to preempt state laws insofar as they apply to operating subsidiaries of national banks because operating subsidiaries are chartered under state law and must therefore comply with all applicable state laws. One commenter also argues that the OCC may not take the position that § 7.4006 preempts the GFLA with respect to operating subsidiaries

because the OCC did not comply with the Federalism requirements of Executive Order 13132 when it adopted the rule. This commenter also contends that if the OCC grants National City's request, it would create a "decisional rule" applicable to all national banks doing business in Georgia. As such, the commenter believes that Executive Order 13132 also would apply to this proceeding and the OCC should postpone any decision on National City's request until it satisfies its obligations under the Executive Order to consult with state officials.

We recognize that this preemption determination necessarily will affect the practices of lenders in Georgia in addition to National City. As discussed at length below, most of the GFLA provisions already are preempted by Federal law. Accordingly, those provisions are preempted for all national banks and their operating subsidiaries. For the remaining GFLA provisions preempted by operation of this determination and order, it would be incongruous for the law to preempt GFLA provisions for only one institution.³² Therefore, this order will apply to all national banks engaged in real estate lending activities in Georgia.

We also agree with the commenters who argued that, consistent with 12 CFR 7.4006, the GFLA is preempted for national bank operating subsidiaries to the same extent it is preempted for their parent banks.³³ Accordingly, this determination applies equally to national bank operating subsidiaries engaged in real estate lending activities in Georgia. This determination will not, however, affect lenders who are not otherwise subject to the GFLA. Therefore, we decline to adopt the suggestion of some commenters that this order apply to all national banks and national bank operating subsidiaries, regardless of whether they make real estate loans. Those lenders will, however, be subject to the results of the rulemaking commenced today, which proposes to apply the results of our analysis here by expanding the list of the types of state laws that are expressly preempted by Federal law concerning national banks' real estate lending powers.

These and other comments will be addressed in more detail in the following sections, which present an overview of the national banking laws and the Federal court precedents

³² This determination depends on an analysis of the GFLA and national bank authority and is therefore not fact-specific to National City.

³³ See *infra* note 110 and accompanying text for a detailed discussion of the commenter's arguments concerning the Federalism order.

concerning the applicability of state law to national banks, followed by an analysis of the extent to which provisions of the GFLA are preempted by Federal law.

II. Overview of Federal Preemption of State Laws With Respect to National Banks

In the earliest decades of this country's existence, the Supreme Court recognized that under the Supremacy Clause of the U.S. Constitution—paragraph 2 of Article VI—states "have no power, by taxation or otherwise, to retard, impede, burden, or in any other manner control, the operations" of an entity created by lawful exercise of Federal authority.³⁴ The entity involved in the landmark case in which these principles were articulated was the Second Bank of the United States. The history of the national banking laws and 140 years of Federal court precedents considering the applicability of state laws to national banks consistently reflect this principle and demonstrate that the exercise by a national bank of a Federally authorized power is ordinarily not subject to state law.

A. Legislative History of the Early National Banking Laws

Congress enacted the National Currency Act (Currency Act) in 1863 and modified it with the National Bank Act the year after for the purpose of establishing a new national banking system that would operate distinctly and separately from the existing system of state banks. The Currency Act and National Bank Act were enacted to create a uniform and secure national currency and a system of national banks designed to help stabilize and support the national economy both during and after the Civil War.

Both proponents and opponents of the new national banking system expected that it would supersede the existing system of state banks.³⁵ Given this

³⁴ *M'Cullach v. Maryland*, 17 U.S. (4 Wheat.) 316, 436 (1819).

³⁵ Representative Samuel Hooper, who reported the bill to the House, stated in support of the legislation that one of its purposes was "to render the law [i.e., the Currency Act] so perfect that the State banks may be induced to organize under it, in preference to continuing under their State charters." Cong. Globe, 38th Cong., 1st Sess. 1256 (Mar. 23, 1864). While Rep. Hooper did not believe that the legislation was necessarily harmful to the state bank system, he did "look upon the system of State banks as having outlived its usefulness." *Id.* Opponents of the legislation believed that it was intended to "take from the States * * * all authority whatsoever over their own State banks, and to vest that authority * * * in Washington." Cong. Globe, 38th Cong., 1st Sess. 1267 (Mar. 24, 1864) (statement of Rep. Brooks). Rep. Brooks made that statement to support the idea that the legislation was intended to transfer control over

af Provident Nat'l Bank, Tilton, New Hampshire, Consent Order No. 2000-53 (June 28, 2000) (requiring payment by the bank in excess of \$300 million and imposing numerous conditions on the conduct of future business), available at <http://www.occ.treas.gov/ftp/release/2000%2D49b.pdf>. This approach seems to be successful, as explained in the 2000 Treasury-HUD Joint Report, *supra* note 27.

anticipated impact on state banks and the resulting diminution of control by the states over banking in general,³⁶ proponents of the national banking system were concerned that states would attempt to undermine it. Remarks of Senator Sumner illustrate the sentiment of many legislators of the time: "Clearly, the [national] bank must not be subjected to any local government, State or municipal; it must be kept absolutely and exclusively under that Government from which it derives its functions."³⁷

The allocation of any supervisory responsibility for the new national banking system to the states would have been inconsistent with this need to protect national banks from state interference. Congress, accordingly, established a Federal supervisory regime and created a Federal agency within the Department of Treasury—the OCC—to carry it out. Congress granted the OCC the broad authority "to make a thorough examination of all the affairs of [a national bank],"³⁸ and solidified

banking from the states to the Federal government. Given the legislation's objective, its passage would, in Rep. Brooks' opinion, mean that there would be no state banks left over which the states would have authority. Thus, by observing that the legislation was intended to take authority over state banks from the states, Rep. Brooks was not suggesting that the Federal government would have authority over state banks; rather, he was explaining the bill in a context that assumed the demise of state banks. Rep. Pruyn opposed the bill stating that the legislation would "be the greatest blow yet inflicted upon the States." Cong. Globe, 38th Cong., 1st Sess. 1271 (Mar. 24, 1864). See also John Wilson Million, *The Debate on the National Bank Act of 1863*, 2 J. Pol. Econ. 251, 267 (1893-94) regarding the Currency Act ("Nothing can be more obvious from the debates than that the national system was to supersede the system of state banks.")

³⁶ See, e.g., *Tiffany v. Nat'l Bank of Missouri*, 85 U.S. 409, 412-413 (1874) ("It cannot be doubted, in view of the purpose of Congress in providing for the organization of National banking associations, that it was intended to give them a firm footing in the different States where they might be located. It was expected they would come into competition with State banks, and it was intended to give them at least equal advantages in such competition. * * * National banks have been National favorites. They were established for the purpose, in part, of providing a currency for the whole country, and in part to create a market for the loans of the General government. It could not have been intended, therefore, to expose them to the hazard of unfriendly legislation by the States, or to ruinous competition with State banks."). See also B. Hammond, *Banks and Politics in America from the Revolution to the Civil War 725-34* (1957); P. Studenski & H. Krooss, *Financial History of the United States 155* (1st ed. 1952).

³⁷ Cong. Globe, 38th Cong., 1st Sess., at 1893 (Apr. 27, 1864). See also *Beneficial Nat'l Bank*, 123 S.Ct. at 2064 ("[T]his Court has also recognized the special nature of federally chartered banks. Uniform rules limiting the liability of national banks and prescribing exclusive remedies for their overcharges are an integral part of a banking system that needed protection from possible unfriendly State legislation.") (citations omitted).

³⁸ Act of June 3, 1864, c. 106, § 54, 13 Stat. 116, codified at 12 U.S.C. 481.

this Federal supervisory authority by vesting the OCC with exclusive visitorial powers over national banks. These provisions assure, among other things, that the OCC will have comprehensive authority to examine all the affairs of a national bank and protect national banks from potential state hostility by establishing that the authority to examine, supervise, and regulate national banks is vested only in the OCC, unless otherwise provided by Federal law.³⁹

B. The Supremacy Clause and the Federal Preemption Standards Articulated by the Supreme Court

In certain circumstances, a state law may be preempted by Federal law and thus rendered invalid by reason of the Supremacy Clause of the Constitution.⁴⁰ The Supreme Court has identified three ways in which Congress can displace state law. First, Congress can adopt express language setting forth the existence and scope of preemption.⁴¹ Second, Congress can adopt a scheme of regulation that "occupies the field" and leaves no room for states to adopt supplemental laws.⁴² Third, Congress can adopt a statute that is in "irreconcilable conflict" with state law.⁴³ Irreconcilable conflict will be found when either: (i) Compliance with both laws is a "physical impossibility";⁴⁴ or (as noted by *National City* in its request) (ii) when the state law stands "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."⁴⁵

As noted above, many commenters pointed to the consumer protective nature of the GFLA in support of their position that preemption of the statute

³⁹ Writing shortly after the Currency Act and National Bank Act were enacted, then-Secretary of the Treasury, and formerly the first Comptroller of the Currency, Hugh McCulloch observed that "Congress has assumed entire control of the currency of the country, and, to a very considerable extent, of its banking interests, prohibiting the interference of State governments." Cong. Globe, 39th Cong., 1st Sess., Misc. Doc. No. 100, at 2 (Apr. 23, 1866).

⁴⁰ "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof * * * shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, cl. 2.

⁴¹ See *Jones v. Roth Pucking Co.*, 430 U.S. 519, 525 (1977).

⁴² See *Rice v. Sonto Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

⁴³ *Rice v. Norman Willioms Co.*, 458 U.S. 654, 659 (1982).

⁴⁴ *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

⁴⁵ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *Barnett*, 517 U.S. at 31 (quoting *Hines*).

would be inappropriate. Because the origins of Federal preemption are Constitutional, however, the underlying purpose of the state legislation, *albeit* salutary, is not relevant to determining whether the law applies. As explained in *Association of Banks in Insurance, Inc. v. Duryee*,⁴⁶ "[w]here state and federal laws are inconsistent, the state law is pre-empted even if it was enacted by the state to protect its citizens or consumers."⁴⁷

C. Supreme Court Precedents Leading to Barnett

From the earliest years of the national banking system, up to and including a decision rendered only months ago, the Supreme Court has consistently recognized the unique status of the national banking system and the limits placed on states by the National Bank Act.⁴⁸ The Supreme Court stated in one of the first cases to address the role of the national banking system that "[t]he national banks organized under the [National Bank Act] are instruments designed to be used to aid the government in the administration of an important branch of the public service. They are means appropriate to that end."⁴⁹ Subsequent opinions of the Supreme Court have been equally clear about national banks' unique role and status.⁵⁰

The Supreme Court also has recognized the clear intent on the part of Congress to limit the authority of

⁴⁶ 55 F. Supp. 2d 799 (S.D. Ohio 1999).

⁴⁷ *Id.* at 802. Agreeing with this conclusion, the Sixth Circuit stated that "the fact that the state legislature enacted the [state law at issue] to protect general insurance agents and consumers does not, for that reason alone, preclude federal preemption." *Ass'n of Banks in Ins., Inc. v. Duryee*, 270 F.3d 397, 408 (6th Cir. 2001); see also *Franklin Nat'l Bank of Franklin Square v. New York*, 347 U.S. 373, 378 (1954).

⁴⁸ See *Beneficial Nat'l Bank*, 123 S.Ct. at 2064.

⁴⁹ *Farners' & Mechanics' Nat'l Bank v. Deoring*, 91 U.S. 29, 33 (1875).

⁵⁰ See *Morquette Nat'l Bank v. First of Ohio Service Corp.*, 439 U.S. 299, 314-315 (1978) ("Close examination of the National Bank Act of 1864, its legislative history, and its historical context makes clear that * * * Congress intended to facilitate * * * a national banking system.") (citation omitted); *Franklin Nat'l Bank*, 347 U.S. at 375 (1954) ("The United States has set up a system of national banks as federal instrumentalities to perform various functions such as providing circulating medium and government credit, as well as financing commerce and acting as private depositories."); *Dovis v. Elmira Sov. Bank*, 161 U.S. 275, 283 (1896) ("National banks are instrumentalities of the federal government, created for a public purpose, and as such necessarily subject to the paramount authority of the United States."); *Guthrie v. Horkness*, 199 U.S. 148, 159 (1905) ("It was the intention that this statute should contain a full code of provisions upon the subject, and that no state law or enactment should undertake to exercise the right of visitation over a national corporation.")

states over national banks precisely so that the nationwide system of banking that was created in the Currency Act could develop and flourish. For instance, in *Easton v. Iowa*,⁵¹ the Court stated that Federal legislation affecting national banks—

Has in view the erection of a system extending throughout the country, and independent, so far as powers conferred are concerned, of state legislation which, if permitted to be applicable, might impose limitations and restrictions as various and as numerous as the States * * *. It thus appears that Congress has provided a symmetrical and complete scheme for the banks to be organized under the provisions of the statute * * *. [W]e are unable to perceive that Congress intended to leave the field open for the States to attempt to promote the welfare and stability of national banks by direct legislation. If they had such power it would have to be exercised and limited by their own discretion, and confusion would necessarily result from control possessed and exercised by two independent authorities.⁵² The Court in *Farmers' & Mechanics' Bank*, after observing that national banks are means to aid the government, stated—

Being such means, brought into existence for this purpose, and intended to be so employed, the States can exercise no control over them, nor in any wise affect their operation, except in so far as Congress may see proper to permit. Any thing beyond this is "an abuse, because it is the usurpation of power which a single State cannot give."⁵³

Thus, as recognized by the Supreme Court in *Barnett*, the history of national bank powers is one of "interpreting grants of both enumerated and incidental "powers" to national banks as grants of authority not normally limited by, but rather ordinarily preempting, contrary state law."⁵⁴ "[W]here Congress has not expressly conditioned the grant of "power" upon a grant of state permission, the Court

has ordinarily found that no such condition applies."⁵⁵

D. Recent Lower Federal Court Decisions Concluding that State Laws Are Preempted

This principle has been recognized and applied in a series of recent cases invalidating state and local restrictions upon national bank practices authorized under Federal law. In each case, the court determined that the state or local restriction obstructed, in whole or in part, the exercise of an authorized national bank power and therefore was preempted by operation of the Supremacy Clause.

For example, ordinances passed by four municipalities in California and New Jersey specifically to prohibit ATM access fees were promptly enjoined by district court order on grounds that included National Bank Act preemption. In California, the district court entered a preliminary injunction against the fee prohibition ordinances adopted by San Francisco and Santa Monica, and the Ninth Circuit affirmed. On remand, the district court entered a permanent injunction against the ordinances, and the Ninth Circuit once again affirmed.⁵⁶ Similarly, a Federal district court in New Jersey entered temporary restraining orders preventing fee prohibition ordinances adopted by Newark and Woodbridge from becoming effective. The combined case was ultimately settled by each city's consent to a permanent injunction against its ordinance.⁵⁷ A Federal district court in Des Moines declared a longstanding Iowa prohibition on ATM access fees to be in conflict with the national bank power to charge fees and therefore preempted.⁵⁸ For similar reasons, the Fifth Circuit upheld a Federal district court ruling that Federal law displaced a Texas statute that prohibited the charging of fees for cashing checks drawn upon accounts at the payor bank.⁵⁹ A Federal district court in Georgia reached the same conclusion with respect to a Georgia law that similarly attempted to restrict the authority of national banks under Federal law to charge such fees.⁶⁰

Restrictions on national bank activities other than the charging of fees have also been held preempted. Deferring to the OCC's interpretations of the National Bank Act, the Eighth Circuit held that Federal law preempted Iowa restrictions on ATM location, operation, and advertising as applied to national banks.⁶¹ More recently, a Federal district court in California permanently enjoined the California Attorney General and Director of the Department of Consumer Affairs from enforcing a California statute requiring that certain language and information be placed on the billing statements credit card issuers provide their cardholders.⁶² In so doing, the court held that there is "no indication in the NBA that Congress intended to subject that power [to loan money on personal security] to local restriction."⁶³ Thus, the court applied "the ordinary rule . . . of preemption of contrary state law."⁶⁴ Contrary state law may be preempted by Federal regulation. "Federal regulations have no less pre-emptive effect than federal statutes."⁶⁵

E. The Limited Circumstances Under Which State Laws Apply to National Banks

State laws apply to national banks' activities under circumstances that have been described variously by the courts as not altering or conditioning a national bank's ability to exercise a power that Federal law grants to it.⁶⁶ "Thus, states retain some power to regulate national banks in areas such as contracts, debt collection, acquisition and transfer of property, and taxation, zoning, criminal, and tort law."⁶⁷ Notably, these types of laws do not actually regulate the manner and content of the business of banking authorized for national banks under Federal law, but rather establish the legal infrastructure that surrounds and supports the conduct of that business. They promote a national bank's ability to conduct business; they do not

⁵¹ See *Bank One, Utah, v. Guttou*, 190 F.3d 844 (8th Cir. 1999), cert. denied sub nom *Foster v. Bank One, Utah*, 529 U.S. 1087 (2000).

⁵² See *Lockyer*, 239 F. Supp. 2d 1000.

⁵³ *Id.* at 1016; see also *Wells Fargo Bank, N.A. v. Boutris*, 252 F. Supp. 2d 1065, 1069 (E.D. Cal. 2003) ("The National Bank Act was enacted to "facilitate * * * a national banking system," and "to protect national banks against intrusive regulation by the States.") (citations omitted).

⁵⁴ *Lockyer*, 239 F. Supp. 2d at 1016.

⁵⁵ *Fjd. Fed. Sov. & Loan Ass'n. v. de lo Cuesto*, 458 U.S. 141, 153 (1982).

⁵⁶ See *Bornett*, 517 U.S. at 33.

⁵⁷ *Bank of America*, 309 F.3d at 559. Notably, "[c]onsumer protection is not reflected in the case law as an area in which the states have traditionally been permitted to regulate national banks." *Lockyer*, 239 F. Supp. 2d at 1016.

⁵⁸ *Bornett*, 517 U.S. at 34.

⁵⁹ See *Bank of America, N.A. v. City & County of San Francisco*, 2000 WL 33376673 (N.D. Cal. June 30, 2000), *off'd.*, *Bank of America*, 309 F.3d 551.

⁶⁰ See *New Jersey Bankers Ass'n v. Township of Woodbridge*, No. CV-00-702 (JAG) (D.N.J.), Nov. 8, 2000.

⁶¹ See *Metrobank v. Foster*, 193 F. Supp. 2d 1156 (S.D. Iowa 2002).

⁶² See *Wells Fargo Bank of Texas, N.A. v. Jones*, 321 F.3d 488 (5th Cir. 2003).

⁶³ See *Bank of America, N.A. v. Sorrell*, 248 F. Supp. 2d 1196 (N.D. Ga. 2002).

⁵¹ 188 U.S. 220 (1903).

⁵² *Id.* at 229, 231-232 (emphasis added).

⁵³ *Formers' & Mechanics' Bank*, 91 U.S. at 34 (citation omitted).

⁵⁴ *Barnett*, 517 U.S. at 32. The Supreme Court has recognized that the "business of banking" is not limited to the powers enumerated in section 24(Seventh), *NationsBank v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 258 n.2 (1995). As the scope of the underlying national bank power may evolve, the OCC "may authorize additional activities if encompassed by a reasonable interpretation of § 24(Seventh)." *Indep. Ins. Agents of America, Inc. v. Howke*, 211 F.3d 638, 640 (D.C. Cir. 2000). Thus, the effect of a state law on the exercise of a Federal power may change as the character of the power changes.

obstruct a national bank's exercise of powers granted under Federal law.⁶⁸

This does not mean, as asserted by some commenters, that state laws presumptively apply to national banks. These commenters suggest that all preemption analysis begins with the presumption against preemption. As explained recently by the Court, however, this presumption is "not triggered when the States regulate in an area where there has been a history of significant federal presence."⁶⁹ As further explained by the Ninth Circuit in *Bank of America*, "because there has been a 'history of significant federal presence' in national banking, the presumption against preemption of state law is inapplicable."⁷⁰

Nor, contrary to these commenters' assertions, did Congress specifically endorse the presumptive application of state laws in the Riegle-Neal Act. Although the Riegle-Neal Act, at 12 U.S.C. 36(f)(1)(A), initially makes applicable the laws of the host state regarding community reinvestment, consumer protection, and fair lending to branches of an out-of-state national bank located in the host state, the statute expressly excepts any state laws that are preempted under Federal law. In a few situations, Federal law has incorporated provisions of state law for specific purposes.⁷¹ Congress may more generally establish standards that govern when state law will apply to national banks' activities.⁷² In such cases, the OCC applies the law or the standards that Congress has required or established.

III. Discussion and Analysis

The GFLA affects a national bank's ability to engage in real estate lending, the rate of interest a national bank may charge for a loan, and a national bank's ability to charge non-interest fees. Our discussion analyzes the provisions of the GFLA according to these categories. Following that analysis, we discuss the extent to which Federal law preempts the remaining provisions. We first review the provisions of the GFLA as they apply to a national bank, then

apply those conclusions to the bank's operating subsidiaries.

A. The GFLA Conflicts With the Federal Grant of Power to a National Bank to Engage in Real Estate Lending Activities

In *Barnett*, the Supreme Court analyzed a statute, 12 U.S.C. 92, similar in structure to section 371, to determine the extent to which section 92 leaves room for state regulation of the activities the statute authorizes. There, the Supreme Court stated that:

[section 92's] language suggests a broad, not a limited, permission. That language says, without relevant qualification, that national banks "may * * * act as the agent" for insurance sales. 12 U.S.C. 92. It specifically refers to "rules and regulations" that will govern such sales, while citing as their source not state law, but the federal Comptroller of the Currency.⁷³

The Court concluded that "where Congress has not expressly conditioned the grant of 'power' upon a grant of state permission, the Court has ordinarily found that no such condition applies."⁷⁴

Section 371 authorizes national banks to engage in real estate lending "subject to section 1828(o) of this title and such restrictions and requirements as the Comptroller of the Currency may prescribe by regulation or order." This express language specifically addresses the sources of restrictions on national banks' real estate lending activities and, by its terms, does not envision that the exercise of those powers, granted by section 371, would be subject to compliance with any state requirement.⁷⁵

The legislative history of section 371 lends further support to this

construction. National banks' real estate lending activities have consistently been subject to comprehensive Federal regulation ever since the authority to lend on the security of real estate was first granted to them in the Federal Reserve Act of 1913. For many years, national banks' real estate lending authority was governed by the express terms of section 371. As originally enacted in 1913, section 371 contained a limited grant of authority to national banks to lend on the security of "improved and unencumbered farm land, situated within its Federal reserve district."⁷⁶ In addition to the geographic limits inherent in this authorization, the Federal Reserve Act also imposed limits on the term and amount of each loan as well as an aggregate lending limit. Over the years, section 371 was repeatedly amended to broaden the types of real estate loans national banks were permitted to make, to expand geographic limits, and to modify loan term limits and per-loan and aggregate lending limits.

In 1982, Congress removed these "rigid statutory limitations"⁷⁷ in favor of a broad provision authorizing national banks to "make, arrange, purchase or sell loans or extensions of credit secured by liens on interests in real estate, subject to such terms, conditions, and limitations as may be prescribed by the Comptroller of the Currency by order, rule, or regulation."⁷⁸ The purpose of the 1982 amendment was "to provide national banks with the ability to engage in more creative and flexible financing, and to become stronger participants in the home financing market."⁷⁹ In 1991, Congress removed the term "rule" from this phrase and enacted an additional requirement, codified at 12 U.S.C. 1828(o), that national banks (and other insured depository institutions) conduct real estate lending pursuant to uniform standards adopted at the Federal level by regulations of the OCC and the other Federal banking agencies.⁸⁰ The two versions of section 371—namely, the lengthy and prescriptive approach prior to 1982 and the more recent statement of broad authority qualified only by reference to Federal law—may be seen

⁷³ *Barnett*, 517 U.S. at 32.

⁷⁴ *Id.* at 34.

⁷⁵ One commenter argued that this construction of national banks' real estate lending authority is refuted by the 1896 case of *McClellan v. Chipman*, 164 U.S. 347 (1896). In that case, a national bank unsuccessfully asserted that the statute then applicable to national banks' real estate lending activities left no room for the application of a state insolvency law. The state insolvency law at issue in *McClellan* is easily distinguished from the GFLA, however. The Supreme Court recognized two propositions in *McClellan*. First, "general state laws upon the dealings and contracts of national banks" apply to the banks' operations. *Id.* at 357. Second, there is an exception to this general rule for state laws that "expressly conflict with the laws of the United States, or frustrate the purpose for which the national banks were created, or impair their efficiency to discharge the duties imposed upon them by the law of the United States." *Id.* The Supreme Court held that the state insolvency law at issue in *McClellan* was the type of law governed by the first proposition. The GFLA is not a general state contract law that only incidentally impacts national banks' real estate lending activities, however. Because the GFLA directly regulates the real estate lending of national banks, it is inapplicable to national banks pursuant to the second proposition recognized in *McClellan*.

⁶⁸ See *Barnett*, 517 U.S. at 15, 33–34, and cases cited therein.

⁶⁹ *United States v. Locke*, 529 U.S. at 108.

⁷⁰ 309 F.3d at 559.

⁷¹ See, e.g., 12 U.S.C. 92a(a) (the extent of a national bank's fiduciary powers is determined by reference to the law of the state where the national bank is located).

⁷² See, e.g., 15 U.S.C. 6701 (codification of section 104 of the GLBA, Pub. L. 106–102, 113 Stat. 1338, 1352 (1999), which establishes standards for determining the applicability of state law to different types of activities conducted by national banks, other insured depository institutions, and their affiliates).

⁷⁶ Federal Reserve Act, ch. 6, § 24, 38 Stat. 251, 273 (1913).

⁷⁷ S. Rep. No. 97–536, at 27 (1982).

⁷⁸ Carn-St Germain Depository Institutions Act of 1982, Pub. L. 97–320, section 403, 96 Stat. 1469, 1510–11 (1982).

⁷⁹ S. Rep. No. 97–536, at 27 (1982).

⁸⁰ See section 304 of the Federal Deposit Insurance Corporation Improvement Act, codified at 12 U.S.C. 1828(o). These standards governing national banks' real estate lending are set forth in Subpart D of part 34.

as evolving articulations of the same idea.

In no respect does the statute express or imply that the power granted is limited, to some variable degree, by application of fifty different state laws. Part 34 of our rules, which was issued pursuant to the OCC's authority under section 371, already identifies certain types of state laws that do not apply to national banks. Section 34.4(a) expressly preempts state laws concerning five areas of fixed-rate mortgage lending. Section 34.4(b) provides that, when considering whether to preempt state laws in other areas of mortgage lending, the OCC will apply recognized principles of Federal preemption.

We analyze first the provisions of the GFLA that are preempted under § 34.4(a). Two of the five types of state laws expressly preempted by § 34.4(a)—state laws concerning the schedule for the repayment of principal and interest (§ 34.4(a)(2)) and the term to maturity of the loan (§ 34.4(a)(3))—are relevant here. Following our analysis of the GFLA provisions preempted by §§ 34.4(a)(2) and (3), we analyze GFLA provisions preempted under recognized principles of Federal preemption as provided by § 34.4(b).⁸¹

1. Provisions of GFLA Preempted by § 34.4(a)(2) (State Laws Concerning the Schedule for Repayment of Principal and Interest)

Section 34.4(a)(2) preempts state laws "concerning * * * [t]he schedule for the repayment of principal and interest." The inherent and inseparable elements of any repayment schedule are: (1) The timing of the expected payments; and (2) the amount of the expected payments. The following six provisions of the GFLA concern one or both of these elements and are therefore preempted pursuant to § 34.4(a)(2):

- *Balloon payments.* Under the GFLA, no scheduled payment on a high-cost home loan may be more than twice as much as the average of earlier scheduled payments, except where payment schedules are adjusted to the seasonal or irregular income of a borrower. A limitation on the ability to offer balloon loans limits the ability of the lender and the borrower to agree on a repayment schedule that would permit lower principal payments initially.

- *Negative amortization.* The GFLA prohibits a high-cost home loan from

including payment terms under which the principal balance increases because regular periodic payments fail to pay interest due. A prohibition on negative amortization limits the ability of the lender and borrower to agree on terms for the repayment and schedule of payment of principal and interest.⁸²

- *Advance payments.* The GFLA provides that a high-cost home loan contract may not include a payment schedule that consolidates more than two periodic payments and pays them in advance from loan proceeds. This provision is an express limitation on a lender's and borrower's ability to agree to a schedule for the repayment of principal and interest.

- *Late fees.* Under the GFLA, a creditor or servicer may not assess a late payment fee on a home loan unless the loan document specifically authorizes the fee, the payment is at least ten days late, and the fee does not exceed 5% of the amount of the late payment. Late fees may be imposed only once for each late payment. If a late fee is deducted from a payment and causes a default on a subsequent payment, no late fee may be imposed for such default. A lender may apply any payment made in order of maturity to a prior period's payment due even if it results in late payment charges accruing on subsequent payments due. Late fees are considered "interest" under the OCC's regulations at 12 CFR 7.4001(a).⁸³ The GFLA limitation on this form of interest is an impermissible state law concerning the schedule for repayment of interest and principal under § 34.4(a)(2). A limitation on late fees limits the ability of a lender and a borrower to agree to terms allowing for the imposition of increased interest charges if the borrower fails to adhere to the agreed-upon repayment schedule.

- *Prepayment fees.* Prepayment fees on a high-cost home loan under the GFLA are limited to 2% of the amount prepaid in first year of loan; 1% of the amount prepaid in second year of loan; and zero thereafter. Like late fees, prepayment fees, when imposed in connection with non-ARM loans, are considered "interest."⁸⁴ A limitation on

⁸² In other contexts, however, failure to disclose the existence of a negative amortization feature may be an unfair or deceptive practice. See, e.g., OCC, "Interagency Account Management and Loss Allowance Guidance" (Jan. 8, 2003), available at <http://www.OCC.Treas.Gov./ftp/bulletin/2003-1a.pdf>.

⁸³ For this reason, the GFLA limits on late fees are also analyzed below under 12 U.S.C. 85, and are preempted under that provision for national banks not located in Georgia that make loans secured by property located in Georgia.

⁸⁴ See OCC Interpretive Letter No. 803 (Oct. 7, 1997). For this reason, the GFLA limits on

prepayment fees limits the ability of a lender and a borrower to agree to terms allowing for alteration of the timing and amount of expected payments.

- *Default rates of interest.* The GFLA prohibits increasing the interest rate charged after default on a high-cost home loan unless the rate is changed due to a variable-rate feature in the loan. This provision limits the ability of a borrower and lender to agree to loan terms permitting the imposition of increased interest charges if the borrower fails to adhere to the agreed-upon repayment schedule.

Each provision of the GFLA summarized above concerns the schedule for repayment of principle and interest. Accordingly, each is preempted by § 34.4(a)(2).

2. Provisions of GFLA Preempted by § 34.4(a)(3) (State Laws Concerning Term to Maturity)

The following three provisions of the GFLA concern the term to maturity of a real estate loan and, as such, are preempted by § 34.4(a)(3):

- *Prepayment fees limited.* As described above, the GFLA limits prepayment fees on a high-cost loan to 2% of the amount prepaid in first year of loan; 1% of the amount prepaid in second year of loan; and zero thereafter. In addition to establishing impermissible restrictions on a national bank's authority to establish the schedule for repayment of interest and principal under § 34.4(a)(2), this provision also frustrates the ability of a national bank to structure the maturity of loans it originates by prohibiting the use of incentives designed to achieve the desired maturities.

- *Acceleration in absence of default prohibited.* Under the GFLA, a high-cost loan agreement may not contain a provision that permits a creditor or servicer, in its sole discretion, to accelerate the indebtedness unless there is a *bona fide* default by borrower. A limitation on the ability to accelerate the indebtedness in situations where there is no default but the borrower's creditworthiness may have significantly deteriorated limits the ability of a lender and a borrower to agree to terms that would alter the term to maturity of a loan.

- *Right to "cure" a default.* If a high-cost home loan is accelerated, the GFLA gives the borrower the right to "cure" the default at any point up to foreclosure. Cure of default reinstates

prepayment fees are also analyzed below under 12 U.S.C. 85 and, like limits on late fees, are preempted under that provision for national banks not located in Georgia that make loans secured by property located in Georgia.

⁸¹ Although National City's request does not raise issues under Federal law governing adjustable rate mortgage lending, we note that Subpart B of part 34 states as a general rule that national banks may engage in ARM lending without regard to any state law limitation. See 12 CFR 34.21(a).

the borrower to the same position as if the default had not occurred and nullifies the acceleration. This provision thus requires the original term of the loan to be reinstated upon curing a default, notwithstanding the possibility that prudent underwriting would suggest a modification of terms (including maturity).

3. GFLA Provisions Preempted Under Recognized Principles of Preemption as Provided by § 34.4(b)

Section 34.4(a) is not a comprehensive list of all of the types of state real estate lending laws that are inapplicable to national banks. Section 34.4(b) acknowledges that the OCC evaluates additional types of state laws on a case-by-case basis. It says:

The OCC will apply recognized principles of Federal preemption in considering whether State laws apply to other aspects of real estate lending by national banks.⁸⁵

The "recognized principles of Federal preemption" derive from the substantial body of Federal precedent considering the applicability of state law to the exercise of national bank powers. Courts and the OCC have consistently held that states may not condition the exercise of permissible Federal powers upon the approval of the states.⁸⁶

Consistent with these precedents, we conclude that the following provisions

of the GFLA are preempted. Even though based on laudable motives, they impermissibly seek to impose requirements that a national bank would have to satisfy before being permitted to exercise powers authorized under Federal law.

- *Restriction on financing of credit insurance and debt suspension and debt cancellation fees.* A creditor of a home loan may not finance credit insurance premiums, debt suspension fees, debt cancellation fees,⁸⁷ or certain other premiums. Premiums or fees paid for certain types of insurance on a monthly basis are permitted.⁸⁸

- *Restriction on refinancings.* Creditors may not knowingly or intentionally refinance a home loan in a transaction defined under the GFLA as "flipping." "Flipping" occurs when (a) a creditor makes a high-cost home loan to a borrower that refinances an existing home loan that was consummated within the prior five years, and (b) the new loan does not provide a reasonable and tangible net benefit to the borrower considering all of the circumstances. "Flipping" will be presumed to have occurred if the loan refinances a home loan that was: (a) Consummated within the past five years; (b) a special mortgage originated, subsidized, or guaranteed by a state, tribal, or local government or nonprofit organization; and (c) originated at a below-market interest rate or with nonstandard terms beneficial to the borrower. The refinance of a loan originated or purchased by the Georgia Housing and Finance Agency (GHFA) will be presumed not to have been flipped.

- *Borrower counseling required.* A creditor may not make a high-cost home loan unless it receives a certificate from a counselor approved by HUD or the GFHA that the borrower has received counseling on the advisability of the loan transaction.

- *Underwriting standards limited.* A creditor may not make a high-cost home loan unless a reasonable creditor would believe at the time the loan is consummated that the borrower can make scheduled payments based on income, obligations, employment status, and other financial resources. There is a rebuttable presumption that a borrower can make scheduled payments if total debt service does not exceed 50% of gross monthly income.

- *Restrictions on home improvement loans.* A creditor or servicer may not pay a contractor under a home improvement contract from proceeds of a high-cost home loan unless (a) the lender or servicer receives an affidavit from the contractor that work has been completed, and (b) the loan proceeds are disbursed in an instrument payable either to the borrower alone, to the borrower and the contractor, or to a third-party escrow agent.

- *Notice requirements.* A creditor of a high-cost home loan must comply with the GFLA's notice requirements for originating and foreclosing high-cost home loans. Under these requirements, a creditor must provide a borrower certain notices in the documents that create a debt or pledge collateral and before initiating foreclosure proceedings.

We note, however, that although the foregoing provisions are inapplicable to national banks and their operating subsidiaries, the concerns underlying those provisions are addressed through the OCC's supervision of national banks and their subsidiaries. As mentioned above, the OCC recently issued Advisory Letters 2003-2 and 2003-3, which contain the most comprehensive supervisory standards ever published by any Federal financial regulatory agency to address predatory and abusive lending practices and detail steps for national banks to take to ensure that they do not engage in such practices. As explained in the Advisory Letters, if the OCC has evidence that a national bank has engaged in abusive lending practices, we will review those practices not only to determine whether they violate specific provisions of law such as HOEPA, the Fair Housing Act, or the Equal Credit Opportunity Act, but also to determine whether they involve unfair or deceptive practices that violate the FTC Act. Indeed, several practices that we identify as abusive in our Advisory Letters—such as equity stripping, loan flipping, and the refinancing of special subsidized mortgage loans that originally contained terms favorable to the borrower—generally can be found to be unfair practices that violate the FTC Act.

⁸⁵ 12 CFR 34.4(b). The OCC proposed to add this provision to part 34 in 1995. At that time, we explained that the purpose of § 34.4(b) was to "clarify that the list of areas [set forth currently in § 34.4(a)] where State law is preempted * * * is not exhaustive." 60 FR 35353, 35355 (July 7, 1995) (emphasis added.) The final rule adopted the proposed rule with only minor stylistic edits. See 61 FR 11294, 11296 (Mar. 20, 1996). This rulemaking superseded a 1983 revision to part 34, in which the OCC stated that we were clarifying a "limited scope of preemption" by preempting "at this time, only those state laws that govern in those areas" now encompassed in § 34.4(a). 48 FR 40698, 40700 (Sept. 9, 1983) (emphasis added.) Thus, the 1983 rulemaking left room for an expanded preemptive scope in the future and has been superseded by the present text of § 34.4.

⁸⁶ See, e.g., *Barnett*, 517 U.S. at 34-35; *Franklin Nat'l Bank*, 347 U.S. at 378; *Bank of America Nat'l Trust & Sav. Ass'n v. Lima*, 103 F. Supp. 916, 918, 920 (D. Mass. 1952) (exercise of national bank powers is not subject to state approval; states have no authority to require national banks to obtain a license to engage in an activity permitted to them by Federal law). See also Letter dated Mar. 7, 2000, from Julie L. Williams to Thomas P. Vartanian. 65 FR 15037 (Mar. 20, 2000) (Federal law would preempt state statute regulating the conduct of auctions if applied to a national bank's online auction program); OCC Interpretive Letter No. 866 (Oct. 8, 1999) (state law requirements that purport to preclude national banks from soliciting trust business from customers located in states other than where the bank's main office is located would be preempted); OCC Interpretive Letter No. 749 (Sept. 13, 1996) (state law requiring national banks to be licensed by the state to sell annuities would be preempted); OCC Interpretive Letter No. 644 (Mar. 24, 1994) (state registration and fee requirements imposed on mortgage lenders would be preempted).

⁸⁷ OCC regulations at 12 CFR part 37 already prohibit contract terms that require a lump sum, single payment for a debt cancellation contract or debt suspension agreement where the debt subject to the contract is a residential real estate loan. See 12 CFR 37.3(c)(2). Part 37 applies to debt cancellation contracts and debt suspension agreements entered into by national banks in connection with extensions of credit they make and provides that those contracts and agreements are not governed by state law. See *id.* § 37.1(c).

⁸⁸ When insurance is financed as part of a home loan, the GFLA restricts the options available to the lender and borrower concerning how the loan proceeds are to be applied. This has the effect of imposing a condition on real estate lending in violation of section 371. The applicability of state laws regarding credit insurance sales, solicitation, and cross-marketing is governed by section 104 of the GLBA. See 15 U.S.C. 6701. The National City request raises no issues pertaining to the preemption of such state laws.

Moreover, our enforcement record amply demonstrates the OCC's commitment to using the FTC Act to address consumer abuses that are not specifically prohibited by regulation.⁸⁹

Finally, the following provisions of the GFLA impermissibly impose restrictions on, and interfere with, the exercise of the Federal power of national banks to make real estate loans and accordingly are preempted:

- *Discouraging use of ADR prohibited.* "[A]ny provision of a high-cost loan that allows a party to require a borrower to assert any claim or defense in a forum that is less convenient, more costly, or more dilatory for the resolution of a dispute than a judicial forum established in this state where the borrower may otherwise properly bring the claim or defense or limits in any way any claim or defense the borrower may have is unconscionable and void."

- *No encouraging borrower to default.* In connection with a home loan or high-cost home loan, "[n]o creditor or servicer shall recommend or encourage default on an existing loan or other debt prior to and in connection with the closing or planned closing of a home loan that refinances all or any portion of such existing loan or debt."

- *Assignee liability.* A purchaser of a high-cost home loan is subject to all claims and defenses that the borrower could assert against the lender, unless the purchaser shows that it exercised reasonable due diligence to prevent the purchase of a high-cost home loan.

- *Assignment of contractor liability.* Under the GFLA, where a home loan was "made, arranged, or assigned by a person selling home improvements to the dwelling of a borrower, the borrower may assert against the creditor all affirmative claims and defenses that the borrower may have against the seller or home improvement contractor." This provision applies to high-cost home loans and home loans where applicable law requires a certificate of occupancy, inspection, or completion to be obtained and the certificate was not obtained.

Each of these provisions adds a special restriction to the making of real estate loans in Georgia. Unlike state laws that provide the legal infrastructure needed for real property conveyances generally, the GFLA provisions single out a subset of real estate transactions authorized by section 371 and our part 34 for additional regulation. They

introduce new standards for a category of subprime loans that are untested, vague, and different from well-understood Federal requirements. They also create new potential liabilities and penalties for any lender that missteps in its efforts to comply with the new standards and restrictions. Thus, they materially increase a bank's costs and compliance risks in connection with an entire category of subprime lending. Given the already generally higher credit risk of lending to subprime borrowers, bank lenders are simply unable to effectively cover these increased costs and risks.

For example, the standards of the alternative dispute provision—"less convenient, more costly, or more dilatory"—are vague and not susceptible of certainty before an action is filed. Similarly, while a lender may not intend to "recommend or encourage" conduct that would fit within the GFLA prohibition on encouraging a borrower to default, an argument by a borrower that the lender did so may be difficult to disprove, given the imprecise nature of those words. Moreover, the assignment of contractor liability provision requires the impossible—namely, that a creditor ascertain and manage all potential legal risks generated by third party contractors notwithstanding that the contractors act independently and beyond the lender's control. Where a bank cannot ascertain precisely what is necessary to comply with a statute, on pain of potential civil liability imposed on both the bank and assignees of loans originated by the bank, that uncertainty in itself imposes costs weighing upon national banks' ability to conduct real estate lending operations in Georgia.⁹⁰

These costs and uncertainties have been amply publicized in the months since the GFLA was enacted, particularly in connection with the assignee liability provision. As mentioned above, following the enactment of the original GFLA, Moody's Investors Service and Standard and Poor's took the unusual step of announcing that including GFLA-covered loans in securitizations was too risky, causing lenders to scale back loans in the state and leading issuers to remove Georgia loans from securitizations. The recent amendments

to the GFLA capped the originally unlimited liability imposed on assignees of GFLA loans, but did not entirely remove the threat of liability, which continues to create substantial uncertainty in the secondary market. For example, Standard and Poor's has announced that it "may consider" rating transactions that include GFLA "high-cost" loans.⁹¹ Moody's Investors Service recently indicated that loans subject to predatory lending laws may be included in residential mortgage-backed securitizations only if seven conditions are satisfied.⁹² In addition, GFLA high-cost home loans remain ineligible for purchase by Freddie Mac and Fannie Mae.⁹³ Without a reliable secondary market for these loans, banks will be required to hold more of these loans to maturity. This, in turn, ties up more of a bank's resources, requiring it to hold capital against the full amount of these loans, and thus adversely affects the ability of the bank to originate or acquire other real estate loans. As such, the assignee liability provision of the GFLA, if the rest of the GFLA's provisions were applicable to national banks notwithstanding the conclusions reached in this Determination and Order, would stand as an obstacle to the exercise of national banks' real estate

⁹¹ For such transactions, the criteria will be stringent. Standard and Poor's will require lenders to identify which loans are "high-cost" and which of those loans are predatory, and prevent their transfer into the securitization. Natalie Abrams, Esq., "Evaluating Predatory Lending Laws: Standard & Poor's Explains its Approach" (Apr. 15, 2003), *ovoible* at <http://www.standordondpoores.com>. By putting the onus on the lender to identify which loans are predatory, many banks may simply decline to make any "high-cost" home loans to avoid exposure. Indeed, several studies have documented that an unfortunate and unintended consequence of legislation similar to the GFLA adopted in other jurisdictions has been the overall reduction in subprime loans being originated. See *supra* note 26 and studies discussed therein.

⁹² "Moody's Investors Service Special Report: Impact of Predatory Lending Laws on RMBS - Securitizations" (May 6, 2003). Among these seven conditions is that the "statute must be sufficiently clear so that the lender can effectively comply." *Id.* at 5. The Moody's Report does not specifically address the GFLA but gives as an example of insufficiently clear statutory language a provision, such as the GFLA provision on "flipping," that requires a lender to only make loans for which there is a "tangible net benefit" to the borrower. The Moody's Report notes that until such time that a regulation or court decision provides clear guidelines of what constitutes "tangible net benefit," "it may be impossible for a lender to demonstrate compliance." *Id.* at 3.

⁹³ See Fannie Mae Announcement 03-02, "Purchase of Georgia and New York 'High Cost Home Loans'" (Mar. 31, 2002); see also Freddie Mac Industry Letter, "Revisions to Freddie Mac's mortgage purchase requirements based on Section 6-L of the New York State Banking Law and amendments to the Georgia Fair Lending Act" (Mar. 31, 2003), *ovoible* at <http://www.freddiemac.com/sell/selbultn/0331indltr.html>.

⁸⁹ Since the Provident settlement in 2000, see *supra* note 31, the OCC has taken action under the FTC Act to address unfair or deceptive practices and consumer harm involving five other national banks. These orders can be found at <http://www.occ.treas.gov/foio/foiadocs.htm>.

⁹⁰ The OCC made a similar argument recently in connection with a California statute requiring creditors to provide minimum payments warnings on credit card billing statements. In granting a permanent injunction against enforcement of the state statute, a federal district court found "the OCC's interpretation of the preemptive effect of the NBA on [the state law] to be reasonable." *Lockyer*, 239 F. Supp. 2d at 1014.

lending powers, including the power to sell real estate loans into the secondary market or to securitize these loans.

Under *Franklin, Barnett*, and other Federal cases, a conflict between a state law and Federal law need not amount to a whole, or even partial, prohibition in order for the Federal law to have preemptive effect.⁹⁴ Where a Federal grant of authority is unrestricted, state law that attempts to obstruct the scope and effective exercise by a national bank of its express or incidental powers will be preempted.⁹⁵ Moreover, as noted in *Lockyer*, the degree of state interference or intrusion need not be notably high to warrant a conclusion that a state law is preempted.

B. The GFLA Provisions Limiting the Rate of Interest a National Bank Charges Are Inapplicable to National Banks Pursuant to 12 U.S.C. 85 and 12 CFR 7.4001

As we have described, under 12 U.S.C. 85, a national bank is authorized to charge interest according to the most favored lender rate permitted by the laws of the state in which the bank is located. OCC regulations at 12 CFR 7.4001 provide that a national bank located in a state may charge interest at the maximum rate permitted to any state-chartered or licensed lending institution by the law of that state. This "most favored lender" status permits a national bank to contract with borrowers in any state for interest at the maximum rate permitted by the law of the state in which the national bank is located. As discussed below, for a bank, such as National City, which is not located in Georgia for purposes of section 85 and 7.4001, this means that its permissible rates of interest are not tied to Georgia law, but instead are determined by reference to the most favored lender rates in the state where the bank is located. Applying this rule to National City, any limits on interest imposed by Georgia are preempted by section 85 and 7.4001. For a national bank that is located in Georgia for this purpose, the limits on rates set by the GFLA are simply inapplicable, for the reasons explained below.

Pursuant to the recent amendments to the GFLA and the OTS determination that the GFLA is preempted for Federal

thrifts, state-chartered savings associations are the most favored lenders in Georgia for purposes of national banks that apply Georgia rates of interest under section 85. As mentioned above, the recent amendments to the GFLA created preemption parity for state-chartered institutions if "federal law * * * preempts or has been determined to * * * preempt the application of the provisions of [the GFLA]" to their Federally-chartered counterparts. The OTS concluded that, because it occupied the field of regulation for lending activities of Federal savings associations, the GFLA provisions that purport to regulate the terms of credit, loan-related fees, disclosures, or the ability of a lender to originate or refinance a loan, do "not apply to Federal savings associations" home lending.⁹⁶ As a result, the GFLA provisions that limit the rate of interest a lender may charge a borrower—those limiting late fees, prepayment fees for non-ARM loans, and default rate of interest—do not apply to state-chartered thrifts. By operation of section 85, these limits also would not apply to national banks located in Georgia because such banks are permitted to charge the maximum rates permitted to these "most favored lenders."⁹⁷

C. The GFLA Conflicts With the Federal Grant of Power to National Banks to Charge Non-Interest Fees

As described above, section 24(Seventh) authorizes national banks to engage in activities that are part of, or incidental to, the business of banking as well as to engage in certain specified activities listed in the statute. Mortgage lending is expressly authorized for national banks and therefore part of the business of banking. Moreover, a bank's authority to provide the products or services authorized by section 24(Seventh) to its customers necessarily encompasses the ability to charge a fee

for the product or service.⁹⁸ The authority to charge fees for the bank's services is expressly set out in the OCC's regulations at 12 CFR 7.4002(a). Three provisions of the GFLA restrict or prohibit a creditor or servicer from imposing various non-interest fees for its products and services:

- *Prohibition on payoff balance and release fees.* Under the GFLA, a creditor or servicer may not charge a fee to inform a person of the payoff balance or to provide a release upon prepayment of a home loan. Payoff balances must be provided within five business days of a request. A processing fee of up to \$10 may be charged if information is provided by fax or if provided within 60 days of a previous request.
- *Prohibition on certain other fees.* The GFLA prohibits a creditor or servicer from charging a borrower any fee to modify, renew, extend, or amend a high-cost home loan or to defer any payment due.
- *Right to "cure" a default.* A borrower may not be charged a fee attributable to curing a default of a high-cost home loan unless the fee is otherwise authorized by the GFLA.

These provisions conflict with well-established statutory and regulatory authority permitting national banks to charge such fees. As explained above, section 24(Seventh) authorizes a national bank to engage in activities that are part of, or incidental to, the business of banking as well as to engage in certain specified activities listed in the statute. A bank's authority to provide these services to its customers necessarily encompasses the ability to charge a fee for them, and this ability to charge a fee for the bank's services is expressly affirmed in 12 CFR 7.4002(a).⁹⁹

Restrictions on a national bank's ability to impose fees have consistently been held to be preempted by section 24(Seventh) and 7.4002.¹⁰⁰ The fees at issue here are fees that a national bank may charge in the exercise of its authority under section 24(Seventh) and § 7.4002. In accordance with the case

⁹⁶ OTS Op. Chief Counsel, *supra* note 5, at 3.

⁹⁷ We note that Federal thrifts have most favored lender authority under a statute (12 U.S.C. 1463(g)) and regulation (12 CFR 560.110) that are identical to section 85 and § 7.4001 in all material respects. It is not clear that the OTS opinion addressed preemption issues raised by the GFLA by applying section 1463(g) and § 560.110 since the thrift requesting the OTS opinion appeared not to be located in Georgia. The OTS appears instead to have based its preemption analysis solely on the OTS's occupation of the entire field of lending. To the extent that (a) that theory supercedes specific standards in sections 1463(g) and 560.110, and (b) Federal thrifts are thus free to set interest either pursuant to the most favored lender rule set out in § 560.110 or pursuant to the maximum rate permitted in light of the preemption rule set out in § 560.2, national banks in Georgia would similarly be free to set interest under either part 34 or § 7.4001.

⁹⁸ See *supra* note 13 and accompanying text.

⁹⁹ We note that a fee to defer a payment due is, in substance, a debt suspension agreement subject to 12 CFR part 37, which expressly occupies the field in this area and imposes uniform, nationally applicable safeguards on national banks offering this product. Part 37 states:

"This part applies to debt cancellation contracts and debt suspension agreements entered into by national banks in connection with extensions of credit they make. National banks' debt cancellation contracts and debt suspension agreements are governed by this part and applicable Federal law and regulations, and not by part 14 of this chapter or by State law."—12 CFR 37.1(c).

¹⁰⁰ See *supra* notes 56–60 and accompanying text.

⁹⁴ See *Barnett*, 517 U.S. at 31–32.

⁹⁵ See, e.g., *Franklin Nat'l Bank*, 347 U.S. at 378; *Duryee*, 270 F.3d at 409 ("The intervenors' attempt to redefine 'significantly interfere' as 'effectively thwart' is unpersuasive."); *New York Bankers Ass'n, Inc. v. Levin*, 999 F. Supp. 716, 719 (W.D.N.Y. 1998) (holding that a New York statute that restricted the types of insurance banks could sell to their customers was preempted on the grounds that the state law "constitutes an interference with [banks'] rights" to sell insurance).

law, the GFLA's attempt to prevent national banks from charging these fees is, therefore, preempted.

D. Certain GFLA Provisions Are Moot in Light of the Preceding Analysis

- **Structuring.** The GFLA provides that no person may avoid application of the law by dividing one loan transaction into separate parts or structuring a home loan transaction as an open-end loan for the purpose of evading a provision of the GFLA.

- **Severability.** As described above, the GFLA provides that if any portion of it is declared to be invalid or preempted by Federal law or regulation, the validity of its remaining provisions will not be affected.

- **Disclosure required.** Documents that create a debt or pledge property as collateral for a high-cost home loan must contain a notice specifying that the mortgage is subject to special rules under GFLA and that purchasers or assignees may be liable for all claims and defenses of the borrower.

The structuring provision has the salutary goal of preventing evasion of the state law. The question whether the provision applies to National City is moot, however, because, for the reasons set forth above, the substantive provisions of the GFLA are inapplicable. Accordingly, there is no state law to evade. For the same reason, the severability clause and disclosure requirements are also moot.

As mentioned above, some commenters argued that the OCC does not enjoy exclusive visitatorial powers over national banks under 12 U.S.C. 484. These commenters assert that section 484 does not prevent state officials from suing in state courts to enforce applicable laws against national banks. It is unnecessary to address this issue, or other provisions related to enforcement of the GFLA, because the GFLA is not applicable to national banks.

E. Applicability of the GFLA to National Bank Operating Subsidiaries

As mentioned above, pursuant to their authority under 12 U.S.C. 24 (Seventh) to exercise "all such incidental powers as shall be necessary to carry on the business of banking," national banks have long used separately incorporated entities to engage in activities that the bank itself is authorized to conduct. This authority to operate through such subsidiaries has been expressly recognized for nearly 40 years.

In 1966, the OCC issued rules codifying and regulating the authority of national banks to engage in activities

through operating subsidiaries.¹⁰¹ The current version of this Operating Subsidiary Rule, codified at 12 CFR 5.34, specifies the licensing requirements when national banks seek permission from the OCC to conduct business through an operating subsidiary.¹⁰² Pursuant to this licensing process, the OCC licenses the operating subsidiary as a means through which a national bank is authorized to conduct activities permissible for the bank itself. That this relationship involves the bank conducting activities through the operating subsidiary is reflected in the express language of the regulation, which provides that "[a] national bank may conduct in an operating subsidiary activities that are permissible for a national bank to engage in directly either as part of, or incidental to, the business of banking, as determined by the OCC, or otherwise under other statutory authority."¹⁰³

Moreover, the regulation makes clear that in conducting permissible activities on behalf of its parent bank, the operating subsidiary is acting "pursuant to the same authorization, terms and conditions that apply to the conduct of such activities by its parent national bank."¹⁰⁴ These regulations reflect express Congressional recognition in section 121 of the GLBA that national banks may own subsidiaries that engage "solely in activities that national banks are permitted to engage in directly and are conducted subject to the same terms and conditions that govern the conduct of such activities by national banks."¹⁰⁵

¹⁰¹ See 31 FR 11459 (Aug. 31, 1966).

¹⁰² See 12 CFR 5.34(b).

¹⁰³ 12 CFR 5.34(e)(1).

¹⁰⁴ 12 CFR 5.34(e)(3).

¹⁰⁵ Pub. L. 106-102, section 121, 113 Stat. 1338, 1373 (1999), codified at 12 U.S.C. 24a(g)(3)(A) (emphasis supplied). One commenter argued that this section of GLBA only permits national banks to establish financial subsidiaries that are authorized to engage in activities that are not permissible for the bank and is intended solely to limit the authority of financial subsidiaries by stating that the definition of financial subsidiaries does not include operating subsidiaries. Thus, this commenter argues that this section of GLBA does not grant any powers and does not express any intent to bar the states from regulating operating subsidiaries. In *Nat'l City Bank of Indiana v. Boutris*, Civ. No. S-03-0655 GEB JFM (E.D. Cal. May 7, 2003), a Federal district court rejected a similar argument. In so doing, the Court noted that "[n]ot only does this language [of GLBA section 121] reference operating subsidiaries, it indicates the OCC exercises visitatorial authority over them." *Id.* at 11. Moreover, as the Court also pointed out, the Report of the Senate Committee on Banking, Housing, and Urban Affairs on GLBA noted that:

For at least 30 years, national banks have been authorized to invest in operating subsidiaries that are engaged only in activities that national bank may engage in directly. For example, national banks are authorized directly to make mortgage loans and engage in related mortgage banking activities. Many banks choose to conduct these activities through

When established in accordance with the procedures mandated by the OCC's Operating Subsidiary Rule and approved by the OCC, the operating subsidiary is a Federally-authorized means by which a national bank may conduct Federally-authorized activities. Recognizing this status, courts have consistently treated the operating subsidiary and the national bank as equivalents, unless Federal law requires otherwise, in considering whether a particular activity was permissible for a national bank.¹⁰⁶ Recently, in *Wells Fargo Bank, N.A. v. Boutris*,¹⁰⁷ a Federal district court issued a permanent injunction enjoining the Commissioner of the California Department of Corporations from exercising visitatorial powers over a national bank operating subsidiary. In so doing, the Court took note of this well-established case law and concluded that "[t]he OCC's regulation authorizing national banks to conduct permissible banking business activities through operating subsidiaries is within its discretionary authority delegated to it by Congress and is a reasonable interpretation of the Act."¹⁰⁸ Similarly, in *National City Bank of Indiana v. Boutris*,¹⁰⁹ a Federal district court enjoined California officials from exercising visitatorial powers over National City Bank of Indiana and its operating subsidiary, National City Mortgage Company.

In accordance with this longstanding regulatory and judicial recognition of operating subsidiaries as corporate extensions of the parent bank, OCC regulations specifically address the application of state law to national bank operating subsidiaries. That regulation provides:

Unless otherwise provided by Federal law or OCC regulation, State laws apply to national bank operating subsidiaries to the same extent that those laws apply to the parent national bank.¹¹⁰

subsidary corporations. Nothing in this legislation is intended to affect the authority of national banks to engage in bank permissible activities through subsidiary corporations, or to invest in joint ventures to engage in bank permissible activities with other banks or nonbank companies.

S. Rep. No. 106-44, at 8 (1999).

¹⁰⁶ See *Variable Annuity Life Ins. Co.*, 513 U.S. at 254 (brokerage subsidiary acting as an agent in the sale of annuities); *Marquette*, 439 U.S. at 299 (credit card subsidiary); *American Ins. Ass'n v. Clarke*, 865 F.2d 278 (D.C. Cir. 1988) (subsidiary offering municipal bond insurance); *M & M Leasing Corp. v. Seattle First Nat'l Bank*, 563 F.2d 1377 (9th Cir. 1977) (motor vehicle leasing by subsidiary).

¹⁰⁷ 2003 WL 21277203 (E.D. Cal. May 9, 2003).

¹⁰⁸ *Id.* at *6.

¹⁰⁹ 2003 WL 21536818 (E.D. Cal. July 2, 2003).

¹¹⁰ 12 CFR 7.4006. One commenter argues that the OCC cannot rely on this regulation because the commenter contends that the OCC failed to abide by Executive Order 13132 in promulgating it. We

The provisions of part 34 expressly apply equally to national banks and their operating subsidiaries:

This part applies to national banks and their operating subsidiaries as provided in 12 CFR 5.34.¹¹¹

Accordingly, the same preemption conclusions about the GFLA reached above for national banks pursuant to sections 34.4(a) and (b) of the OCC's regulations, and those concerning the GFLA's restrictions on components of interest¹¹² or fees, apply equally to their operating subsidiaries.

IV. Results of the Analysis

For the reasons stated above, we are issuing an order concluding that the GFLA does not apply to National City or any other national bank or national bank operating subsidiary that engages in real estate lending activities in Georgia. This order is expressly authorized by section 371.¹¹³ The authority vested in the OCC

disagree. Executive Order 13132 requires intergovernmental consultation if a rule preempts state law, and an agency must consult to the extent practicable with state and local officials early in the process of developing the proposed regulation. Office of Management and Budget guidance on the Executive Order notes that the consultation "should seek comment on * * * preemption as appropriate to the nature of the rulemaking under development. The timing, nature, and detail of the consultation involved should also be appropriate to the nature of the regulation involved." M-00-02, "Guidance for Implementing E.O. 13132, 'Federalism,'" at 5 (Oct. 28, 1999), available at <http://www.whitehouse.gov/omb/memoranda/m00-02.pdf>. This process was followed in connection with the promulgation of § 7.4006. As we explained in the preamble to the final rule adopting § 7.4006:

"In addition to publishing our proposal for comment by all interested parties, including State and local officials, we also brought the proposal to the attention of the Conference of State Bank Supervisors and specifically invited its views, and the views of its constituent members, on the revisions we proposed. In the preamble to this final rule, we have described the comments we received from State officials or their representatives and our responses thereto. Finally, we have made those written comments we received from State or local officials available to the Director of OMB."—66 FR 34784, 34790 (July 2, 2001).

The same commenter argues that this order or determination should be delayed until the requirements of Executive Order 13132 have been met by the OCC. We note that the consultative process required by the Executive Order has been met by our solicitation (and receipt) of comment from interested parties.

¹¹¹ 12 CFR 34.1(b).

¹¹² See OCC Interpretive Letter No. 954 (Dec. 16, 2002) (12 U.S.C. 85 applies equally to national bank operating subsidiaries and their parent national banks).

¹¹³ Even if the OCC's express authority under section 371 were construed not to be broad enough to permit it to issue this order, the Administrative Procedure Act (APA) authorizes agencies to issue orders "to terminate a controversy or remove uncertainty." 5 U.S.C. 554(e) ("The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty."). Although section 554(e) is contained within the

to establish the terms, conditions, and requirements that apply to national bank real estate lending necessarily encompasses the authority to say which terms, conditions, and requirements do not apply to national bank real estate lending. This Order has the force and effect of law.¹¹⁴

Order

The conditions imposed by the GFLA on the real estate lending activities of national banks do not apply to National City, or any other national bank, or national bank operating subsidiary, that engages in real estate lending activities in Georgia.

Dated: July 30, 2003.

John D. Hawke, Jr.,
Comptroller of the Currency.

[FR Doc. 03-19907 Filed 8-4-03; 8:45 am]

BILLING CODE 4810-33-P *

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Area 6 Taxpayer Advocacy Panel (Including the States of Alaska, Arizona, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

APA provisions for matters that are required by statute to be determined on the record after an opportunity for a hearing, there is considerable case law and agency practice of issuing orders in other circumstances. For example, in *American Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788 (5th Cir. 2000), the court of appeals upheld a DOT declaratory order under section 554(e) that preempted certain municipal regulations. The court specifically found authority for such an order and that procedural provisions of section 554 were not applicable. In short, the court found that section 554(e) was a source of authority for a declaratory order independent of the remainder of section 554.

Examples of agencies issuing legally binding orders pursuant to authority other than section 554(e) of the APA are numerous. For example, under section 3 of the Bank Holding Company Act, applications to become a bank holding company are approved by Federal Reserve Board orders. In *Farmers & Merchts. Bank of Las Cruces v. Bd. of Governors of Fed. Reserve Sys.*, 567 F.2d 1082 (D.C. Cir. 1977), the court of appeals affirmed the Board's order approving the formation of a holding company, noting that the protesting bank had no right to a hearing before the Board in light of the OCC's recommended approval of the acquisition. A similar result was reached in *Grandview Bank & Trust Co. v. Bd. of Governors of Fed. Reserve Sys.*, 550 F.2d 415 (8th Cir. 1977).

¹¹⁴ As noted above, the OCC is issuing at the same time as this Determination and Order is issued a Notice of Proposed Rulemaking that invites comments on a proposed codification of broadly applicable preemption provisions. We have elected to respond to National City through an order given the narrower focus of the request.

SUMMARY: An open meeting of the Area 6 Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel (TAP) is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. The TAP will use citizen input to make recommendations to the Internal Revenue Service.

DATES: The meeting will be held Monday, August 18, 2003.

FOR FURTHER INFORMATION CONTACT: Anne Gruber at 1-888-912-1227, or 206-220-6098.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Area 7 Taxpayer Advocacy Panel will be held Monday, August 18, 2003 from 2 p.m. Pacific Time to 4 p.m. Pacific Time via a telephone conference call. The public is invited to make oral comments. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1-888-912-1227 or 206-220-6098, or write to Anne Gruber, TAP Office, 915 2nd Avenue, MS W-406, Seattle, WA 98174. Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Anne Gruber. Ms. Gruber can be reached at 1-888-912-1227 or 206-220-6095.

The agenda will include the following: various IRS issues.

Dated: July 31, 2003.

Deryle J. Temple,

Director, Taxpayer Advocacy Panel.

[FR Doc. 03-19929 Filed 8-4-03; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel will be conducted (via teleconference).

DATES: The meeting will be held Wednesday, August 27, 2003, from 12 noon e.d.t. to 1 p.m. e.d.t.

FOR FURTHER INFORMATION CONTACT:

Sallie Chavez at 1-888-912-1227, or 954-423-7979.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel will be held Wednesday, August 27, 2003. from 12

noon e.d.t. to 1 p.m. e.d.t. via a telephone conference call. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1-888-912-1227 or 954-423-7979, or write Sallie Chavez, TAP Office, 1000 South Pine Island Road, Suite 340,

Plantation, FL 33324. Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Sallie Chavez. Ms. Chavez can be reached at 1-888-912-1227 or 954-423-7973.

Dated: July 31, 2003.

Deryle J. Temple,

Director, Taxpayer Advocacy Panel.

[FR Doc. 03-19931 Filed 8-4-03; 8:45 am]

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Corrections

Federal Register

Vol. 68, No. 150

Tuesday, August 5, 2003

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21, 61, 65, 77, 107, 109, 121, 135, 145, and 154

[Docket Nos. 23781, 25642, 26305, 27699, and FAA-2001-11172]

RIN 2120-AI02

Withdrawal of Proposed Rules: Miscellaneous Amendments; Improved Water Survival Equipment; Objects Affecting Navigable Airspace; Type Certificates for Some Surplus Aircraft of the Armed Forces; Procedures for Reimbursement of Airports, On-Airport Parking Lot and Vendors of On-Airfield Direct Services to Air Carriers for Security Mandates

Correction

In proposed rule document 03-18592 beginning on page 43885 in the issue of

Thursday, July 24, 2003 make the following corrections:

1. On page 43885, in the third column, in the second full paragraph, in the 14th line, "proposals" should read "proposal".

2. On the same page, in the same column, under the heading **Type Certificates for Some Surplus Aircraft of the Armed Forces, RIN 2120-AE41**, in the eighth line, "Forces," should read "Forces."

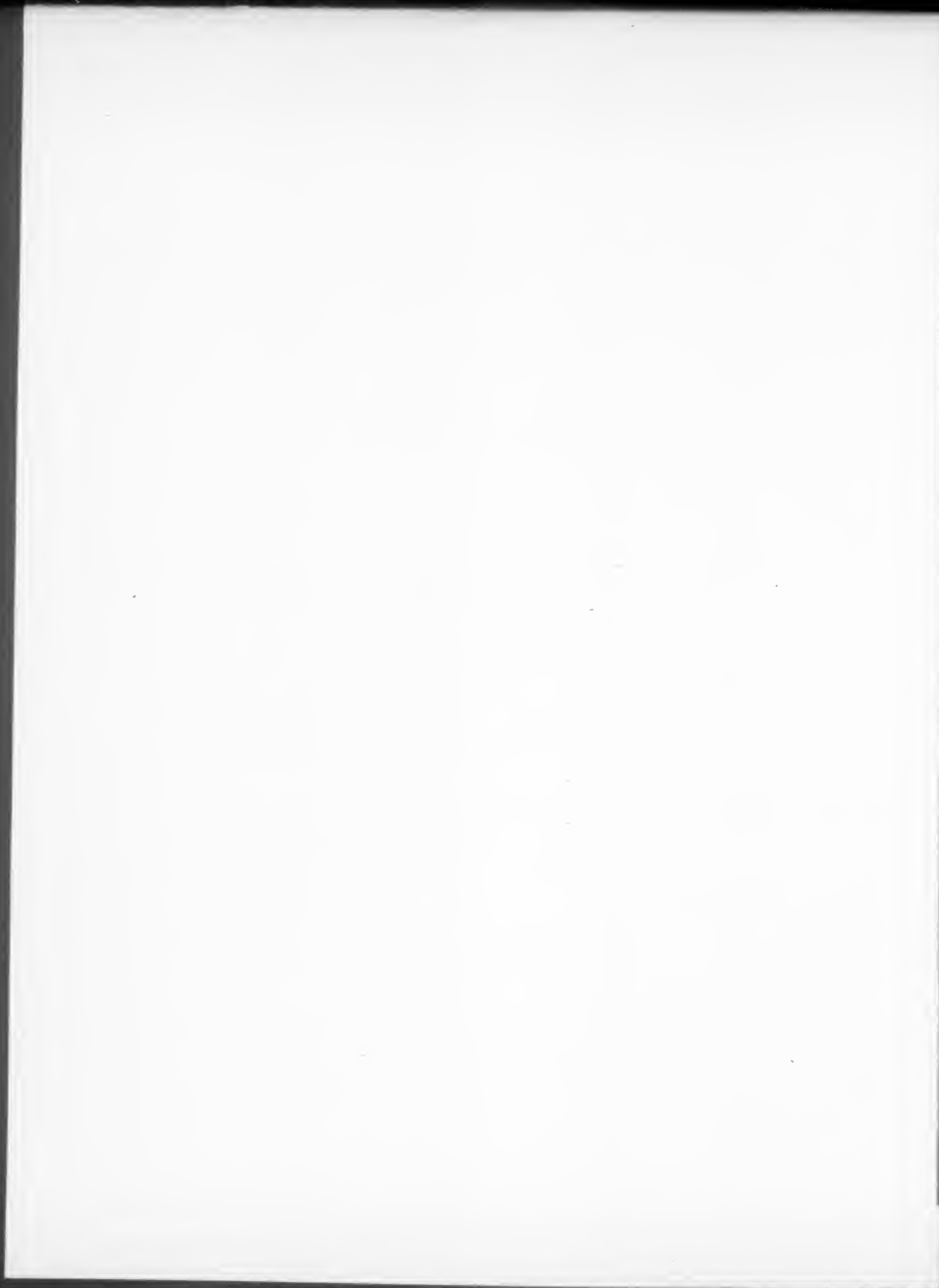
3. On page 43886, in the first column, in the first paragraph, in the eighth line, "safety perspective" should read "safety perspective."

4. On the same page, in the same column, in the same paragraph, in the same line, "also" should read "Also".

5. On the same page, in the second column, in the last paragraph, in the last line, "have been appropriated" should read "have not been appropriated".

[FR Doc. C3-18592 Filed 8-4-03; 8:45 am]

BILLING CODE 1505-01-D





Federal Register

Tuesday,
August 5, 2003

Part II

Federal Communications Commission

47 CFR Part 73

Broadcast Ownership Rules, Cross-Ownership of Broadcast Stations and Newspapers, Multiple Ownership of Radio Broadcast Stations in Local Markets, and Definition of Radio Markets; and Definition of Radio Markets for Areas Not Located in an Arbitron Survey Area; Final Rule and Proposed Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket 02-277, and MM Dockets 01-235, 01-317, and 00-244; FCC 03-127]

Broadcast Ownership Rules, Cross-Ownership of Broadcast Stations and Newspapers, Multiple Ownership of Radio Broadcast Stations in Local Markets, and Definition of Radio Markets

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document completes the Commission's biennial review of its broadcast ownership rules. The Commission replaces its absolute prohibition on common ownership of daily newspapers and broadcast outlets in the same market and its restrictions on common ownership of radio and television outlets in the same market with Cross Media Limits. The Commission also revises the market definition and the way it counts stations for purposes of the local radio rule, revises the local television multiple ownership rule, modifies the national television ownership cap from a 35% national audience reach limit to a 45% reach limit, and retains the dual network rule. The action is taken in response to section 202(h) of the Telecommunications Act of 1996, which requires the Commission to review its broadcast ownership rules on a biennial basis to determine whether the rules remain "necessary in the public interest." The action is necessary to comply with this legislative mandate.

DATES: Effective September 4, 2003, except for §§ 73.3555 and 73.3613 which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date of these sections. A separate notice will be published in the **Federal Register** soliciting public and agency comments on the information collections, and establishing a deadline for accepting such comments.

FOR FURTHER INFORMATION CONTACT: Mania Baghdadi, Deputy Division Chief, Industry Analysis Division, Media Bureau, 202-418-2133. For further information concerning the information collection requirements contained in this Report and Order, contact Les Smith, Federal Communications Commission, 202-418-0217, or via the Internet at Leslie.Smith@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (R&O) in MB Docket No. 02-277 and MM Docket Nos. 01-235, 01-317, and 00-244; FCC 03-127, adopted June 2, 2003, and released July 2, 2003. The complete text of the R&O and the Final Regulatory Flexibility Analysis is available on the Commission's Internet site, at www.fcc.gov, and is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC. The text may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., CY-B4202, Washington, DC 20554 (telephone 202-863-2893).

Synopsis of the Report and Order

1. This R&O brings to completion the Commission's third biennial ownership review of all six broadcast ownership rules. The Commission addresses these rules in light of the mandate of section 202(h) of the Telecommunications Act of 1996 (1996 Act), which requires the Commission to reassess and recalibrate its broadcast ownership rules every two years. (Telecommunications Act of 1996, Public Law 104-104, 110 Stat. 56 (1996).)

2. The *Notice of Proposed Rulemaking* (NPRM) in this proceeding (67 FR 65751, October 28, 2002), initiated review of four ownership rules: the national television multiple ownership rule;¹ the local television multiple ownership rule;² the radio-television cross-ownership rule;³ and the dual network rule.⁴ The first two rules have been reviewed and the proceedings remanded to the Commission by the U.S. Court of Appeals for the District of Columbia Circuit. (*Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1044 (D.C. Cir. 2002) (*Fox Television*), *rehearing granted*, 293 F. 3d 537 (D.C. Cir. 2002) (*Fox Television Re-Hearing*) addressing the national TV ownership rule, and *Sinclair Broadcast Group, Inc. v. FCC*, 284 F.3d 148 (DC Cir. 2002), (*Sinclair*) addressing the local TV ownership rule.) After the Commission issued the NPRM, the Commission issued 12 Media Ownership Working Group (MOWG) studies for public comment. A summary of the studies, a public notice, and the text of the studies may be found at www.fcc.gov/ownership.

¹ 47 CFR 73.3555(e).

² 47 CFR 73.3555(b).

³ 47 CFR 73.3555(c).

⁴ 47 CFR 73.658(g).

3. In this R&O, the Commission examines the legal context within which this review is conducted, identifies and describes the public interest policy goals that guide our decision, assesses changes in the media marketplace over time, repeals some rules, modifies others, and adopts some new rules. In consideration of the record and our statutory charge, the Commission concludes that neither an absolute prohibition on common ownership of daily newspapers and broadcast outlets in the same market (the newspaper/broadcast cross-ownership rule) nor a cross-service restriction on common ownership of radio and television outlets in the same market (the radio-television cross-ownership rule) remains necessary in the public interest. With respect to both of these rules, the Commission finds that the ends sought can be achieved with more precision and with greater deference to First Amendment interests through our modified Cross Media Limits (CML). The Commission also revises the market definition and the way it counts stations for purposes of the local radio rule, revises the local television multiple ownership rule, modifies the national television ownership cap, and retains the dual network rule.

4. The Commission, in the R&O, adopts limits both for local radio and local television station ownership. Both of these rules are premised on well-established competition theory and are intended to preserve a healthy and robust competition among broadcasters in each service. As explained in the R&O, however, because markets defined for competition purposes are generally more narrow than markets defined for diversity purposes, the Commission's ownership limits on radio and television ownership also serve our diversity goal. By ensuring that several competitors remain within each of the radio and television services, the Commission also ensures that a number of independent outlets for viewpoint will remain in every local market, thereby protecting diversity. Further, though, because local television and radio ownership limits cannot protect against losses in diversity that might result from combinations of different types of media within a local market, the Commission adopts a set of specific cross-media limits.

5. Similarly, by virtue of the staff's extensive information gathering efforts and the voluminous record assembled in this rulemaking docket, the Commission has, for the first time substantial evidence regarding the localism effects of our national broadcast ownership rules. The

Commission can, therefore, with more confidence than ever, establish a reasonable limit on the national station ownership reach of broadcast networks. In addition, under our dual network rule, the Commission continues to prohibit a combination between two of the largest four networks primarily on competition grounds, but the beneficial effects of this restriction also protect localism. In combination, the Commission's new national broadcast ownership reach cap and our "dual network" prohibition will ensure that local television stations remain responsive to their local communities.

I. Legal Framework

6. The Commission conducts this biennial ownership review within the framework established by section 202(h) of the 1996 Act, which provides: "The Commission shall review its rules adopted pursuant to this section and all of its ownership rules biennially as part of its regulatory reform review under section 11 of the Communications Act of 1934 and shall determine whether any of such rules are necessary in the public interest as the result of competition. The Commission shall repeal or modify any regulation it determines to be no longer in the public interest." 1996 Act, section 202(h).

7. Two aspects of this statutory language are particularly noteworthy. First, as the court recognized in both *Fox Television* and *Sinclair*, "Section 202(h) carries with it a presumption in favor of repealing or modifying the ownership rules." That is, Section 202(h) appears to upend the traditional administrative law principle requiring an affirmative justification for the modification or elimination of a rule. Second, Section 202(h) requires the Commission to determine whether its rules remain "necessary in the public interest."

8. The Commission concludes that in its current form only the dual network rule remains necessary in the public interest as a result of competition. The Commission also concludes that the other ownership rules should be modified as described in the R&O.

9. The ownership rules adopted in the R&O must be consistent not only with the legal standard in section 202(h), but also with the First Amendment rights of affected media companies and consumers. The Commission concludes, based on the decisions in the *Fox Television* and *Sinclair* cases, that the rational basis standard is the correct First Amendment standard to apply to the broadcast ownership rules.

10. The Commission rejects, as did the court, the application of the

intermediate scrutiny (*O'Brien*) standard applicable to cable operators or the strict scrutiny standard applicable to the print media and to content-based regulations. Under *O'Brien*, government regulation of speech will be upheld only if: (1) It furthers an important or substantial governmental interest; (2) the interest is unrelated to the suppression of free expression; and (3) the incidental restriction on alleged First Amendment freedom is no greater than is essential to the furtherance of that interest. In general, ownership limits on cable operators have been subject to the *O'Brien* test. The Supreme Court has determined that "promoting the widespread dissemination of information from a multiplicity of sources" is a government interest that is not only important, but is of the "highest order" and is unrelated to the suppression of free speech. *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 662-63 (1984); *Turner Broadcasting System v. FCC*, 520 U.S. 180 (1997). On the other hand, the Commission may not burden cable operators' speech with "illimitable restrictions in the name of diversity."

11. Strict scrutiny First Amendment analysis would require the Commission to demonstrate that its rules are the "least restrictive means available of achieving a compelling state interest."

12. Under the rational basis standard, the Commission's broadcast regulations satisfy the First Amendment if they are "a reasonable means of promoting the public interest in diversified mass communications." *FCC v. National Citizens Committee for Broadcasting*, 436 U.S. 775, 802 (1978) (*NCCB*). As the court has noted, there is no unbridgeable First Amendment right to hold a broadcast license; would-be broadcasters must satisfy the public interest by meeting the Commission criteria for licensing, including demonstrating compliance with any applicable ownership limitations.

13. In applying the rational basis test, the *Fox* and *Sinclair* courts relied on longstanding Supreme Court precedent which also supports our decision. *NCCB*, 436 U.S. at 802. In *NCCB*, the Supreme Court applied the rational basis test to the Commission's newspaper/broadcast cross-ownership rules, finding that they "are a reasonable means of promoting the public interest in diversified mass communications; thus they do not violate the First Amendment rights of those who will be denied broadcast licenses pursuant to them." The *NCCB* Court explained that the rational basis test is the appropriate standard to govern our broadcast ownership regulations because

spectrum scarcity requires "Government allocation and regulation of broadcast frequencies" and because these regulations are not content related. The rational basis standard therefore governs the Commission's broadcast ownership regulations, whether they govern those that own only broadcast outlets or those that might seek to combine ownership of a broadcast outlet with a newspaper.

14. First Amendment interests are implicated by any regulation of media outlets, including broadcast media. The Commission endeavors to be sensitive to those interests and to minimize the impact of our rules on the right of speakers to disseminate a message. As discussed below, our decision today to eliminate the newspaper/broadcast cross-ownership rule and the radio-television cross-ownership rule, and to modify our other local ownership rules and our national audience reach cap, turns in part on our determination that these rules in their current form are not a reasonable means to accomplish the public interest purposes to which they are directed. The Commission turns next to identifying the policy goals that will inform this determination.

II. Policy Goals

15. The Commission, in the NPRM, identified diversity, competition and localism as longstanding goals that would continue to be core agency objectives that would guide its actions in regulating media ownership. To fulfill our biennial review obligation, the Commission will first define our goals and the ways it will measure them. The Commission can then assess whether our current broadcast ownership rules are necessary to achieve these goals.

A. Diversity

16. There are five types of diversity pertinent to media ownership policy: viewpoint, outlet, program, source, and minority and female ownership diversity.

17. *Viewpoint Diversity*. Viewpoint diversity refers to the availability of media content reflecting a variety of perspectives. A diverse and robust marketplace of ideas is the foundation of our democracy. Consequently, "it has been a basic tenant of national communications policy that the widest possible dissemination of information from diverse and antagonistic sources is essential to the welfare of the public." This policy is given effect, in part, through regulation of broadcast ownership. Because outlet owners select the content to be disseminated, the Commission has traditionally assumed that there is a positive correlation

between viewpoints expressed and ownership of an outlet. The Commission has sought, therefore, to diffuse ownership of media outlets among multiple firms in order to diversify the viewpoints available to the public. Prior Commission decisions limiting broadcast ownership concluded that a larger total number of outlet owners increased the probability that their independent content selection decisions would collectively promote a diverse array of media content. The Commission sought comment on whether this longstanding presumed link between ownership and viewpoint could be established empirically. After reviewing studies and comments, the Commission adheres to its longstanding determination that the policy of limiting common ownership of multiple media outlets is the most reliable means of promoting viewpoint diversity. The balance of evidence, although not conclusive, appears to support the Commission's conclusion that outlet ownership can be presumed to affect the viewpoints expressed on an outlet. The Commission therefore continues to believe that broadcast ownership limits are necessary to preserve and promote viewpoint diversity. A larger number of independent owners will tend to generate a wider array of viewpoints in the media than would a comparatively smaller number of owners.

18. Further, owners of media outlets clearly have the ability to affect public discourse, including political and governmental affairs, through their coverage of news and public affairs. Even if the Commission's inquiry were to find that media outlets exhibited no apparent "slant" or viewpoint in their news coverage, media outlets possess significant potential power in our system of government. The Commission believes sound public policy requires it to assume that power is being, or could be, exercised.

19. The Commission does not pass judgment on the desirability of owners using their outlets for the expression of particular viewpoints. Indeed, the Commission has always proceeded from the assumption that they do so and that its rules should encourage diverse ownership precisely because it is likely to result in the expression of a wide range of diverse and antagonistic viewpoints. The Commission merely observes here that evidence from a variety of researchers and organizations appears to disclose a meaningful connection between the identity of the outlet owner and the content delivered via its outlet(s). This evidence provides an additional basis to reaffirm the Commission's longstanding conclusion

that regulating ownership is an appropriate means to promote viewpoint diversity.

20. The Commission's conclusion also should not be read to suggest that each and every incremental increase in the number of different outlet owners can be justified as necessary in the public interest. To the contrary, there certainly are points of diminishing returns in incremental increases in diversity. Moreover, such increases may, in some instances, harm the public interest in localism and competition. The balancing of these interests are addressed in the sections below dealing with individual rules.

21. *Measuring viewpoint diversity.* Viewpoint diversity is a paramount objective of this Commission because the free flow of ideas undergirds and sustains our system of government. Although all content in visual and aural media have the potential to express viewpoints, the Commission finds that viewpoint diversity is most easily measured through news and public affairs programming. Not only is news programming more easily measured than other types of content containing viewpoints, but it relates most directly to the Commission's core policy objective of facilitating robust democratic discourse in the media. Accordingly, the Commission has sought in this proceeding to measure how certain ownership structures affect news output.

22. Nonetheless, the Commission agrees with Fox and CFA that content other than traditional newscasts also contributes to a diversity of viewpoints. Television shows such as 60 Minutes, Dateline NBC, and other newsmagazine programs routinely address matters of public concern. In addition, as Fox points out, entertainment programming such as Will & Grace, Ellen, The Cosby Show, and All in the Family all involved characters and storylines that addressed racial and sexual stereotypes. In so doing, they contributed to a national dialogue on important social issues.

23. Although the Commission agrees that entertainment programs can contribute to its goal of viewpoint diversity, it will focus on the news component of viewpoint diversity where the record permits it to do so. The Commission's objective of promoting program diversity in this proceeding subsumes the viewpoint diversity contained within entertainment programming. Finally, the Commission concludes that the diversity of viewpoints by national media on national issues is greater than that regarding local issues. This is

principally due to the vast array of national news sources available on the Internet, cable television and DBS.

24. *Program Diversity.* The Commission concludes that program diversity is a policy goal of broadcast ownership regulation. Program diversity refers to a variety of programming formats and content. With respect to television, this includes dramas, situation comedies, reality shows, and newsmagazines, as well as targeted programming channels such as food, health, music, travel, and sports. With respect to radio, program diversity would be reflected in a variety of music formats such as jazz, rock, and classical as well as all-sports and all-news formats. Programming aimed at various minority and ethnic groups is an important component of program diversity for both television and radio. In general, the Commission finds that program diversity is best achieved by reliance on competition among delivery systems rather than by government regulation. The rules adopted in this proceeding will ensure competition in the delivered video and radio programming markets.

25. *Outlet Diversity.* Outlet diversity means that, in a given market, there are multiple independently-owned firms. The Commission has previously found that outlet diversity has not been viewed as an end in itself, but a means through which the Commission seeks to achieve our goal of viewpoint diversity. The Commission finds that independent ownership of outlets by multiple entities in a market contributes to our goal of promoting viewpoints.

26. The Commission's review of the record persuades us that outlet diversity within radio broadcasting continues to be an important aspect of the public interest that the Commission should seek to promote. The Commission is committed to establishing a regulatory framework that promotes innovation in the field of broadcasting. Because new entrants are often a potent source of innovation, the Commission seeks to preserve opportunities for new entry in radio which remains one of the most affordable means for entering the media business.

27. The Commission believes that one benefit of outlet diversity is the promotion of public safety. In an emergency, the separation of broadcast facilities and personnel among multiple independent broadcast companies in a given market will avoid any possibility that the failure of one broadcast company to transmit critical public safety information will not leave that area without other broadcast owners to perform that service.

28. *Source Diversity.* Source diversity refers to the availability of media content from a variety of content producers. The record before us does not support a conclusion that source diversity should be an objective of the Commission's broadcast ownership policies. In light of dramatic changes in the television market, including the significant increase in the number of channels available to most households today, the Commission finds no basis in the record to conclude that government regulation is necessary to promote source diversity. Given the explosion of programming channels now available in the vast majority of homes today, and in the absence of evidence to the contrary, the Commission cannot conclude that source diversity should be a policy goal of our broadcast ownership rules.

29. *Minority and Female Ownership Diversity.* Encouraging minority and female ownership historically has been an important Commission objective, and the Commission reaffirms that goal here. NABOB recommends that the Commission should maintain our current ownership rules; use Arbitron markets to define radio markets; give greater consideration to the promotion of viewpoint diversity and minority ownership when the Commission reviews assignment of license and transfer of control applications; eliminate our policy of granting temporary waivers of our multiple ownership rules (which allow merging broadcasters 6-24 months to come into compliance with the rules); adopt a bright-line test to limit radio ownership consolidation; and urge Congress to reinstate the minority tax certificate policy.

30. IPI argues that maintenance of broadcast ownership caps will best serve the distinct programming preferences of minority groups. AWRT asks us to include the goal of increasing the number of female-owned broadcast businesses as the Commission considers changes to its broadcast ownership rules. UCC urges the Commission to "explicitly advance through its ownership rules" the policy goal of promoting broadcast ownership opportunities for women, minorities and small businesses.

31. MMTC proposes business and regulatory initiatives that "would go a long way toward increasing entry into the communications industry by minorities." MMTC's initiatives include: (1) Equity for specific and contemplated future acquisitions; (2) enhanced outreach and access to debt financing by major financial institutions; (3) investments in institutions specializing in minority and

small business financing; (4) cash and in-kind assistance to programs that train future minority media owners; (5) creation of a business planning center that would work one-on-one with minority entrepreneurs as they develop business plans and strategies, seek financing, and pursue acquisitions; (6) executive loans, and engineers on loan, to minority owned companies and applicants; (7) enhanced access to broadcast transactions through sellers undertaking early solicitations of qualified minority new entrants and affording them the same opportunities to perform early due diligence as the sellers afford to established non-minority owned companies; (8) nondiscrimination provisions in advertising sales contracts; (9) incubation and mentoring of future minority owners; (10) enactment of tax deferral legislation designed to foster minority ownership; (11) examination of how to promote minority ownership as an integral part of all FCC general media rulemaking proceedings; and (12) ongoing longitudinal research on minority ownership trends, conducted by the FCC, NTIA, or both; (13) sales to certain minority or small businesses as alternatives to divestitures. The Commission has received many creative proposals to advance minority and female ownership. Clearly, a more thorough exploration of these issues, which will allow us to craft specifically tailored rules that will withstand judicial scrutiny, is warranted. The Commission will issue a Notice of Proposed Rulemaking to address these issues and incorporate comments on these issues received in this proceeding into that proceeding.

32. The Commission sees significant immediate merit in one commenter's proposal regarding the transfer of media properties that collectively exceed our radio ownership cap. Minority Media & Telecommunications Council (MMTC) recommends that the Commission generally forbid the wholesale transfer of media outlets that exceed our ownership rules except where the purchaser qualifies as a "socially and economically disadvantaged business." The Commission agrees with MMTC that a limited exception to a "no transfer" policy for above-cap combinations would serve the public interest. The Commission also agrees with MMTC that the benefits to competition and diversity of a limited exception allowing entities to sell above-cap combinations to eligible small entities outweigh the potential harms of allowing the above-cap combination to remain intact.

33. The Commission intends to refer the question of how best to ensure that interested buyers are aware of broadcast properties for sale to the Advisory Committee on Diversity for further inquiry and will carefully review any recommendations this Committee may proffer. As soon as the Commission receives authorization to form this committee it will ask it to make consideration of this issue among its top priorities.

B. Competition

34. From its inception, the Commission has sought to ensure that transfers and assignments of station licenses remain consistent with the policy of free competition embodied in the Communications Act. The Commission sees nothing in the 1996 Act that signifies a retreat from our deep and abiding interest in promoting and preserving competition in broadcasting. It is clear that competition is a policy that is intimately tied to our public interest responsibilities and one that the Commission has a statutory obligation to pursue. The Commission affirms our longstanding commitment to promoting competition by ensuring pro-competitive market structures. Consumers receive more choice, lower prices, and more innovative services in competitive markets than they do in markets where one or more firms exercises market power. These benefits of competition can be achieved when regulators accurately identify market structures that will permit vigorous competition.

35. In limiting broadcast ownership to promote economic competition, the Commission also takes major strides toward protecting and promoting its separate policy goal of protecting competition in the marketplace of ideas. In many markets, the record evidence shows that the Commission's competition-based ownership limits more than adequately protect viewpoint diversity in a large number of markets. Nonetheless, the Commission's analysis of the record leads it to conclude that preserving competitive markets will not, in all cases, adequately protect viewpoint diversity. The Commission finds that certain combinations in smaller markets would unreasonably threaten viewpoint diversity even if they would not result in competitive harms.

36. *Measurement of competition.* Historically the Commission has relied on assessments of competition in advertising markets as a proxy for consumer welfare in media markets.

37. Although advertising markets continue to be a reasonable basis on

which to evaluate competition among media companies, in this R&O the Commission will rely more heavily on other metrics. In the past, television stations generally faced economic competition from other television stations, and radio stations from other radio stations. The television and radio markets relied principally on advertising revenues to fund their businesses. Today, a large portion of the revenue in the television business consists of direct payment by consumers. Eighty-five percent of American households subscribe to television programming supplied by cable or direct broadcast satellite. Therefore, in analyzing markets comprised of both free over-the-air broadcasters as well as subscription delivery systems, the Commission will look to audience share as one metric for assessing the state of competition. The Commission will not discard advertising market analysis where appropriate, but it limits its reliance to discrete markets where it believes the foregoing analysis is inapplicable.

38. The Commission's public interest focus must be first and foremost on the interest, the convenience, and the necessity of the public, and not on the interest, convenience, or necessity of the individual broadcaster, or the advertiser. Thus, in evaluating the Commission's interest in preserving competitive broadcast markets, it will consider the ultimate effect that a diminution in competition would have on the consuming public. The Commission has a public interest responsibility to ensure that broadcasting markets remain competitive so that all the benefits of competition—including more innovation and improved service—are made available to the public. In setting its local television and local radio ownership caps, the Commission will rely, where possible, on measures other than shares of advertising markets in order to reflect the decreasing relevance of advertising market shares as a barometer of competition.

39. *Innovation.* The Commission concludes that it should seek to promote innovation through its broadcast ownership limits. Where a market such as broadcasting is characterized by a significant degree of non-price competition, it may be particularly important for the Commission to focus on how its ownership rules affect innovation incentives. Innovation, over longer periods of time, may represent a critical driver of consumer welfare.

40. The transition from analog to digital services by broadcasters represents a potentially significant

enhancement to consumer welfare. Digital transmission of video and audio programming by television and radio stations may facilitate new services for consumers by permitting more efficient bandwidth utilization. With respect to local television stations, this additional bandwidth could be used to transmit high-definition programming; to transmit one or more additional program streams; or to deliver entirely new services. NAB/NASA has argued that local television ownership structures are very likely to affect stations' ability to proceed with the ongoing digital transition. NAB contends that the fixed costs associated with digital television equipment upgrades fall disproportionately on stations in smaller markets and that station combinations will speed the transition. In addition, the introduction of digital transmission by radio stations may permit greater competition and innovation in radio markets by facilitating improved signal quality and by permitting stations to deliver data along with audio to users' receivers.

41. In sum, the Commission concludes that it should seek to promote innovation through its broadcast ownership limits. Consumer welfare is likely to be enhanced when, all else being equal, the Commission permits broadcast market structures that encourage innovation. The Commission agrees with IPI, however, that multiple factors influence the pace of innovation, only one of which is market structure. The Commission will therefore make ownership decisions that promote innovation in media markets based principally on evidence that particular market structures or firm characteristics tend to encourage innovation.

C. Localism

42. The Commission agrees that localism continues to be an important policy objective. Localism is rooted in Congressional directives to this Commission and has been affirmed as a valid regulatory objective many times by the courts. The Commission hereby reaffirms its commitment to promoting localism in the broadcast media. Today, the Commission seeks to promote localism to the greatest extent possible through market structure that take advantage of media companies' incentive to serve local communities.

43. Federal regulation of broadcasting has historically placed significant emphasis on ensuring that local television and radio stations are responsive to the needs and interests of their local communities. In the Communications Act of 1934, Congress directed the Commission to "make such

distribution of licenses, frequencies, hours of operation, and power among the several States and communities as to provide a fair, efficient, and equitable distribution of radio service to each of the same." In the legislative history of the 1996 Act, Congress strongly reaffirmed the importance of localism.

44. The courts too have long viewed localism as an important public interest objective of broadcast regulation. In *NBC v. United States*, the Supreme Court wrote: "Local program service is a vital part of community life. A station should be ready, able, and willing to serve the needs of the local community." Last year the DC Circuit affirmed the legitimacy of Commission regulation to preserve localism, stating: "[T]he public interest has historically embraced diversity (as well as localism) * * * and nothing in section 202(h) signals a departure from that historic scope."

45. *Measurement of Localism.* The Commission remains firmly committed to the policy of promoting localism among broadcast outlets. Today the Commission seeks to promote localism to the greatest extent possible through market structures that take advantage of media companies' incentives to serve local communities. In addition, the Commission seeks to identify characteristics of those broadcasters that have demonstrated effective service to individual local communities and to encourage their entry into markets currently prohibited by our existing rules. To measure localism in broadcasting markets, the Commission will rely on two measures: the selection of programming responsive to local needs and interests, and local news and public affairs programming quantity and quality. The Commission decided long ago that local station licensees have a responsibility to air programming that is suited to the tastes and needs of their community and that the station licensee, not a network or any other party, must decide what programming will best serve those needs. Program selection, then, is a means by which local stations respond to local community interests, and the Commission will use it as one measure of localism. Its second measure of localism can serve as a useful measure of a station's effectiveness in serving the needs of its community. As discussed below, this measure of service to local markets is relevant to the Commission's consideration of both the national television cap and its local broadcast rules.

D. Regulatory Certainty

46. The Commission considered both a case-by-case analysis and bright line rules to determine the particular regulatory framework that would best achieve our policy goals. Based on the record and our own experience administering structural ownership rules, the Commission concludes that the adoption of bright line rules, on balance, continue to play a valuable role in implementing the Commission's goals. The Commission has also decided to retain our existing framework of targeted, outlet-specific, multiple ownership rules, that cover the various media and perceived areas of potential competition and diversity concerns rather than adopting a single rule to cover all media.

47. The Commission is required to examine any proposed transfer of a broadcast license and must affirmatively find that the transfer is in the public interest. In the context of broadcast transactions, the Commission's analysis is simplified by the extensive body of structural rules it adopts herein. Thus, the extensive rulemaking proceeding used to develop these broadcast ownership rules takes full account of the Commission's public policy goals of diversity, competition, and localism. These rules squarely embody the Commission's public interest goals of limiting the effect of market power and promoting localism and viewpoint diversity.

48. The bright line rules the Commission establishes in this Order will protect diversity, competition, and localism while providing greater regulatory certainty for the affected companies than would a case-by-case review. Any benefit to precision of a case-by-case review is outweighed, in the Commission's view, by the harm caused by a lack of regulatory certainty to the affected firms and to the capital markets that fund the growth and innovation in the media industry. Companies seeking to enter or exit the media market or seeking to grow larger or smaller will all benefit from clear rules in making business plans and investment decisions. Clear structural rules permit planning of financial transactions, ease application processing, and minimize regulatory costs.

49. The Commission recognizes that bright line rules preclude a certain amount of flexibility. A case-by-case analysis would allow the Commission to reach decisions by taking into account particular circumstances of every case. For instance, bright line rules may be over-inclusive, by preventing

transactions that would result in increased efficiencies, or under-inclusive, by allowing transactions that would raise concerns, if the circumstances of the case were reviewed. However, the Commission's experience with the current case-by-case analysis used for radio transactions leads it to believe that this approach in the area of media ownership is fraught with administrative problems. Currently, any radio transaction that proposes a radio station combination that would provide one station group with a 50% share of the advertising revenue in the local radio market, or the two station groups with a 70% advertising revenue, undergoes additional public interest analysis. For each of these transactions, the staff conducts an individual competitive analysis and may request additional information from the parties if it is necessary in order to reach a decision on a particular transaction. The administrative time and resources required for such an undertaking are considerable. Moreover, such an approach hinders business planning and industry investment for all radio firms falling within the ambit of our case-by-case review. The Commission is not persuaded that this approach is necessary in order to administer its ownership rules effectively.

50. The bright line rules adopted today have been developed based upon the Commission's review of the media marketplace and our assessment of what ownership limits are necessary in order to promote our goals in applying ownership rules. The Commission is confident that the modified rules will reduce the chances of precluding transactions that are in the public interest or, alternatively, permitting transactions that are not in the public interest. In addition, the Commission has discretion to review particular cases, and the Commission is obligated to give a hard look both to waiver requests, where a bright line ownership limit would proscribe a particular transaction, as well as petitions to deny.

III. Modern Media Marketplace

A. Introduction—The Evolution of Media

51. Today's media marketplace is characterized by abundance. Traditional modes of media have greatly evolved since the Commission first adopted media ownership rules in 1941, and new modes of media have transformed the landscape, providing more choice, greater flexibility, and more control than at any other time in history. In short, the number of outlets for national and local

news, information, and entertainment is large and growing.⁵

52. Section 202 (h) requires the Commission to consider whether any of its broadcast ownership rules are "necessary in the public interest as a result of competition." This R&O confronts that challenge by determining the appropriate regulatory framework for broadcast ownership in a world characterized not by information scarcity, but by media abundance. This section tracks the history of the modern media marketplace to illustrate the rapid evolution of media outlets over the past sixty years.

B. History of the Modern Media Marketplace

53. *The Age of Radio.* At the time commercial broadcast radio was introduced during the early 1920s, newspapers were the primary source of news and information, with circulation reaching nearly 28 million readers. By 1926, just six years after the first official commercial broadcasts, there were 528 stations and 5.7 million radio sets, generating a weekly radio audience of 23 million listeners. Unlike today's targeted, niche programming, however, a typical radio station's programming in the early 1930's was largely "variety" format, including a small amount of many different types of programming. Notable and newsworthy events were, of course, the exception to the variety format. During World War II, radio proved a vital asset in the dissemination of news and public-service messages, and it boosted the morale of those remaining on the home-front.

54. *The Introduction of Television.* Although General Electric began regular television broadcasting in 1928, it was not until 1941 that the first commercial television station was introduced. In addition to a proliferation of new programming, many radio stars began to move their acts to television in the late 1940's. With World War II over, and the Depression behind them, Americans began to accept television as a cogent means of receiving information and entertainment. In 1951, just ten years after television's introduction to the public, there were more than 108 stations on the air and more than 15 million households with television sets.

55. *The Multimedia Landscape I—1960's.* By 1960, a multi-media landscape began to form, though media at that time was still dominated by broadcast radio and television. Forty

⁵ Today, there are more than 308 non-broadcast networks available for carriage by cable systems, whereas ten years ago in 1993, there were only 106 non-broadcast programming services available for carriage.

years after the introduction of commercial broadcast radio, and 19 years after the introduction of commercial broadcast television, there were 4,086 radio stations and 573 television stations. Approximately 45 million homes had a television in 1960, and about six million of those had more than one television. Relatively few markets had cable systems in 1960, and nationwide there were only about 750,000 cable subscribers. There were approximately 1,700 daily newspapers in 1960 with a total circulation of about 58 million readers. According to MOWG Study No. 1, the number of outlets per market in 1960 varied largely by size of the market.⁶ The smallest markets had few choices, while large markets had comparatively more outlets for news, information, and entertainment.

56. An informal analysis⁷ of the news and public interest programming available to the public over television in 1960, revealed that, in most markets, there was less than one-hour of national news programming broadcast daily by all the stations combined in a given market. Programming characterized as "public interest programming"⁸ on average was aired for about two to three hours per-station, per-day (or approximately six to nine hours of public interest programming produced per-day by all stations combined in the markets it reviewed).

57. *Television Evolves.* Between 1960 and 1963, several historical events were broadcast over television, changing the very medium itself and its role in society. The use of television by John F. Kennedy and Richard M. Nixon during the Presidential election of 1960, ushered in a new era in American politics and a new era for television as an important medium of communications. Television coverage of

Martin Luther King Jr.'s "I Have a Dream" speech provided activists nationwide the information and the inspiration on which to mobilize America into one of the most turbulent and progressive eras in its history. And when word of President Kennedy's assassination was announced in 1963, an estimated 180 million Americans watched their television sets almost continuously for four days, witnessing the same tragic event in unison.

58. *The Introduction of Non-Broadcast Networks.* From its beginnings in 1948, through the late 1960's, cable television extended the reach of broadcast television. Early cable systems were born out of the need to carry television signals into areas where over-the-air reception was either non-existent or of poor quality because of interference. The creation of nationally distributed, non-broadcast cable programming enabled cable to become a competitive medium for the dissemination of news, information, and entertainment. Unlike the general interest, "variety" programming of the broadcast television networks, many non-broadcast basic cable networks provided highly specialized programming and provided it on a 24-hour basis. Thus, the inclusion of non-broadcast networks in the array of media choices gave the public continuous access to national news, information, and entertainment.

59. In 1980, with the addition of numerous pay-TV and basic cable networks, there were more than 19.2 million subscribers, an increase of 95.3%. But as a competitor to broadcast radio and television, cable's appeal was primarily national in orientation. Although some regional and local non-broadcast networks were distributed during the 1970's and 1980's, the banner offerings of cable systems during that period were nationally-distributed networks.

60. *The Introduction of Home-Use Satellite Television Technology.* Home satellite dish ("HSD") technology was based on the same system used by cable operators to receive network signals from satellites for delivery over their terrestrial cable systems. HSD systems could gain access to hundreds of channels of programming further enhancing consumer access to non-broadcast television programming, much the same way cable served to enhance broadcast television service in its early years.

61. *The Multimedia Landscape II—1980's.* By 1980, traditional media still dominated mainstream use, but the public did have other options. Many could now choose among both broadcast

and non-broadcast television programming to access news, information and entertainment. In addition to the traditional broadcast television stations offered over-the-air and via cable systems, there were also approximately 20 nationally-distributed non-broadcast networks available to the public nationwide and an unknown number of regionally distributed non-broadcast networks. The number of media outlets per market varied in 1980 based on market size, as they had in 1960. Overall, however, most markets seemed to have at least doubled the number of television stations and station owners than they had in 1960.

62. The Commission's informal analysis of the news and public interest programming available to the public via television revealed that, on average, most television stations in the markets it reviewed were airing more local news programming in 1980 than they did in 1960, though some small market stations were airing less local news programming. In addition, in the large market that the Commission studied, New York, there were more television broadcast stations available to the public than there were in 1960, resulting in a greater total amount of local news produced in these markets, on a given day. In addition, a non-broadcast television network, CNN, aired national news programming for 24-hours per day, and was available to all those with access to cable or HSD systems. More broadcast television stations aired public interest programming in 1980 than in 1960, particularly in large and medium-sized markets. In addition, there were several new non-broadcast television networks providing public interest programming on a 24-hour basis. In short, the addition of nationally distributed non-broadcast television networks, an increase in the number independent and affiliate broadcast television stations and in the number of hours broadcast per station, resulted in an increase in the news and public interest programming available in markets of all sizes between 1960 and 1980.

63. *Competitive Pressure Builds: A Crowded Programming Market.* The amount of competitive programming available on cable continued to increase during the eighties and into the nineties. The concise format of a majority of non-broadcast programming networks was attractive to audiences who were developing a preference for scanning quickly through the many new channel offerings available to them. While some non-broadcast networks were providing general interest fare in the mold of the traditional broadcast networks, many

⁶ This market definition is not necessarily consistent with the market definition of the Commission's rules.

⁷ In this analysis, Commission staff examined current and historic *TV Guide* magazines to determine the amount of differing types of programming (local news, national news and public interest programming) provided by stations in markets of differing sizes. The study examined the amount of programming available in a sample day in three cities, New York, Little Rock, and Terre Haute, selected from the larger group of ten cities represented in MOWG Study No. 1. The three cities chosen for this particular informal study were each chosen to respectively represent small, medium, and large television markets. Programming schedules for between the hours of 6 am and midnight on July 1st of the given year were examined for each city to determine how much of each type of programming was available to consumers in the selected market. ("Three City Study").

⁸ Public Interest Programming is defined for these purposes as programming of cultural, civic, children's, family, public affairs and educational interest.

provided programming geared towards a particular audience interest. Regionally distributed non-broadcast networks also flourished in the 1980's through the 1990's. Some provided regional sports, while others provided regional and local news or general regional-interest programming.

64. When the Fox broadcast network launched as a challenger to the "Big Three" networks in 1985, it entered the market building on the niche concept employed by the non-broadcast networks. Fox provided general interest fare, like its broadcast competitors, but targeted its programming to the teenage demographic. Later, in January 1995, Paramount and Warner Brothers launched the UPN and WB networks, respectively, both building on similar demographics on which Fox had initially entered the market.

65. *Significant Technological Advances: Recorded Media, Digital Compression, and the Internet.* Several significant advances in technology during the 1980's and 1990's supplied the footing for increased competitive pressure on the media marketplace. The video-cassette recorder ("VCR") empowered the public with the ability to stray from the pre-set video programming schedule inherent in broadcast television content. Furthermore, content not available over other video media, or content which had been previously available over broadcast television was created specifically for VCR consumption. By 1986, more than 13 million VCRs had been sold in the United States.

66. Digital technology was used in the development of advanced satellite distribution systems. Direct broadcast satellite systems ("DBS") provided an all-digital transmission of video programming, employing a small satellite dish, practical for both rural and urban deployment. DBS provides more than 200 channels of video programming to subscribers. The presence of DBS in the market for the delivery of subscription video programming has expanded the market, such that now almost all television households have access to subscription video. In addition, the competitive presence of DBS has forced cable television services to expand channel capacity and service options. At the end of 1994, DBS services had approximately 600,000 subscribers. Today there are more than 18 million subscribers.

67. As a result of the widespread acceptance of DBS, cable television operators began replacing much of their original infrastructure, and began employing digital technology to

transmit high-quality video signals to their customers. Digital technology also expanded the channel capacity of the networks, enabling cable operators to provide vastly more channels of video programming, and furthered the ability of cable operators to implement advanced two-way services.

68. Digital versatile disc ("DVD") players were introduced in 1997, and the personal video recorder ("PVR") was introduced in 1999. PVR's use a hard disk drive, software, and other technology to digitally record and access programming. In addition to these other significant technological advancements of the 1980's and 1990's, the Internet has spawned an entirely new way of looking at media. Today the Internet affects every aspect of media, from video and audio, to print and personal communications. Whereas other forms of media allow for only a finite number of voices and editorially-controlled viewpoints, the Internet provides the forum for an unlimited number of voices, independently administered. Furthermore, content on the Web is multi-media; it can be read, viewed, and heard simultaneously. Since Web pages are stored on Web-hosting file servers, accessing Web content is a highly individualized activity, and any individual with access to a Web browser can access all available Web content 24-hours a day throughout the world.

69. Virtually every major media company has a corresponding Web site, today, and any individual with access to a Web-hosting file server can create a Web site for public access. As such, the Web provides an unrestrained forum for the dissemination and consumption of ideas. News and information are available on the Internet like they have never been available to the public before. Internet users can view the news source of their own choosing, or can use a news gathering service which presents information culled from thousands of news sources worldwide. Furthermore, Internet users can access content that may have appeared in print or on broadcast television at an earlier time, giving them greater control over traditionally available content.

70. *The Multimedia Landscape III—2000.* Since the 1960's, there has been tremendous growth in the media market. By 2000, American consumers had access to a multitude of media outlets, hundreds of channels of video programming, and enormous amounts of content not available just twenty, or even ten years earlier. There were more than 12,615 radio stations in 2000, and 1,616 broadcast television stations.

71. Approximately 100.8 million homes had a television in 2000 and 76.2 million of those had more than one television. There were 68.5 million cable subscribers in 2000, approximately 14.8 million DBS subscribers and 1.2 million HSD subscribers. There also were 1,480 daily newspapers in 2000 with a total circulation of 55.8 million readers. In addition to the traditional broadcast television stations offered over-the-air and via cable systems, there were 281 nationally-distributed non-broadcast networks available in 2000 and 80 regional non-broadcast networks. Approximately 42.5 million households subscribed to an Internet access provider in 2000.

72. The number of outlets per market also grew significantly between 1960 and 2000. The number of radio outlets grew by 142% from 1960 to 2000 and the number of independent radio station owners grew by 74% in that same time period. The number of television outlets grew by 217% from 1960 to 2000 and the number of independent television station owners grew by 150% in that same time period. The number of daily newspapers declined by 9% from 1960 to 2000 and the number of newspaper owners was the same in 2000 as it was in 1960.

73. The number of hours of news and public interest programming has also grown significantly since 1980. Although in most markets, only a few stations increased the amount of national news programming available from 1980, when national news was aired for about thirty to forty five minutes per station per day, there were more broadcast stations airing national news in 2003, and several non-broadcast news networks airing national news programming on a 24-hour a day basis. Public interest programming also has proliferated. Although television broadcast stations in various markets were airing about the same amount of public interest programming per-station in 2003 as they were in 1980, in 2003, there are more television broadcast stations per-market and numerous new non-broadcast networks providing such programming.

74. *The Current Competitive Landscape and Developments Since 2000.* Non-broadcast television programming continues to proliferate. We are moving to a system served by literally hundreds of networks serving all conceivable interests. Today, there are more than 308 satellite-delivered national non-broadcast television networks available for carriage over cable, DBS and other multichannel video program distribution ("MVPD")

systems. Of the 102 channels received by the average viewing home, the four largest broadcast networks have an ownership interest in approximately 25% of those channels.

75. Since its inception, non-broadcast programming has gained significantly in popularity as compared with broadcast programming. In 2002, for the first time, cable television collectively had more primetime viewers on average over the course of the year than broadcast programming. In June 2002, cable networks for the very first time collectively exceeded a 50% share for the month, while the broadcast networks collectively registered a 38% primetime share.

76. Broadcasters are currently experimenting with, and beginning to commercially deploy, digital and high-definition television ("DTV" and "HDTV"). Digital television offers improved picture quality, the ability to provide such additional enhancements as HTDV, multicasting, and interactivity. Cable operators and DBS service providers are also beginning to provide DTV and HDTV options.

77. Today's media marketplace also provides choices to the public on an entirely new, personal level. In addition to the Web, for example, video-on-demand ("VOD") is the newest technology being developed and deployed by cable and DBS operators. VOD services provide advertising-free material on a program-by-program basis. In addition, satellite radio became available in 2001, providing subscribers over 100 channels of commercial-free, digital audio.

78. In short, there are far more types of media available today, far more outlets per-type of media today, and far more news and public interest programming options available to the public today than ever before. Although many of these new outlets are subscription-based the competitive pressure placed upon free, over-the-air media has led to better quality and in some cases, an increase in the quantity of some types of content. In the next five to ten years, it expects more free, over-the-air content to become available as new technologies are applied to these traditional media.

IV. Local and National Framework

79. The Commission, in the R&O, adopts limits both for local radio and local television ownership. Both of these rules are premised on well-established competition theory and are intended to preserve a healthy and robust competition among broadcasters in each service. As explained in the R&O, however, because markets defined

for competition purposes are generally more narrow than markets defined for diversity purposes, the Commission's limits on radio and television ownership also serve our diversity goal. By ensuring that several competitors remain within each of the radio and television services, the Commission also ensures that a number of independent outlets for viewpoint will remain in every local market, thereby ensuring that our diversity goal will be promoted. Further, though, because local television and radio ownership limits cannot protect against losses in diversity that might result from combinations of different types of media within a local market, the Commission adopts a set of specific cross-media limits.

80. Similarly, by virtue of the staff's extensive information gathering efforts and the voluminous record assembled in this rulemaking docket, the Commission has, for the first time substantial evidence regarding the localism effects of our national broadcast ownership rules. The Commission can, therefore, with more confidence than ever, establish a reasonable limit on the national station ownership reach of broadcast networks. The Commission continues to prohibit a combination between two of the largest four networks primarily on competition grounds, but the beneficial effects of this restriction also protect our interest in preserving localism. In combination, the Commission's new national broadcast ownership reaches cap and our "dual network" prohibition will ensure that local television stations remain responsive to their local communities. In sum, the modified broadcast ownership structure the Commission adopts in the R&O will serve our traditional goals of promoting competition, diversity, and localism in broadcast services. The new rules are not blind to the world around them, but reflective of it; they are, to borrow from our governing statute, necessary in the public interest.

V. Local Ownership Rules

A. Local TV Multiple Ownership Rule

81. The current local TV ownership rule allows an entity to own two television stations in the same DMA, provided: (1) The Grade B contours of the stations do not overlap; or (2)(a) at least one of the stations is not ranked among the four highest-ranked stations in the DMA, and (b) at least eight independently owned and operating commercial or non-commercial full-power broadcast television stations would remain in the DMA after the proposed combination ("top four-

ranked/eight voices test"). Only those stations whose Grade B signal contours overlap with the Grade B contour of at least one of the stations in the proposed combination are counted as voices under the rule.

82. Having examined the competitive impact of other video programming outlets on television broadcast stations, the Commission concludes, in light of the myriad sources of competition to local television broadcast stations, that our current local TV ownership rule is not necessary in the public interest to promote competition. The Commission also concludes that media other than television broadcast stations contribute to viewpoint diversity in local markets. Because our current local TV ownership rule is premised on the notion that only local TV stations contribute to viewpoint diversity and does not account for the contributions of other media, the Commission concludes the current rule is not the best means to promote our diversity goal. Moreover, the Commission concludes that retaining our current rule does not promote, and may even hinder, program diversity and localism. However, the Commission finds that some limitations on local television ownership are necessary to promote competition. Accordingly, the Commission modifies our local TV ownership rule.

83. The Commission's modified local TV ownership rule will permit an entity to have an attributable interest in two television broadcast stations in markets with 17 or fewer television stations; and up to three stations in markets with 18 or more television stations. To further ensure that no single entity possesses excessive market power, however, the Commission will prohibit combinations which would result in a single entity acquiring more than one station that is ranked among the top four stations in the market based on audience share. As a result, no combinations will be permitted in markets with fewer than five television stations. Because the Commission has determined that Nielsen DMAs are the relevant geographic market, common ownership of stations in the same market will be subject to this standard without regard to whether the affected stations have overlapping contours, and the Commission eliminated the provision of its local TV ownership rule that permits same-market combinations where there is no Grade B contour overlap. The Commission also modifies our existing standard for waiver of the local TV ownership rule.

84. *The Current Rule Cannot Be Justified Under Section 202(h)*. Under Section 202(h), the Commission

considers whether the local TV ownership rule continues to be "necessary in the public interest as a result of competition."

85. *Competition.* The Commission concludes that the current local TV ownership rule is not necessary to protect competition. By limiting common ownership of television stations in local markets where at least eight independently owned TV stations would remain post-merger, the current rule prohibits mergers that would increase efficiency in small and mid-sized markets—mergers that would thereby promote competition. In addition, by limiting common ownership to no more than two television stations, the current rule prohibits efficiency enhancing mergers in the largest markets. The current rule also prohibits mergers among the top four-ranked stations.⁹ After reviewing all of the record evidence, the Commission concludes that this restriction remains necessary to promote competition, so it is retaining a prohibition on mergers of the top four-ranked stations in the modified local TV ownership rule adopted in the R&O.

86. The NPRM requested comment on the definition of the product and geographic markets in which broadcast television stations compete. Based on the record, the Commission concludes that broadcast television stations operate in three product markets: a market for delivered video programming ("DVP"); a video advertising market; and a video program production market. Although each of these markets is discussed in the R&O, the Commission's primary concern is promoting competition for viewers. Therefore, the Commission will focus on competition in the DVP market. It is this market that directly affects viewers. The advertising market and the program production market are of concern to the Commission only to the extent that protecting competition in these markets may add an extra level of protection for the public and enable all television broadcasters to compete fairly for advertising revenue and programming. What is critical to our competition policy goals, however, is the assurance of a sufficient number of strong rivals actively engaged in competition for viewing audiences. As long as there are numerous rival firms in the DVP market,

viewers' interests will be advanced. The Commission first analyzes the DVP market.

87. *The DVP Market.* The evidence in the record suggests that television viewers do not consider non-video entertainment alternatives and non-delivered video to be good substitutes for watching television. In defining the market, the Commission asks whether the availability of entertainment alternatives is sufficient to prevent a significant and non-transitory increase in price. If they were good substitutes to watching television, relative changes in prices or other competitive variables should change household consumption of television. The record evidence suggests, however, that, while the price of subscribing to cable and DBS has increased faster than the rate of inflation, these price increases have not resulted in households dropping their subscriptions to cable and DBS, or reducing the amount of time households spend watching television. Thus, DVP providers have indeed been able to impose non-transitory price increases. This suggests that the relevant product market is no broader than DVP and should not include all entertainment activities.

88. For most viewers the programming choices offered by local broadcast television stations and cable networks represent good alternatives for one another. Most households subscribe to cable or DBS and receive DVP from cable networks and local broadcast television stations. These viewers need only touch their remote control to switch between the programming offered by cable networks and that of local broadcast television stations. The ease of switching from broadcast to cable networks for these households provides strong incentives for cable networks and local broadcast television stations to provide programs that attract viewers. The Commission thus finds that all the broadcast television stations and cable networks available to a significant number of cable subscribers in a DMA should be included as participants in the market for DVP.

89. The programming quality delivered to the minority of households that do not subscribe to cable or DBS is protected by the majority of households that do subscribe. Although non-subscribing households have fewer program choices than subscribing households, broadcasters cannot reduce the viewer appeal of their programming to non-subscribing households, without also reducing the viewer appeal of their programming to subscribing households. Broadcasters deliver the same programming to both subscribing

and non-subscribing households. Thus, the majority of households that subscribe to cable or DBS assure that non-subscribing households receive appealing programming.

90. Although viewers easily switch between the programming offered by broadcast television stations and the programming offered by cable networks, broadcast television stations and cable networks may respond differently to changes in local market concentration. Therefore, in formulating our revised local broadcast television ownership rules, the Commission continues to draw a distinction between television broadcast stations and cable networks. It is unlikely that mergers between broadcast television stations in any local market would alter the competitive strategy of a national cable network. In contrast, local broadcast television stations offer a mix of national programming and local programming in a geographic area typically no larger than a DMA. As such, local broadcast television stations have incentives to respond to conditions in local markets. It is the unilateral and coordinated responses of local broadcast television stations to mergers between local broadcast television stations that may result in potential competitive harms. Thus, the Commission focuses on ownership of television broadcast stations, not cable networks, to promote competition in local television markets.

91. *Geographic Market for DVP.* As the Commission evaluates the competitive effects of mergers between local broadcast television stations, it must define the relevant geographic market for the DVP market. Generally, cable systems carry all the broadcast stations assigned to the DMA in which they are located, pursuant to the Commission's must-carry/retransmission consent requirements. Cable systems providing service to the majority of households also carry most major cable networks. As such, the relevant geographic market for DVP is the DMA for most mergers between local broadcast television stations.

92. *Efficiencies of Common Ownership of Television Broadcast Stations in DVP Markets.* The Commission recognizes that common ownership of stations may result in consumer welfare enhancing efficiencies. First, common ownership of broadcast television stations in a local market can facilitate efficiencies and cost savings. Joint operations can eliminate redundant studio and office space, equipment, and personnel, and increase opportunities for cross-promotion and counter-programming. The Commission's current rule hinders

⁹ "The 'top four-ranked station' component of this standard is designed to ensure that the largest stations in the market do not combine and create potential competition concerns. These stations generally have a large share of the audience and advertising market in their area, and requiring them to operate independently will promote competition."

the realization of efficiencies by prohibiting common ownership of television stations in most DMAs. To enhance the ability of broadcast television to compete with cable and DBS in more DMAs, the Commission believes that the potential efficiencies and cost savings of multiple station ownership should be available to stations in a larger number of DMAs than permitted by our current rule.

93. Common ownership of broadcast television stations in a local market may also spur the transition to digital television. In developing DTV build-out rules for broadcast stations, the Commission has recognized the particular financial challenges faced by stations in smaller markets. Nevertheless, many DTV construction costs do not vary with market size and thus it still may be relatively more difficult for stations in these markets to finance the transition to DTV.

94. The Commission believes that our modified rule, which permits the common ownership of at least two television stations in most markets, will have a beneficial impact on the DTV transition. One study shows that stations that are commonly owned and stations involved in joint operating arrangements are further along in the DTV transition. Common ownership could facilitate cost savings by sharing DTV equipment. Common ownership would also allow the expertise gained in transitioning one station to DTV to be transferred to other commonly owned stations.

95. The Commission's competition goal seeks to ensure that for each television market, numerous strong rivals are actively engaged in competition for viewing audiences. Although mergers among participants in the DVP market would not affect the number of delivered video program streams, they might adversely affect the types or characteristics of the programming offered by the merged entities to the detriment of viewers. The evidence for common ownership of two television stations, however, suggests that more viewers prefer the post-merger programming. The Commission therefore concludes that our current rule, which prohibits common ownership of broadcast television stations in most markets, is overly restrictive. Because some relaxation of the current rule to permit additional consolidation in local television markets would facilitate efficiencies and likely result in the delivery of programming preferred by viewers, the Commission concludes that our current rule cannot be justified on grounds of competition in the market for DVP.

96. *Video Advertising Market.* The Commission concludes that the current rule is not necessary to promote competition in the video advertising market. The Commission concludes that our local TV ownership rule restricts many broadcasters to suboptimal size and, therefore, hinders their ability to compete with other media for advertising revenue. That said, competitive broadcast television advertising markets may require a larger number of owners of DVP than are necessary to protect competition in the DVP market. As such, assuring competition in video advertising markets may provide the public with an added level of protection. A larger number of television station owners in a local television market may also lower the potential for the exercise of market power by any one broadcaster and, therefore, help smaller or non-consolidating broadcasters compete for advertising revenue.

97. The Commission has determined that broadcast television advertising is a relevant product market. Advertisers differ in their ability to substitute between alternative media. Although some advertisers that use broadcast television stations may consider cable networks or the advertising time sold by local cable operators to be good substitutes, other advertisers may not consider these alternatives to be good substitutes. In addition, most advertisers that use broadcast television stations do not consider radio, newspapers, and other non-video delivery media to be good substitutes.

98. Our experience suggests that common ownership of two local broadcast television stations has produced efficiencies without facilitating the exercise of market power in the broadcast television advertising market. In light of evidence detailed in the R&O, that the current rule prohibits some consumer welfare enhancing combinations, the Commission concludes that the current rule is overly restrictive and not necessary to protect competition in the broadcast television advertising market.

99. *Video Program Production Market.* The Commission concludes that the current rule is not needed to protect competition in the video program production market. Broadcast television stations, along with TV networks, cable networks, program syndicators, and cable and DBS operators purchase or barter for video programming. The channel capacity of today's cable operators and DBS operators provides many more opportunities for sellers of existing and new video programming, compared with 20 years ago. Many of

the programs sold today are specifically targeted to the niche audiences available on cable networks. In addition, many video programs initially sold to TV networks migrate to cable networks, and a few programs initially sold to cable networks migrate to local broadcast television stations. Same-market combinations are only of concern to the few program syndicators that sell their programming directly to individual local television stations. These program syndicators would not consider sales to group owners of television stations in multiple markets, TV networks, and cable networks to be good substitutes for the sale of programming to individual stations. These program syndicators play one television broadcast station against another in the same market to sell their programming. By precluding common ownership of broadcast television stations in most markets, our current rule provides for more owners of television broadcast stations in most markets than are necessary to assure that program syndicators receive a fair price for their programming.¹⁰ The Commission concludes, therefore, that the current rule is not necessary to protect competition in the video program production market.

100. *Localism.* The adoption of the local TV ownership rule was not predicated on promoting localism. To the contrary, the Commission has previously recognized that relaxation of the rule was likely to promote localism. The primary evidence of "programming and service" benefits was anecdotal evidence of increases in the amount of local news and public affairs programming aired by stations participating in LMAs.

101. The Commission concludes that our current local TV ownership rule poses a potential threat to local programming, and that modification of the rule is likely to result in efficiencies that will better enable local television stations to acquire content desired by their local audiences.

102. *Local Programming Quantity and Quality.* On balance, evidence presented by commenters concerning the amount and quality of local news and public affairs programming suggests that owners/operators of same-market combinations have the ability and incentive to offer more programming responsive to the needs and interests of their communities and that in many cases, that is what they do. Thus, modifications to the rule that will allow

¹⁰ The current rule ensures that there are at least eight independent owners in all markets with eight or more stations.

for greater common ownership are likely to advance our localism goal.

103. *Effect of Local Market Consolidation on Local Control Over Content.* Contrary to views expressed by some commenters, the Commission has no record evidence linking relaxation of our local ownership rule to a reduction in local control over content. The Commission also has no means of measuring the extent to which news professionals' fear of retribution by their employers is reducing the ability of television broadcast stations to offer news focused on the needs and interests of their local communities, nor can it connect such concerns to its local ownership rules.

104. *News Programming Costs and Viability of Local News Operations.* Several commenters contend that the rising cost of producing news and public affairs programming is forcing broadcasters to reduce news production and that relaxation of the local TV ownership rule would allow broadcasters to invest in new local news and public affairs programming, or at least to maintain existing programming. The Commission finds that the current local TV ownership rule is not necessary in the public interest to promote localism. More likely, the current rule is hindering our efforts to promote localism. Anecdotal and empirical evidence in the record demonstrates post-combination increases in the amount of local news and public affairs programming offered by commonly owned stations. Moreover, rising news production costs and other factors may cause broadcasters to turn to less costly programming options. Having found that there is a positive correlation between same-market combinations and the offering of local news, the Commission further agrees with those commenters who contend that modifying the local TV rule is likely to yield efficiencies that will allow broadcasters to invest in new local news and public affairs programming, or at least to maintain existing local programming.

105. *Diversity.* Section 202(h) requires that the Commission consider whether the local TV ownership rule is necessary in the public interest to promote our diversity goal. The current rule measures viewpoint diversity largely through its voice test, which ensures that all television markets have at least eight independent broadcast television voices. The Commission finds that multiple media owners are more likely to present divergent viewpoints. Upon review of the record in this proceeding as well as its own analysis of local

media markets, the Commission finds that media other than television broadcast stations contribute to viewpoint diversity in local markets. The data in the record indicate that the majority of markets have an abundance of viewpoint diversity. The Commission therefore concludes that its existing local TV ownership rule is not necessary to achieve its diversity goal. In order to promote viewpoint diversity, the Commission will rely on a combination of its cross media limits as well as revised local television and local radio ownership caps. The Commission also concludes that the current rule is not necessary to promote program diversity.

106. *Viewpoint Diversity.* The Commission recognizes that a single media owner may elect to present a range of different perspectives on a particular political or social issue. It may also be accurate that a single owner of multiple media outlets in a local market may have a greater incentive to appeal to more viewers by presenting more perspectives than do multiple owners of single outlets. Even if a single owner of multiple television stations in the same market has an enhanced ability and incentive to present a broader range of viewpoints, that single owner still retains "ultimate control over programming content, who is hired to make programming decisions, what news stories are covered, and how they are covered." The Commission concludes that it cannot rely exclusively on the economic incentives that may or may not be created by ownership of multiple television stations to ensure viewpoint diversity. However, because the Commission finds that other media contribute to viewpoint diversity in local markets, it concludes that the existing local TV ownership rule is not necessary to achieve its diversity goal.

107. *Contribution of Other Media to Viewpoint Diversity in Local Markets.* The local television ownership rule has traditionally focused only on the contribution of television broadcast stations to diversity in local markets. Based on the evidence in the record, including our own evaluation of the media marketplace, the Commission finds that media outlets other than television stations contribute significantly to viewpoint diversity in local markets, and that our current rule fails to account for this diversity.

108. The Commission finds that television broadcast stations are not the only media outlets contributing to viewpoint diversity in local markets. The market for viewpoint diversity and the expression of ideas is, therefore, much broader than the economic

markets in which broadcast stations compete. In particular, in focusing on the delivered video market alone, the Commission would ignore countless other sources of news and information available to the public. As a corollary, however, limits imposed on television station combinations designed to protect competition in local delivered video markets necessarily also protect diversity; indeed they are more protective of competition in the broader marketplace of ideas given the difference in market definition.

109. The Commission does not, therefore, necessarily disagree with those commenters who maintain that a local television ownership cap can help to protect the public's First Amendment interest in a robust marketplace of ideas. We disagree, however, to the extent that they advocate a diversity-based rule that looks to broadcast-only television voices. Accepting this narrowly-defined view would result in a rule that is overly restrictive both for competition and diversity purposes, because it would fail to include other participants in some relevant product markets and in the marketplace of ideas. Such an approach cannot be squared with our statutory mandate under section 202(h) or our desire to minimize the impact of our rules on the rights of speakers to disseminate messages.

110. Accordingly, by setting our local television ownership caps only so high as necessary to protect competition in the delivered video market, the Commission will achieve necessary protection for diversity purposes without unduly limiting speech. The current rule is not necessary to protect competition and, indeed, may be harming competition in the delivered video market. It likewise cannot be justified on diversity grounds as it is overly restrictive. The Commission's modifications to the rule remedy that failing.

111. *Program Diversity.* The local TV ownership rule has not traditionally been justified on program diversity grounds. However, the NPRM sought comment on whether common ownership of multiple stations promotes program diversity, and if so, how this affects the need for the current local TV ownership rule.

112. The Commission finds that modification of the current local TV ownership rule may enhance program diversity. Program diversity is best achieved by reliance on competition among delivery systems rather than by government regulation. The Commission's local TV ownership rule will ensure robust competition in local DVP markets. As long as these markets

remain competitive, the Commission expects program diversity to be achieved through media companies' responses to consumer preferences. Nothing in the record seriously calls that conclusion into question.

113. The Commission shares the concern of Children Now that the diversity of children's educational and informational programming could be reduced if commonly owned stations in the same market air the same children's programming. The Commission therefore clarifies that where two or more stations in a market are commonly owned and air the same children's educational and informational program, only one of the stations may count the program toward the three-hour processing guideline set forth in 47 CFR 73.761.

114. *Modification of the Local Television Ownership Rule.* Based on the Commission's section 202(h) determination that the current local TV rule is no longer necessary in the public interest to promote competition and diversity, as well as our finding that the current rule may hinder achievement of our localism policy goal, the Commission must either eliminate or modify our local TV ownership restrictions. The Commission concludes that elimination of the rule would result in harm to competition in local DVP markets, thereby harming the public interest. Elimination of the rule also would adversely affect competition in the advertising and program production markets. Accordingly, the Commission modifies the rule.

115. The Commission's modified local TV ownership rule will allow ownership combinations that satisfy a two-part test: a numerical outlet cap and a top four-ranked standard. Our outlet cap will allow common ownership of no more than two television stations in markets with 17 or fewer television stations; and up to three stations in markets with 18 or more television stations. In counting television stations for purposes of this outlet cap, the Commission will include full-power commercial and noncommercial television broadcast stations assigned by Nielsen to a given DMA. For purposes of counting the television broadcast stations in the market, the Commission will include only full power authorizations (*i.e.*, it will not include Class A TV, LPTV stations or TV translators). The Commission also will exclude from our count any non-operational or dark stations. Newly constructed television stations that have commenced broadcast operations pursuant to program test authority will be included in the DMA count.

Television satellite stations will be excluded from our count of full power television stations in the DMA where the satellite and parent stations are both assigned by Nielsen to the same DMA. A satellite station assigned to a DMA different from that of its parent, however, will be included in the TV station count for that DMA. DTV stations will be included in our count only if they are operating and are not paired with an analog station in the market. For purposes of our local TV ownership rule, a station will be considered to be "within" a given DMA if it is assigned to that DMA by Nielsen, even if that station's community of license is physically located outside the DMA. For purposes of our local TV ownership rule, geographic areas that are not assigned a DMA by Nielsen (*i.e.*, Puerto Rico, Guam, and the U.S. Virgin Islands) each will be considered a single market. Our current local TV multiple ownership rule does not restrict the number of noncommercial television stations that can be owned by one entity. Consistent with past practice, our modified rule also will not affect ownership of noncommercial television stations. The Commission's top four-ranked standard will prohibit combinations which would result in a single entity owning more than one station that is ranked among the top four stations in the market based on audience share. Hence, same-market combinations will not be permitted in markets with fewer than five television stations. For purposes of applying the top four-ranked standard, a station's rank will be determined using the station's most recent all-day audience share, as measured by Nielsen or by any comparable professional and accepted rating service, at the time an application for transfer or assignment of license is filed, the same method as under our current rule.

116. The contour overlap provision of the rule will be eliminated, and the modified rule will be applied without regard to Grade B contour overlap among stations. Thus, if two stations in a market do not have overlapping contours, they still cannot be combined unless there are five or more stations in the market and at least one station in the combination is not among the top four. The Commission has determined that, because of mandatory carriage requirements, the DMA—not the area within a particular station's Grade B contour—is the geographic market in which DVP providers compete. Therefore, permitting station combinations solely on grounds that they do not have overlapping contours

would be inconsistent with our market definition. The majority of viewers—including those who reside in geographically large DMAs—have access to television broadcast stations that they could not view over-the-air because they can view the stations via cable. Increasingly, local stations also are available via DBS. To avoid imposing an unfair hardship on parties that currently own combinations that do not comply with the modified rule, the Commission will grandfather existing combinations. In addition, because the Commission's assumption regarding DMA-wide carriage is not universally true, and in recognition of the signal propagation limitations of UHF signals, the Commission adopts a waiver standard that will permit common ownership of stations where a waiver applicant can show that the stations have no Grade B overlap and that the stations are not carried by any MVPD to the same geographic area.

117. The public is best served when numerous rivals compete for viewing audiences. In the DVP market, rivals profit by attracting new audiences and by attracting existing audiences away from competitors' programs. The additional incentives facing competitive rivals are more likely to improve program quality and create programming preferred by existing viewers. The R&O discusses how the Commission's analysis of competition in local DVP markets supports the modified rule.

118. *Evaluating Potential Competitive Harms Within Local DVP Markets.* Consistent with the Commission's competition policy goal, our local television ownership rule seeks to preserve a healthy level of competition in the market for DVP. The state of competition in this market affects the quality and diversity of programming content and therefore the overall welfare of DVP viewers. In formulating our local TV multiple ownership rule, the Commission must assess the nature of this competition and weigh the potential benefits and anticompetitive harms that may arise from the increase in market concentration that results from a single firm owning multiple broadcast stations in a market.

119. There are two potential competitive harms that may be caused by a single firm owning multiple television stations in a market. First, ownership of multiple stations may result in "unilateral effects," *i.e.*, the firm acquiring multiple licenses may find it profitable to alter its competitive behavior unilaterally to the detriment of viewers. An example of such an effect would be the decision to cancel local

news programming on one of the commonly-owned channels. Second, the acquisition of multiple licenses in a local market by a single firm may lead to "coordinated effects." That is, the increase in concentration may induce a joint change in competitive behavior of all the market participants in a manner that harms viewers.

120. The Commission recognizes the importance of competition from cable networks in the market for DVP. Nevertheless, in formulating our revised ownership rules, the Commission continues to draw a distinction between television broadcast stations and non-broadcast DVP outlets. This is because television broadcast stations and cable programming networks have different incentives to react to a change in local market concentration, which suggest differing levels of unilateral and coordinated effects. In particular, cable networks are almost exclusively offering national or broadly defined regional programming. Therefore, the profit-maximizing decisions of a national cable programmer reflect conditions in the national market. It is improbable that a change in concentration in any single local market would affect the competitive strategy of a national cable network. In contrast, the Commission needs to consider the possible competitive responses from other DVP outlets in local markets, which are almost exclusively television broadcast stations. Because of the differing footprints of cable networks and television broadcast stations, any possible competitive harms are more likely to arise from changes in the behavior of stations. Thus, the Commission's rules to promote local television competition are focused on ownership of television broadcast stations.

121. *Welfare Enhancing Mergers in Local Delivered Video Markets.* The standard approach to evaluating the competitive harms of an increase in horizontal market concentration is outlined in the DOJ/FTC Merger Guidelines. The DOJ/FTC Merger Guidelines recognize the HHI level of 1800 as the maximum level of "moderate concentration." The Commission chooses this threshold rather than the lower limit of 1000 because it recognizes the competitive pressures exerted by the cable networks. The 1800 threshold corresponds to having six equal-sized competitors in a given market. The DOJ/FTC Merger Guidelines however, are written not for a specific industry, but rather as guidelines intended for application across all industries. The Commission's rules are formulated for a specific

market—the delivery of video programming—and are based on an extensive record on the extent of competition in this market and the effect of our current local TV ownership rule. This record allows the Commission to craft a more finely-tuned rule for this industry.

122. First, the nature of the DVP market is such that there is constant product innovation with new program choices each season. In such a market, a firm's market share is more fluid and subject to change than in other industries. Hence a firm's "capacity" to deliver programming can be as important a factor in measuring the competitive structure of the market as its current market share. Second, as each broadcast station requires a license, the number of licenses that a firm controls in a market is the measure of its capacity to deliver programming. Therefore, as a starting point, a simple application of the DOJ/FTC Merger Guidelines six-firm threshold suggests that, a single firm holding three licenses in a market with 18 or more licenses, or a firm holding two licenses in a market with 12 or more licenses, would not raise competitive concerns. However, given the structure of the DVP market, a strict, overly simplistic application of the DOJ/FTC Merger Guidelines would potentially prohibit some welfare enhancing mergers and allow some anticompetitive mergers.

123. In local markets, there is a general separation between the audience shares of the top four-ranked stations and the audience shares of other stations in the market. A review of the audience shares of stations in every market with five or more commercial television stations (*i.e.*, 120 markets) indicates that in two-thirds of the markets, the fourth-ranked station was at least two percentage points ahead of the fifth-ranked station. Two percentage points represents a significant difference in audience share because for a station to jump from, for example, an eight share to a ten share, it would have to increase its audience share by 25%. Thus, although the audience share rank of the top four-ranked stations is subject to change and the top four sometimes swap positions with each other, a cushion of audience share percentage points separates the top four and the remaining stations, providing some stability among the top four-ranked firms in the market. Nationally, the Big Four networks each garner a season to date prime time audience share of between ten and 13 percent, while the fifth and sixth ranked networks each earn a four percent share. While there is variation in audience shares within

local markets, these national audience statistics are generally reflected in the local market station rankings. The gap between the fourth-ranked national network and the fifth-ranked national network represents a 60% drop in audience share (from a ten share to a four share), a significant breakpoint upon which the Commission bases the rule.

124. The Commission's analysis of the top four local stations is related to its analysis of the four leading broadcast networks in connection with the dual network rule. There the Commission concludes that Big Four networks continue to comprise a "strategic group" within the national television advertising market. That is due largely to those networks' continued ability to attract mass audiences. It is this network programming that explains a significant portion of continued market leadership of the top four local stations in virtually all local markets. Thus the continued need for the Dual Network rule to protect competition at the network level also supports our decision to separate ownership of local stations carrying the programming of Big Four networks.¹¹

125. Permitting mergers among top four-ranked stations also would generally lead to large increases in the HHI. Although the Commission believes that mechanical application of the *DOJ/FTC Merger Guidelines* may provide misleading answers to competitive issues in the context of local broadcast transactions, as a general matter, sufficiently large HHIs establish a *prima*

¹¹ The local television ownership rule is consistent with a key aspect of the Commission's national television ownership rule in recognizing competitive disparities among stations. The national television ownership cap recognizes competitive disparities between stations through use of the UHF discount, while the local television ownership cap recognizes competitive disparities between stations by prohibiting mergers of the top four-ranked stations in the market. The national ownership rule is an audience reach limitation, so it makes sense to adjust that limitation based on the diminished coverage of UHF stations. The local ownership rule, on the other hand, places a limitation on the number of stations that one entity may own in a market. Thus, that rule limits mergers of the top four-ranked stations in a market. Furthermore, in the local television ownership rule, we take account of a station's UHF status in considering certain waiver requests, as discussed further below. Finally, the Commission notes that the top-four merger restriction in the local television ownership rule and the UHF discount in the national television ownership rule, while analogous, are not identical and do not serve exactly the same purpose. The UHF discount is premised, in part, on promoting the development of new and emerging networks. This rationale does not apply in the local television ownership context because ownership of multiple stations in a market does not promote development of new networks. The top-four limitation in the local television ownership rule, in contrast, is premised on competition theory, which is not the basis for the national television ownership rule.

facie case in antitrust suits. By allowing firms to own multiple stations, but prohibiting combinations among the top four-ranked stations, the Commission enables the market to realize efficiency gains and improve the quality of product in the video programming market while mitigating the risk of harmful coordinated or unilateral competitive harms.

126. One reason that combinations involving top four-ranked stations are less likely to yield public interest benefits such as new or expanded local news programming is that such stations generally are already originating local news. Some commenters contend that the Commission has never demonstrated that top four-ranked stations are generally the market's news providers. Yet the data provided by some of these very commenters confirms that this is the case. Further, the Commission has determined that, because there are less than four stations in some markets, the total number of top four-ranked stations is 779. Therefore, fully 85% of top four-ranked stations offer local news. Because top four-ranked stations already provide local news programming, a combination involving more than one top four-ranked station is less likely to result in a new or enhanced local news offering than would a combination involving only one top four-ranked station.

127. The Commission has also determined that same-market combinations yield efficiencies that may expedite a station's transition to DTV. However, combinations involving more than one top four-ranked station also are less likely to provide public interest benefits in the form of new DTV service. The financial position of top four-ranked stations makes the transition to DTV more affordable for these stations. Top four-ranked stations also are more likely to have made the transition to DTV than other stations. The Commission therefore concludes that it is less likely that allowing same-market combinations involving more than one top four-ranked station will expedite the provision of DTV service to the public.

128. Permitting combinations among the top four would reduce incentives to improve programming that appeals to mass audiences. The strongest rival to a top four-ranked station is another top four-ranked station. Because top four-ranked stations typically offer programming designed to attract mass audiences, as opposed to niche audiences, a new popular program offered by one top four-ranked station will have a substantial negative impact on the audience shares of the other top four-ranked stations. The enormous

potential gains associated with new popular programs provide strong incentives for top four-ranked stations to develop programming that is more appealing to viewers than the programming of their closest rivals. The large number of viewers looking for new programs with mass audience appeal are the direct beneficiaries of this rivalry. When formerly strong rivals merge, they have incentives to coordinate their programming to minimize competition between the merged stations. Such mergers harm viewers.

129. The Commission's decision to allow common ownership of two television stations in markets with fewer than twelve television stations will result in levels of concentration above our 1800 HHI benchmark in markets with fewer than 12 television stations. The Commission permits this additional concentration because the economics of local broadcast stations justify graduated increases in market concentration as markets get smaller.¹² The record demonstrates that owners of television stations in small and mid-sized markets are experiencing greater competitive difficulty than stations in larger markets. Moreover, Congress and the Commission previously have allowed greater concentration of broadcast properties in smaller markets than in larger markets precisely because the fixed costs of the broadcasting business are spread over fewer potential viewers. The limits the Commission adopts in the R&O for local television ownership replicate this graduated tradeoff between optimal competition in the delivered video market (six station owners) and recognition of the challenging nature of broadcast economics in small to mid-sized markets.

130. Thus, the Commission must avoid an oversimplified application of the DOJ/FTC Merger Guidelines. In particular, the analysis suggests that anticompetitive harms may result from allowing the largest firms to merge, and that the Commission might lose welfare enhancing efficiency gains by

¹² For purposes of applying the Commission's cross media limits, which are diversity based, it found that markets with nine or more television stations have a sufficiently large number of media outlets that viewpoint diversity will be protected by its caps on local television and local radio ownership. Measuring the extent of diversity in a market is a separate question from measuring the extent of competition among a particular class of outlets, such as local television stations. Thus, a market with ten television stations can be characterized as "large" from a viewpoint diversity standpoint because of the substantial number of media outlets available in such markets, but "small to mid-sized" when considering solely competition in the delivered video market (which excludes outlets such as radio, newspaper, and the Internet).

disallowing mergers between stations with large audience shares and stations with small audience shares. To allow the market to realize these efficiency gains and prevent potential harms from undue increases in concentration, the Commission therefore allow combinations of two stations provided they are not both among the top four-ranked broadcast stations in the local market. In markets with at least 18 television stations, the Commission further allows a firm to own up to three stations (thus ensuring a minimum of six owners) provided that only one of them is ranked among the top four.

131. *Proposals to Retain the Existing Rule in its Current Form or With Minor Modifications.* A number of commenters urge the Commission to retain the existing rule, or make minor modifications. Children Now proposes that the Commission modify the existing rule by prohibiting common ownership of television stations with overlapping Grade B contours in the same market, as it did prior to its 1999 revisions to the rule. Other commenters urge the Commission to retain the existing rule, but to count only those voices that actually provide local programming. Children Now, among others, states that if the Commission chooses to revise the current rule by expanding the types of media voices that are considered for purposes of the local television ownership rule, it should raise the threshold voice count required to form a same-market combination.

132. The Commission has determined that retaining our current rule does not comport with our statutory mandate under section 202(h) on competition, diversity, or localism grounds. For the same reasons, the Commission disagrees with commenters who contend that an equally restrictive or more restrictive ownership rule is necessary in the public interest. Although our modified rule does not rely upon a "voice test," it calculates the number of stations one can own in a market based, in part, on the number of stations within that market. However, our decision to "count" only broadcast television stations is based on the likely responses of participants in the DVP market to changes in local market concentration, and is aimed at achieving competition in local markets.

133. Another commenter proposes that if the Commission relaxes the rule, it should prohibit common ownership of more than one station affiliated with a top four network. The Commission's revised rule prohibits common ownership of stations that are among the top four in terms of audience share. Although such stations are often

affiliated with top four networks, the Commission concludes that audience share rank is a more accurate measure of market power than network affiliation. Therefore, the Commission does not adopt the proposal to prohibit common ownership of more than one station affiliated with a top four network.

134. Another commenter asserts that while the Commission has ample justification for retaining the current rule, if it chooses to revise the rule, it should apply an "HHI-adjusted voice count" to local TV ownership. Under this proposal, the Commission would calculate the market shares of television broadcast stations in the relevant geographic market, which would be either the DMA or a "weighted average DMA," calculated to account for the fact that certain stations do not have cable carriage throughout the market. This commenter proposes that the Commission define highly concentrated markets as those with fewer than six equal-sized voices or a four-firm concentration ratio above 60%. Moderately concentrated markets would be those with between six and ten equal-sized voices or a four-firm concentration ratio of 40–60%. They further urge the Commission to prohibit any combination that would result in a highly concentrated market. Where a combination would result in moderate concentration, the commenter proposes that the Commission permit the combination only if it finds that the merger will serve the public interest and if the owner of the merging stations agrees to retain separate news and editorial departments in different subsidiaries of the merged entity.

135. The Commission's modified local TV ownership rule will ensure that there are at least six firms in significant number of markets (i.e., all markets with 12 or more television stations), much like the commenter's proposal. The proposal does not, however, adequately address record evidence of differences in the economics of broadcast stations in smaller markets. Much like the strict application of the DOJ/FTC Merger Guidelines, the proposed test would prohibit certain mergers that will result in welfare enhancing efficiencies. Accordingly, the Commission declines to adopt this proposal. With regard to the commenter's waiver proposal, the Commission does not agree that conditioning assignments/transfers on retention of separate news departments within separate subsidiaries of a merged entity is necessary to advance our diversity, competition or localism goals. Requiring compliance with our rules, rather than conducting case-by-case

evaluations or imposing merger conditions, is a more effective way to achieve these goals.

136. Entravision does not take a position on whether the rule should be relaxed, but proposes that if the rule is relaxed, the Commission should require periodic certification by owners of same-market combinations that they are not engaged in certain types of anticompetitive conduct that would adversely affect smaller broadcasters in their markets. The Commission does not agree with Entravision that modifying the local TV ownership rule will increase the likelihood of anticompetitive conduct by broadcasters that own more than one station in a market, or that a certification requirement is necessary to protect against such conduct. Certainly, if broadcasters engage in anticompetitive conduct that is illegal under antitrust statutes, remedies are available pursuant to those statutes. In addition, an antitrust law violation by a licensee would be considered as part of our character qualifications review in connection with any renewal, assignment, or transfer of a license.

137. *Proposals to Eliminate or Substantially Modify the Rule.* Several commenters propose that the Commission eliminate the current rule or substantially modify the rule in order to permit more same-market combinations. Among these are a proposal to allow common ownership of two television stations in all markets with four or more stations, a proposal to eliminate the top four-ranked standard, a proposal to eliminate the voice test provision of the rule but to retain the top four-ranked restriction, NAB's proposed "10/10" standard, and Hearst-Argyle's AMI proposal.

138. The Commission does not agree with commenters who propose that it eliminate all local television ownership restrictions. The Commission believes that the public is best served when numerous rivals compete for viewing audiences. In the DVP market, rivals profit by attracting new audiences and by attracting existing audiences away from competitors' programs. Monopolists, on the other hand, profit only by attracting new audiences; they do not profit by attracting existing audiences away from their other programs. The additional incentives facing competitive rivals are more likely to improve program quality and create programming preferred by viewers. Most commenters proposing elimination of the rule believe that antitrust authorities will protect against any public interest harms that may result from combined ownership of multiple

television stations in a market. The Commission does not agree with commenters who urge us to eliminate our rules and defer all competition concerns to the antitrust authorities.

139. The Commission concludes that, as compared to the modified rule, the rule modification proposals advanced by commenters are more likely to result in anomalies and inconsistencies, or will otherwise fail to serve our policy goals. For example, by proposing that the Commission permit common ownership of two television stations in all markets with four or more stations, Nexstar attempts to account for the differing economics of stations in small markets. However, unlike our modified rule, the Nexstar proposal does not protect against combinations of the market participants with the largest audience shares, combinations that are more likely to cause competitive harms. It also permits extremely high concentration levels in the very smallest markets—there could be as few as two competitors in markets with four television stations. The Commission finds that the levels of concentration permitted by the Nexstar proposal are likely to result in harm to competition in local DVP markets.

140. Similar competitive harms would result if the Commission were to adopt proposals to eliminate or modify the top four-ranked standard. Several commenters claim that the top four-ranked standard cannot be justified on diversity or competition grounds. The Commission is not relying on the top four-ranked provision of our modified local TV ownership rule to promote diversity, although the Commission recognizes that because the marketplace for ideas is broader than the DVP market, rules intended to promote competition also will promote diversity. The Commission disagrees with commenters' claims that the top four-ranked standard is not justified on competition grounds. At the time of our last review of the local TV ownership rule, the Commission lacked sufficient record data concerning competitors to local television stations. In the instant proceeding, the Commission faces no such shortage of evidence concerning which media compete with local TV. Having determined that television competes with all providers of DVP, the Commission has crafted a rule that appropriately takes account of competition from other sources of DVP, and will ensure competition in local DVP markets. The Commission does not agree that elimination of our top four-ranked standard, use of a top three-ranked standard, or use of a tiered system that would ban mergers among

top four-ranked stations only in the largest markets and permit certain top four-ranked combinations in smaller markets, would serve the public interest. The top four-ranked combinations are likely to harm competition in the DVP market, and are less likely to produce offsetting public interest benefits.

141. The Commission believes that a more targeted approach to account for possible harms of application of the top four-ranked restriction is to establish a waiver standard tailored to the top four-ranked restriction. This approach will preserve competition in the DVP market while accommodating those instances where application of the top four-ranked restriction would harm the public interest.

142. Belo takes a nearly opposite approach, proposing that the Commission permit same-market combinations provided that they satisfy our top four-ranked standard, but eliminate our voice test. The Commission agrees that, as it is used in our modified rule, a top four-ranked prohibition is an appropriate means of protecting against combinations that would have an enhanced ability or incentive to engage in anticompetitive conduct.

143. NAB proposes that the Commission permit combinations where at least one of the stations has had, on average over the course of a year, an all day audience share of ten or less (the "10/10" proposal). NAB asserts that the audience share data used for this calculation should include viewing of out-of-market broadcast stations and cable networks, to account for competition from these sources. NAB proposes that the Commission treat the 10/10 standard as a presumption, and urges us to consider proposed combinations that do not meet this standard (including same-market combinations of three stations) on a case-by-case basis, considering factors which the Commission discusses along with other waiver proposals. NAB urges the Commission to allow broadcasters to transfer combinations created pursuant to the 10/10 standard even if one or both stations has increased its viewing share above the ten threshold at the time of such transfer. NAB asserts that requiring licensees to find separate purchasers will be disruptive and will tend to discourage investment in broadcast stations. Of the commenters who support the 10/10 proposal, some support the proposal as advanced by NAB; others support it with modifications; others suggest it be used only as a safe harbor, allowing for many other types of combinations.

144. The record in this proceeding supports a rule that will allow financially weak stations to combine with each other or with stronger stations in order to realize efficiencies. The 10/10 proposal, however, would permit mergers between financially strong stations, including top four-ranked stations, in a significant number of markets. Neither the record nor standard competitive analysis justifies a rule that will permit such mergers. The Commission's analysis suggests that combinations among the top four rated broadcast stations would create welfare harms. The Commission also finds that the proposal does not adequately justify the use of ten as a threshold. The record demonstrates that in many markets ten is the average share for any given station, sometimes even the very highest rated stations, in the market. In addition, the proposal provides no clear rationale to justify why, for example, a combination involving two stations with respective audience shares of 25 and 9 should be permitted, although a combination involving two stations with respective audience shares of 12 and 11 should be prohibited. For these reasons, the Commission rejects the 10/10 approach.

145. Hearst-Argyle advances an alternative proposal that would permit common ownership of any number of television stations in the same market provided that the stations' combined audience share does not exceed 30%. Combinations that would result in an audience share above 30% would be subject to an Audience Market Index ("AMI") cap that is calculated in a manner similar to an HHI, but uses audience share data rather than advertising share data. If a combination would result in AMI below 1000, the combination would be permitted, regardless of the increase in concentration. A combination resulting in an AMI between 1000 and 1800 would be permitted if the increase in AMI is less than 100 points, and a combination resulting in an AMI above 1800 would be permitted only if it increases AMI by less than 50 points. Hearst-Argyle asserts that by using an audience share metric, its proposal objectively measures and protects both diversity and competition. Hearst-Argyle contends that its proposal also is likely to survive judicial scrutiny because its 30% hard cap and AMI analysis are both based on antitrust law and analysis. In addition, Hearst-Argyle contends that its proposal avoids several pitfalls of the NAB 10/10 proposal.

146. The Commission does not agree with Hearst-Argyle that simply because courts have accepted presumptions of

30% market share as demonstrating market power in the context of the antitrust statutes, it should establish a presumption that 30% is an appropriate audience share limit. The Hearst-Argyle proposal does not place specific limits on the number of broadcast television stations an entity could own in a local market. An entity could acquire any combination of stations in a local market as long as its audience share is 30 percent or less, and the AMI cap is satisfied. In many markets, this approach would permit an entity to own four, five, six or more stations. The Commission does not believe that consolidation in a market of a large number of stations with low audience share is in the public interest. Although an individual station may currently have a small audience share in the DVP market, each station's audience share has the potential to change over time. The number of stations a firm owns is a measure of its capacity to deliver programming. This capacity can be as important a factor in measuring the competitive structure of the market as is its current audience share. Moreover, much like the 10/10 proposal, the AMI test will frequently result in common ownership of stations ranked among the top four in the market. It will also permit common ownership of three stations in many more markets than will our modified rule—including some very small markets. As shown by one of Hearst-Argyle's own examples, under certain circumstances, the AMI test would even permit common ownership of three of the top four-ranked stations in a market with just five full-power television stations. Because of the anticompetitive harms that would result from combinations allowed by the AMI test, the Commission will not adopt Hearst-Argyle's AMI proposal.

147. NAB proposes an alternative that would combine the 30% audience share cap of the AMI test with a ban on common ownership of more than three stations in any market, and a ban on common ownership of more than two top four-ranked stations in the same market. For similar reasons, the Commission does not accept this proposal. The Commission believes that (1) a ban on combinations among the top four-ranked stations is necessary to promote competition; (2) a 30% share cap would permit combinations that undermine that goal; and (3) ownership of three television stations in markets with fewer than 18 stations would harm competition by consolidating capacity in the hands of too few owners. The Commission's modified rule better

effectuates our goal of promoting competition in local DVP markets.

148. *Waiver Standard.* In the Commission's Local TV Ownership Report and Order, it established a waiver standard for purposes of our local TV ownership rule. The standard permits a waiver of the current rule where a proposed combination involves at least one station that is failed, failing, or unbuilt. The Commission defines a "failed station" as one that has been dark for at least four months or is involved in court-supervised involuntary bankruptcy or involuntary insolvency proceedings. The Commission's "failing" station standard provides that it will presume a waiver is in the public interest if the applicant satisfies each of the following criteria: (1) One of the merging stations has had low all-day audience share (*i.e.*, 4% or lower); (2) the financial condition of one of the merging stations is poor; and (3) the merger will produce public interest benefits. The Commission's unbuilt station waiver standard presumes a waiver is in the public interest if an applicant meets each of the following criteria: (1) The combination will result in the construction of an authorized but as yet unbuilt station; and (2) the permittee has made reasonable efforts to construct, and has been unable to do so. For each type of waiver, the Commission also requires that the waiver applicant demonstrate that the "in-market" buyer is the only reasonably available entity willing and able to operate the subject station, and that selling the station to an out-of-market buyer would result in an artificially depressed price for the station. Any combination formed as a result of a failed, failing, or unbuilt station waiver may be transferred together only if the combination meets our local TV ownership rules or one of our three waiver standards at the time of transfer.

149. The Commission's rationale for adopting these waiver criteria was that failed, failing and unbuilt stations could not contribute to competition or diversity in local markets, and that the public interest benefits of activating a dark or unbuilt station, or preventing a failing station from going dark, outweighed any potential harm to competition or diversity. Most commenters addressing the waiver standard urge us to relax or eliminate the standard.

150. The Commission concludes that tightening our waiver standard would not promote our public interest goals. Moreover, the Commission agrees with the NAB and other commenters who urge us to expand our waiver standard

to include consideration of combinations that will yield other public interest benefits. The Commission's treatment of waivers will follow the competition principles established in the DOJ/FTC Merger Guidelines, with a specific focus on the industry at hand. In particular, as in the DOJ/FTC Merger Guidelines, the Commission will consider combinations that involve firms that are not failing but that could better serve the public interest through a merger not otherwise permitted by our rules. The Commission also will consider a waiver of our local TV ownership rule where a proposed combination involves stations that do not engage in head-to-head competition because they do not have overlapping Grade B contours and are not carried by MVPDs in the same geographic areas.

151. First, for failed, failing, and unbuilt stations, the Commission retains the existing waiver standard with one exception. We remove the requirement that a waiver applicant demonstrate that it has tried and failed to secure an out-of-market buyer for the subject station. In many cases, the buyer most likely to deliver public interest benefits by using the failed, failing, or unbuilt station will be the owner of another station in the same market. The Commission believes that the efficiencies associated with operation of two same-market stations, absent unusual circumstances, will always result in the buyer being the owner of another station in that market.

152. Otherwise, however, a failed, failing, or unbuilt station clearly cannot contribute to localism, competition or diversity in local markets. Nothing in the record in the instant proceeding leads us to find otherwise. The Commission concludes that the public interest benefits of activating a dark or unbuilt station outweigh the potential harm to competition or diversity. Therefore, if it can be shown that, absent the transfer, the licensee's assets will exit the market, then the transfer is not likely to either enhance market power or facilitate its exercise. In such cases, the granting of a waiver would not be inconsistent with our competition goal.

153. The record also suggests that local television stations outside the largest markets may, in some cases, better serve the public interest through station combinations not permitted by our local television ownership rules. The Commission's new rules allow one company to own two stations in a market provided both are not ranked in the top four in ratings. This top four-ranked prohibition promotes competition by preventing the strongest competitors in each market from

combining. The top four restriction is premised on evidence that the four leading stations in each market are already the strongest competitors and that combinations among them would harm the public interest by diminishing competition in the DVP market. However, NAB data shows that, as a class, smaller market stations (including both top four and other stations) are less effective competitors in the DVP market relative to stations in large markets. Therefore, the Commission allowed station combinations that would not be permitted in larger markets. However, our concern for the economics of broadcast television in small markets does not lead us to relax the top four prohibition generally because the Commission concluded that this restriction remains necessary to promote competition in the DVP market. Nonetheless, the Commission does recognize that there may be instances where application of this top four restriction will disserve the public interest by preventing marginal—but not yet "failing"—stations from effectively serving the needs of their communities. Such stations may not be financially capable of producing the amount of news and local affairs programming that they would like to provide their communities, which in turn may make them less competitive in the local marketplace. Accordingly, in order to effectuate our goals of diversity, localism, and competition, the Commission will consider waivers of the top four-ranked restriction in markets with 11 or fewer television stations. Those are the markets in which the Commission has already recognized that the economics of broadcast television justify relatively greater levels of station consolidation and better serve the public interest.

154. In considering waivers of our top four-ranked restriction, the Commission will consider a number of factors. For instance, mergers between stations that reduce a significant competitive disparity between the merging stations and the dominant station in the marketplace are particularly likely to be pro-competitive. Accordingly, waiver applicants should supply television ratings information for the four most recent ratings periods for all local stations so that the Commission may assess the competitive effect of the merger.

155. Second, the Commission also will evaluate the effect of the proposed merger on the stations' ability to complete the transition to digital television. Waiver applicants claiming that the merger is needed to facilitate

the digital transition should provide data supporting this assertion.

156. The Commission also will consider the effect of the proposed merger on localism and viewpoint diversity. Waiver applicants should submit information about current local news production for all stations in the local market and the effect of the proposed merger on local news and public affairs programming for the affected stations. Applicants stating that the merger is needed to preserve a local newscast should document the financial performance of the affected news division. Applicants for waiver of our top four-ranked restriction must demonstrate that the proposed combination will produce public interest benefits. As in the context of failing station waivers, the Commission will require that, at the end of the merged stations' license terms, the owner of the merged stations must certify to the Commission that the public interest benefits of the merger are being fulfilled. This certification must include a specific, factual showing of the program-related benefits that have accrued to the public. Cost savings or other efficiencies, standing alone, will not constitute a sufficient showing. Finally, the Commission's review of waiver requests will account for the diminished reach of UHF stations. As discussed in our national television ownership rule section, UHF stations reach fewer households than VHF stations because of UHF stations' weaker broadcast signals. Reduced audience reach diminishes UHF stations' impact on diversity and competition in local markets. Accordingly, the Commission will consider whether one or both stations sought to be merged are UHF stations.

157. The revised local TV ownership rule no longer permits combinations involving stations that do not have overlapping Grade B contours, on grounds that, because of statutory mandatory carriage requirements, most stations compete with each other on a DMA-wide basis. However, the Commission recognizes that certain stations are not carried throughout their assigned DMAs, and thus do not compete with each other within their assigned markets. Accordingly, the Commission will consider waivers of our local TV ownership rule where a party can demonstrate that the signals of the stations in a proposed combination:

- Do not have overlapping Grade B contours; and
- Have not been carried, via DBS or cable, to any of the same geographic areas within the past year.

158. With respect to a licensee's ability to transfer or assign a

combination involving a station acquired pursuant to a waiver, the Commission does not find support in the record for permitting such transfers where they do not comply with our rules. The transfer or assignment of such a combination must comply with our rules or waiver standards at the time an application to transfer or assign the station is filed.

159. *Satellite Stations.* Television satellite stations retransmit all or a substantial part of the programming of a commonly owned parent station. Satellite stations are generally exempt from the Commission's broadcast ownership restrictions. The Commission believes that continued exemption of satellite stations from the local TV ownership rule is appropriate. Our satellite station policy rests on such factors as the questionable financial viability of the satellite as a stand-alone facility, and establishment of service to underserved areas. By adding stations to local television markets where stations otherwise would not have been established, the policy advances the same goals as those underlying our local TV ownership restrictions. Since these stations are licensed only if they cannot survive as standalone, independently operated stations, the Commission finds that exempting them from the local TV ownership rule will not harm competition or diversity.

160. *Transferability of Combinations Under Modified Rule.* If an entity acquires a second or third station that complies with the Commission's modified rule, it will not later be required to divest if the number of stations in the market subsequently declines below the level consistent with our outlet cap, or if more than one commonly owned station subsequently becomes a top four-ranked station in the market. The impact of such a "springing" rule would be highly disruptive to the market. Like our other rules, however, the Commission will not ignore the public interest underpinnings at the time of a subsequent sale of the combination. Thus, absent a waiver, a combination may not be assigned or transferred to a new owner if the combination does not satisfy our local TV ownership cap at the time of the proposed assignment or transfer.

B. Local Radio Ownership Rule

161. The local radio ownership rule limits the number of commercial radio stations overall and the number of commercial radio stations in a service (AM or FM) that a party may own in a local market. In the 1996 Act, Congress directed the Commission to revise those limits to provide that: (1) In a radio

market with 45 or more commercial radio stations, a party may own, operate, or control up to 8 commercial radio stations, not more than 5 of which are in the same service (AM or FM); (2) in a radio market with between 30 and 44 (inclusive) commercial radio stations, a party may own, operate, or control up to 7 commercial radio stations, not more than 4 of which are in the same service (AM or FM); (3) in a radio market with between 15 and 29 (inclusive) commercial radio stations, a party may own, operate, or control up to 6 commercial radio stations, not more than 4 of which are in the same service (AM or FM); and (4) in a radio market with 14 or fewer commercial radio stations, a party may own, operate, or control up to 5 commercial radio stations, not more than 3 of which are in the same service (AM or FM), except that a party may not own, operate, or control more than 50 percent of the stations in such market.

162. The Commission concludes that the numerical limits in the local radio ownership rule are "necessary in the public interest" to protect competition in local radio markets. The Commission concludes, however, that the rule in its current form does not promote the public interest as it relates to competition because (1) its current contour-overlap methodology for defining radio markets and counting stations in the market is flawed as a means to protect competition in local radio markets, and (2) the current rule improperly ignores competition from noncommercial radio stations in local radio markets. To address those concerns, the Commission modifies the rule to replace the contour-overlap market definition with an Arbitron Metro market and to count noncommercial stations in the radio market; and the Commission initiates a new rulemaking proceeding as part of this item to define markets for areas of the country where Arbitron Metros are not defined. Although the Commission primarily relies on competition to justify the rule, the Commission recognizes that localism and diversity are fostered when there are multiple, independently owned radio stations competing in the same market; its competition-based rule, therefore, will also promote those public interest objectives. The Commission also concludes that, consistent with our focus on competition, joint sales agreements ("JSAs") will result in attribution of the brokered station to the brokering party under certain conditions.

163. *Section 202(h) Determination.* Under section 202(h), the Commission considers whether the local radio

ownership rule continues to be "necessary in the public interest as a result of competition." In determining whether the rule meets that standard, the Commission considers whether the rule serves the public interest, which, in radio broadcasting, traditionally has encompassed competition, localism, and diversity. The Commission examines each of these public interest objectives in turn.

164. *Competition.* In the Policy Goals section, the Commission explained how the public interest is served by preserving competition in relevant media markets. Although limits on local radio ownership are generally necessary to serve the public interest, the Commission concludes that the current local radio ownership rule does not serve the public interest as it relates to competition for two reasons. First, the current rule uses a methodology for defining radio markets and counting the number of radio stations in a market that has not protected against undue concentration in local radio markets. Second, the current rule fails to account for the competitive presence of noncommercial stations in a market. Accordingly, the Commission modifies the rule to address these concerns.

165. *The Product Market Definition.* To measure the state of competition in radio broadcasting, the Commission first must determine the relevant product markets in which radio stations compete and the other media, if any, that compete in those markets. The Commission concludes that radio broadcasters operate in three relevant markets: radio advertising, radio listening, and radio program production.

166. *The Radio Advertising Market.* The Commission concludes that advertisers do not view radio stations, newspapers, and television stations as substitutes. A number of commenters have argued that there is little substitution between advertising on broadcast TV and newspapers. Further, empirical studies confirm that advertisers do not view ads in newspapers and broadcast radio as substitutes. The Commission acknowledges that the studies discussed in the full text of the R&O focus on national advertising markets. Nothing has been submitted in the record, however, that suggests that local advertisers are better able to substitute between radio and other media than are national advertisers, and the studies' results are consistent with the results of MOWG Study No. 10, which did examine local advertisers.

167. *The Radio Listening Market.* The Commission concludes that radio

listening is a relevant product market. There is no evidence that radio listeners consider non-audio entertainment alternatives to be good substitutes for listening to the radio. The Commission therefore disagrees with commenters who argue that the relevant market should be broadened from radio listening to include non-audio entertainment options. The Commission also disagrees with commenters who argue that the relevant product market should be broadened to include other delivered audio media, such as Internet audio streaming and satellite radio. Internet audio streaming may be a substitute for broadcast radio when listening takes place while working on a computer or in a small office environment. A significant portion of audio listening, however, occurs while driving or otherwise outside of the office or home. Since most people do not access Internet audio from a mobile location, the Commission concludes that Internet audio streaming is not a substitute for broadcast radio for a significant portion of audio listening. Similarly, satellite radio may be a substitute for broadcast radio for the fewer than 600,000 people that subscribe to satellite radio. But the vast majority of the population does not subscribe to a satellite radio service. Accordingly, the Commission concludes that satellite radio is not yet a good substitute for broadcast radio for most listeners.

168. Preserving competition for listeners is of paramount concern in the Commission's public interest analysis. Although competition in the radio advertising market and the radio program production market indirectly affects listeners by enabling radio broadcasters to compete fairly for advertising revenue and programming—critical inputs to broadcasters' ability to provide service to the public—it is the state of competition in the listening market that most directly affects the public. When that market is competitive, rivals profit by attracting new audiences and by attracting existing audiences away from competitors' programs. Monopolists, on the other hand, profit only by attracting new audiences; they do not profit by attracting existing audiences away from their other programs. Because the additional incentives facing competitive rivals are more likely to improve program quality and create programming preferred by existing listeners, it is critical to the Commission's competition policy goals that a sufficient number of rivals are actively engaged in competition for

listening audiences. Limits on local radio ownership promote competition in the radio listening market by assuring that numerous rivals are contending for the attention of listeners.

169. *Radio Program Production Market.* Radio stations seek to acquire audio programming from a variety of audio program producers. Many sellers of audio programming do not have adequate substitutes for local radio stations. The record indicates that radio stations are an important mechanism by which the American public is made aware of new music. Moreover, the record suggests no reasonable alternative available to producers of radio talk shows—a type of radio programming that has become increasingly popular in the last decade. To the extent that the radio stations in a local community are owned by one or a few firms, those firms could constitute a bottleneck that would impede the ability of radio programming producers to make their programming available to consumers in that community. Accordingly, the Commission concludes that radio programming constitutes a separate relevant product market.

170. *Geographic Market Definition.* There is no serious dispute that the relevant geographic market for the product markets in which radio stations compete is local. The parameters of the local market, however, have been a source of considerable debate and controversy. The Commission currently uses a contour-overlap methodology for defining radio markets and determining the number of radio stations that are in those markets. That methodology has been subject to intense criticism for producing unrealistic and irrational results. Based on the record and our own experience, the Commission now concludes that the contour-overlap system should be replaced by a more rational and coherent methodology based on geographically-determined markets to promote more effectively our competition policy goals.

171. *Problems with the Existing Radio Market Definition and Counting Methodologies.* The Commission currently relies on the principal community contours of the commercial radio stations that are proposed to be commonly owned to determine the relevant radio market in which those stations participate and to count the other radio stations that are in the market. We first consider whether an area of overlap exists among the principal community contours of all of the stations proposed to be commonly owned. If no such overlap area exists, then the radio stations involved are presumed to be in separate radio

markets, and the local radio ownership rule is not triggered. If one or more areas of contour overlap exist, however, the rule is triggered, and the Commission must determine whether the proposed combination complies with the limits specified in the rule.

172. The Commission first asks how many stations a party would own in the relevant radio market (*i.e.*, the "numerator" of the fraction upon which the numerical limits in the local radio ownership rule are based). Under our current methodology, the Commission deems the radio stations whose principal community contours mutually overlap to be in the same market, and it deems those stations to be the only stations owned by the common owner in that market. In some instances, a radio station's principal community contour will overlap some, but not all, of the principal community contours of other commonly owned radio stations. In those cases, separate radio markets will be formed from the mutual contour overlaps of different subsets of commonly owned radio stations. We nevertheless apply the same rule: In each of those separate markets, it deems the radio stations whose principal community contours mutually overlap to be in the same market, and it deems those stations to be the only stations owned by the common owner in that market.

173. After calculating the numerator for a particular radio market, the Commission next determines the size of the market. To do this, the Commission again relies on principal community contours. The Commission counts as being in the relevant radio market the radio stations that are included in the numerator. We add to this number every other commercial radio stations whose principal community contour overlaps the principal community contour of at least one of the stations counted in the numerator. The total represents the size of the market against which the number of commonly owned stations is evaluated to determine whether the proposed combination complies with the local radio ownership rule.

174. One significant problem with the current contour-overlap system is what is known as the "Pine Bluff" problem, or the "numerator-denominator" inconsistency. A party is deemed to own only those stations that are represented in the numerator. In calculating the denominator, however, any radio station whose principal community contour overlaps the principal community contour of at least one of the radio stations in the numerator is counted as being in the market, regardless of who owns that

station. As a result, the denominator may include radio stations that are owned by the same party that owns the radio stations represented in the numerator. Because those stations are counted in the denominator, they are by definition "in" the market, but they would not count against the party's ownership limit in that market unless their principal community contours overlap the principal community contours of all of the radio stations in the numerator.

175. The numerator-denominator inconsistency has two potential and interrelated effects that highlight the problems with our current methodology. First, by counting commonly owned stations in the denominator that are not counted in the numerator, a party may be able to use its own radio stations to increase the size of the radio market and thereby "bump" itself into a higher ownership tier. Second (and more commonly), the inconsistency enables a party to own radio stations that are in the relevant radio market (as determined by our rules) without having those stations count against the party's ownership limit in that market. The current system of counting radio stations thus enables a party, by taking advantage of the effects of the numerator-denominator inconsistency, to circumvent our limits on radio station ownership, which are intended to protect against excessive concentration levels in local radio markets.

176. The Commission cannot fix the problems associated with our current methodology merely by excluding commonly owned stations from the denominator or including those stations in the numerator. If the Commission excludes commonly owned stations from the denominator, then it would be determining which radio stations are in the market based on who owns those stations, a distinction that would be both unprincipled and unprecedented in the history of competition analysis. If the Commission includes in the numerator commonly owned stations represented in the denominator, a party's ownership level in a particular market may be overly inflated by outlying stations far from the area of concentration. Each of these proposals thus would create new "reverse" anomalies to cancel out the effects of the numerator-denominator inconsistency.

177. The Commission's experience with the current contour-overlap methodology leads us to the conclusion that it is flawed as a means to preserve competition in local radio markets, and that the Commission should take an entirely new approach to market definition. As is clear from our

description of the current market definition and counting methodologies, the size of a radio market under our current system is unique to the proposed combination being evaluated. A different combination of radio stations, or the addition or subtraction of a radio station from the combination, has the potential to change the area covered by the principal community contours of the combination and, thus, to change the number of commercial radio stations that are counted as being in the market. This is a singular and unusual method for determining the size of a market. Under traditional antitrust principles, the "relevant geographic market" is used to identify the parties that compete in that market. Our contour-overlap methodology, in contrast, uses the outlets of one party—commonly owned stations with mutually overlapping principal community contours—to define the local radio market and identify other market participants. This is an inherent aspect of the contour-overlap methodology that is not in line with coherent and accepted methods for delineating geographic markets for purposes of competition analysis.

178. The conceptual problems with the contour-overlap methodology have significant implications for our ability to guard against undue concentration in local radio markets. Because radio stations with larger signal contours are more likely to reach a wider audience, consolidation of these radio stations in the hands of one or a few owners increases the potential for market power in local radio markets. Yet the contour-overlap system actually encourages consolidation of powerful radio stations because stations with larger signal contours are more likely to create larger radio markets, which make it more likely that a party would be able to acquire additional radio stations in that market. Thus, by creating this perverse incentive, the contour-overlap methodology may undermine the primary public interest rationale for the local radio ownership rule.

179. Other aspects of our contour-overlap methodology also limit its usefulness in protecting and promoting competition. The method for determining which stations are in a market often does not reflect the area of true competition among radio stations. The Commission currently counts a radio station as being a competitor in a radio market if its principal community contour overlaps any one of the principal community contours that form the market boundary. Those radio stations may be too distant to serve effectively either the listeners or the

advertisers in the geographic area in which concentration is occurring, but they are included in the market because of the happenstance of the size, shape, or location of one or more of the principal community contours of the radio stations involved.

180. The contour-overlap methodology also makes it difficult to measure concentration levels in local radio markets accurately. As currently implemented, the methodology does not examine the number of radio station owners in a market; it only considers how many radio station signals cross the market boundary created by the principal community contours of commonly owned stations with mutually overlapping contours. Those signals may be owned by only one other party; indeed, because of the numerator-denominator inconsistency, those radio stations may be owned by the same party. The current methodology simply does not take ownership into account, which makes an accurate measure of local radio concentration difficult to achieve.

181. Consistency suffers as well. Under the contour-overlap methodology, every combination operates in a radio market that is unique to that combination. Thus, there is no common metric that the Commission can use to compare the effect of two different combinations on competition. In fact, the Commission cannot even rationally evaluate the effect that adding a new radio station to an existing combination would have on competition because the relevant radio markets before and after the acquisition may be completely different, depending on the vagaries of the contour overlaps.

182. The Commission does not agree that it must demonstrate actual harm to move from an irrational market definition to a rational one. Any analysis of the potential harms of concentration should be focused on the limits on how many stations a party may own in a market, rather than on whether a distorted methodology for defining radio markets and counting radio stations should be preserved.

183. In short, the Commission's experience with the contour-overlap system leads it to believe that it is ineffective as a means to measure competition in local radio markets, and that a different method of defining the market will more effectively serve its goals. The Commission sees scant evidence in the record to lead it to a different conclusion. Some commenters correctly note that any methodology the Commission develops may create anomalous situations in certain instances. But the Commission cannot

agree that its inability to achieve perfection in every instance justifies maintaining the current system. The Commission concludes that its methodology for defining radio markets and counting market participants must be changed.

184. *Statutory Authority.* Before explaining our modified market definition and counting methodologies, the Commission addresses arguments that it lacks the statutory authority to revise those methodologies in a way that would prohibit radio station combinations that are permissible under the current framework. After reviewing the relevant statutory provisions, the Commission finds that argument to be without merit. The Communications Act grants us the authority to "[m]ake such rules and regulations, not inconsistent with law, as may be necessary to carry out the provisions of" the Act. 47 U.S.C. 303(r). The Commission is also authorized to "make such rules and regulations * * * not inconsistent with [the] Act, as may be necessary in the execution of [our] functions." *Id.* section 154(i). The Supreme Court has held that these broad grants of rulemaking power authorize us to adopt rules to ensure that broadcast station ownership is consistent with the public interest. The Commission finds nothing in the 1996 Act or its legislative history that diminishes that authority. To the contrary, section 202(b) contemplated that the Commission would exercise our rulemaking authority to make the revisions to the rule that Congress required, and section 202(h) contemplates that it will exercise our rulemaking authority to repeal or modify ownership rules that it determines are no longer in the public interest. The Commission accordingly finds that it has the authority to revise the local radio ownership rule in a manner that serves the public interest.

185. Some commenters nevertheless argue that the 1996 Act restricts how the Commission may define the "public interest." The Commission finds that argument flawed. In *Fox Television*, 280 F.3d at 1043, the court held, in the context of the national television ownership cap, that the numbers Congress selected "determined only the starting point" for analysis and instructed us not "to defer to the Congress's choice" of numbers in our analysis. Thus, even if Congress believed in 1996 that section 202(b) set the appropriate radio station ownership levels, *Fox* holds that the Commission retain the authority—indeed, the obligation—to determine ourselves whether a change in the rules would serve the public interest.

186. The Commission recognizes that the section 202(h) presumption requires it to justify a decision to retain the rule. The purpose of the presumption is thus to shift the traditional administrative law burden from those seeking to modify or eliminate the rule to those seeking to retain it. It would be a substantial leap, however, to read this presumption as having the additional effect of limiting the types of changes that we may conclude are in the public interest. The Commission sees no basis for such a view. Had Congress intended to curtail the Commission's regulatory powers so drastically, it would have done so in more express terms.

187. Invocation of the ratification, or reenactment, doctrine does not alter the analysis. The Commission finds nothing in the 1996 Act or in its legislative history that evidences a congressional intent to adopt the market definition and counting methodologies that the Commission adopted in 1992. Even if the ratification doctrine could be invoked, moreover, that would not "preclude [an] agency, in the exercise of its rulemaking authority, from later adopting some other reasonable and lawful interpretation of the statute." *McCoy v. United States*, 802 F.2d 762, 766 (4th Cir. 1986). The ratification doctrine "does not mean that the prior construction has become so embedded in the law that only Congress can effect a change," but permits changes "through exercise by the administrative agency of its continuing rule-making power." *Helvering v. Reynolds*, 313 U.S. 428, 432 (1941). Because Congress has left the Commission's general rulemaking powers intact, the ratification doctrine—even if properly invoked—would not bar us from exercising those powers to change the method used to define local radio markets and count radio stations for purposes of the local radio ownership rule.

188. *Geography-Based Radio Markets.* The Commission concludes that a local radio market that is objectively determined, *i.e.* that is independent of the radio stations involved in a particular transaction, presents the most rational basis for defining radio markets. As explained below, the Commission will rely on the Arbitron Metro Survey Area (Arbitron Metro) as the presumptive market. The Commission also establishes a methodology for counting the number of radio stations that participate in a radio market. The Commission initiates below a new rulemaking proceeding to define radio markets for areas of the country not located in an Arbitron Metro, and adopts a modified contour-overlap

approach to ensure the orderly processing of radio station applications pending completion of that rulemaking proceeding.

189. Applicants will be required to demonstrate compliance with the rule when filing applications to obtain a new construction permit or license, to assign or transfer an existing permit or license, or to make certain modifications, such as a change in the community of license of a radio station. The Commission makes clear that any radio station that is included in the radio market under our methodology will also be counted against a station owner's ownership limit in such market.

190. *Arbitron Metro Survey Areas.* Where a commercially accepted and recognized definition of a radio market exists, it seems sensible to the Commission to rely on that market definition for purposes of applying the local radio ownership rule. Arbitron, as the principal radio rating service in the country, has defined radio markets for most of the more populated urban areas of the country. The record shows that Arbitron's market definitions are an industry standard and represent a reasonable geographic market delineation within which radio stations compete. Indeed, the DOJ consistently has treated Arbitron Metros as the relevant geographic market for antitrust purposes. As NABOB succinctly states, "Radio stations compete in Arbitron markets." Given the long-standing industry recognition of the value of Arbitron's service, we believe there is strong reason to adopt a local radio market definition that is based on this established industry standard.

191. Although Arbitron Metro boundaries do occasionally change, the Commission is not convinced that such changes occur with such frequency, or that they are so drastic, that we must reject reliance on those boundaries in defining the relevant radio markets. The Commission believes, moreover, that we can establish safeguards to deter parties from attempting to manipulate Arbitron market definitions for purposes of circumventing the local radio ownership rule. Specifically, the Commission will not allow a party to receive the benefit of a change in Arbitron Metro boundaries unless that change has been in place for at least two years. This safeguard includes both enlarging the Metro (to make a market larger) and shrinking the Metro (to split a party's non-compliant station holdings into separate markets). Similarly, a station combination that does not comply with the rule cannot rely on a change in Arbitron Metro definitions to show compliance and thereby avoid the

transfer restrictions outlined in the grandfathering section of the R&O, unless that change has been in effect for two years. The Commission also will not allow a party to receive the benefit of the inclusion of a radio station as "home" to a Metro unless such station's community of license is located within the Metro or such station has been considered home to that Metro for at least two years. A party also may not receive the benefit of changing the home status of its own station if such change occurred within the two years prior to the filing of an application. The Commission believes these safeguards will ensure that changes in Arbitron Metro boundaries and home market designations will be made to reflect actual market conditions and not to circumvent the local radio ownership rule. To the extent, of course, that the Commission determines that, despite these safeguards, an Arbitron Metro boundary has been altered to circumvent the local radio ownership rule, we can and will consider that fact in evaluating whether a radio station combination complies with the rule's numerical limits.

192. *Counting Methodology.* For each Arbitron Metro, Arbitron lists the commercial radio stations that obtain a minimum audience share in the Metro. Some of these stations are designated by Arbitron as "home" to the Metro. These "home" radio stations usually are either licensed to a community within the Arbitron Metro or are determined by Arbitron to compete with the radio stations located in the Metro. These radio stations are also known as "above-the-line" stations because, in ratings reports, Arbitron uses a dotted line to separate these stations from other radio stations—known as "below-the-line" stations—that have historically received a minimum listening share in a Metro.

193. The Commission traditionally has relied on BIA's Media Access Pro database to obtain information about particular Arbitron Metros. The BIA database relies on Arbitron's market definitions and builds upon Arbitron's data to provide greater detail about the competitive realities in Metro markets. Given our experience with the BIA database and its acceptance in the industry, we will count as being in an Arbitron Metro above-the-line radio stations (*i.e.*, stations that are listed as "home" to that Metro), as determined by BIA. The Commission also will include in the market any other licensed full power commercial or noncommercial radio station whose community of license is located within the Metro's geographic boundary. A radio station located outside of a Metro occasionally

may be included as home to that Metro. In such cases, the Commission will count that station as participating in the radio market in which its community of license is located in addition to the Metro. The Commission believes this simple rule will help prevent odd results in cases where a station requests "home" status in order to be viewed as a participant in another (usually larger) Metro. With these rules, our counting methodology will reflect more accurately the competitive reality recognized by the radio broadcasting industry.

194. The Commission rejects arguments that we should count below-the-line stations in determining the size of a Metro's radio market. Below-the-line stations can be a considerable distance from the Metro, and in many cases serve different population centers, if not altogether different Metros, from radio stations located in the market. Although the Commission recognizes that, in certain instances, certain below-the-line radio station may have a competitive impact in the market for radio listening, we believe that, on balance, counting every below-the-line radio station would produce a distorted picture of the state of competition in a particular Metro.

195. *Areas Not Located in an Arbitron Metro.* Arbitron Metros do not cover the entire country. The Commission accordingly will develop radio market definitions for non-Metro areas through the rulemaking process. The Commission initiates in a separate notice, published elsewhere in the *Federal Register*, a new rulemaking proceeding to seek comment on that issue.

196. While that rulemaking proceeding is pending, the Commission will need to process applications proposing radio station combinations in non-Metro areas and determine whether such combinations comply with the local radio ownership rule. Although we find the contour-overlap methodology problematic for the reasons stated above, we conclude that its temporary use during the pendency of the rulemaking proceeding cannot be avoided. The contour-overlap methodology is, at a minimum, well understood, and continuing its use for a few additional months would allow for the orderly processing of radio station applications.

197. Although the Commission finds it necessary to maintain the contour-overlap market definition for an additional period of time, we will make certain adjustments to minimize the more problematic aspects of that system. Specifically, the Commission adopts

NAB's proposal to exclude from the market radio stations that are commonly owned with the stations in the numerator. This will prevent a party from "piggy-backing" on its own stations to bump into a higher ownership tier. The Commission also will adopt NAB's suggestion that we exclude from the market any radio station whose transmitter site is more than 92 kilometers (58 miles) from the perimeter of the mutual overlap area. This will alleviate some of the gross distortions in market size that can occur when a large signal contour that is part of a proposed combination overlaps the contours of distant radio stations and thereby brings them into the market.

198. The Commission will require parties proposing a radio station combination involving one or more stations whose communities of license are not located within an Arbitron Metro boundary to show compliance with the local radio ownership rule using the interim contour-overlap methodology. The interim methodology will be triggered even if a radio station is "home" to an Arbitron Metro, as long as its community of license is located outside of the Metro. In making that showing, parties should include in the numerator and denominator radio stations that meet the criteria for inclusion under that methodology (as modified by the preceding paragraph) regardless of whether they are included in Arbitron Metros. The Commission emphasizes, however, that the interim contour-overlap methodology may not be used to justify radio station combinations in Arbitron Metros that exceed the numerical limits of the local radio ownership rule; in all cases, parties must demonstrate—using the standards for Arbitron Metros described above—that they comply with those limits in each Metro implicated by the proposed combination.

199. *Modification to The Local Radio Ownership Rule.* Having discussed the relevant product and geographic markets for radio, the Commission now undertakes its obligation under Section 202(h) to determine whether the current limits on radio station ownership are necessary to promote the public interest in competition. With respect to the ownership tiers, the Commission concludes that the current rule meets that standard. The Commission finds, however, that the rule improperly fails to consider the effect that noncommercial stations can have on competition in the local radio market. Accordingly, the Commission modifies the rule to count noncommercial radio stations in determining the size of the radio market.

200. The Commission concludes that the ownership tiers in the current rule represent a reasonable means for promoting the public interest as it relates to competition. In radio markets, barriers to entry are high because virtually all available radio spectrum has been licensed. Radio broadcasting is thus a closed entry market, *i.e.*, new entry generally can occur only through the acquisition of spectrum inputs from existing radio broadcasters. The closed entry nature of radio suggests that the extent of capacity that is available for new entry plays a significant role in determining whether market power can develop in radio broadcasting. Numerical limits on radio station ownership help to keep the available capacity from becoming "locked-up" in the hands of one or a few owners, and thus help prevent the formation of market power in local radio markets.

201. Although competition theory does not provide a hard-and-fast rule on the number of equally sized competitors that are necessary to ensure that the full benefits of competition are realized, both economic theory and empirical studies suggest that a market that has five or more relatively equally sized firms can achieve a level of market performance comparable to a fragmented, structurally competitive market. The current tiers ensure that, in markets with between 27 and 51 radio stations, there will be approximately five or six radio station firms of roughly equal size. An analysis of the top 100 Metro markets indicates that many of them fall within this range.

202. The Commission finds that the concentration levels permitted by the current rule represent a reasonable and necessary balance for radio broadcasting that comports with general competition theory, and we decline to relax the rule to permit greater consolidation in local radio markets. The Commission acknowledges that many radio markets currently have more than 6 radio station firms. The Commission also considers, however, that radio stations are not all equal in terms of their technical capabilities (*i.e.*, each radio station covers a population with varying levels of signal quality), and that the technical differences among stations can cause radio stations groups with similar numbers of radio stations to have vastly different levels of market power. Thus, although the top 50 Metros have an average of 19.9 owners, the top station group in each of those Metros has, on average, 35.2% of the revenue share, and the top four groups receive, on average, 86.1% of the revenue share. The top four firms also dominate audience share. According to the Future

of Music Coalition, the top four firms receive 77.1% of the audience share in the top 10 Metros, 84.7% in Metros 11 to 25, and 85.8% in Metros 26–50. Bear Stearns' analysis also shows that, in the top 100 radio markets, the top three radio groups receive a median of 82.9% of the revenue share and 58.9% of the audience share. And MOWG Study No. 4 indicates that the increase in concentration in radio markets has resulted in an appreciable, albeit small, increase in advertising rates. This data suggests that the current numerical limits are not unduly restrictive. The Commission sees no significant benefit in tinkering with the basic structure of the tiers.

203. For markets with more than 51 radio stations, the number of radio station firms ensured by the rule increases as the size of the market increases. Because of this, some parties argue that we should raise the numerical limits to permit common ownership of more than eight radio stations in larger markets. The Commission rejects that argument. There is no evidence in the record that indicates that the efficiencies of consolidating radio stations increase appreciably for combinations involving more than eight radio stations. On the other hand, extremely large radio markets tend to cover a large area geographically and also tend to be more "crowded" in terms of radio signals. As a result, large markets may include a greater number of extremely small radio stations, as well as radio stations that are a significant distance from each other. Both of these phenomena may make a large market appear more competitive than it actually is. By capping the numerical limit at eight stations, we seek to guard against consolidation of the strongest stations in a market in the hands of too few owners and to ensure a market structure that fosters opportunities for new entry into radio broadcasting.

204. The Commission also declines to make the numerical limits more restrictive. In the smallest radio markets, the current rule provides that one entity may own up to half of the commercial radio stations in a market. Although this would be considered highly concentrated from a competitive point of view, greater levels of concentration may be needed to ensure the potential for viability of radio stations in smaller markets. Given these concerns, we find it reasonable to allow greater levels of concentration in smaller radio markets, but to require more independent radio station owners as the size of the market increases and viability concerns become less acute.

205. The Commission also reaffirms the AM and FM ownership limits in the current rule. Eliminating the service limits would improperly ignore the significant technical and marketplace differences between AM and FM stations. AM stations have significantly less bandwidth than FM stations, and the fidelity of their audio signal is inferior to that of FM stations. Unlike FM stations, moreover, AM signal propagation also varies with time of day. During the day, AM signals travel through ground currents for between 50 to 200 miles; at night, AM signals travel further because they are reflected from the upper atmosphere. As a result, many AM stations are required to cease operation at sunset. These and other technical differences have an effect on radio listenership patterns. Radio formats also can be affected. In Los Angeles, for example, our analysis indicates that many of the AM stations have a news/talk/sports or ethnic format, while music formats are more likely on commercial FM stations. The Commission cannot agree, therefore, that eliminating the service caps and treating AM and FM radio stations equally for purposes of the overall station limit is consistent with our interest in protecting competition in local radio markets.

206. Although the Commission reaffirms the ownership tiers in the local radio ownership rule, we conclude that it is not necessary in the public interest to exclude noncommercial radio stations in determining the size of the radio market. Although noncommercial stations do not compete in the radio advertising market, they compete with other radio stations in the radio listening and program production markets. Indeed, noncommercial stations can receive a significant listening share in their respective markets. Their presence in the market therefore exerts competitive pressure on all other radio stations in the market seeking to attract the attention of the same body of potential listeners. In television, the Commission has recognized the contribution that noncommercial stations can make to competition by counting noncommercial stations in determining the size of the television market. The Commission sees no reason to treat noncommercial radio stations differently.

207. *Rejection of Repeal and Other Modifications.* The Commission rejects arguments that we should repeal the local radio ownership rule. We see nothing in the record that persuades us that the acquisition of market power in radio broadcasting serves the public

interest. Competition breeds innovation in programming and creates incentives to continually improve program quality. Because competition—and the benefits that flow from it—is lessened when the market is dominated by one or a few players, the Commission seeks through its rules to prevent that type of market structure from developing.

208. Without some check, a party could acquire all or a significant portion of the limited number of broadcast radio channels in a local community, leaving listeners, advertisers, and program producers with fewer substitutes. That situation also would raise the cost of entry into the market by new entrants because there would be fewer radio stations available from which a party could construct a competing station group. Because the most potent sources of innovation often arise from new entrants, a market structure that significantly raises the costs of entry leads to less-than-optimal results in terms of innovation and program quality and thereby harms the public interest. It is therefore necessary for us to impose limits on the number of radio stations a party may own in a local market to preserve competition in the relevant markets in which radio stations compete.

209. The Commission does not dispute that a certain level of consolidation of radio stations can improve the ability of a group owner to make investments that benefit the public. Our responsibility under the statute, however, is to determine the level at which the harms of consolidation outweigh its benefits, and to establish rules to prevent that situation from developing. Several commenters express concern that, in markets with a high level of concentration, small radio firms may be forced to "sell out" to group owners. Specifically, the concern is that, in a concentrated market, dominant radio station groups can exercise market power to attract revenue at the expense of the small owner. As a result, the small owner has greater difficulty obtaining the revenue it needs to develop and broadcast attractive programming and to compete generally against the dominant station groups. The concerns raised by these commenters comport with the competition analysis that underlies this order and supports our decision not to repeal the local radio ownership rule.

210. The Commission also rejects arguments that we incorporate a market share analysis into the local radio ownership rule or that we continue to "flag" applications that propose radio station combinations above a certain

market share. The Commission recognizes that competition analysis generally looks to market share as the primary indicator of market power. Market share, however, must be considered in conjunction with the overall structure of the industry in determining whether market power is present. In radio, the availability of a sufficient number of radio channels is of particular importance in ensuring that competition can flourish in local radio markets. The numerical caps and the AM/FM service limits are designed to address that interest, and in our judgment, establishing an inflexible market share limit in our bright-line rule would add little, if any, benefit. The Commission does not seek to discourage radio firms from earning market share through investment in quality programming that listeners prefer; our objective is to prevent firms from gaining market dominance through the consolidation of a significant number of key broadcast facilities. The Commission does not believe that developing a market share limit would significantly advance that objective.

211. The Commission recognizes that its conclusion differs from the Commission's view in 1992 that an audience share cap was necessary "to prevent consolidation of the top stations in a particular local market." But the audience share cap was never intended to be more than a "backstop" to the new numerical limits the Commission had established, which for the first time allowed a party to own multiple radio stations in a local market. The audience share cap was eliminated as a result of the revisions to the local radio ownership rule that Congress mandated in the 1996 Act, which left only the numerical caps in place. But because of the problems associated with the contour-overlap market definition and counting methodologies, the Commission could not rely with confidence on those numerical limits to protect against undue concentration in local markets. As a result, the Commission began looking at revenue share in our "flagging" process and the interim policy that we established in the *Local Radio Ownership NPRM*. Now that the Commission has established a rational system for defining radio markets and counting market participants, it believes that the numerical limits will be better able to protect against harmful concentration levels in local radio markets that might otherwise threaten the public interest. To the extent an interested party believes this not to be the case, it has a statutory right to file a petition to deny

a specific radio station application and present evidence that makes the necessary *prima facie* showing that a proposed combination is contrary to the public interest.

212. *Localism*. The Commission's localism goal stems from our interest in ensuring that licensed broadcast facilities serve and are responsive to the needs and interests of the communities to which they are licensed. In a competitive market, the efficiencies arising out of consolidation will be passed on to listeners through greater innovation and improved service quality, which in this context contemplates programming that is responsive to the needs and interests of the local community. In a concentrated market, radio station firms have diminished incentive to compete vigorously. Smaller firms, moreover, may have insufficient resources to compete aggressively with the dominant firms in the market, which makes smaller firms less effective in meeting the needs and interests of their local communities. Thus, by preserving a healthy, competitive local radio market, the local radio ownership rule also helps promote our interest in localism.

213. Aside from the positive effect on localism that ensues from a competitive radio market, we see little to indicate that the local radio ownership rule significantly advances our interest in localism. In prior rulemaking proceedings, the Commission has not emphasized localism as one of the justifications for the local radio ownership rule, and the record suggests no reason for adopting a different view here. Although some parties suggest that localism has suffered as a result of consolidation, the source of the alleged harm appears to be the overall *national* size of the radio station group owner rather than the number of radio stations commonly owned in a local market. National radio ownership limits are outside the scope of this proceeding.

214. *Viewpoint Diversity*. Viewpoint diversity "rests on the assumption that the widest possible dissemination of information from diverse and antagonistic sources is essential to the welfare of the public." *Associated Press v. United States*, 326 U.S. 1 (1945). Many outlets contribute to the dissemination of diverse viewpoints, and provide news and public affairs programming to the public. Elsewhere in the R&O, the Commission discusses in exacting detail the various sources of local news and information that are available to the public. Here, it is sufficient to say that media other than radio play an important role in the

dissemination of local news and public affairs information.

215. That, of course, does not mean that radio broadcasting is irrelevant to viewpoint diversity. The Commission recognizes that radio can reach specific demographic groups more easily than other forms of mass media. Because of this, and because of its relative affordability compared to other mass media, radio remains a likely avenue for new entry into the media business, particularly by small businesses, women, minorities, and other entrepreneurs seeking to meet a market demand or provide programming to underserved communities. Our competition-based limits on local radio ownership thus promote viewpoint diversity, not only by ensuring a sufficient number of independent radio voices, but also by preserving a market structure that facilitates and encourages entry into the local media market by new and underrepresented parties.

216. *Programming Diversity*. In theory, program diversity promotes the public interest by affording consumers access to a greater array of programming choices. The difficulty is in finding a way to measure program diversity in a coherent and consistent manner so that we can determine how it is affected by concentration. The record indicates that different measures of format diversity produce strikingly different results. Overall, the results suggest that consolidation in the radio industry neither helped nor hindered playlist diversity between radio stations.

217. The studies on program diversity also do not draw a sufficiently reliable causal link between ownership concentration and the purported increase in format diversity. After a careful review of the economic literature, however, the Commission cannot confidently adopt the view that we should encourage more consolidation in order to achieve greater format diversity.

218. In light of this record, the Commission cannot conclude that radio ownership concentration has any effect on format diversity, either harmful or beneficial. Accordingly, we do not rely on it to justify the local radio ownership rule.

219. *Attribution of Joint Sales Agreements*. A typical radio Joint Sales Agreements (JSAs) authorizes the broker to sell advertising time for the brokered station in return for a fee paid to the licensee. Because the broker normally assumes much of the market risk with respect to the station it brokers, JSAs generally give the broker authority to hire a sales force for the brokered station, set advertising prices, and make

other decisions regarding the sale of advertising time, subject to the licensee's preemptive right to reject the advertising. Currently, JSAs are not attributable under the Commission's attribution rules. Therefore, radio stations subject to JSAs do not count toward the number of stations the brokering licensee may own in a local market.

220. Based on the record in this proceeding, and on its experience with JSAs and local radio ownership rules, the Commission will now count the brokered station toward the brokering licensee's permissible ownership totals under the revised local ownership rules. Where an entity owns or has an attributable interest in one or more stations in a local radio market, joint advertising sales of another station in that market for more than 15 percent of the brokered station's advertising time per week will result in counting the brokered station toward the brokering licensee's ownership caps. The Commission does not believe that out-of-market JSAs pose the same economic concerns. Therefore, JSAs will not be attributable when a party does not own any stations or have an attributable interest in stations in the local market in which the brokered station is located.

221. In considering revisions to our attribution rules, the Commission has always sought to identify and include those positional and ownership interests that convey a degree of influence or control to their holder sufficient to warrant limitation under our ownership rules. The Commission finds that the use of in-market JSAs may undermine its continuing interest in broadcast competition sufficiently to warrant limitation under the multiple ownership rules.

222. The Commission finds that where one station owner controls a large percentage of the advertising time in a particular market, it has the ability potentially to exercise market power. Many times, the broker will sell advertising packages for the group of stations, offer substantial discounts and create incentives not available to other broadcasters in the market. In any given radio market, a broker may own or have an ownership interest in stations, operate stations pursuant to a local marketing agreement, or sell advertising time for stations pursuant to a JSA. Control over spot sales by one station affords significant power over the other. Thus, JSAs raise concerns regarding the ability of smaller broadcasters to compete, and may negatively affect the health of the local radio industry generally. JSAs put pricing and output decisions in the hands of a single firm.

Instead of stations competing against one another, a single firm sells packages of time for all stations, eliminating competition in the market.

223. The Commission has not previously attributed JSAs based on its earlier conclusion that JSAs do not convey sufficient influence or control over a station's core operations to be considered attributable. Upon reexamination of the attribution issue, the Commission finds that, because the broker controls the advertising revenue of the brokered station, JSAs convey sufficient influence over core operations of a station to raise significant competition concerns warranting attribution. Licensees of stations subject to JSAs typically receive a monthly fee regardless of the advertising sales or audience share of the station. Therefore, licensees of stations subject to JSAs have less incentive to maintain or attain significant competitive standing in the market.

224. Although the Commission continues to believe that JSAs may have some positive effects on the local radio industry, it finds that the threat to competition and the potential impact on the influence over the brokered station outweighs any potential benefits and requires attribution. The Commission finds that modification of its regulation also is warranted given the need for attribution rules to reflect accurately competitive conditions of today's local radio markets. It would be inconsistent with its rules to allow a local station owner to substantially broker a station that it could not own under the local radio ownership limits.

225. The Commission believes that a 15 percent advertising time threshold will identify the level of control or influence that would realistically allow holders of such influence to affect core operating functions of a station, and give them an incentive to do so. At the same time, a 15 percent threshold will allow a station the flexibility to broker a small amount of advertising time through a JSA with another station in the same market without that brokerage rising to an attributable level of influence. The Commission believes that the 15 percent threshold (which is the same threshold used for determining attribution of radio and television LMAs) balances these interests.

226. Under the Commission's modified rules, JSAs currently in existence will be attributable. Parties with existing, attributable JSAs in Arbitron Metros under the new rules will be required to file a copy of the JSA with the Commission within 60 days of the effective date of this R&O. Both the licensee and the broker should submit

copies of their JSAs as supplements to their Ownership Reports on file at the Commission. For JSAs involving stations located outside of Arbitron Metros, the Commission will require such JSAs to be filed within 60 days of the effective date of our decision in Docket No. 03-130, unless a different date is announced in that decision. In addition, the Commission is modifying FCC Application Forms 314 and 315 to require applicants to file attributable JSAs at the time an application is filed, regardless of whether the markets implicated by the application are located in Arbitron Metros.

227. *Existing JSAs.* The Commission is aware that attribution of in-market radio JSAs may affect licensees' compliance with the modified local radio ownership rules. In addition, the Commission does not want to unnecessarily adversely affect current business arrangements between licensees and brokers. Therefore, the Commission will give licensees sufficient time to make alternative business arrangements where they have in-market JSAs entered into prior to the adoption date of this R&O that would cause them to exceed relevant ownership limits. In such situations, parties will have 2 years from the effective date of this R&O to terminate agreements, or otherwise come into compliance with the local radio ownership rules adopted herein. However, if a party sells an existing combination of stations within the 2-year grace period, it may not sell or assign the JSA to the new owner if the JSA causes the new owner to exceed any of our ownership limits; the JSA must be terminated at the time of the sale of the stations. JSAs that do not cause a party to exceed the modified local radio rules may continue in full force and effect and may be transferred or assigned to third parties. Finally, parties are prohibited from entering a new JSA or renewing an existing JSA that would cause the broker of the station to exceed our media ownership limits.

228. *Waiver Standards.* The Commission declines at this time to adopt any specific waiver criteria relating to radio station ownership. Parties who believe that the particular facts of their case warrant a waiver of the local radio ownership rule may seek a waiver under the general "good cause" waiver standard in our rules.

C. Cross Ownership

229. In this section the Commission addresses (1) the newspaper/broadcast cross-ownership rule and (2) the radio-television cross-ownership rule to determine whether they are necessary in

the public interest pursuant to section 202(h). Based on the record in this proceeding, the Commission finds that neither its current nation-wide prohibition on common ownership of daily newspapers and broadcast outlets in the same market nor its cross-service restriction on commonly owned radio and television outlets in the same market, is necessary in the public interest. With respect to both rules, the Commission concludes that the ends sought can be achieved with more precision and with greater deference to First Amendment interests by modifying the rules into a single set of cross-media limits.

230. *Newspaper/Broadcast Cross-Ownership Rule.* Adopted in 1975, the newspaper/broadcast cross-ownership rule prohibits in absolute terms common ownership of a full-service broadcast station and a daily newspaper when the broadcast station's service contour encompasses the newspaper's city of publication.¹³ The rule was intended to promote media competition and diversity. Upon review, the Commission now concludes that (1) the rule cannot be sustained on competitive grounds, (2) the rule is not necessary to promote localism (and may in fact harm localism), and (3) most media markets are diverse, obviating a blanket prophylactic ban on newspaper-broadcast combinations in all markets. Instead, the Commission will review proposed license transfers and renewals involving the combination of daily newspapers and broadcast properties only to the extent that they would implicate the cross-media limits.

231. *Competition.* The Commission first defines the relevant product and geographic markets in which broadcasters and newspapers compete, and then assess whether the rule is necessary to promote competition in these markets. As the Commission noted in the newspaper/broadcast proceeding, its focus is on the primary economic market in which broadcast stations and newspapers compete: advertising. The Commission concludes, based on the record in this proceeding, that most advertisers do not view newspapers, television stations, and radio stations as close substitutes. The Department of Justice and several federal courts have concluded that the local newspaper market is distinct from the local

¹³ For AM radio stations, the service contour is the 2mV/m contour, 47 CFR 73.3555(d)(1); for FM radio stations, the service contour is the 1mV/m contour, 47 CFR 73.3555(d)(2); for TV stations, the service contour is the Grade A contour, 47 CFR 73.3555(d)(3). A daily newspaper is one that is published in the English language four or more times per week. 47 CFR 73.3555 n.6.

broadcast market. This conclusion is supported by a number of commenters and MOWG Study No. 10. Some commenters criticize MOWG Study No. 10 and argue that radio, TV, and newspapers, compete vigorously for advertising dollars.

232. Although the overall evidence appears to suggest little substitution between newspapers, broadcast TV, and radio, the Commission agrees that there may be a small group of advertisers that benefit from using various media to advertise their products.¹⁴ These advertisers could be harmed if owners of newspaper/broadcast combinations can identify this group and price discriminate. These advertisers, however, are not without remedy. The Department of Justice, the Federal Trade Commission, as well as state attorney generals, review mergers generally and are concerned about the effects in the advertising market. Further, both federal and state antitrust laws allow private suits to be brought. In any event, even if the Commission were to focus exclusively on the advertising markets alone, the potential for harm to advertisers who substitute between various media outlets would be greatest if one entity owned all the newspapers and all the broadcast facilities. Through the constraining effect of the Commission's local radio and TV ownership rules, the Commission expects that the majority of the potential newspaper/broadcast combinations would continue to face competition from separately owned media outlets in the local market.

233. *Localism.* The record indicates that the newspaper/broadcast cross-ownership prohibition is not necessary to promote broadcasters' provision of local news and information programming. Indeed, evidence suggests that the rule actually works to inhibit such programming. Many newspapers provide local content that far exceeds that provided by local broadcast outlets. Newspapers and broadcast stations—particularly television stations—continue to be the dominant sources, in terms of consumer use, for news and information to local communities. The Commission's rules should promote the ability of newspapers, television stations, and all other sources of local news and information to serve their communities.

¹⁴ There is nothing in the record regarding the number of advertisers that may be targeted for such price discrimination, nor the magnitude of the potential price increases. The Commission believes however, that the number of advertisers that may be potential targets of price discrimination would be very small for most newspaper/broadcast combinations.

234. While eliminating the rule may not be essential to achieve the efficiencies of common ownership—because the rule prohibits only ownership of newspapers and broadcast stations serving the same market—the breadth and depth of news coverage can be enhanced by collocation and the rule's elimination will increase the opportunities to realize these benefits by permitting combinations in areas where the rule currently prohibits them.

235. Specifically, MOWG Study No. 7 found that newspaper-owned affiliated stations provide almost 50% more local news and public affairs programming than do non-network owned network affiliated stations. In addition, the study found that the average number of hours of local news and public affairs programming provided by the same-market cross-owned television-newspaper combinations was 25.6 hours per week, compared to 16.3 hours per week for the sample of television stations owned by a newspaper that is not in the same market as the station. For each quality and quantity measure in the Commission's analysis, the newspaper network-affiliated stations exceed the performance of other, non-newspaper-owned network affiliates.

236. The benefits of combined ownership are not likely to be achieved through joint ventures as opposed to combined ownership. Many commenters illustrate how combining a newspaper's local news-gathering resources with a broadcast platform contributes to, rather than detracts from, the production of local news programming that serves the community. These results follow from the particular journalistic experience associated with local daily newspapers, as well as the tangible economic efficiencies, such as sharing of technical support staff, which can be realized through common ownership of two media outlets. There are several anecdotes in the record that illustrate how efficiencies resulting from cross-ownership translate into better local service. Efficiencies not involving the sharing of news staffs may also be realized through cross-ownership.

237. Although the Commission's conclusions pertain to markets of all sizes, newspaper-broadcast combinations may produce tangible public benefits in smaller markets in particular. In this regard, West Virginia Media argues that the rule may have the unintended effect of stifling local news by prohibiting efficient combinations that would produce better output. We assume that the benefits cited by West Virginia Media can benefit small businesses with respect to the

production of news and public affairs programming.

238. The Commission disagrees with those who argue that the relaxation or elimination of the newspaper/broadcast cross-ownership rule will create additional pressures on local news editors and directors to curtail coverage of public interest news. Also, the Commission does not find it troubling that newspaper owners use their media properties to express or advocate a viewpoint. To the contrary, since the beginning of the Republic, media outlets have been used by their owners to give voice to, among others, opinions unpopular or revolutionary, to advocate particular positions, or to defend, sometimes stridently, social or governmental institutions. The Commission's broadcast ownership rules may not and should not discourage such activity. Nor is it particularly troubling that media properties do not always, or even frequently, avail themselves to others who may hold contrary opinions. Nothing requires them to do so. The media are not common carriers of speech. Nor is it troubling that media properties may allow their news and editorial decisions to be driven by "the bottom line." Again, the need and desire to produce revenue, to control costs, to survive and thrive in the marketplace is a time honored tradition in the American media. In short, to assert that cross-owned properties will be engaged in profit maximizing behavior or that they will provide an outlet for viewpoints reflective of their owner's interests is merely to state truisms, neither of which warrants government intrusion into precious territory bounded off by the First Amendment.

239. *Diversity.* The Commission adopted the newspaper/broadcast cross-ownership rule because it believed that diversification of ownership would promote diversification of viewpoint. This proposition has been both defended and called into question. Although the Commission continues to believe that diversity of ownership can advance the Commission's goal of diversity of viewpoint, the local rules that it is adopting herein will sufficiently protect diversity of viewpoint while permitting efficiencies that can ultimately improve the quality and quantity of news and informational programming. Accordingly, the Commission will eliminate the newspaper/broadcast cross-ownership prohibition and consider any such proposed merger in light of the Commission's new rules.

240. The record indicates that cross-ownership of newspapers and broadcast

outlets creates efficiencies and synergies that enhance the quality and viability of media outlets, thus enhancing the flow of news and information to the public. Relaxing the cross-ownership rule could lead to an increase in the number of newspapers in some markets and foster the development of important new sources of local news and information.

241. Evidence that common ownership can enhance the flow of news and information to the public can be found in grandfathered newspaper-television combinations of which there are 21. The Commission's review of the record indicates that such combinations often serve the public interest by adding information outlets and creating high quality news product. Empirical research confirms that newspaper/television combinations frequently do a superior job of providing news and informational programming. MOWG Study No. 7 found that network affiliated TV stations that are co-owned with a newspaper "experience noticeably greater success under our measures of quality and quantity of local news programming than other network affiliates."

242. The newspaper/broadcast cross-ownership rule may be preventing efficient combinations that would allow for the production of high quality news coverage and broadcast programming, including coverage of local issues, thereby harming diversity. Newspapers and local over-the-air television broadcasters alike have suffered, audience declines in recent years. Given the decline in newspaper readership and broadcast viewership/listenership, both newspaper and broadcast outlets may find that the efficiencies to be realized from common ownership will have a positive impact on their ability to provide news and coverage of local issues. The Commission must consider the impact of the Commission's rules on the strength of media outlets, particularly those that are primary sources of local news and information, as well as on the number of independently owned outlets.

243. As suggested by MOWG Study No. 2, authored by David Pritchard, commonly-owned newspapers and broadcast stations do not necessarily speak with a single, monolithic voice. Several parties, however, assert that ownership affects editorial decisions and, ultimately, viewpoints expressed by media outlets. Although there is evidence to suggest that ownership influences viewpoint, the degree to which it does so cannot be established with any certitude. In order to sustain a blanket prohibition on cross-ownership, the Commission would

need, among other things, a high degree of confidence that cross-owned properties were likely to demonstrate uniform bias. The record does not support such a conclusion. Indeed, as the market becomes more fragmented and competitive, media owners face increasing pressure to differentiate their products, including by means of differing viewpoints. While such differentiation may occur, however, the Commission's analysis does not turn on that premise, and it is not determinative of our decision with respect to our current newspaper/broadcast cross-ownership rule. The Commission's analysis turns, rather, on the availability of other news and informational outlets. Thus, while the Commission does not dispute that a particular outlet may betray some bias, particularly in matters that may affect the private or pecuniary interest of its corporate parent such anecdotes do not show a pattern of bias in the vast majority of news comment and coverage where such self-interest is not implicated. Nor, moreover, do such incidents mean that the public was left uninformed about the situation by other available media.

244. The record in this proceeding provides ample evidence that competing media outlets abound in markets of all sizes—each providing a platform for civic discourse. Television and radio stations, both commercial and noncommercial, are important media for news, information, entertainment, and political speech. Cable television systems, which originated as passive conduits of broadcast programming, have expanded to carry national satellite-delivered networks. Many also carry local public, educational, and governmental channels. Cable systems in larger markets are now evolving into platforms for original local news and public affairs programming. Daily newspapers, while declining in number, continue to provide an important outlet for local and national news and expression. The Internet, too, is becoming a commonly-used source for news, commentary, community affairs, and national/international information.

245. The Commission disagrees with parties that assert that there is little diversity in media markets. The average American has a far richer and more varied range of media voices from which to choose today than at any time in history. Given the growth in available media outlets, the influence of any single viewpoint source is sharply attenuated. The Commission concludes that its new local rules will protect the diversity of voices essential to achieving its policy objectives. A blanket prohibition on newspaper-broadcast

combinations, however, can no longer be sustained.

246. In short, the magnitude of the growth in local media voices shows that there will be a plethora of voices in most or all markets absent the rule. Indeed, the question confronting media companies today is not whether they will be able to dominate the distribution of news and information in any market, but whether they will be able to be heard at all among the cacophony of voices vying for the attention of Americans. The Commission's rules should account for these changes and promote, rather than inhibit, the ability of media outlets to survive and thrive in this evolving media landscape. They must "give recognition to the changes which have taken place and to see to it that [they] adequately reflect the situation as it is, not was."

247. *Conclusion.* The Commission finds that a newspaper-broadcast combination cannot adversely affect competition in any relevant product market and, thus, the Commission cannot conclude that the current newspaper-broadcast cross-ownership rule is necessary to promote competition.

248. Similarly, the Commission concludes that the evidence in the record of this proceeding demonstrates that combinations can promote the public interest by producing more and better overall local news coverage and that the current rule is thus not necessary to promote its localism goal. Instead, the Commission finds that it, in fact, is likely to hinder its attainment. Finally, the record does not contain data or other information demonstrating that common ownership of broadcast stations and daily newspapers in the same community poses a widespread threat to diversity of viewpoint or programming. The Commission concludes, therefore, that the current rule is no longer necessary in the public interest.¹⁵

249. *Radio/Television Cross-Ownership Rule.* The radio/television cross-ownership rule limits the number of commercial radio and television stations an entity may own in a local market. Currently, the rule allows a party to own up to two television stations (provided it is permitted under the television duopoly rule) and up to

¹⁵ On March 11, 2003, Media General, Inc., filed a "Motion to Bifurcate and Repeal." That Motion asked the Commission to break the newspaper/broadcast cross-ownership rule out of the biennial review, and repeal the rule, if it could not act in the biennial review in the spring of 2003. Because the Commission is acting in the biennial review in the spring of 2003 and is repealing the subject rule, the Commission dismisses Media General's Motion as moot.

six radio stations (to the extent permitted under the local radio ownership rule) in a market where at least 20 independently owned media voices would remain post-merger. Where parties may own a combination of two television stations and six radio stations, the rule allows a party alternatively to own one television station and seven radio stations. A party may own up to two television stations (as permitted under the current television duopoly rule) and up to four radio stations (as permitted under the local radio ownership rule) in markets where, post-merger, at least ten independently owned media voices would remain. A combination of one television station and one radio station is allowed regardless of the number of voices remaining in the market.

250. Based on the record in this proceeding, the Commission does not find that the radio/television cross-ownership rule remains necessary in the public interest to ensure competition, diversity or localism. The Commission's decision reflects the substantial growth and availability of media outlets in local markets, as well as the potential for significant efficiencies and public interest benefits to be realized through joint ownership. The Commission finds that its diversity and competition goals will be adequately protected by the local ownership rules adopted herein.

251. In 1970, the Commission restricted the combined ownership of radio and television stations in local markets. The purpose of the rule (originally referred to as the one-to-a-market rule) was twofold: (1) To foster maximum competition in broadcasting, and (2) to promote diversification of programming sources and viewpoints. In 1995, the Commission requested comment to determine whether the cross-ownership limitations were still warranted in light of the then current market conditions. Before the Commission issued a decision, Congress passed the 1996 Act. Section 202(d) of the 1996 Act required the Commission to extend the radio-television cross-ownership presumptive waiver policy to the top 50 television markets "consistent with the public interest, convenience and necessity." Prior to implementing the statutory change, the Commission issued a Second Further Notice of Proposed Rulemaking (61 FR 66978, December 19, 1996) requesting comment on whether modification of the rule was warranted beyond the Section 202(d) requirements. In 1999, the Commission modified the rule to its current form.

252. Under the Commission's statutory mandate pursuant to section

202(h) of the 1996 Act, the Commission is required to consider biennially whether "to 'repeal or modify' any rule that is not 'necessary in the public interest.'" In determining whether the rule meets this standard, the Commission considers whether it is necessary to promote any of its public interest objectives. With respect to cross-ownership of radio and television stations in the same market, the Commission reexamines the impact of the rule on competition, localism and diversity.

253. *Competition.* To assess the competitive impact of its radio/television cross-ownership rule, the Commission needs to determine whether radio and television stations compete for sources of revenue generation—in this case, advertising.¹⁶ If the Commission finds that they do, *i.e.*, that a significant number of advertisers consider radio and television to be good substitutes, then its concern would be that elimination or relaxation of the cross-ownership restrictions may enable a single firm to acquire sufficient market power to hinder small and independent broadcasters' efforts to generate revenue, and thereby put their continued viability at risk. However, if radio and television are not in the same product market, then the Commission would have little concern that elimination or relaxation of the rule would have any negative effects on competition.

254. The Commission concludes that most advertisers do not consider radio and television stations to be good substitutes for advertising and, therefore, that generally combinations of these two types of media outlets likely would not result in competitive harm. In MOWG Study No. 10, Anthony Bush found weak substitutability between local media, including radio and television. Other studies confirm Bush's conclusion that advertisers do not consider radio and television to be good substitutes. In addition to the empirical evidence, differences between radio and

¹⁶ The competitive analysis for both the local radio and the local television ownership rules focuses on two additional markets, delivered programming and programming production. However, in analyzing the effects of combined ownership of radio and television stations in a local market, neither of the latter product markets is relevant. Radio and television broadcasting are distinct programming markets with little overlap. The bulk of video entertainment and news programming available on commercial television is not suitable for radio. Similarly, audio radio programming, which is predominately music and talk show formats, cannot be replicated on television. Thus, because the essential nature of each medium determines the type of programming each medium broadcasts, the content is not interchangeable.

television programming and formats suggest that they do not compete in the same product market. Radio and television broadcast distinct programming. Video is not suitable for radio and vice versa. The difference is important for viewers and advertisers alike. The essential nature of each medium determines, in large measure, the type of programming each will broadcast. Thus, some advertisers may prefer, while others avoid, the radio listener as a significant audience to target. Additionally, television advertisements typically are more expensive than radio ads. In sum, television and radio stations neither compete in the same product market nor do they bear any vertical relation to one another.¹⁷ A television-radio combination, therefore, cannot adversely affect competition in any relevant product market. Accordingly, the Commission cannot conclude that the current television-radio cross-ownership rule is necessary to promote competition.

255. *Localism.* The NPRM sought comment on how cross-ownership limitations affect localism, as measured by the quantity and quality of news and public affairs programming that stations provide to local communities. The NPRM sought comment on the quantities of local news and public affairs programming provided by radio and television combinations as opposed to stand-alone stations in the same markets. The NPRM asked whether radio and television combinations produce more, less, or the same amount of news programming than stand-alone stations. The NPRM also asked commenters to address the implications of any such differences. The Commission finds that by prohibiting combinations of news gathering resources between radio and television stations, the current rule prohibits owners from maximizing local news and information production, which would benefit consumers.

256. There is no compelling or substantial evidence in the record that the rule is necessary to protect localism. The record in this proceeding includes evidence to the contrary that efficiencies and cost savings realized from joint ownership may allow radio and television stations to offer more news reporting generally, and more local news reporting specifically, than otherwise may be possible. The record in this proceeding suggests that station

¹⁷ Generally we identify both the product and the geographic markets. Because we find that radio and television advertising are separate product markets, it is not necessary to define the geographic market for these purposes.

owners will use additional revenue and resource savings from television-radio combinations to provide new and innovative programming, provide more in-depth local interest programming, and provide better service to the public, including locally oriented services.

257. The parties arguing to retain the current rule have failed to show that the rule remains necessary in the public interest. First, isolated anecdotes of changes in news programming schedules following a transaction do not provide the kind of systematic empirical evidence necessary to support a general allegation that cross-owned stations produce lesser quantities of news, or news of lower quality, than do non-cross-owned stations. Second, shared support staff and conservation of resources does not necessarily mean a reduction in local news. The efficiencies derived from some of these practices may in fact, increase the amount of diverse, competitive news and local information available to the public. Thus, the record does not demonstrate that the current rule specifically promotes localism, or that elimination of the rule would harm it.

258. *Diversity*. The NPRM asked whether the cross-ownership rule is necessary to foster viewpoint diversity in today's media marketplace. The NPRM sought comment on the types of media that contribute to viewpoint diversity and how the cross-ownership rule affects viewpoint diversity. The NPRM noted that the current rule counts as a media voice commercial and non-commercial broadcast television and radio stations, certain daily newspapers, and cable systems. The NPRM asked whether additional types of media should also be counted as contributing to viewpoint diversity, such as the Internet, DBS, cable overbuilders, individual cable networks, magazines, and weekly newspapers.

259. The Commission has previously concluded that "the information market relevant to diversity includes not only television and radio outlets, but cable, other video media and numerous print media as well." Not only has the Commission seen an increase in the types of outlets available, but local markets have also experienced enormous growth in broadcast outlets. The record shows that in local broadcast markets of all sizes the numbers of radio and television stations have increased over the years.

260. The Commission concludes that the current television/radio cross-ownership rule is not necessary to ensure viewpoint diversity. The Commission agrees with the commenters that argue that a cross-

ownership rule applicable only to radio and television is "inequitable and outdated." Although several commenters argue that retention of the radio/television cross-ownership rule is necessary to protect the availability of diverse views, information, and local programming, the Commission believes that a rule limited to just radio and television fails to take into account all of the other relevant media in local markets available to consumers.

261. The Commission agrees with the commenters, however, that fostering the availability of diverse viewpoints remains an important policy goal, and that diversity of ownership promotes diversity of viewpoints. The Commission is adopting modified service-specific local ownership rules that will protect and promote competition in the local television and radio markets and, as a result, will also protect and preserve viewpoint diversity within those services. In addition, the Commission is adopting a new cross-media limit rule, described below, that is specifically designed to protect diversity of viewpoint in those markets in which the Commission believes consolidation of media ownership could jeopardize such diversity.

262. *Conclusion*. The Commission does not have evidence in the record sufficient to support retention of the current radio/television cross-ownership rule. From a competitive perspective, radio and television are not good substitutes for the same revenue producing opportunities, and thus, cannot be regarded as competing in the same product market. There is little evidence that the current rule promotes localism and, to the contrary, the record indicates that combined station groups may be able to achieve cost savings that may accrue to the benefit of listeners and viewers. Finally, radio and television stations compete with many other electronic and print media in providing programming and information to the public, and the targeted cross-media limits adopted herein are therefore better designed to achieve the Commission's diversity goal in markets where diversity could be jeopardized by cross-ownership than the stand-alone radio/television cross-ownership rule. In addition, the Commission's local television and local radio ownership rules, which are designed to preserve competition in those markets, will also foster diversity of voices. The Commission now turns to a discussion of the Diversity Index, which is intended to help us analyze outlets that contribute to viewpoint diversity in local markets.

263. *The Diversity Index*. In order to provide its media ownership framework with an empirical footing, the Commission has developed a method for analyzing and measuring the availability of outlets that contribute to viewpoint diversity in local media markets. The measure the Commission is using, the Diversity Index or DI, accounts for certain, but not all media outlets (newspapers, broadcast television, radio, and the Internet) in local markets available to consumers, the relative importance of these media as a source of local news, and ownership concentration across these media. The DI builds on the Commission's previous approach to the diversity goal: The Commission retains the principle that structural regulation is an appropriate and effective alternative to direct content regulation; the Commission retains the principle that viewpoint diversity is fostered when there are multiple independently-owned media outlets in a market; the Commission retains its emphasis on the citizen/viewer/listener and on ensuring that viewpoint proponents have opportunities to reach the citizen/viewer/listener. What the Commission adds is a method, based on citizen/viewer/listener behavior, of characterizing the structure of the "market" for viewpoint diversity. The Commission uses the DI as a tool to inform its judgments about the need for ownership limits. This section explains the rationale for the diversity index and discusses calculation methodology.

264. The DI is based partly on the results of a consumer survey, which the Commission acknowledges is not without flaws, and partly on its expert judgment and analysis of the local viewpoint diversity marketplace. While the Diversity Index is not perfect, nor absolutely precise, it is certainly a useful tool to inform the Commission's judgment and decision-making. It provides us with guidance, informing us about the marketplace and giving us a sense of relative weights of different media. It informs, but does not replace, the Commission's judgment in establishing rules of general applicability that determine where the Commission should draw lines between diverse and concentrated markets.

265. Because of the limitations in the Nielsen survey, and the specific assumptions underlying the DI, it is a useful tool only in the aggregate. It cannot, and will not, be applied by the Commission to measure diversity in specific markets. Indeed, it could not be used on a particularized basis to review the diversity available in a specific market. For example, in determining the

appropriate weights to apply to the various media, the Commission has decided to give no weight to cable television or magazines as sources of local news, notwithstanding the results in the Nielsen survey to the contrary. The Commission recognizes that consumers in certain markets do have access to local news from local magazines, local cable news channels, and PEG channels, but the Commission believes that the Nielsen survey overstates this influence. On a national basis, the Commission believes most consumers either do not have access to such sources (such as a local news magazine) or rely very little on them (such as PEG channels). In sum, excluding these sources or factors from the DI does not undermine the general conclusions the Commission reaches about market concentration because the DI is not capable of capturing particularized market characteristics; it is intended to capture generalized, typical market structures and identify trends.

266. *Rationale for the Diversity Index.* Fostering diversity is one of the principal goals of the Commission's media broadcast ownership rules. In the past, the Commission has described its diversity goal as fostering "competition in the marketplace of ideas." Viewpoint diversity refers to availability of a wide range of information and political perspectives on important issues. Information and political viewpoints are crucial inputs that help citizens discharge the obligations of citizenship in a democracy. The Commission recognizes that the number of political viewpoints or the number of perspectives on a particular issue may be greater than the number of media outlets in a market. And the Commission recognizes that, in an effort to cater to viewer/listener/reader preferences any single outlet may choose to present multiple viewpoints on an issue. However, the Commission does not expect every outlet to present every perspective on every issue. The competition analogy suggests that having multiple independent decision-makers (*i.e.*, owners of media outlets) ensures that a wide range of viewpoints will be made available in the marketplace.

267. News and public affairs programming is the clearest example of programming that can provide viewpoint diversity. The Commission regards viewpoint diversity to be at the core of its public interest responsibility, and recognizes that it is a product that can be delivered by multiple media. Hence, in contrast to the Commission's competition-based rules, diversity

issues require cross-media analysis. Because what ultimately matters here is the range of choices available to the public, the Commission believes that the appropriate geographic market for viewpoint diversity is local, *i.e.*, people generally have access to only media available in their home market. To assist in its analysis of existing media diversity, and to help us determine whether any cross-media restrictions are necessary in the public interest, the Commission uses a summary index that reflects the general or overall structure of the market for diverse viewpoints. By analogy with competition analysis, the diversity index is inspired by the Herfindahl-Hirschmann Index (HHI) formulation, calculating the sum of squared market shares of relevant providers in each local market. The HHI measure, however, is particularly attractive for two reasons. First, its mathematical properties correspond to the Commission's beliefs about the effects a merger would cause. Each possible measure of market concentration has benefits and weakness that can be captured by the list of mathematical properties, or axioms, that that particular measure satisfies. In the case of measuring market concentration, a list of reasonable requirements or axioms limit us to the choice of few mathematical formulas. Within this class of admissible indices, the HHI can be thought of as a very conservative choice in the following sense. If the Commission asks "what is the loss of competition from a merger," known as the "delta" in the antitrust field, the HHI measure reflects the assumptions that: (i) An acquisition of a firm with given size will lead to a larger harm the larger the acquiring firm, and (ii) this harm is proportional to the size of both the merging parties.

268. Applying a similar analysis to the Diversity Index, the Index reflects the assumptions that if newspapers have twice the diversity importance of television, a newspaper's acquisition of a broadcast television station will cause twice the loss of diversity as will a merger of two broadcast television stations. Conversely, if radio has less diversity weight than television, then a merger of a television and a radio station will cause less of a loss of diversity than will a merger of two television stations. In contrast, if the Commission were to adopt a simple "voice test," for example, then it would be assuming that the loss of voice due to a merger is independent of the diversity importance of either party. Similarly, if the Commission were to

adopt a concentration ratio measure, then it would implicitly be assuming that the loss of diversity is independent of the size of the larger firm in the transaction. It is in this sense—that the size of the diversity loss increases as does the diversity importance of either merging party—that the Diversity Index developed here is a conservative measure, and one which the Commission adopts in the interest of prudence. Moreover, the HHI, from which the Commission's chosen measure derives, is widely used in economics and in antitrust. Thus, the Commission can draw on its experience with the HHI in competition policy to determine threshold values for the Diversity Index.

269. The Commission assigns market shares to these providers based in part on the results of responses to the Nielsen survey described in MOWG Study No. 8. The Diversity Index itself, however, is a blunt tool capable only of capturing and measuring large effects or trends in typical markets. Thus, the DI change from a particular transaction in a particular market might be more or less than the Commission anticipates, or that it might result in a market DI higher or lower than that suggested by the Commission's examples. This is of no moment as the DI is a tool useful only in the aggregate and will not—and cannot in its current form—be applied on a particularized basis.

270. There are several conservative assumptions in the Commission's analysis of viewpoint concentration. First, the Commission premises its analysis on people's actual usage patterns across media today. The Commission's method for measuring viewpoint diversity weights outlets based on the way people actually use them rather than what is actually available as a local news source. The Commission adopts this approach out of an abundance of caution because the Commission is protecting its core policy objective of viewpoint diversity. Second, the Commission's diversity analysis is based on preserving viewpoint diversity among local, not national, news sources. The effect is that the Commission excludes, for purposes of measuring viewpoint concentration, the large number of national news sources such as all-news cable channels and news sources on the Internet and instead focus exclusively on the smaller set of outlets that people rely on for local news. Excluding those national sources thus leaves us with a smaller set of "market participants" that the Commission regulates to protect local news diversity in a way that might be unnecessary to protect diversity among

national news sources. Third, the Commission does not include low power television and low power radio stations in measuring viewpoint diversity. These stations are often operated with the express purpose of serving niche audiences with ethnic or political content that larger media outlets do not address. These low power outlets promote viewpoint diversity in a way that the Commission has not addressed because of their more limited reach, but collectively they enhance viewpoint diversity beyond the levels that are reflected in the Diversity Index measurements.

271. The Commission concludes that each of these judgments that inform its viewpoint diversity analysis are sound, but in each case the Commission makes the most conservative assumption possible. Thus, the results of the Commission's diversity index analysis can fairly be said to understate the true level of viewpoint diversity in any given market.

272. *Choice of Media.* The Commission has determined which media to include in the Diversity Index based on the survey information derived from the "Consumer Survey on Media Usage" prepared by Nielsen Media Research (FCC MOWG Study No. 8). This survey tells us how consumers perceive the various media as sources of news and information. The key threshold implication of this study is that consumers use multiple media as sources of news and current affairs, and hence that different media can be substitutes in providing viewpoint diversity.

273. FCC MOWG Study No. 8 asked respondents to identify the sources, if any, "used in the past 7 days for local news and current affairs." The same question was posed for national news and current affairs. The choices offered were television, newspaper, radio, Internet, magazines, friends/family, other, none, don't know, and refuse. The survey then asked follow-up questions regarding the first five choices. For each one of the five sources, respondents who did not mention a source were asked specifically if they used that source for local news and current affairs. The survey posed analogous questions with regard to national news and current affairs. Based on the initial and follow-up questions, the survey presents "summary data" on sources of local and of national news and current affairs information.

274. In an *ex parte* communication filed May 28, 2003, Media General submitted a critique of MOWG Study No. 8 by Prof. Jerry A. Hausman. Hausman argues that the Nielsen Survey

has a number of serious flaws and questions its usefulness in any rule-making concerning cross-ownership of newspapers and broadcast stations. The Commission recognizes Professor Hausman's concerns, but the Commission believes that the Nielsen survey sample of 3,136 households provides us with useful information. In addition, Professor Hausman provides no evidence that the sample is, in fact, biased. Concerning Hausman's second point, the Commission agrees that answers to hypothetical questions are less useful than information about actual behavior. MOWG Study No. 8 provides a substantial amount of information on reported actual behavior. It is this information, not the hypotheticals, on which the Commission relies to conclude that media can be substitutes in providing viewpoint diversity and to construct its Diversity Index. Regarding Hausman's third point, although the Nielsen survey may not directly ask respondents for their views concerning specific cross-ownership scenarios, the Commission finds that the results of the survey are useful in a number of areas, such as which forms of media are most heavily used for news. While questions could have been posed that contained more specificity concerning cross-ownership rules, the Commission understands that such complexities could have made the survey design more difficult, as well as possibly lowered the response rate. Overall, while Hausman claims that the Nielsen survey does not "provide a basis for the measurements necessary for the specification of policy," the survey does, in fact, help us establish an "exchange rate" for converting newspaper, television, radio, and other media into common units so the Commission can measure the extent of concentration in the "market of ideas." Finally, the Commission emphasizes that it has not relied solely on the results of the Nielsen survey, but has used a number of studies and its own expert judgment on media in reaching its decision.

275. The data in the Nielsen study indicate that television, newspapers, radio, Internet, and magazines are the leading sources of news and current affairs programming. Based on the initial question, the average respondent uses two of the five major sources for news and current affairs, whether the category is local or national. Taking account of the follow-up questions, the average respondent uses three of the five major sources for news and current affairs, again regardless of whether the category is national or local. These data

strongly suggest that citizens do use multiple media as sources of viewpoint diversity, and that media can be viable substitutes for one another for the dissemination of news, information and viewpoint expression. On the basis of this finding, the Commission proceeds to an analysis of local media markets and whether there are particular kinds of cross-media transactions in particular kinds of markets that would likely result in high levels of concentration. To assist in making that determination, the Commission relies in part on its Diversity Index.

276. The Commission's Diversity Index focuses on availability of sources of local news and current affairs. As the Commission explained in the policy goals section of the R&O, it is concerned with promoting viewpoint diversity in local media markets. Owners of media outlets clearly have the ability to affect public discourse. Consumers have numerous sources of national news and information available to them. Therefore the Commission does not believe that governmental regulation is needed to preserve access to multiple sources of national news and public affairs information.

277. The Diversity Index incorporates information on respondents' usage of television, newspapers, radio, and the Internet. Respondents also reported getting local news and information from magazines. The Commission excludes magazines, however, from its Diversity Index. First, as the description above makes clear, most (but not all) news magazines have a national rather than a local focus. Nonetheless, the decision to exclude magazines will be re-examined in the next biennial review, and the Commission will take the opportunity to gather additional survey data at that time on magazine usage.

278. For similar reasons, the Commission also excludes cable from its Diversity Index. The Commission is concerned that some consumers may have confused broadcast and cable television. Thus, the Commission believes some consumers who replied that they receive their local news from cable may have been viewing broadcast channels over the cable platform. The Commission also recognizes, however, that cable systems do provide local news and current affairs information through PEG channels and, in some markets, local news channels. However, the Commission does not have accurate data for this measure. Because the Commission does not have reliable data

on this point, it excludes cable from the DI to simplify its general analysis.¹⁸

279. *Weighting Different Media.* The Commission has concluded that various media are substitutes in providing viewpoint diversity, but the Commission has no reason to believe that all media are of equal importance. Indeed the responses to the survey make it clear that some media are more important than others, suggesting a need to assign relative weights to the various media. In view of the Commission's focus on local news and current affairs, it chooses to base its weights on survey responses to the question asking respondents to identify the sources, if any, "used in the past 7 days for local news and current affairs." The Commission recognizes that this is not a perfect measure, and that it requires some adjustment. The Commission justifies these adjustments and assumptions, however, by emphasizing that it is using the DI only to inform itself of general market trends, not for precise measurements.

280. The average respondent uses three different media for local news and current affairs information. It is likely that, for a given respondent, the three are not all of equal importance. If media differ in importance systematically across respondents then it would be misleading to weight all responses equally. Unfortunately, the Commission does not have data on this question specifically with regard to local news and current affairs. The available "primary source" data address local and national news together and do show that different media have different importance, in the sense that primary usage differs across media. Because "primary source" data are not available for local news and current affairs alone, the Commission uses the data identifying sources of local news and public affairs programming to weight the various media to reflect relative usage. This leads to lower shares for television and higher shares for radio than the "primary source" shares reflect.

281. The local response summary data, Table 97 of MOWG Study No. 8, include five categories of media—Internet, magazines, radio, newspaper, television. Magazines account for 6.8% of responses to the questions on source of local news and current affairs. We exclude magazines as explained above and normalize the shares of the four remaining media to sum to 100%. The

resulting weights are television (33.8%), newspapers (28.8%), radio (24.9%), and Internet (12.5%).¹⁹ The local response summary data do not break down the television responses between broadcast television and cable/satellite television. Nor do these data separate out usage of daily and weekly newspapers. We make use of other FCC MOWG Study No. 8 questions to apportion the newspaper shares further.

282. Although the responses to one question in MOWG Study No. 8 suggests that cable is a significant source of local news and current affairs, other data from the study casts some doubt on this result. The following discussion explains the reasoning that leads us to exclude cable/satellite television from the current analysis of local news and current affairs for diversity purposes. DBS currently provides little or no local nonbroadcast content. The Commission will review the status of cable as a local news provider in the 2004 biennial review. The Commission's review will include a follow-up to MOWG Study No. 8, which will include more detailed questions regarding the use of nonbroadcast video media for local news and current affairs.

283. With regard to newspapers, MOWG Study No. 8 indicates that 61.5% of those who cite newspapers as a source of local news and current affairs acquire that information from dailies only, 10.2% from local weeklies only, and 27.3% from both. The next biennial review will provide the Commission with an opportunity for re-examination of the role of weekly newspapers. Accounting for the additional information on newspapers results in a revised set of weights. They are: broadcast television 33.8%, daily newspapers 20.2%, weekly newspapers 8.6%, radio 24.9%, and Internet 12.5%.

284. The most detailed analysis of MOWG Study No. 8 comes from the Consumer Federation of America (CFA). CFA agrees that citizens get viewpoint diversity from multiple media. Their comments refer to the "two dominant political media—daily newspapers and television," although CFA asserts that these media "appear to play very different roles." Television has the largest weight in the DI (33.8%) and daily newspapers also loom large at 20.2%. Although the radio weight is somewhat higher at 24.9%, the fact that markets generally have far more radio stations than daily newspapers make the Commission's weights consistent with

CFA's conclusion that newspapers are among the two most influential media. CFA finds that the Internet plays a small but growing role in citizen acquisition of news and information, a finding not inconsistent with the relatively low weight of Internet in the Commission's DI. CFA quotes statistics on daily use of television, newspapers, radio, and Internet that yield usage shares not too different from the Commission's DI weights. Drawing on two surveys, CFA suggests that people spend 4 minutes per day on average gathering news from the Internet, 25 minutes reading newspapers, 15 minutes listening to radio news, and "over half an hour" watching television news. Ascribing half an hour to television leads to shares of 40.5% for television, 33.8% for newspapers, 20.3% for radio, and 5.4% for Internet. These are fairly close to the Commission's DI weights of 33.8%, 28.8%, 24.9%, and 12.5% for television, newspapers, radio, and Internet, respectively.

285. Although CFA does not dispute the proposition that different media address the same issues and stories, it asserts that they do so in different ways, suggesting, *inter alia*, that television is "the primary source for breaking news," that newspapers have a larger role in "the follow-up function," and that talk shows are a new and significant element of radio's role in disseminating viewpoints. Although CFA does not discuss the role of radio as a source of breaking news, the Commission acknowledges that different media do present information in different ways. Thus, CFA appears to conclude that media are substitutes for some citizens and complements for others.

286. The Commission disagrees with CFA's conclusion that the DI is invalid because some citizens may consider certain media outlets complements rather than substitutes. In the technical economic sense, two goods are substitutes if an increase in the price of good A (which leads to a decrease in consumption of good A) leads to an increase in the consumption of good B. In the context of the Commission's diversity goal, the Commission is concerned with the question of what happens when one or more media outlets refuses to transmit a particular viewpoint. If most citizens accessed only one type of outlet, e.g., radio but not newspapers or television, then its diversity goal would prompt us to analyze separately the structure of the "radio marketplace of ideas." If, on the other hand, most citizens access multiple media, then the Commission can rely on the reasonable probability that, if, e.g., the local newspaper refused

¹⁸ As with magazines, we will review this issue in the next biennial review, and may collect at that time more accurate survey data on consumers' use of cable for local news and current affairs.

¹⁹ The "primary use" weights, excluding magazines, are television (57.8%), newspapers (25.8%), radio (10.3%), and Internet (6.1%). When magazines are included their weight is 0.6%.

to cover a particular story, citizens would be exposed to that story via independently-owned other media, such as radio or television. In other words, evidence that media are complements in the sense that, for at least some citizens, there is a positive correlation between use of one medium and use of another, does not invalidate the premise underlying the DI.

287. *Weighting Outlets Within the Same Medium.* Having decided on relative weights for the various media, the Commission next confronts whether and how to weight different media outlets within each category. The decision of whether to do weighting turns on whether the Commission's focus is on the availability of outlets as a measure of potential voices or whether it is on usage (*i.e.*, which outlets are currently being used by consumers for news and information). The Commission has chosen the availability measure, which is implemented by counting the number of independent outlets available for a particular medium and assuming that all outlets within a medium have equal shares. In the context of evaluating viewpoint diversity, this approach reflects a measure of the likelihood that some particular viewpoint might be censored or foreclosed, *i.e.*, blocked from transmission to the public. The case for a usage measure is that it reflects actual behavior. However, current behavior is not necessarily an accurate predictor of future behavior. Moreover, in order to implement a usage measure accurately, it would be necessary for us to define which content should be considered local news and current affairs. Current behavior, *e.g.*, viewing or listening to a broadcast station, is based on the content provided by the station in question. However, media outlets can change the amount of news and current affairs that they offer, perhaps in response to competitive conditions in the "viewpoint diversity" marketplace. Such changes are unpredictable, so current market shares (*e.g.*, of viewing or listening) may not be good predictors of future behavior.

288. If the Commission were to adopt a usage measure designed to reflect its concern with local news and current affairs, it would need information on viewing/listening/reading of local news and current affairs material. To implement this procedure, it would be necessary first to determine which programming constituted news and current affairs. The Commission believes that this type of content analysis would present both legal/Constitutional and data collection problems. News and current affairs

content is not necessarily limited to regularly-scheduled news programs. So the Commission could be faced with deciding which other programs were news and current affairs, whether some portion of a program not primarily news should count as news, and, indeed, whether portions of a news report devoted, *e.g.*, to movie reviews should count as news. Ultimately, the Commission's goal is not to prescribe what content citizens access, but to ensure that a wide range of viewpoints have an opportunity to reach the public. This goal, the limitations of current usage as a predictor of future usage, and the content classification requirements for implementing a usage measure all lead us to adopt an "equal share" approach to weighting outlets within the same medium.

289. The Commission deviates from this approach only in the case of the Internet. The Commission used subscription shares to divide the Internet category among the two current significant sources of Internet access—telephone companies and cable companies. The Commission thinks it prudent to use subscriber figures to calculate how to divide the Internet category between cable and telephone companies.

290. Table 78 of FCC MOWG Study No. 8 provides information on Internet access. If the Commission takes the 99.7 percent of respondents who picked cable, DSL, or telephone line as the base, and if the Commission combines telephone and DSL, the resulting shares are 19 percent cable and 81 percent telephone. The Commission recognizes that, given the relatively small share of Internet in the total diversity market (12.5% weight), using subscriber shares rather than equal availability for Internet providers has a very small impact on its Diversity Index calculation.²⁰ In this regard, however, the Commission rejects the argument made by some commenters that the Commission should not include the Internet at all because people only utilize the Internet to access their newspapers' and local broadcast

stations' Web sites and, therefore, the Internet does not add to diversity. Although many local newspapers and broadcast stations maintain Web sites with news content, that does not begin to plumb the extent of news sources on the Internet.

291. *Calculation Methodology.* The Diversity Index is structured like an HHI, *i.e.*, it is simply the sum of squared market shares. As explained above, squaring market shares, unlike measures based on the "raw" market shares, permits construction of an index that takes account of the market shares of all providers in the "market" for viewpoint diversity. As noted above, the geographic market the Commission is using is local. The Commission currently defines television markets in terms of the Nielsen DMA. DMAs are exhaustive classifications, covering the entire United States, and it is straightforward to count the number of television stations in a DMA. The Commission is including public as well as commercial stations. The Commission chooses not to include television stations from outside the DMA in question, even if they obtain a measurable audience share in the DMA. The Commission's focus is on local news and current affairs and it is not reasonable to assume that stations outside of the DMA in question will devote significant resources to news and current affairs programming targeted to that DMA. The Commission's cable television signal carriage rules generally permit a television broadcast station within a DMA to obtain cable carriage throughout the DMA, and its DBS signal carriage rules generally ensure that all television stations within a DMA are treated the same with respect to satellite retransmission. For this reason, the Commission assumes that all television broadcast stations in a DMA are available throughout the DMA. Each broadcast television station receives an equal share of the broadcast television weight.

292. The Commission combines the television stations in each DMA with the radio stations in the Arbitron radio metro with which the DMA is paired. There are 287 Arbitron radio metros in the country. Each one is smaller than the DMA within which it lies.²¹ Arbitron radio metros do not cover the entire country. More sparsely populated areas are not included in radio metros; approximately one-half of radio stations are not in a metro market. As explained below in the cross-media limits section

²⁰ As explained in the section Calculation Methodology of the R&O, the diversity index is calculated by squaring relevant market shares. If the Commission assumes that the two Internet sources have equal shares, the contribution to the index of Internet would be 78 points. The assumption leads to a contribution to the index of 109 points. We do not attribute common ownership to Internet Service Providers. We will assume (subject to examination at the next biennial review and to future findings), that ISPs do not restrict subscriber access to Internet content based on the identity of the content provider. The Commission is looking at the availability of news and information sources generally—and Web sites particularly—not their popularity.

²¹ Most radio metros lie wholly within a single DMA; virtually all of the others are predominantly within a single DMA.

of this Order, the Commission uses the Diversity Index to help it identify markets that are "at risk" for excessive concentration in the "viewpoint diversity market." Once those markets have been identified, and cross-media limits imposed, the actual implementation of the cross-media diversity limits will not require information on a local radio market, only on the television market (DMA) within which the radio stations are located that are part of a proposed merger. As detailed in the cross-media limits section, the analysis that the Commission uses to identify at-risk markets is based on examination of a substantial sample of the 287 Arbitron radio metro markets.

293. Daily newspaper publication and circulation data are not collected based on Arbitron radio metros. A different market concept, developed by the Department of Commerce, is used by the industry. The basic building block is the "Metropolitan Statistical Area," or "MSA." The Department of Commerce recognizes 318 metropolitan areas, which include 248 MSAs, 58 "PMSAs" (primary metropolitan statistical areas), and 12 "NECMAs" ("New England county metropolitan statistical areas"). For Diversity Index calculation purposes, these areas are matched to Arbitron radio metros. Each daily newspaper that is locally published in the metropolitan area is included in the market. The daily newspaper share of the Diversity Index is divided evenly among all daily newspapers included in the market. In the absence of market-specific information on weekly newspaper availability, the Commission makes the most conservative assumption that there is one independently-owned weekly newspaper in each local market, and assign to it the entire weekly newspaper share.

294. In terms of calculating the Index, within each medium the Commission combines commonly-owned outlets and calculate each owner's share of the total availability of that medium. The Commission then multiplies that share by the share of the medium in question in the total media universe (television plus newspaper plus radio plus Internet). Once these shares in the overall "diversity market" have been calculated, the Commission adds together the shares of properties that are commonly-owned (for example, a newspaper and a television station), square the resultant shares, and sum them to get the base Diversity Index for the market in question.

295. *Cross-Media Limits.* The Commission modifies its rules by

adopting a new set of cross-media limits ("CML") in lieu of the Commission's former newspaper/broadcast and television/radio cross-ownership rules. The CML have been designed specifically to check the acquisition by any single entity of a dominant position in local media markets—not in economic terms, but in the sense of being able to dominate public debate—through combinations of cross-media properties. Because the Commission has traditionally relied upon blanket prohibitions on certain cross-media combinations, it has never before had to confront head-on the challenge of identifying specifically which types of markets give us the greatest cause for concern in terms of preserving diversity of viewpoint, and which types of transactions are most problematic in this regard. This effort is complicated by the nature of the public interest the Commission are seeking to protect—diversity—which is as elusive as it is cherished.

296. The Commission's modification of the newspaper/broadcast and television/radio cross ownership rules into a set of cross-media limits or CML is the Commission's first comprehensive attempt to answer this difficult and complex set of questions. The CML derives from data in the record regarding the relative reliance by consumers of various types of media outlets for news and information. To help us analyze that data, the Commission uses a methodological tool—a diversity index or "DI"—that allows us to measure the degree to which any local market could be regarded as concentrated for purposes of diversity. Based on an analysis of a large sample of markets of various sizes, the diversity index suggests that the vast majority of local media markets are healthy, well-functioning, and diverse.

297. Moreover, because the Commission is adopting herein intra-service competition caps for radio and television properties, those caps will ensure that local markets will continue to be served by a diversity of voices within each of these respective services. By the nature of the exercise, markets defined for competition purposes are no broader than, and generally are narrower than, markets defined for diversity purposes. Thus, the Commission's radio and television competition caps will not only serve to promote and protect competition within the radio and television services, they will also be protective of diversity interests when television-only or radio-only transactions are at issue. For example, in a market with 12 TV stations, the Commission's intra-service

caps guarantee at least six different owners of television stations. If there are forty radio stations in the market, the Commission's radio cap will ensure at least six different owners of radio properties.

298. The Commission recognizes, however, that its intra-service caps will not address diversity concerns that may result from cross-media combinations. Although the Commission's local radio and television caps will ensure a significant number of independent voices in larger markets, cross-media combinations in very small markets might result in problematical levels of concentration for diversity purposes. Accordingly, the Commission supplements its two intra-service local rules with a narrowly drawn set of cross-media limits to reach those combinations that are not already prohibited by its television or radio caps, but which would give rise to serious diversity concerns. The cross-media limits are based on a set of assumptions drawn directly from the record evidence in this proceeding and premises that are consistent with past Commission policy and practice. Although the Commission relies in part on its data analysis to help define the CML, it clearly respects that diversity is inherently subjective and cannot be reduced to scientific formula. The CML, therefore, ultimately rests on the Commission's independent judgments about the kinds of markets that are most at-risk for viewpoint concentration, and the kinds of transactions that pose the greatest threat to diversity.

299. *Competition Caps Protect Diversity.* The Commission has adopted a cap both on the number of television stations that any one owner may hold in a market, and on the number of radio stations that any one owner may hold in a market. These caps were designed to promote and protect competition within these two distinct services. The caps are, therefore, based on product market definitions that consider only those products or services that may be regarded as reasonable substitutes for competition purposes. The Commission recognizes, however, that although radio and television outlets may not compete in economic terms with other types of speech outlets, e.g., newspapers, they all inhabit the mass media landscape that Americans turn to for news and information. In that sense, whatever the confines of their markets for competition purposes, many different outlets serve core democratic functions as purveyors of ideas, outlets for opinion, and distributors of news.

300. The data in the record evidence this difference. Radio and television

compete in economic terms in separate and distinct product markets. Both radio and television outlets, however, inhabit the larger speech market, as do several other types of entities. For example, MOWG Study No. 8, a consumer survey on media usage, reveals that, when asked to identify their primary source of all news and information—both local and national—approximately 40% of Americans responded that broadcast television was their primary source and approximately 10% of Americans responded that radio was their primary source. However, nearly 24% of respondents identified daily newspapers as their primary source of news and information, 18% identified cable news networks, 6% identified the Internet, and 2% identified weekly newspapers or magazines. Other studies confirm that, today, Americans substitute among and between many different sources for news and information on a regular basis. The record reflects, in short, that the “viewpoint” market in which television and radio stations participate is broader than the economic product markets, as defined by standard competition theory, in which either competes. As a result, intra-service caps designed to ameliorate competition concerns necessarily also will protect against undue concentration of speech outlets for diversity purposes.

301. The Commission’s diversity index helps to illustrate this point. Pursuant to the Commission’s new local radio rule, no single owner, even in the smallest markets, will own more than 50% of the radio outlets. In larger markets, the percentage of radio outlets that can be held by any one entity is considerably smaller. Thus, using the most extreme set of facts, and using Altoona, Pennsylvania, as the Commission’s test case, the diversity index focused on local news and information alone (again, the most conservative assumption) reveals a relatively minimal impact on viewpoint diversity even should the radio outlets become split between only two owners. The current base case DI for local news and information for Altoona is 960. If the local radio market were to become restructured into a duopoly, the DI would rise to only 1,156. This hypothetical posits the most extreme restructuring of radio outlets in the smallest market among those in the Commission’s test cases. The change in the diversity index will be far smaller as a result of radio transactions in larger markets or where the restructuring is less extreme.

302. Similarly, pursuant to the Commission’s new local television rule,

no single owner will be permitted to own more than two television outlets in most markets. Using a set of randomly sampled markets of varying sizes, the average change in DI as a result of an owner of one television property buying another to create a television duopoly in a small market with only five licensed television stations is 91. In markets with twenty licensed television stations the change in DI as a result of the creation of a television duopoly is only six.²² Thus, although the Commission’s intra-service television and radio caps are designed to protect and promote competition, they have a corollary benefit of also guarding against concentration in the viewpoint markets, at least with respect to intra-service combinations.

303. The Commission recognizes, however, that cross-media combinations that may impact the range and diversity of voices in local markets will not be captured by its television and radio caps. The Commission therefore adopts new cross-media limits targeted specifically and solely at the types of transactions that would give it the most concern and which are not already prohibited by its intra-service caps.

304. *Foundations of the Cross-Media Limits.* The Commission begins with the proposition that, because this rule will limit the speech opportunities not only for broadcasters, but also for other entities that may seek to own and operate broadcast outlets (including those with the fullest First Amendment protection—newspapers), the Commission should draw the rule as narrowly as possible in order to serve its public interest goals while imposing the least possible burden on the freedom of expression. The Commission also recognizes that the tools that the Commission is using to evaluate market diversity involve as much art as science. “Diversity” is not susceptible to microscopic examination; it cannot be mapped with any known formal system or reduced to mathematical equations. Although the Commission attempts to measure it and assign some quantitative value to it in order to understand relative diversity of different types of markets, it recognizes that this process is inherently approximate.²³ The

²² The local television ownership cap includes a prohibition on top-four combinations. This will have the effect of prohibiting combinations of the local television stations most likely to produce and carry significant local news programming. Thus, although the top-four restriction is based on competition theory, the rule will also have beneficial effects on local diversity.

²³ Using the Diversity Index allows the Commission to see different market characteristics in markets of different sizes. It has also found, however, that differentiating markets by the number

Commission must exercise great care, therefore, before categorically prohibiting any particular transaction or set of transactions as a prophylactic matter.

305. Nonetheless, it is apparent, based on the record in this proceeding, that certain types of transactions in certain markets present an elevated risk of harm to the range and breadth of viewpoints that may be available to the public. Using the Commission’s diversity index analysis and its independent judgment regarding desired levels of diversity, the Commission first identifies “at-risk” markets that might already be thought to be moderately concentrated for diversity purposes. It then identifies the types of transactions that pose the greatest risk to diversity, and imposes specific limits on those transactions in at-risk markets. Finally, because certain transactions in less concentrated markets pose a high risk of rapid concentration, the Commission imposes separate restrictions on transactions outside of the at-risk markets.

306. *Identifying At-Risk Local Markets.* The Commission begins by identifying those markets most susceptible to high levels of viewpoint concentration; i.e., those markets where its diversity concerns cut most deeply. At the outset, consistent with the Commission’s past practice and precedent, the Commission focuses in this regard on local, not national, viewpoint market(s). Evidence in the record before us supports the conclusion that the number of outlets for national news and information is large and growing, and that government regulation is thus unnecessary to protect it.

307. With respect to local markets, the Commission’s ten city study and its DI test cases reveal that most local markets today are well-functioning, healthy markets for speech. Not all voices, however, speak with the same volume. Using its Diversity Index, the Commission has examined the concentration of media outlets in the ten markets that were the subject of its Ten City Study using weighted voices. New York has a base DI for local news and information of 373; Lancaster, Pennsylvania, has a DI of 939; and Myrtle Beach, South Carolina, has a DI of 989. Indeed, the average DI for all ten markets, which range from the largest to near the smallest, is 758. A DI of 758 is the equivalent of 13 equally-sized firms.

of newspapers present is too blunt while differentiating markets by the number of radio stations is too fine. Therefore, the Commission uses the number of television stations as an identifier of market size.

308. Moreover, to ensure that the results of its ten city study were not anomalous, the Commission has calculated the average DI for a different set of randomly selected markets, both large and small. The average DI for markets in which there are 20 television stations is 612; the average DI for markets in which there are 15 television stations is 595; the average DI for markets in which there are 10 television stations is 635; and the average DI for markets in which there are 5 television stations is 911—all well below the point at which one would characterize them as highly concentrated if one were using the analogous HHI to measure competition in the market.

309. The Commission believes the analogy to the HHI is apt. The HHI is an indicator of economic concentration; it provides an analytical framework for determining when and if an entity or group of entities is likely to wield market power in an economic market. The Commission's DI, which was inspired by and modeled after the HHI, similarly is an indicator of viewpoint concentration. Using the DI as an analytical tool, the Commission can assign approximate weights to different types of media outlets, account for the diversity effects of commonly-owned properties, and measure relative concentration between and among markets. The DI can help the Commission, therefore, identify the point at which an entity or group of entities is likely to wield inordinate power in the marketplace of ideas.

310. Although competition theory does not provide a hard-and-fast rule on the number of competitors necessary to ensure that the benefits of competition are realized, a market that has ten or more equally-sized firms normally can be considered fully competitive.²⁴ A 1000 DI correlates to market in which there are roughly ten firms with approximately equal market power. An 1800 DI would correspond to a market with six roughly equal voices. Using the Commission's DI analysis of sample markets, it notes that it is not until it reaches markets with three or fewer licensed television stations that the average DI exceeds 1000, the point at which the market normally would be characterized as moderately concentrated for competition purposes.²⁵

²⁴ A market with 10 or more equally-sized firms has an HHI of 1000 or less. DOJ/FTC regards markets in this region to be unconcentrated. Mergers resulting in unconcentrated markets are unlikely to have adverse competitive effects and ordinarily require no further analysis.

²⁵ The average DI for markets with three television stations is 1027; the average DI for

311. The Commission's DI analysis of these sample markets, however, is not the end of its inquiry. Because of the importance the Commission associates with maintaining diversity among the three principal platforms—newspaper, radio and television—for the expression of viewpoint at the local level, and because these same three outlets produce a large share of local news content, the Commission previously has used a "voice test" focused on one or more of these outlets for measuring diversity. In larger markets, the Commission expects that the number of distribution outlets for local news content will be larger, and that consumers will have greater access to secondary outlets for news and information.

312. Finally, the Commission is concerned not merely with the absolute level of diversity that might already exist in any market or type of market, but also with the degree to which diversity might be sacrificed as a result of likely transactions. Accordingly, in defining "at-risk" markets, the Commission has used its DI and sampled the effect of transactions, in large and small markets, involving heavily used sources of local news and information. In so doing, the Commission has focused on the types of transactions that most likely will lead to large DI changes and rapid concentration. The Commission's line-drawing effort is informed by the approach the DOJ has taken in assessing competition issues. Although DOJ policy is to review any transaction in a moderately concentrated market that would result in a change in HHI of 100 points or more, the Commission has found no case in many years in which DOJ has filed suit to block a merger that produced less than a 400 or more point HHI change. Based on the Commission's analysis, cross-media combinations involving newspaper and television, newspaper and radio, or radio and television properties do not produce a change in the DI of anything even approaching that magnitude other than in markets with three or fewer television stations.

313. These changes, of course, reflect approximations based upon sample data and are provided only to be illustrative of the diversity losses that can occur as a result of cross-media combinations in small markets. Nonetheless, based on all of the foregoing, the Commission concludes that a market with the equivalent of ten or more equally-sized

markets with two television stations is 1316; and the average DI for markets with a single television station is 1707.

firms cannot be regarded as even moderately concentrated for diversity purposes. In light of that conclusion, and in consideration of the properties of small markets and on its analysis of potential transactional impacts in those markets, the Commission concludes that markets with three or fewer licensed television stations should be regarded as "at-risk" markets for purposes of diversity concentration. Markets of that size, the Commission expects, will be moderately concentrated and subject to rapid concentration if cross-media combinations are created involving radio, television and/or newspaper properties.²⁶ Accordingly, the Commission will prohibit certain cross-media combinations involving those properties in markets with three or fewer television stations.

314. *Local Cross-Media Limits in At-Risk Markets.* With respect to the limits themselves, the Commission treads lightly in view of the sensitive First Amendment interests at stake and the deregulatory purpose of Section 202(h). The Commission's intent is to draw its rules narrowly, focusing on those transactions that are likely to have a substantial impact on the diversity of voices available in the market. The record shows that broadcast television, daily newspapers, and broadcast radio are the three media platforms that Americans turn to most often for local news and information. They are, accordingly, the focus of the Commission's diversity concerns, and the Commission declines to impose any cross-media limit on transactions involving media properties other than radio, television, and newspaper outlets.

315. Further, the Commission is establishing rules of nationwide applicability. The Commission desires, therefore, to provide the industry and the public with clear, easy to administer rules reflective of common market trends and characteristics. The Commission recognizes that, in any given market, the lines the Commission draws here may appear under- or over-inclusive. Again, although they have a methodological foundation in the DI, these judgments are based on agency expertise and experience dealing with broadcast markets and the media

²⁶ A market with an HHI of more than 1800 is regarded as highly concentrated. We noted above that a DI of 1800 would correspond to six equally-sized "voices." Because of the amorphous nature of diversity as an interest and the difficulty of measuring it with precision, we decline to draw an absolute line prohibiting transactions that would take a market beyond the 1800 DI (*i.e.*, six voice) level. The rules we are adopting herein, however, are intended to protect against markets becoming highly concentrated—in a qualitative sense—for diversity purposes.

industries generally. Accordingly, except as specifically prohibited herein, cross-media combinations will not be subject to anything other than routine Commission review, *i.e.*, unless the transaction is barred by the CML or the Commission's other ownership rules, the combination is permissible under the Commission's rules, and the Commission will not apply the DI to it.²⁷

316. Combinations of daily newspaper and broadcast properties in at-risk markets present a serious threat to local viewpoint diversity. The Commission therefore, adopts a rule prohibiting common ownership of broadcast stations and daily newspapers, and TV/radio combinations, in markets with three or fewer television stations. In order to determine which markets have 3 or fewer broadcast television stations, the Commission will rely on Nielsen television Designated Market Areas (DMAs). The Commission includes for these purposes, commercial and noncommercial television stations assigned to the DMA.

317. A number of parties have questioned whether a cross-ownership rule applicable to entities other than broadcasters, *e.g.*, newspaper owners, would be constitutional. The Commission continues to believe that a narrowly-drawn rule prohibiting or limiting common ownership of broadcast properties and daily newspapers is consistent with its constitutional framework. The Commission's current newspaper/broadcast cross-ownership rule has been upheld by the Supreme Court against constitutional challenge and, as discussed above, broadcast/newspaper and radio/television cross-ownership rules, like broadcast ownership rules, are reviewed under the rational basis standard. The Commission believes that its new cross-media limits satisfy this standard because they are "a reasonable means of promoting the public interest in diversified mass communications," and they are founded on a substantial record.

318. *Television-Newspaper.* Nielsen survey data reveal that daily newspapers and broadcast television remain the two most important sources of local news and information. The

importance of these outlets is reflected in the Commission's DI. A combination of a daily newspaper and a television station in a market with only three television stations leads to an average DI change of 331 points. These combinations in markets with only two or one television station lead to DI changes of 731 and 910 DI points, respectively. In these at-risk markets, a single combination of a daily newspaper and a television station could quickly jeopardize the range of viewpoints available to consumers in the market. The Commission therefore, adopts a rule prohibiting the combination of a daily newspaper and a broadcast television facility in any market with three or fewer television properties. To trigger the rule, the Commission will count all television stations assigned to the DMA that contains the newspaper's community of publication. The Commission presumes that broadcast television stations are generally carried throughout the DMA to which the station is assigned. The Commission's rules will not, however, bar a broadcast television station in such a market from starting a new newspaper, as that would expand, not decrease, diversity.

319. One additional issue in the cross-interest context is the definition of "daily newspaper" for the purposes of newspaper/broadcast cross-ownership. Currently, Note 6 to the multiple ownership rule defines a daily newspaper as "one which is published four or more days per week, which is in the English language and which is circulated generally in the community of publication." The exclusion of non-English language daily newspapers in areas where the dominant language of the market is not English creates a discrepancy in treatment that must be ended. Since the definition of a daily newspaper was adopted in 1975, the percentage of households in which Spanish was spoken has approximately doubled. It is appropriate, therefore, at this point in time, that the Commission applies the CML to non-English daily papers in markets in which the language that they are printed in is the dominant language of their market.²⁸

320. *Radio-Newspaper.* Although broadcast radio generally has less of an impact on local diversity than broadcast television, according to the results of the Nielsen survey, in at-risk markets the

combination of a daily newspaper with one or more broadcast radio facilities can nonetheless have significant negative implications for the range of viewpoints available. Indeed, markets with three or fewer television stations have, on average, only 21 radio stations. Under the Commission's radio cap, a single owner in a market with 21 stations could own six stations, or 29% of all the radio outlets in the market. Combining such a station group with, perhaps, the only daily newspaper could, therefore, seriously impair the range of independent viewpoints available in the market. The Commission therefore, adopts a rule prohibiting the combination of a daily newspaper and a broadcast radio facility in any market with three or fewer television properties. To trigger the rule for newspaper/radio combinations the Commission will retain its current standard. That standard requires complete encompassment of the newspaper's community of publication by the requisite signal strength contour of the commonly owned radio station(s).²⁹

321. *Television-Radio.* Combinations involving daily newspapers and broadcast properties are not the only cross-media combinations that present diversity concerns in at-risk markets. Approximately one-fourth of Americans rely on radio as a source of local news and information, and one-third use broadcast television for this purpose.

²⁹ For AM radio stations that standard is complete encompassment of the newspaper's community of publication by the predicted or measured 2mV/m contour computed in accordance with Section 73.183 or Section 73.186 of the Commission's Rules. For FM radio stations the standard is complete encompassment of the newspaper's community of publication by the 1 mV/m contour computed in accordance with Section 73.313 of the Commission's Rules. Previously, we discussed the inherent flaws in defining radio markets using a contour-based definition, and decided to move to a geographic based definition. Specifically, we found that a contour based definition for defining radio markets can create inconsistencies in counting stations that comprise a market, counting stations that an entity owns in a market, and determining a radio market's size and geographic area. See *Local Radio/Problems with the Existing Radio Market Definition and Counting Methodologies*, Section VI(B)(1)(a)(ii)(a) of the R&O. However, such problems do not arise in the context of using contours to determine whether the cross-media limits rule is triggered. Here, we are concerned with the physical proximity of the broadcast station and the newspaper's community of publication, or in the case of radio/television cross-ownership, we are concerned with the relative distance between two specific stations. Because the cross-media rule relies, in part, on a geographic location, *i.e.*, the community of publication or the communities of license, parties cannot take advantage of such discussed inconsistencies to circumvent the rules. Moreover, we are not relying on a contour-based definition to define a cross-media market; we are only using it to determine whether the rule is triggered.

²⁷ Bright lines provide the certainty and predictability needed for companies to make business plans and for capital markets to make investments in the growth and innovation in media markets. Conversely, case-by-case review of even below-cap mergers on diversity grounds would lead to uncertainty and undermine our efforts to encourage growth in broadcast services. Accordingly, petitioners should not use the petition to deny process to relitigate the issues resolved in this proceeding.

²⁸ To trigger the rule, the Commission will count all television stations assigned to the DMA that contains the newspaper's community of publication. For the purposes of evaluating whether the non-English daily is printed in the primary language of the "market," however, the market shall be defined as the newspaper's community of publication.

Cross-media combinations involving television and radio properties also, therefore, are likely to give rise to systematic diversity concerns in at-risk markets. The Commission's DI analysis confirms this fact. The Commission therefore adopts a rule prohibiting the combination of broadcast radio and broadcast television facilities in any market with three or fewer television properties. The television/radio cross-ownership rule is triggered when the radio station's community of license is in the commonly owned television station's DMA. Similar to requests for waiver of the newspaper/broadcast cross-ownership rule, parties seeking waiver of the television/radio cross-ownership rule can rebut this by showing that the stations' signals do not overlap and the television station is not carried on cable systems in the radio station's market.

322. Additional Cross-Media Limits in Small to Medium-Size Markets.

Although markets with four or more licensed television stations do not qualify, in the Commission's judgment, as at-risk markets, a combination of a daily newspaper with a television duopoly and a significant radio presence can, in small to medium-size markets result in substantial changes in the level of diversity. The potential for rapid concentration that may result from a combination of a newspaper with a television duopoly in markets with between four and eight licensed television stations leads the Commission to conclude that it would be prudent, in these markets, to impose additional local ownership restrictions as part of its CML.

323. The Commission is cognizant, however, of the fact that substantial public interest benefits may flow from broadcast/newspaper combinations. Television stations that are co-owned with daily newspapers tend to produce more, and arguably better, local news and public affairs programming than stations that have no newspaper affiliation. Because of the news resources available to local newspapers, the Commission expects similar benefits to be associated with newspaper ownership of radio stations (e.g., radio stations affiliated with a local newspaper may have an enhanced ability to produce local, all-news radio programming and to cover local political and cultural events in greater depth than stations unaffiliated with a newspaper). Accordingly, the Commission is not inclined to prohibit outright newspaper/ broadcast combinations in markets with 4-8 television stations (referred to below as "small to medium size markets").

324. Balancing these interests, the Commission believes it appropriate, in small to medium size markets (those with between four and eight television stations) to allow the following: (1) One entity may own a combination that includes radio, television and newspaper properties, but the entity may not exceed 50% of either of the applicable local radio or the local television caps in the market; (2) a radio station group owner that also owns a newspaper in the market, but which does not own any television properties in the market, may acquire radio stations up to 100% of the applicable radio cap. In these small to medium size markets, therefore, the Commission will prohibit: television broadcasters that also own a daily newspaper in the market from having a television duopoly in that market; a broadcaster with a duopoly from obtaining a daily newspaper in the same DMA; a newspaper owner from purchasing more than a single television station within the DMA; and a radio station owner that also owns a daily newspaper and a television station in the market from exceeding 50% of the applicable radio cap for the market.³⁰

325. Although there may be economic benefits to the owner from more extensive combinations, it is not as clear that those benefits will accrue to the public in any meaningful way; at least the public interest component of these benefits is likely to decline incrementally as the number of stations increases. Given that no owner will be permitted, in accordance with the Commission's local television cap, to hold more than two television stations in a small to medium size market, a limit of one station in these markets for owners of local newspapers will maximize the public interest benefits, while reducing any loss of diversity. Although the loss of diversity that might result were that owner to add a significant radio presence in the market warrants a further 50% limit in the number of radio properties that owner might hold, such is not the case if the combination does not include any television properties.

³⁰ For these purposes, the Commission uses the Arbitron or contour-overlap market definitions discussed above in determining whether the newspaper and a radio station serve the same market. We are not imposing a limitation that would preclude a top four television stations in a market from being combined in common with a newspaper or radio station similar to the restriction imposed in the local television rule context. The top four restriction imposed under the local TV ownership rule is specifically designed to protect competition, as fully discussed in that section. The cross-media limit, on the other hand, is designed to protect viewpoint diversity, not economic competition.

326. The Commission has engaged in this analysis using its DI and a randomly selected sample of markets not with the idea of slavishly following the numbers that the index generated, but to confirm and support the judgments the Commission makes regarding the kinds of markets that are most susceptible to viewpoint concentration, and the kinds of transactions that are most likely to have a significant impact on the level of diversity available in any given market. The Commission does not believe that markets with between four and eight television stations can be regarded as moderately concentrated for viewpoint purposes or otherwise "at risk." The Commission does, however, believe, and the DI confirms, that these markets are approaching a level of viewpoint concentration that the Commission would regard as moderate, and it is concerned that some combinations involving the three major sources of local news and public affairs information in these markets would lead to inordinate diversity losses. Accordingly, the Commission will permit television/radio combinations in small to medium size markets, provided they comply with the local radio and television rules.

327. With respect to markets with nine or more TV stations ("large markets"), the Commission imposes no cross-media restrictions. To begin with, markets of this size today tend to have robust media cultures characterized by a large number of outlets and a wide variety of owners. New York City, for instance, which has 23 licensed television stations, 61 radio stations, and 21 daily newspapers, had 61 different owners of broadcast stations and daily newspapers as of November 2002. Using the Commission's diversity index as a measure, New York City today has a base DI of only 373. More striking, perhaps, is the example provided by Kansas City, Missouri, which has only nine licensed television stations. The Commission's Ten City Study reveals that Kansas City had 35 different owners and the Commission's Diversity Index analysis shows that Kansas City has a base DI today of only 509.

328. Again, to ensure that the results of the Commission's Ten City Study were not anomalous, the Commission conducted a DI analysis on a random sample of markets of various sizes, including markets with nine licensed television stations, markets with ten television stations, markets with fifteen television stations, and markets with twenty television stations. Among the Commission's sample markets, the

average DI for those with nine television stations is 705; the average DI for those with ten television stations is 635; the average for those with fifteen television stations is 595; and the average DI for those with twenty television stations is 612. That is, markets with nine or more television stations today are very much un-concentrated.

329. Beginning in markets with nine licensed television stations, the Commission sees that, on average, the change in DI that would result from a television owner acquiring a radio group consisting of the maximum number of radio stations permissible under the Commission's local radio rule is only 64 points. If instead it were the owner of a daily newspaper acquiring that radio group, the DI change would be 198 points, leaving the market below 1000 DI. If the owner of a daily newspaper were to purchase a television station instead of a large radio group in a market of this size, the DI would increase only 86 points. Indeed, the largest combination possible in the market—a combination that would include a daily newspaper, a television duopoly, and a large radio group—would result in a DI increase of 473 points, taking the average nine television market to a base DI of under 1200 points, only marginally in the range that the Commission would consider moderately concentrated.

330. This analysis is premised on the creation of very large combinations of media properties at the local level. Even so, the results show that markets with nine or more television stations are un-concentrated today and are unlikely to become highly concentrated even in the absence of cross-media limits. Section 202(h) requires that the Commission justify broadcast ownership limits on more than supposition or inchoate fears; the Commission's governing law requires that the Commission target its structural limits at real and demonstrable harms. Based on the foregoing, the Commission cannot, therefore, justify cross-media restrictions in markets with nine or more licensed television stations.

331. The tiers adopted in the R&O, "at-risk" markets, "small to medium size" markets, and "large" markets—are derived from the Commission's DI analysis and our independent judgment regarding market operation and the effect of various combinations on diversity. The Commission's diversity concerns are greatest in at-risk markets and the Commission has accordingly prohibited all forms of cross-media combinations in those markets. In small to medium markets the Commission has imposed specific limitations on

particular kinds of combinations that would, in its estimation, most likely result in unacceptable harm to viewpoint diversity. In large markets, the Commission's analysis indicates that no cross-media limit is necessary, nor can one be justified, given the large number of outlets and owners that typify these markets and the operation of its intra-service television and radio caps.

332. *Conclusion.* Although the Commission generally prohibits television-radio, and newspaper-broadcast, cross-ownership in at-risk markets, and the Commission limits newspaper-broadcast combinations in small to medium size markets, the Commission recognizes that special circumstances may render these cross-media limits unnecessary or counter-productive in particular markets. Accordingly, the Commission will continue to entertain requests for waiver of these cross-media limits and, in particular, will give special consideration to waiver requests demonstrating that an otherwise prohibited combination would, in fact, enhance the quality and quantity of broadcast news available in the market.³¹ In addition, of course, the Commission will review its entire local broadcast ownership framework, including its new cross-media limits, beginning next year, in the 2004 biennial review. The Commission will not, however, permit collateral attack upon its rules in individual cases on diversity grounds based upon more particularized showings using the DI in a given market. The rules adopted in the R&O are rules of general applicability. The lines that have been drawn and the judgments that have been made reflect the Commission's conclusions regarding the probable effects of given transactions in the run of cases. Those conclusions necessarily rely upon generalizations, approximations, and assumptions that will not hold true in every case. Indeed, many of these assumptions would not be true in a particular context or specific market. The Diversity Index itself is a blunt tool capable only of capturing and

measuring large effects and general trends in typical markets. It is of no use, therefore, for parties to attempt to apply the DI to a particular transaction in a particular market.

D. Grandfathering and Transition Procedures

333. *Grandfathering Provisions.* There may be some existing combinations of broadcast stations that exceed the new ownership limits due to the modifications of both the local TV and the local radio ownership rules. In addition, there may be instances in which a party currently owns a radio/television combination that may not comply with the new cross-media limits.³²

334. The Commission is persuaded by the record to grandfather existing combinations of radio stations, existing combinations of television stations, and existing combinations of radio/television stations. The Commission will not require entities to divest their current interests in stations in order to come into compliance with the new ownership rules. As suggested by commenters, doing so would unfairly penalize parties who bought stations in good faith in accordance with the Commission's rules. Also, the Commission is also sensitive to commenters' concerns that licensees of current combinations should be afforded an opportunity to retain the value of their investments made in reliance on our rules and orders. The Commission also agrees with the commenters that argue that compulsory divestiture would be too disruptive to the industry. On balance, any benefit to competition from forcing divestitures is likely to be outweighed by these countervailing considerations.

335. While commenters overwhelmingly support grandfathering existing combinations, many nonetheless argue that grandfathering will create competitive imbalances which favor existing group owners—those that assembled combinations under the current rules—and disfavor those that cannot assemble competing combinations because of new ownership restrictions. Like all grandfathering decisions, some disparity will exist between grandfathered owners and non-grandfathered owners. The Commission does not believe this fact outweighs the

³¹ As is the case with our new local television ownership rules, we will require that a licensee who obtains a waiver of our cross-media limits show at renewal time the benefits that have accrued to the public as a consequence of the waiver. At the end of the broadcast station's (or stations') license term(s), the licensee of the station(s) must certify to the Commission that the public interest benefits of the Commission's grant of the waiver are being fulfilled. This certification must include a specific, factual showing of the program-related benefits that have accrued to the public. Cost savings or other efficiencies, standing alone, will not constitute a sufficient showing.

³² While we are not aware of any existing newspaper/broadcast combinations that have been previously grandfathered or approved by the Commission that would be barred under the new rules, to the extent such combinations do exist, they will be subject to the grandfathering and transferability provisions described in this section.

equitable considerations that persuade us to grandfather existing combinations.

336. *Transferability.* In general, the Commission will prohibit the sale of existing combinations that violate the modified local radio ownership rule, the local television ownership rule, or the cross media limits. Parties must comply with the new ownership rules in place at the time a transfer of control or assignment application is filed. However, in order to help promote diversity of ownership, the Commission will allow sales of grandfathered combinations to and by certain "eligible entities." The Commission does not agree with commenters that advocate allowing grandfathered combinations to be freely transferable in perpetuity, irrespective of whether the combination complies with our adopted rules. Such an approach would hinder our efforts to promote and ensure competitive markets. Unlike our decision not to require existing station owners to divest stations, here, the threat to competition is not outweighed by countervailing considerations. Buyers will be on notice that ownership combinations must comply at the time of the acquisition of the stations. Thus, they do not have the same expectations as present owners who acquired stations under the current ownership rules. Because of the limited number of broadcast licenses available, station spin-offs that would be required upon sales of stations in a grandfathered group could afford new entrants the opportunity to enter the media marketplace. They could also give smaller station owners already in the market the opportunity to acquire more stations and take advantage of the benefits of combined operations. Because divestitures are not required until a sale of the station groups, owners have sufficient time to minimize any specific complications due to joint operations. Therefore, the Commission rejects the argument that prohibiting transfers of station groups that exceed the new ownership limits would be unacceptably disruptive or would negatively impact the availability of bank financing, as some commenters suggest. Requiring future assignments and transfers to comply with our ownership rules upon sale is consistent with Commission precedent. The prohibition on the transfer of grandfathered stations will not apply to pro-forma changes in ownership or to involuntary changes of ownership due to a death or legal disability of the licensee.

337. *Eligible Transfer.* The Commission is adopting an exception to its prohibition on the transfer of grandfathered combinations in violation

of the new rules. This exception applies to grandfathered radio and television combinations that exceed the ownership limits adopted in this R&O, cross-media combinations in at-risk markets, and cross-media combinations in small to medium sized markets that exceed the ownership limits adopted in this R&O. Entities may transfer control of or assign a grandfathered combination to "eligible entities" as defined herein.³³ In addition, "eligible entities" may sell existing grandfathered combinations without restriction. As the Commission defines in greater detail below, it limits "eligible entities" to small business entities, which often include businesses owned by women and minorities.

338. The Commission defines an "eligible entity" as an entity that would qualify as a small business consistent with SBA standards for its industry grouping. For example, the SBA small business size standard for radio stations is \$6 million or less in annual revenue. For TV stations the limit is \$12 million. The Commission will further require that any transaction pursuant to this exception may not result in a new violation of the rules. Control of the eligible entity purchasing the grandfathered combination must meet one of the following control tests. The eligible entity must hold (1) 30% or more of the stock/partnership shares of the corporation/partnership, and more than 50% voting power, (2) 15% or more of the stock/partnership shares of the corporation/partnership, and more than 50% voting power, and no other person or entity controls more than 25% of the outstanding stock, or (3) if the purchasing entity is a publicly traded company, more than 50% of the voting power.

339. The Commission will allow entities that meet the definition of "eligible entity" to transfer any existing grandfathered combination generally without restriction. The Commission believes that small businesses that qualify as eligible entities require greater flexibility than do larger entities for the disposition of assets. Restrictions on the sale of assets could disproportionately harm the financial stability of smaller firms compared to that of larger firms, which have additional revenue streams. However, an eligible entity may not transfer a grandfathered combination acquired

³³ We are not grandfathering existing combinations of stations that exceed the ownership limits because of an attributable interest in a station pursuant to an LMA or JSA. Existing LMAs and JSAs that result in a combination of stations exceeding the ownership limits must be terminated at the time of the sale or within two years, whichever comes first.

after the adoption date of this R&O to an entity other than another eligible entity unless it has held the combination for a minimum of three years. The Commission will prohibit eligible entities from granting options to purchase, or rights of first refusal to prevent non-eligible entities from financing an acquisition in exchange for an option to purchase the combination at a later date. Any transaction pursuant to this policy may not result in a new violation of the rules.

340. *Radio LMA Combinations.* The Commission will give licensees two years from the effective date of this R&O to terminate any LMAs that result in a violation of the new ownership limits, or otherwise come into compliance with the new rules. If the licensee sells an existing combination of stations within the two year grace period, it may not sell or assign the LMA to the buyer if the LMA causes the buyer to exceed the ownership limits adopted in this R&O. Parties are prohibited from entering into an LMA or renewing an existing LMA that would cause the broker of the station to exceed the ownership limits.

341. *TV LMA Combinations.* In our Local TV Ownership Report and Order, the Commission grandfathered LMA combinations that were entered into prior to November 5, 1996, through the end of our 2004 biennial review. The Commission does not alter this policy. These LMAs are not affected by the grandfathering policy adopted in the R&O.

342. *TV Temporary Waivers.* A few licensees have been granted temporary waivers of our local TV ownership rule, and some have filed requests for an extension of waivers that are currently pending, or have sought permanent waivers. Any licensee with a temporary waiver, pending waiver request, or waiver extension request must, no later than 60 days after the effective date of this R&O or the date on which the waiver expires, whichever is later, file one of the following: (i) A statement describing how ownership of the subject station complies with the modified local TV ownership rule; or (ii) an application for transfer or assignment of license of those stations necessary to bring the applicant into compliance with the new rules.

343. *Cross-Media Conditional Waivers.* A few licensees have been granted conditional waivers of the previous one-to-a-market rule. Parties that currently have conditional waivers for radio/television combinations must submit a statement to indicate whether the combination they hold: (1) Is located in an at-risk market, (2) is located in a small to medium size market, and (3) is

in compliance with the cross-media limits. For the combinations that comply with the cross-media limits adopted herein, the Commission will issue a letter replacing the conditional grant with permanent approval. For any combinations that violate the cross-media limits, the Commission will issue a letter indicating that the combination will continue to be grandfathered until a decision in the 2004 Biennial Review is final. As part of the 2004 Biennial Review, the Commission will review and reevaluate the status of such grandfathered combinations to determine whether they should continue to be grandfathered. On a case-by-case basis, the Commission will consider the competition, diversity, equity, and public interest factors the combinations may raise.

344. *Other Cross-Media Waivers.* The Commission's cross-media limits are founded on the presumption that, by reason of cable carriage, television stations are available throughout the DMA to which they are assigned. The Commission recognizes, however, that this may not be true in every case. Accordingly, those requesting waiver of our cross-media limits may attempt to rebut this presumption in individual cases

345. *Elimination of Flagging and Interim Policy.* In August 1998, the Commission began "flagging" public notices of radio station transactions. Under this policy, the Commission flagged proposed transactions that would result in one entity controlling 50% or more of the advertising revenues in the relevant Arbitron radio market or two entities controlling 70% or more of the advertising revenues in that market.

346. The Commission believes that the changes made today to the market definition will address many of the market concentration concerns that led the Commission to begin flagging radio station transactions. Accordingly, effective upon adoption of this R&O, the Commission will no longer flag radio sales transactions or apply the interim policy procedures adopted in the Local Radio Ownership NPRM in processing them.

347. *Processing of Pending and New Assignment and Transfer of Control Applications.* The processing guidelines below will govern pending and new commercial broadcast applications for the assignment or transfer of control of television and radio authorizations commencing as of the adoption date of this R&O. These guidelines also cover pending and new modification applications that implicate our multiple ownership rules. Applications filed on or after the effective date of this R&O as

well as applications that are still pending as of such effective date will be processed under the new multiple ownership rules, including, where applicable, the interim methodology for defining radio markets as adopted in the R&O.

348. *New Application.* The Commission has established a freeze on the filing of all commercial radio and television transfer of control and assignment applications that require the use of FCC Form 314 or 315 ("New Applications"). The Commission will revise application Forms 301, 314 and 315 to reflect the new rules adopted in the R&O. The freeze will be in effect starting with the R&O's adoption date until notice has been published by the Commission in the *Federal Register* that OMB has approved the revised forms. Upon such publication, parties may file New Applications, but only if they demonstrate compliance with the new multiple ownership rules adopted in the R&O, including where applicable, the interim methodology for defining radio markets outside Arbitron metros, or submit a complete and adequate showing that a waiver of the new rules is warranted. The Commission will continue to allow the filing of short-form (FCC Form 316) applications at any time and will process them in due course.

349. *Pending Applications.* Applicants with long-form assignment or transfer of control applications (FCC Form 314 or 315) or with modification applications (FCC Form 301) that are pending as of adoption of the R&O ("Pending Applications") may amend those applications by submitting new multiple ownership showings to demonstrate compliance with the ownership rules adopted in the R&O, including where applicable, the interim methodology for defining radio markets outside of Arbitron metros, or by submitting a request for waiver of the new rules. Parties may file such amendments once notice has been published by the Commission in the *Federal Register* that OMB has approved the information collection requirements contained in such amendments. Pending Applications that are still pending as of the effective date of the new rules will be processed under the new rules. Applications proposing pro forma assignments and transfers (FCC Form 316) will be processed in the normal course.

350. *Pending Petitions and Objections.* Petitions to deny and informal objections that were submitted to the Commission prior to the adoption date of the R&O and that raise issues unrelated to competition against

Pending Applications will be addressed with respect to those issues at the time the Commission acts on such Applications. Petitions and informal objections that were submitted to the Commission prior to the adoption date of the R&O and that contest Pending Applications solely on grounds of competition pursuant to the interim policy will be dismissed as moot.

VI. National Ownership Rules

351. The Commission considers the national TV ownership rule and the dual network rule. The Commission concludes that it should modify the former by raising the cap to 45%, and the Commission retains the latter.

A. National TV Ownership Rule

352. The current national TV ownership rule prohibits any entity from owning television stations that in the aggregate reach more than 35% of the country's television households. 47 CFR 73.3555(e)(1). The Commission concludes that the current rule cannot be justified and it raises the cap to 45% and retains the UHF discount.

353. In the *1984 Multiple Ownership Report and Order*, the Commission determined that repealing the national TV ownership rule would not harm competition or diversity. Consistent with the decision in 1984, the Commission finds that restricting national station ownership is not necessary to promote either of those policy objectives. It departs, however, from the 1984 decision to repeal the rule because evidence in the record demonstrates that the national television cap serves localism. The localism rationale for retaining the national television cap was articulated in the *1998 Biennial Review Report*. In that decision the Commission explained that preserving a balance of power between the networks and their affiliates serves local needs and interests by ensuring that affiliates can play a meaningful role in selecting programming suitable for their communities. The Commission continues to believe that to be the case and, consequently, that a national cap is necessary to limit the percentage of television households that a broadcast network may reach through the stations it owns. Although the record supports retention of a national ownership cap, it does not support a cap of 35%. The evidence shows that the cap at the current level is not necessary to preserve the balance of bargaining power between networks and affiliates. The record also indicates that the cap appears to have other drawbacks. Most importantly, the cap restrains some of

the largest group owners—broadcast networks—from serving additional communities with local news and public affairs programming that is of greater quantity and at least equal, if not superior, quality than that of affiliates. Moreover, the Commission believes that a modest relaxation of the cap will help networks compete more effectively with cable and DBS operators and will promote free, over-the-air television by deterring migration of expensive programming to cable networks. Balancing these competing interests, the Commission raises the national cap from 35% to 45%.

354. *Background.* Since 1941, the Commission has limited the national ownership reach of television broadcast stations. The Commission has modified the restriction several times to keep pace with the changing marketplace. In 1984, the Commission repealed the rule, concluding that it was not necessary to promote competition or diversity, and instituted a six-year transitional ownership limit of twelve television stations nationwide. On reconsideration, the Commission affirmed its underlying conclusions, but it eliminated the sunset provision out of a concern that repealing the rule would create a disruptive restructuring of the national broadcasting industry. The Commission retained the twelve station limit and, in addition, prohibited an entity from reaching more than 25% of the country's television households through the stations it owned.

355. In 1996, the Commission adopted the current 35% cap in response to the Congress' directive to raise the cap (from 25% to 35%) and to eliminate the rule that an entity could not own more than twelve stations nationwide. The Commission subsequently affirmed the 35% cap as part of its 1998 biennial review of media ownership regulations. In affirming the cap, the Commission reasoned that it would be premature to institute revisions to the national TV ownership limit before fully observing the effects of changes to the local TV ownership rules and the effects of raising the cap from 25% to 35%. The Commission also concluded that the national TV ownership rule helps promote better service to local communities by preserving the power of affiliates to negotiate with the networks and to make independent programming decisions. In addition, the Commission concluded that the national TV ownership rule facilitates competition in the program production market and in the national advertising market.

356. Several broadcast networks challenged the Commission's decision to retain the national TV ownership

rule. In *Fox Television Stations, Inc. v. FCC*, 280 F.2d 1027 (D.C. Cir. 2002), the U.S. Court of Appeals for the District of Columbia Circuit found that the Commission's 1998 decision to retain the rule was arbitrary and capricious, and it remanded the rule for further consideration. The court rejected the Commission's "wait-and-see" approach on the grounds that it was inconsistent with the Commission's statutory mandate to determine on a biennial basis whether its rules are necessary in the public interest. The court also held that the Commission failed to demonstrate that the national cap advanced competition, diversity, or localism.

357. With respect to competition, in its 1998 *Biennial Review Report*, the Commission provided a study and a table showing that large group owners of television stations had acquired additional stations and increased their audience reach since the 1996 Act's passage. The court was not persuaded by the Commission's evidence that large group owners have undue market power, and it agreed with the networks that the figures alone, absent evidence of an adverse effect on the market, were insufficient to support retention of the rule. The court also found unsupported the Commission's statement in the 1998 *Biennial Review Report* that the national cap is necessary to safeguard competition in the national advertising or program production markets. The court concluded that the Commission's analysis of the state of competition in the television industry was incomplete and did not satisfy the requirement under section 202(h) to show that the rule is necessary in the public interest as the result of competition.

358. The court held that diversity and localism are valid public interest goals within the context of broadcast regulation and made it clear that the Commission could determine that the national TV ownership rule was necessary in the public interest under section 202(h) if it served either interest. The court, however, ruled that the Commission had not provided sufficient evidence that either one of these goals was served. The court noted that the Commission, in its 1998 *Biennial Review Report*, "mentioned national diversity as a justification for retaining the [national TV ownership rule], but did not elaborate upon the point." The court found the Commission's statement did not explain why the rule is necessary to further national diversity. The court also found that the Commission failed to justify its departure in the 1998 decision from its 1984 decision, in which the

Commission concluded that the national TV ownership restriction should be phased out after six years because: (1) The rule no longer was necessary for national diversity given the abundance of media outlets and (2) a national rule was irrelevant to local diversity. In addition, the court held that the Commission did not adequately demonstrate that the rule strengthens the bargaining power of independently-owned affiliates and thereby promotes program diversity, particularly in light of its 1984 conclusion that no evidence suggested that stations that are not group-owned responded better to community needs or spent proportionately more revenue on local programming. However, the court acknowledged the Commission's right to reverse course, provided the reversal is supported by a reasoned analysis. Recognizing that sufficient evidence may exist to justify the national TV ownership rule, the court determined that the appropriate remedy was to remand, rather than to vacate, the rule. The Commission now considers whether the current rule can be justified as necessary to promote competition, diversity or localism.

359. *The Current National TV Ownership Rule Cannot Be Justified.* Under section 202(h), the Commission must evaluate whether the national TV ownership rule continues to be "necessary in the public interest as the result of competition." To make this determination, it considers whether the rule serves the public interest by furthering its policy goals of competition, localism, or diversity. The evidence demonstrates that a national TV ownership limit is necessary to promote localism by preserving the bargaining power of affiliates and ensuring their ability to select programming responsive to tastes and needs of their local communities. However, the evidence also demonstrates that the current cap of 35% is not necessary to preserve that balance.

360. *Competition.* In analyzing whether the current rule is necessary to protect competition, the Commission focuses on whether and to what extent market power exists in any relevant market, and what effect the rule has on the existence and exercise of this market power. In the 1984 decision to eliminate the national ownership cap, the Commission limited its competition analysis to the national television advertising market. In this decision, the Commission expands its competition review to include the national program acquisition market. The national cap affects economic concentration in

national markets by limiting the size of group owners of television stations, but does not affect concentration in the local video delivery market, and thus does not raise competition concerns that were discussed in the local ownership rule sections above. The national cap limits the ability of group owners to purchase television stations in individual local markets. The effect of this ownership restriction on station performance in the video delivery market is discussed elsewhere in this summary.

361. Based on its analysis of the relevant markets, the Commission finds that the current rule is not necessary to maintain competition in the three economic markets it examines. As the record indicates, the media marketplace is undergoing unprecedented change. Broadcast stations are subject to competition from cable and DBS, and they face increased competition for viewers, advertising revenues, station network affiliations, and programming. The Commission concludes that the 35% cap is no longer necessary to protect competition in the media marketplace and unnecessarily constrains the organization of, and investment in, free, over-the-air (*i.e.*, non-subscription) broadcast television.

362. *Broadcast competition framework.* The evolution of non-price competition in television has implications for the economic organization of broadcast television networks. Higher channel capacity cable systems and the growth in the number of cable networks, together with the programming options offered by DBS, have intensified the competitive pressure on broadcast television networks to slow the erosion of viewer market share and to build strong network brand identity reflecting program focus, quality and reputation.

363. Two broadcast television network organizational changes, which are viewed as responses to the growth in viewer options, are noteworthy, namely, (1) the extensive backward integration into program supply, and (2) the desire to increase the extent of forward vertical integration through ownership of additional local television stations. Transaction cost economics suggests that such organizational integration induced by increased rivalry within the media industry may improve economic efficiency.

364. Transaction cost economics adopts a contractual approach in understanding the economic organization of firms. The transaction—the exchange of goods or services for money or other goods between parties—is the focal point of economic analysis.

Determining the governance structure that minimizes the economic cost of effectuating a particular type of transaction is a central objective of a transaction cost analysis. Transaction cost economics identifies three, discrete governance structures, namely, (1) the market; (2) hybrid contracting; and (3) hierarchy, where transactions are placed under unified ownership in a firm subject to administrative controls and management. Whether it is economically efficient (cost minimizing) to effectuate exchange using market contracting or through hierarchy (vertical integration) depends on certain behavioral assumptions, and key attributes of any given transaction.

365. In general, ordinary market contracting is an efficient governance structure for transactions supported by general purpose assets not dedicated to the specific output demand of a given customer. As asset specificity deepens, market contracting as a governance structure gives way to either hybrid structures or hierarchy (vertical integration) as the least costly to organize transactions. The pervasiveness of asset specificity in the program production industry suggests that complex contracts between broadcast television networks and program suppliers may not be the least costly governance structure for effectuating transactions.

366. Broadcast television networks have a single, strategic focus, namely, the maximization of the number of television viewers that are attracted to mass audience and niche audience programming. This strategic focus is crucial to broadcast television networks, since the sale of audiences to national advertisers provides their only stream of revenue from broadcast operations in contrast to cable networks which may receive both advertiser and subscriber revenue. By contrast, local broadcast television stations pursue a more complex business strategy as licensed broadcast facilities. First, the local station seeks to maximize the size of the audience it attracts within its local television market. If the local station is a network affiliate, then the local station will promote the network's program schedule together with syndicated programming the station may acquire to help fill out its daily program schedule. Second, the local station will also promote its own locally-produced programming, such as news and public affairs programming, that it believes is responsive to issues or viewer preferences in the communities served by the station. Station management may vary the allocation of time devoted to any particular type of programming,

including network programming, to respond to emerging preferences or news events in the communities located in its local television market. As the networks have lost viewer market share over the last decade in response to the growth in cable and DBS, the traditional contractual relationship between a television network and a local station affiliate may be a less efficient governance structure. From a transaction cost perspective, television networks view their massive sunk investments in network programming as increasingly risky assets as non-broadcast program options proliferate.

367. With respect to contractual safeguards, the networks have attempted to negotiate substantial penalties for failure to clear a full schedule of network programming. With respect to changes in governance structure, the broadcast television networks have argued for elimination of the national ownership cap, which would permit the networks to substitute hierarchy (vertical integration) for the current contractual relationship with independently-owned station affiliates. Presumably, the networks believe, consistent with transaction cost logic, that conflicts in strategic focus between stations and the network respecting programming decisions can be resolved more efficiently, *i.e.*, at minimal transaction cost, if hierarchy, *i.e.*, forward vertical integration, replaces market contracting as the governance structure.

368. Thus, the Commission's transaction cost analysis suggests that the national ownership cap probably restricts the full transition to the least costly way for organizing transactions between television networks and local television stations, *i.e.*, forward vertical integration, assuming that realization of a network's singular strategic focus on mass or niche audience size is the preferred policy objective. If, however, locally produced programming and ultimate program selection authority are a higher policy priority, then the Commission's transaction cost economic framework identifies the relevant policy trade-off, namely, the incremental social benefit of local programming viewed as a component of the Commission's localism policy goal versus the increased social and private costs of inefficient contracting.

369. *Program Production and Acquisition Market.* Competition in the program production and acquisition market is important because networks and owners of individual television stations compete with each other, as well as with cable television networks, to acquire programming that will

continue to attract viewers to their channels. Although television station owners as a group are relatively significant purchasers of programming, the Commission has no evidence that they exercise market power in the program production market.

370. In considering the effect of the national television cap on competition in the program acquisition market, the Commission first must identify the market participants. The broadcast networks contend that the following categories of firms compete in the program acquisition market: broadcast television networks, individual television stations (and group owners thereof), non-broadcast program networks (*i.e.* cable networks), syndicators, pay-per-view systems, VHS and DVD rental stores. The affiliates counter that major broadcast networks are a discrete sub-market, or "strategic group," within the program purchasing market. The Commission generally agrees with the networks' definition of the relevant market participants, although it excludes video sales and rental stores. It disagrees with the networks' contention that such outlets are clearly a substitute for the delivered video programming of broadcast channels and cable channels. Those channels are the most conventional form of television viewing that can be substituted among by viewers almost instantly. It is possible to analyze the impact on the program acquisition market of relaxing the national television ownership cap by examining company expenditure shares. The following describes estimates of expenditure shares and calculation of a hypothetical HHI. The analysis assumes that the buyers in this market are broadcast networks, broadcast stations, and cable networks.³⁴ OPP Working Paper 37 (Table 32) provides estimates for the year 2000 of programming

expenditures by the Big Four commercial networks and by television stations.

371. The table included in this summary provides program expenditure data for the year 2000 for the Big Four broadcast networks in column 2 and for eight firms that own cable networks in column 4. The eight firms include the top four broadcast networks, the two biggest cable network owners that do not own television stations, and the two companies with the biggest cable network shares that also own television stations. There is also a residual category that includes all other cable network expenditures as "Other."

372. Column 3 includes some hypothetical broadcast station owner shares. The Commission does not know exactly how station expenditures are divided up among companies that own television stations. The numbers in this column represent a "worst case scenario" of what could happen if the national television cap were eliminated. In 2000 there were 1248 commercial television stations on the air. The Commission knows that the major commercial networks each reach virtually 100% of U.S. television households and that each network has roughly 200 affiliated stations. If stations were distributed evenly across markets, then there would be room for six television station companies each reaching all U.S. television households.

373. However, stations are not evenly distributed across markets. There are 50 Nielsen DMAs with fewer than four commercial stations, but they account for only 4.6% of U.S. television households, so, from the point of view of station programming expenditures, it is reasonable to assume that each of the top four broadcast networks could achieve 100% coverage of U.S. television households. However, there are 120 markets with fewer than six

commercial television stations, and those markets account for 19.7% of U.S. television households. So it is reasonable to assume that two additional station groups could grow to 80% coverage. This analysis assumes that television station program expenditures are divided among six firms: the four networks with 100% coverage, and Cox and Hearst, each with 80% coverage. The Commission assumes that expenditures are proportionate to coverage. The resulting expenditure estimates are in column 3. These estimates reflect a level of concentration that is higher than the true level. There are 63 markets with more than six commercial stations in them. Adding up the excess over six stations in each market yields a total of 259 stations. The Commission knows that a single company can own multiple stations in the same market, but it is likely that even with more companies owning two stations in a market that there will still be more than six station owners in some markets.

374. Column 5 contains hypothetical total programming expenditures for the eight firms, aggregating across broadcast network, broadcast station, and cable network categories, and using the hypothetical consolidated television station ownership pattern described above. Column 6 shows market shares and column 7 implements the HHI calculation by squaring and summing the market shares. The resulting "worst case" HHI of 1535 is in the moderately concentrated range. Even with the highly unrealistic assumption of a 100% national reach by four companies, and an 80% reach by two companies, these levels of market share provide us with no basis to conclude that the current 35% cap on national television ownership is needed to protect competition in the program acquisition market.

HYPOTHETICAL HHI FOR PROGRAM ACQUISITION

[Data are year 2000 in millions of \$]

	Broadcast network	Broadcast station	Cable network	Total	Market share	Market share squared
Cox	0	969.5	139.4	1,108.9	4.37	19.13502
Hearst	0	969.5	530.0	1,499.5	5.92	34.98944
ABC	2,581.75	1,212.0	1,276.7	5,070.45	20.00	400.071
Fox	2,581.75	1,212.0	521.8	4,315.55	17.02	289.812
GE	2,581.75	1,212.0	300.0	4,093.75	16.15	260.7875
Viacom	2,581.75	1,212.0	1,466.4	5,260.15	20.75	430.5666
Time Warner	0	0	2,162.9	2,162.9	8.53	72.79758
Liberty Media	0	0	786.3	786.3	3.10	9.621009
Other	0	0	1,052.5	1,052.5	4.15	17.23806

³⁴ Our market definition includes pay cable networks as well as pay-per-view networks, but in

the absence of data, they are excluded from this analysis

HYPOTHETICAL HHI FOR PROGRAM ACQUISITION—Continued

[Data are year 2000 in millions of \$]

	Broadcast network	Broadcast station	Cable network	Total	Market share	Market share squared
Total	10,327	6,787	8,236.0	25,350	100.00	1,535.018

375. *National Advertising Market.* The Commission's focus is not on advertisers, but on the ability of broadcasters to compete for advertising revenues. Broadcast networks compete for advertising dollars by creating national audiences for their programming. If the networks cannot generate national audiences, their ability to compete for advertising revenues will decline, thereby diminishing their ability to invest in innovative programming. As a result, viewers will experience a decrease in programming choices and quality.

376. In its 1984 decision, the Commission determined that elimination of the national cap would not harm competition in the national advertising market. The Commission found that the number of firms in the market would ensure continued vigorous competition in that market. In the NPRM, the Commission sought information on whether the conclusion reached in 1984 continues to be valid. To analyze competition in this market, the Commission sought comment on the firms that compete in the national television advertising market, including the extent to which national spot advertisements and/or syndicated programming are fungible with network television advertising from the perspective of advertisers.³⁵ The national television advertising market brings together those advertisers wishing to reach a national audience with television networks that provide national exposure. Broadcast television networks are the leading suppliers of national television advertising.

377. The affiliates claim the record demonstrates that national spot advertising is competitive with national advertising. National advertisers can purchase advertising on a collection of local television stations that can approximate a national advertisement on a single network. Local television stations sell national spot advertising through advertising agencies, which aggregate the available advertising on local stations for national spot buyers.

³⁵ National spot advertising time is sold by stations to national advertisers, which aggregate national or regional coverage by purchasing advertising spots from stations in multiple markets. Syndication refers to advertisements sold in syndicated programs.

The affiliates contend that when demand for national advertising on a particular network show exceeds the available supply of national network advertising time, advertisers turn to the national spot advertising market to reach viewers. Television stations rely in part on the national spot advertising market for a portion of their advertising revenue. The affiliates argue that if the ownership cap is raised, the broadcast networks will increase their ownership of television stations and decrease the national spot availabilities to such an extent that the viability of the national spot market will be impaired. Specifically, the affiliates contend that a network-owned station will not compete against its network for national (spot) advertising revenue. The result, according to the affiliates, is that competition in the national advertising market will be diminished by the decreased viability of national spot advertising as a substitute for network advertising. The affiliates assert that the resulting loss of revenue to local stations will harm their ability to compete with other delivered video providers.

378. *Discussion.* The Commission agrees that a strong national spot advertisement market is an important component of the financial stability and competitiveness of television station owners. The Commission finds, however, that the increase in the cap from 25% to 35% has not harmed national spot advertising revenues. Its analysis of advertising revenue data indicates that despite increases in ownership of stations by CBS, NBC and Fox since 1996, there has been no diminution in the national spot advertising market that can be reliably associated with an increase in network station ownership. With the exception of 2001, national spot advertising has experienced a relatively consistent growth.

379. Although the Commission agrees with the affiliates that network-owned stations have less incentive to compete directly with an affiliated broadcast network in the national advertising markets, it cannot agree that such competition in fact would not occur. If national advertisers are willing to pay a higher per-spot price to network-owned

stations than are local advertisers, network-owned stations might well accept the higher priced advertising. Thus, the profit-maximizing behavior of the network-owned stations might well serve as a substitute for national advertisers seeking to purchase national spot advertising. Such a response by network-owned stations would maintain the viability of national spot advertising as an option for national advertising regardless of the level of the national television cap. Moreover, even if the top four networks were to acquire additional local stations and declined to use the national spot advertising availabilities to compete with their own network's advertising availabilities, there is every reason to think the network-owned stations would seek to take national advertising dollars away from other broadcast networks. That is, even if an NBC-owned station sought not to compete with the NBC network for advertising dollars, the NBC-owned stations have incentives to compete in the national spot market for advertising dollars that might otherwise go to the CBS, ABC, and Fox networks. Consequently, the Commission cannot say that the national cap is necessary to protect competition in the national advertising market.

380. *Innovation.* In the NPRM, the Commission asked whether the national ownership cap promotes or hinders innovation in the media marketplace. Affiliates argue that non-network owners encourage innovation because affiliates provide a competitive outlet for innovative programming. The affiliates provide nine examples of innovation by non-network group owners, such as satellite newsgathering encouraged by affiliates to improve upon network-delivered news; the development of the local newsmagazine format; all-news cable channels developed for cable carriage; digital TV experiments such as the multicasting by several affiliates of the NCAA tournament; the delivery of local news in HDTV format; and the creation of iBlast, a joint venture between affiliates and an outside firm to develop new uses for digital spectrum.

381. Taking an opposing view, the networks contend that the cap limits networks' investment in innovative

programming by "inhibiting economic efficiencies" that come with a larger number of owned and operated stations. As evidence, the networks refer to a study concluding that, by inhibiting the potential economic efficiencies available to group owners, the rule artificially raises the cost of operating television stations and limits the return that group owners can realize on their programming investments. The study argues that the rule drives group owners to direct more of their resources away from free television and toward alternative means of distributing programming content, such as subscription-based cable channels.

382. *Discussion.* The current national ownership cap appears to encourage innovation in broadcast television by preserving a number of separately-owned station groups, including non-network owned station groups. The current number of station group owners has led to innovation in ways that benefit the public. Those developments include the creation of local all-news channels in partnership with local cable companies, the implementation of program formats such as local newsmagazines, and, importantly, experimentation with the spectrum allocated to local broadcasters for digital television. The transition to digital television represents a critical evolutionary step in broadcast television. The Commission is committed to ensuring the rapid completion of that transition in a way that delivers the greatest possible benefits to the viewing public. It believes that the broadcast industry is more likely to rapidly address the technical and marketplace issues associated with digital television if there are a variety of group owners exploring ways to use the spectrum. The record shows that non-network owners of television stations are actively exploring different ways of using digital spectrum. It is also important to have group owners with potentially different economic incentives in this area examining transition mechanisms to digital television. Because of networks' ongoing investment in programming, it is possible that networks may have incentives to use digital spectrum differently from affiliates. The Fox television network, for instance, has indicated its interest in using the spectrum of its owned stations as well as its affiliates for future services. Therefore, the Commission concludes that a national television cap is necessary to preserve a number of separately-owned television station groups, including non-network groups,

that will increase the types of digital transition experiments and ultimately facilitate a rapid and efficient transition to digital broadcast television.

383. *Diversity.* The 1984 *Multiple Ownership Report and Order* concluded that the local community is the relevant market for evaluating viewpoint diversity and that, therefore, the national TV ownership rule is not needed to promote viewpoint diversity. The 1984 *Multiple Ownership Report and Order* also stated that the national market is not relevant for evaluating viewpoint diversity, but even if it were, the proliferation of media outlets renders the national ownership restrictions unnecessary. In the 1998 *Biennial Review Report*, the Commission did not analyze the rule's effects on viewpoint diversity and merely stated, without evidentiary support, that the rule promotes diversity of programming. In remanding the national TV ownership rule, the court in *Fox Television* found that the Commission had failed to support its 1998 conclusion that the rule is necessary to strengthen affiliates' bargaining power and had neglected to address its 1984 determination that the national market is not the relevant geographic area to consider when evaluating diversity. The Commission addresses the issue of affiliates' bargaining power elsewhere in this summary and addresses diversity here.

384. In the NPRM, the Commission observed that the national TV ownership rule does not appear to be relevant to the goal of promoting viewpoint diversity because people gather news and information from sources available in their local market and that the relevant geographic market for viewpoint sources is local, not national. It also noted that the viewpoints aired by television stations in one city do not seem to have a meaningful impact on the viewpoints available in other cities. Commenters do not provide evidence that persuades the Commission to alter those views, and it affirms the 1984 conclusion that the national TV ownership rule is not necessary to promote diversity.

385. *Discussion.* The Commission concludes that the national television cap is not necessary to promote viewpoint diversity. Americans use media outlets available in their local communities as sources of information. The national television cap, by contrast, ensures a larger total number of station owners nationwide, but it has no meaningful impact on viewpoint diversity within local markets. It is possible, of course, that the replacement of one station owner by another could

in fact reduce the number of independently-owned television stations in that market. If the acquiring firm already owned one station in that market and the seller was selling its only station in that market, there would be one less independently-owned station in that market. The impact of such a transaction on viewpoint diversity would be accounted for under the diversity component of the Commission's local rules. Therefore, the Commission affirms its 1984 decision that the national television ownership limit is not necessary to promote viewpoint diversity. It also affirms its decision that the market for viewpoint diversity is local, not national. And it reiterates its 1984 statement that even if the national market were the relevant area to consider, the proliferation of media outlets nationwide renders the current rule unnecessary.

386. Although proponents of the current rule assert that the increased uniformity imposed by the networks' national distribution agenda limits the number of viewpoints available to the public, the Commission does not find convincing evidence in the record indicating that raising the current national TV ownership limit would harm viewpoint diversity. Affiliates assert that maintaining a diversity of ownership across local markets is beneficial because viewers may become aware of investigative news stories presented by stations in other markets, particularly those of strong stations. They argue that "this type of cross-fertilization is less likely to occur in the absence of the national TV ownership rule." For this cross-fertilization to be a plausible scenario, the following minimum conditions must occur: (1) The national cap prevents a station from being acquired by a broadcast network; (2) the non-acquired station produces content that by some measure is meaningfully different (and significant from a viewpoint perspective) from what the network-owned station would have aired; and (3) the airing of that different content becomes known to consumers in other localities. The national cap cannot be justified by reference to such a hypothetical scenario as this.

387. Commenters discussing types of diversity other than viewpoint diversity do not provide an evidentiary basis for retaining the current cap. The 1998 *Biennial Review Report* stated that "[i]ndependent ownership of stations also increases the diversity of programming by providing an outlet for non-network programming." In this R&O, however, the Commission has concluded that it can and should rely on

the marketplace, rather than regulation, to foster program diversity. Further, the record in this proceeding does not contain evidence that affiliates air programming that is more diverse than programming aired by network-owned stations. Therefore, the Commission cannot affirm its earlier determination regarding program diversity, and it does not find that the cap is necessary to foster program diversity.

388. *Localism*. The Commission's decision in the 1984 *Multiple Ownership Report and Order* did not address whether the national TV ownership rule advances its goal of localism. In the 1998 *Biennial Review Report*, however, the Commission did address its localism goal, declining to modify the national TV ownership restriction in part because affiliates "play a valuable counterbalancing role" to network programming decisions by exercising their independent programming discretion regarding what programs best serve the needs and interests of their local communities. In *Fox Television*, the court stated that, although the Commission had failed to present evidence that the cap in fact promoted localism, localism was a legitimate basis for imposing a national ownership cap.

389. Based on its analysis of the extensive record in this proceeding, the Commission concludes that a national television ownership limit is necessary to promote localism on broadcast television. The evidence suggests, however, that the current 35% cap is not needed to protect localism, and may in fact be hindering public benefits that are expected to follow from an increase in the cap. The Commission concludes that a national cap of 45% fairly balances the competing public interest values affected by this rule. It recognizes that its decision to retain a national ownership cap is contrary to its conclusion in 1984. The Commission reaches this different conclusion principally because it finds that a cap is necessary to protect localism by preserving a balance of power between networks and affiliates, a policy objective that was not considered in the 1984 decision. In this section, the Commission details the localism analysis, and then discusses the modified rule.

390. *Whether a National Cap Promotes Localism*. The Commission examines the effect of a national television cap on the economic incentives for locally responsive programming by television stations. It also considers evidence that a national cap results in behavior by network-affiliated stations that is responsive to

the needs and tastes of a station's local community.

391. *Economic Incentives for Localism*. The affiliates contend that the current national cap is needed to preserve their bargaining power with their networks. The affiliates explain that limiting the national audience that networks can reach through their owned stations promotes a balance of power between networks and their affiliates. The affiliates also claim that the cap is necessary to counteract the networks' strong financial incentive to promote the widest distribution across the nation of network programming irrespective of the tastes of one or more particular local cities. The widest possible distribution of programming, according to the affiliates, increases viewership of network programming, which maximizes network advertising revenues. According to the affiliates, maximum national exposure of programming also improves the likelihood that the program owner will realize additional revenues in the program syndication market. The affiliates contend that as broadcast networks have ownership stakes in a larger percentage of their prime time programming, their incentive to create programs with syndication value—and their incentive to stifle local preemption—increases.

392. The affiliates argue that the incentive of independently-owned affiliates, in contrast to network-owned stations, is to make programming decisions that are more closely aligned with the needs and tastes of their communities of license. A network derives its income from the programming that the network produces (and the syndication revenue the programs might generate) as well as from its local stations. A local station maximizes its income by providing programming desired by its local community irrespective of national programming preferences. Therefore, the programming interests are not always the same.

393. *Evidence of Localism by Affiliate*. The affiliates contend that the national cap is needed to preserve a body of network affiliates not owned by the network that can influence network programming so that it is more suited to the tastes and needs of the affiliates' communities. In support of this argument, the affiliates submitted several examples of the influence independent affiliates can have on network programming:

- When NBC aired a special edition of *Fear Factor*, featuring Playboy bunnies, during halftime of the Superbowl (airing on Fox), affiliates

objected to the network promos, which ran during all hours of the day, and included tag lines such as "who needs football when we've got bunnies?"

- When NBC began a trial program to accept liquor advertisements, so many affiliates opted out of airing the ads due to local concerns that NBC dropped the program.

- CBS had scheduled the *Victoria's Secret Fashion Show* for 8 p.m. The affiliates objected to the early showing and urged that the program be moved to the 10 p.m. time slot. In response, CBS moved the show to 9 P.M., although some affiliates nonetheless preempted the show as having inappropriate content for their service areas.

- Promotional ads for NBC's *Dog Eat Dog* included shots of nude contestants promoting the program's challenges such as "strip football" and "strip golf." When affiliates objected to the explicitness of the promos and their airing at all times of day, NBC agreed to eliminate strip stunts from future episodes.

- *NYPD Blue* was originally designed to include more nudity and graphic language than is currently aired, but after ABC affiliates objected, the amount of nudity and graphic language in the show was reduced. Even so, a number of affiliates initially refused to carry the show.

- Affiliates expressed concerns about the violent and mature content of the series *Kingpin*, which concerns the life of a drug lord. In response, NBC agreed to allow affiliates to review episodes in advance to ensure the content is appropriate for their local communities.

- In 2002, CBS worked with affiliates to reformat its morning news program, *The Early Show*. One key issue of affiliate concern was whether they would be permitted to provide local news content during the two-hour time block used by the program, as they had with CBS' prior show, *CBS This Morning*. Although some local affiliates are permitted to use the blended format with *The Early Show*, CBS has refused to permit other affiliates to move to the blended local-network news program format.

- NBC affiliates objected to NBC's intention to broadcast the 2002 Olympic Games live, which would have preempted the evening news on the west coast. After initially resisting the requests of the west coast affiliates to air a delayed broadcast during prime time, the network conducted a viewer survey. Results of the survey, however, substantiated the affiliates' assertion that west coast viewers preferred to watch the games during prime time, and the networks complied.

- NBC affiliates initially objected to NBC's decision to require live broadcasting of the XFL games. On the west coast, games substantially preempted both the affiliates' early evening local news and the national network news. In other parts of the country, overruns of the game preempted the late night local news. When affiliates raised similar concerns about Arena Football, claiming that overruns would preempt the 6 p.m. local newscasts on the east coast, the network agreed to work with the sports league to ensure the games do not run over.

- KYTV in Springfield, Missouri, preempted a January 6, 2003 episode of NBC's *Fear Factor*, which airs at 7 p.m. Central Time, that involved contestants eating horse rectums because it found the material inappropriate for its community.

394. Separate from this "collective negotiation" type of localism, parties also submitted evidence regarding the frequency of station-by-station preemptions for affiliates versus network-owned stations. Preemptions are instances in which local stations, whether they are owned and operated by networks or independently owned but affiliated with these networks, choose to air a program other than the program the network distributes to the station. Affiliates described numerous examples of individual station preemptions of network programming. WRAZ-TV in Raleigh, North Carolina, chose to stop airing *Temptation Island* after Fox revealed that one of the participating couples had a child because "WRAZ will not support a program that could potentially break up the parents of a young child." WFAA-TV in Dallas did not carry the entire first season of *NYPD Blue* because it found the material and language inappropriate for programming scheduled to air at 9 p.m. in that community. KNDX in Bismarck, N.D., refused to clear the Fox network's broadcast of the movie *Scream*, which is targeted to young viewers, because of its graphic and disturbing portrayal of teenage murders. WFAA-TV, an ABC affiliate in Dallas, was denied permission to preempt *Monday Night Football's* half-time show on November 12, 2001 to cover an American Airlines plane crash. American Airlines is based in Dallas. According to the affiliates, ABC permitted two O&Os to preempt the same half-time show to air news covering the same crash. (In this R&O, the Commission uses the terms "network-owned" stations and "O&O" (i.e. owned and operated) stations interchangeably.) CBS did not permit

WTSP-TV in Tampa Bay to air a debate between Jeb Bush and Bill McBride during the Florida gubernatorial debate because the affiliate would have preempted the season premiere of *48 Hours*. WTSP-TV was a co-sponsor of the debate. A Raleigh North Carolina Fox affiliate refused to air *Who Wants to Marry a Multimillionaire?* because it "felt it was demeaning to women and made a mockery of the institution of marriage." WANE-TV, the Fort Wayne, Indiana CBS affiliate, sought to preempt network programming to air a half-hour, early morning local news program geared toward the agricultural community. Although this was initially denied, CBS ultimately relented and granted permission.

395. The networks submitted data comparing prime time preemption rates of network-owned stations versus affiliates for 2001. That data showed that affiliates preempted an average of 9.5 hours of prime time programming per year compared with 6.8 hours per year for network-owned stations. The networks claim that this difference is inconsequential and does not justify retention of a national ownership cap. Affiliates assert that even this hand-picked data by networks confirms that affiliates preempt more than network-owned stations and that a national cap is needed to protect localism.

396. Affiliates seek to explain low preemption rates by arguing that networks have increasingly restricted preemption through their network-affiliate contracts. Affiliates complain that they are subject to preemption caps involving financial penalties or loss of affiliation if they exceed the number of network-authorized preemptions, while affiliates' local programs are often "preempted" by network overruns (e.g., network sports overrunning local news). According to the affiliates, Fox allows only two preemptions per year, and NBC allows only five hours of prime-time preemptions per year. Affiliates that exceed their allowable preemption "basket" may be subject to financial penalties or even loss of affiliation. Thus, while a majority of affiliates did not exceed their permitted preemptions, affiliates argue that there are good reasons for that result. In addition, affiliates note that they often maintain a "cushion" of unused preemption time in case it is needed, requiring them to exercise discretion in "spending" their preemption time during the year to avoid contractual financial penalties associated with excessive preemption.

397. *Discussion.* The Commission finds that a national television ownership cap is necessary to promote localism. The evidence demonstrates

both that network affiliates have economic incentives more oriented towards localism than do network-owned stations, and that affiliates act on those incentives in ways that result in networks delivering programming more responsive to their local communities (in the judgment of the affiliate) than they otherwise would. In order for affiliates to continue to serve local community tastes and needs in this way, a national cap is needed to preserve a body of independently-owned affiliates. The two ways in which affiliates can promote localism are by collective negotiation to influence the programming that the networks provide and by preemption by an individual station owner to provide programming better suited to its community.

398. The record shows that network-owned stations and affiliates have different economic incentives regarding the programming aired by local stations. The Commission agrees with the affiliates that they have an economic incentive to target their local audience by offering programs suited to local tastes. In so doing, affiliates have an incentive to tailor their programming schedule to meet local preferences. Localism is fostered by the affiliates' efforts to promote their own economic interest of maximizing the value of their stations by offering programming that local viewers will prefer to watch, even if the programming replaces the network's nationally scheduled programming.

399. The 2001 preemption data comparing network and affiliate preemption rates also supports retention of a national cap. The record shows that in 2001, affiliates preempted 9.5 hours per year of prime time programming versus 6.8 hours per year for network-owned stations. This data bolsters the Commission's conclusion that affiliates act on their economic incentives to preempt network programming with measurably greater frequency than do network-owned stations. Although the Commission agrees with the networks that the total number of hours preempted by both types of station owners in this comparison is relatively small, these data are for the prime time viewing period, when the vast majority of television viewing occurs. In the Commission's view, the practical effect of prime time preemption is far greater than that of preemption during other dayparts.

400. The Commission does not believe that network-owned stations provide the same localism value that independently-owned affiliates do. The networks argue that they listen to the management of network-owned stations

as well as to the management of affiliates. They claim that managers of O&Os participate during the networks' program development process and provide more credible input than the management of affiliate stations. They also assert that affiliates have an "inherent economic conflict" with the network regarding the distribution of profits, have no influence in the development of new programs, and learn of the new programs at the same time as do advertisers.

401. The Commission agrees that affiliates have an inherent economic conflict with networks. However, the Commission believes that affiliates' economic incentives actually help explain why affiliates regularly raise programming concerns with networks and why affiliates preempt more network programming, on average, than do network-owned stations. In the Commission's view, affiliates' economic incentives to maximize local viewership works to promote localism. In addition, the networks' claim of minimal affiliate influence over programming is overcome by evidence that affiliates regularly raise programming concerns with networks and frequently succeed in altering network programming in ways that protect local interests. These numerous instances of the collective influence brought to bear by affiliates on network programming decisions represent a powerful force for the protection of local viewing interests. They represent empirical evidence that affiliates collectively serve as an important counterweight to network programming decisions by influencing networks to deliver programming responsive to local tastes. In sum, the Commission believes that this affiliate/network dynamic is beneficial to viewers and should be preserved. It concludes that eliminating the cap altogether would shift the balance of power with respect to programming decisions toward the national broadcast networks in a way that would disserve its localism policy.

402. *Appropriate Level of the Cap.* The Commission has found that a national television ownership cap continues to be necessary to promote localism because the record demonstrates that affiliates affect network programming in ways that respond to viewer preferences in affiliates' local communities. In this section, the Commission examines the specific effects of the current 35% cap and whether this particular level achieves its localism objectives.

403. *Preemptions.* Affiliates argue that the networks have limited their ability to preempt network programming in

order to provide programming more geared to local needs and interests, and that these limits have become more formidable as the networks have extended their ownership of stations. Affiliates argue that an increase in the national cap reduces affiliates' ability to resist network pressure not to preempt. The affiliates point to a decline in affiliate preemptions following the 1996 increase in the cap from 25% to 35%. The affiliates' submission indicates that, with respect to all dayparts (as opposed to prime time-only), affiliates preempted, on average, 48 hours per year between 1991 to 1995 and 36 hours per year between 1996 to 2001. It also shows that, in the year 1995, the year before the cap was increased to 35%, there were, on average, 46 hours of programming preempted, but by the year 2001 the average had declined to 33 hours.

404. The networks offer two responses to the affiliates' data. First, the networks submit preemption data that, according to the networks, shows that the 35% cap has no effect on bargaining power between networks and affiliates. The networks contend that if higher levels of network station ownership actually increased networks' leverage over their affiliates, affiliates of the largest network station owners would be expected to preempt less (because of their diminished bargaining power) than affiliates of a network that had significantly less station ownership. The networks' data shows that affiliates of the largest network-owners (CBS and Fox, at 39% and 38% national reach respectively) preempt to an equal or greater extent than do affiliates of ABC, with a national reach of 23%. The networks assert that this data proves that the 35% cap has no effect on bargaining leverage between networks and affiliates.³⁶

405. Second, the networks argue that affiliate preemptions often are not for programming that is of greater public interest, but for syndicated programs.

³⁶ In a motion filed May 28, 2003, NAB/NASA asked the Commission to disregard certain portions of network submissions concerning preemption and local news quantity because the networks have not provided the data underlying those submissions. Alternatively, NAB/NASA asked the Commission to infer that the underlying data would not favor the networks' positions on preemption and news quantity of O&O versus affiliate stations. The portions of the network filings the Commission is asked to disregard include, *inter alia*, EI Study G and Disney Exhibit G, relating to preemptions, and EI Study H, relating to local news quantity. Fox opposed the motion on May 29, 2003. The Commission will afford the record evidence the appropriate weight in light of all circumstances, including the extent to which it believes the underlying data is necessary to make an informed decision about the showing.

The data Disney submits suggests that more affiliates preempted ABC programming in favor of syndicated programming than for local specials. In addition, Disney states that very few half hours of affiliate prime-time preemptions were for news, political, or public affairs programming. Disney's data, however, is countered by the affiliates' survey of affiliated stations, in which respondents reported preempting network programming for: local breaking news (83% of respondents); local news (71% of respondents); local emergencies (70% of respondents); local political programming (74% of respondents); local sports (75% of respondents); religious programming (47% of respondents); "other" programming (e.g., parades, telethons, syndicated programming, movies) (34% of respondents).

406. Apart from contractual restrictions, a majority of affiliates responding to an affiliate survey—68%—report that they have "experienced pressure from [their] network to not preempt programming." The record provides several instances of increased network resistance when affiliates attempted to air programs deemed to be of greater local interest than the network programming. For example, Belo's ABC affiliate in Dallas, the headquarters of American Airlines failed to get the network's permission to preempt the November 12, 2001, Monday Night Football halftime show for local news updates on the American Airlines jet crash in New York that morning.

407. *Discussion.* Although the Commission has concluded that a national cap is needed to balance power between networks and affiliates, the record suggests that maintaining the cap at 35% is not necessary to preserve the balance of bargaining power between networks and affiliates. In reaching this conclusion, the Commission relies principally on the evidence showing that the largest network station owners possess no greater bargaining power—as measured by prime time preemptions—than the smallest network station owner. This evidence is persuasive because it directly compares the extent to which different levels of network ownership of stations actually affect the level of preemption by those networks' affiliates. Implicit in this analysis is an assumption that that data, although not a perfect proxy, is a reliable indicator of relative bargaining power between networks and affiliates. Preemption of network programming by an affiliate has negative consequences to the network, and networks by all accounts seek to avoid preemption by affiliates. So the

ability of an affiliate to preempt in the face of networks' incentives to prevent preemption appears to be a reasonable measure of relative bargaining power between networks and affiliates.

408. The Commission is not persuaded by the affiliates' argument that the 35% cap is needed to protect localism because the most recent national cap increase resulted in fewer affiliate preemptions. The principal deficiency in this argument is that it does not control for other plausible causes of the decline in affiliate preemptions. Although the affiliates suggest that the 1996 increase in the national cap reduced affiliates' bargaining power, the affiliates themselves identify other factors occurring in the same timeframe as the national cap increase that they claim have further eroded affiliate bargaining power. The affiliates assert that the Commission's repeal of its financial interest and syndication rules in the early 1990s gave networks an additional financial incentive (in addition to their incentive to avoid preemption to maximize advertising rates) to discourage affiliate preemption. The affiliates contend that vertical integration, including program ownership and syndication by broadcast networks and the trend toward "repurposing" of network programming on affiliated non-broadcast channels have helped increase the networks' leverage over affiliates. To the extent these additional factors actually enhance network bargaining leverage, they undercut the affiliates' argument that it was specifically the 1996 increase in the national cap that caused affiliates to reduce their preemption of network programming.

409. A more accurate assessment of the impact of the 1996 national cap increase on network-affiliate bargaining leverage could be made if affiliate preemption rates from 1991 through 2001 could be compared to the preemption rates of network-owned stations during that same period. If preemption rates on network-owned stations were similar to affiliate preemption rates over that same period, there might be shown a more certain—and completely different—explanation for the decline. Networks might well have persuaded the Commission that the uniform decline in preemptions by O&Os and affiliates was caused by some plausible reason unrelated to the change in the national cap. On the other hand, if the data had shown preemption rates on network-owned stations remaining steady while affiliate preemptions declined sharply after 1996, then the affiliates' explanation for the decline

(i.e. increase in the national cap) would carry more weight.

410. The foregoing analysis of preemption data excludes consideration of the content of the programming substituted by the local station for the network programming. Other than its interest in promoting market structures that encourage local news production, the Commission seeks to avoid resting broadcast ownership policies on subjective judgments about the public policy value of different types of locally-substituted programming. The Commission agrees with the affiliates that it is enough, for purposes of assessing stations' responsiveness to local communities, that they preempted network programming. The judgment of when to preempt and what to substitute are uniquely within the judgment—and responsibility—of the station.

411. Thus, the Commission reaffirms its conclusion, in the 1998 *Biennial Review Report*, that independently-owned affiliates play a valuable role by "counterbalancing" the networks' economic incentive to broadcast their own programming "because they have the right * * * to air instead" programming more responsive to local concerns. But, the evidence suggests that the current limit of 35% is overly restrictive and that the cap may safely be raised and the benefits of wider network station ownership achieved without disturbing either this balance or affiliates' ability to preempt network programming.

412. *Other Effects of the Current 35% Cap.* The Commission, thus far in the R&O, examined two measures of localism—collective affiliate influence on network programming and specific preemption levels by affiliates versus network-owned stations. In this section it considers a third measure—the effect of the national cap on the quantity and quality of local news and public affairs programming. The Commission examines this area because local news and public affairs programming can play an important role in citizen participation in local and state government affairs. Thus it seeks market structures among broadcasters that encourage stations to produce local news and public affairs programming and thereby contribute to an informed citizenry.

413. In its 1984 decision, the Commission compared the quality and diversity of programming by stations owned by group owners—both network and non-network owners—with that of singly owned stations. It concluded that there was no evidence that group owners provided less or lower quality news and public affairs programming

than single owners. The *Fox* court criticized the Commission for failing to explain in the 1998 *Biennial Review Report* why it departed from this conclusion. With the decline in the number of individually owned stations, an increase has occurred in the number of stations sharing common ownership. The Commission sought in this biennial review to understand whether the national TV ownership rule, by preserving a class of affiliates, affects localism by comparing the local news and public affairs programming of network owned and operated stations to that of non-network owned affiliates. It discusses the evidence and its conclusions in this summary.

414. *Quantity of local news and public affairs programming.* In the NPRM, the Commission requested evidence regarding any clear relationship between the ownership of stations and the quantity and quality of local news and public affairs programming produced by those stations. A study conducted by Commission staff, MOWG Study No. 7, concluded that network-owned stations produced more local news and public affairs programming than affiliates and received local news excellence awards more frequently than affiliates. Responding to that study, the affiliates submitted a study indicating that many of the results of MOWG Study No. 7 changed when data pertaining to stations belonging to Fox were not used. Another study, submitted by Dr. Michael Baumann of Economists Inc., demonstrates that no defensible reason exists for deleting the Fox station data. Dr. Baumann's study provides analysis purporting to demonstrate that network-owned stations, on average, produce more local news than do affiliates across all-sized markets, with an even greater difference in the amount of news offered by network-owned stations in smaller markets.

415. The results of MOWG Study No. 7 show that network-owned stations air 23% more local news and public affairs programming per week than affiliates (22.8 hours versus 18.5 hours). Only MOWG Study No. 7 examined newspaper-owned affiliates separately from the other affiliates. It showed that, on average, newspaper-owned affiliates provided more hours per week of local news and public affairs (about 22 hours) than did the other affiliates (approximately 15 hours). The study also showed that network O&Os provided the most local news of all (almost 23 hours).

416. In response to MOWG Study No. 7, the affiliates conducted a study that revealed no statistically significant

difference between hours of local news aired by affiliates and O&O stations. Unlike MOWG Study No. 7, the affiliates' study included data on ABC, NBC and CBS, but did not include data on Fox Television. Disney argues that there is no policy-based rationale for excluding Fox stations. Using the affiliates' data, but accounting for all four of the networks, Dr. Baumann determined that network-owned stations on average provide more local news—about 4.2 hours per week—than do affiliates in all markets. In markets outside the top 25 markets, network-owned stations provide almost eight more hours of local news each week than affiliates do. Inside the top 25 markets, Disney agrees with the affiliates' study results that the difference between network-owned stations and affiliates was not statistically significant.

417. In Dr. Baumann's study, a third data set was used in analyzing local news and public affairs programming on network-owned and affiliate stations. Results, however, were similar to the first two studies: network-owned stations produce about 6.4 more hours per week of local news than affiliates in all markets tested. As with the modified affiliate data, in markets outside the top 25 markets, network-owned stations provide about 9 hours additional local news each week. This study agrees with the affiliates' results that the difference between network-owned stations and affiliate stations in news provided was not statistically significant in markets inside the top 25 markets.

418. *Local News Quality.* Although the Commission does not regulate programming quality, it has attempted to strengthen the ability of local stations to serve their communities through news and public affairs programming. In the NPRM, it sought to understand whether the national TV ownership rule may have the effect of increasing or decreasing the quantity and/or quality of local news and public affairs programming. Studies discussing programming quality were submitted in the record.

419. MOWG Study No. 7, for example, finds that network O&O stations win more awards for local news programming than non-O&O affiliates. In evaluating the quality of local news programming, the authors used three measures: (1) Ratings received for local evening news; (2) awards from the Radio and Television News Directors Association (RTNDA); and (3) the local television recipients of the Silver Baton of the A.I. Dupont Awards. The ratings of network-owned stations and affiliates were virtually identical during the

period tested. However, with respect to the receipt of RTNDA awards for news excellence, network-owned stations received those awards at a rate of 126% of the national average and affiliates received them at 96% of the national average. The study found, with respect to the DuPont awards, network-owned stations received awards at 337% of the national average, while affiliates received awards at 77% of the national average.

420. The results of a second study, however, indicate that quality differences between network-owned stations and affiliates are virtually nonexistent. In comparing the record of network-owned stations and affiliates' news operations, a study by Economists Inc. on behalf of the networks focused on the RTNDA awards, one of the awards used in MOWG Study No. 7. It reasoned that, because a larger number of RTNDA awards are given out each year, they are more likely to offer a better measure of news quality than the DuPont awards. The study examined the RTNDA awards from two perspectives, first analyzing the awards bestowed in the top 10 markets, and then the top 50 markets. The study concludes that, in either setting, "there is no discernible difference between network-owned stations and affiliates with respect to RTNDA awards." Neither this study nor MOWG Study No. 7 suggests that affiliates provide higher quality local news and public affairs programming than network-owned stations. Thus, the studies provide evidence that a national limit of 35% is not necessary to preserve a class of affiliates in order to maintain high quality local news and public programming.

421. One commenter argues that the number of awards received by stations is not a reliable measure of quality because the awards are not equally available to both network stations and affiliates. It argues that stations must apply for awards and pay entry fees to be considered. Moreover, it argues, networks generally have promotion and publicity departments that handle award entries, while local stations do not. While the Commission agrees that factors unrelated to quality programming can affect the number of awards received, there is no evidence that these factors had any measurable effect on the conclusion that network-owned stations' news programming is at least equivalent in quality to that of affiliates.

422. A third study finds that smaller station groups tend to produce higher quality newscasts than larger groups. In that study, affiliates generally had higher quality scores than network-

owned stations. Sixteen percent of affiliate stations earned "A's" in programming quality versus 11% of network-owned stations. According to the study's survey results, affiliates generally demonstrate somewhat more enterprise, cite more sources, tend to be more local, and are more likely to air stories that affect the community. Network-owned stations, on the other hand, are more likely to air national stories with no local connection, although they tend to air more points of view and score better in finding the larger implications of a story. The study also shows that only 22% of stations owned by the 25 largest group owners earned "A" grades for quality, compared with 48% of midsize and small groups. It acknowledges, however, that ratings for local news programming are growing more rapidly at larger group-owned stations than at smaller ones. Results of this study suggest that being a network-owned station does not "improve the kind of local news that citizens see."

423. A critique prepared by Economists Inc. asserts that the principal findings of this third study are statistically insignificant. In addition, they contend the study relies on subjective measures of newscast quality, and does not account for other factors affecting news quality, such as geographic differences. In the critique, Economists Inc. states that the underlying data will not be available for analysis and review within the time frame of this proceeding; thus only limited information is available for use in determining the validity of the study's results. The authors of this third study respond that the point of its survey was to identify patterns and trends in news quality. It asserts that it was not trying to prove a particular theory of cause and effect with its research, and states it has no financial stake in the outcome. Whether or not the study is unbiased, its results appear statistically insignificant, the underlying data have not been made available, and therefore it cannot be considered reliable or convincing evidence.

424. The affiliates argue, however, that localism cannot be limited to local news and public affairs; rather, it is a rich mix of programming, and that the Commission itself has previously identified other elements, such as opportunities for local self-expression, development and use of local talent, weather and market reports, and sports and entertainment programming as necessary and desirable in serving the broadcast needs and interests of local communities. As the Commission said in the NPRM, stations may fulfill their obligation to serve the needs and

interests of their communities by presenting local news and public affairs programming and by selecting other programming based on the particular needs and interests of the station's community. Thus, the Commission acknowledges that other kinds of programming are important in serving local needs. However, the Commission must rely on the data in the record, which focuses on two aspects of localism—program selection decisions by affiliates (preemption/collective negotiation) and the quality and quantity of local news and public affairs programming. From the data, it concludes that network-owned stations provide local news and public affairs programming that is at least equal, and may be superior, to that of affiliates.

425. *Discussion.* The Commission concludes that the national cap is not necessary to encourage local stations to air local news and public affairs programming. The record actually suggests that the national cap diminishes localism by restraining the most effective purveyors of local news from using their resources in additional markets. The studies in the record show that network-owned stations air, on average, more local news and public affairs programming than affiliates overall. MOWG Study No. 7 found that network-owned stations aired 4.3 hours more local news per week than did affiliates. The Baumann study concluded that the differential was 6.4 hours per week. The principal objection to the findings of these two studies was the affiliates' criticism that exclusion of the Fox stations from those two studies would nullify the differential between the two groups of stations. The Commission agrees with the networks that no valid reason exists for excluding the Fox stations.

426. The record also shows that local news on network-owned stations appears to be of higher quality than news on affiliate stations. MOWG Study No. 7 found that network-owned stations received local news excellence awards at a significantly higher rate than did affiliates. For the DuPont awards, networks received 337% of the national average compared with 77% for affiliates. For the RTNDA awards, networks received 126% to affiliates' 96%. (A score of 100% for a station group would indicate that the stations in that group won precisely the number of awards that would be expected given the number of stations in that group relative to the total number of stations in the U.S.). The Commission disagrees with commenters that smaller group owners tend to produce higher quality local news. It agrees with the networks

that the study's findings are statistically insignificant. In other words, according to widely-accepted scientific standards, there is an unacceptably large risk that the findings are attributable to random noise in the data. The study reports the differences in percentages of newscasts that received a particular grade, but fails to provide any statistical testing on these results. The networks conducted these statistical tests and determined that the differences in news quality were not large enough to conclude that the probability of a newscast getting a particular grade was dependent on the ownership group that aired the newscast. In sum, the record shows that the national cap is not necessary to promote high quality, or relatively larger amounts of, local news programming. The record suggests the opposite—that the current cap prevents networks from acquiring more stations and providing enhanced local news operations.

427. *Modification of the National Television Ownership Rule.* The Commission has concluded that an audience reach cap of 35% is not necessary to promote diversity or competition in any relevant market. It is persuaded, however, that a national cap at some level is needed to promote localism by preserving the balance of power between networks and affiliates. The Commission found that affiliates' incentives are more attuned to their local communities than are those of networks, which seek to assure that the largest audiences possible are watching their programming at the same time. It concludes from the record that preserving a balance of power between a network and its affiliates promotes localism, and accordingly, it will continue to restrict the national audience reach of station owners.

428. Given the benefits to innovation that derive from having a number of separately-owned station groups, the Commission believes the national ownership cap should continue to apply to all station owners, including those that are not networks. The record shows that there have been a number of instances where having a variety of owners has led to innovative programming formats and technical advances, and the Commission believes that applying the national ownership cap to all station owners will continue to spur innovation, which the Commission believes will be particularly valuable in transitioning to digital television. In addition, applying the cap to all station owners adheres to our longstanding policy of refusing to differentiate among different categories of station owners for purposes of the national TV ownership rule.

429. The next task is to determine what the ownership limit should be. As the court in *Sinclair* recognized, the Commission has wide discretion when drawing administrative lines. Having found that 35% is too low and 100% (or no limit) is too high, after considering the evidence in the record, the Commission applies its discretion and raises the national ownership cap to 45%. This modification, fundamentally, is a line-drawing exercise in which it attempts to balance the benefits of a television ownership cap against the factors favoring an incremental increase. Finding a point between 35% and 100% is a matter of judgment falling within the particular expertise of the Commission.

430. The Commission has decided to modify the national cap by raising it 10 percentage points for three primary reasons. First, while affiliates argue that it is necessary to preserve a balance of power between networks and affiliates so that affiliates can maintain adequate preemption rights, it is evident that networks can exceed a nationwide audience reach of 35% without harming affiliates' abilities to preempt network programming. Affiliates of networks with a national reach of greater than 35% seem to have no less bargaining power than affiliates of networks with less than 35% national reach. In accordance with section 202(h), therefore, the cap must be modified upward. The record does not, unfortunately, help to identify with any precision the point at which a network audience reach would be so large that affiliate bargaining power would be substantially undermined. Given that the Commission is interested in finding a point at which the balance of power between networks and affiliates is roughly equal, however, it believes that a national audience reach cap of approximately half of all homes would be appropriate.

431. Second, the Commission is mindful of the predictive nature of this line-drawing exercise, and has some concern about allowing significant new aggregation of network power absent more compelling evidence regarding the possible effects of that aggregation above current limits. Accordingly, and in light of the fact that Congress raised the ownership cap by ten percentage points in 1996, from 25% to 35%, the Commission is inclined to take a similarly incremental approach and increase the cap by an additional 10 percentage points. Although a cap of 45% does not equate to a precisely equal degree of national reach for networks and their affiliates, a 45% limit ensures that networks will not

obtain a greater national audience reach than their affiliates collectively will have.

432. Finally, the Commission believes that the cap should accommodate all existing broadcast combinations and permit some additional room for growth. A 45% cap will allow some, but not unconstrained, growth for each of the top four network owners. Under the current rule, ABC owns ten stations reaching 23.6% of the national audience; CBS owns 39 stations reaching 39% of the national audience (these stations include the CBS as well as the UPN owned and operated stations, including 3 satellite stations); Fox owns 37 stations reaching 37.8% of the national audience (includes two satellite stations); and NBC owns 29 stations reaching 33.6% of the national television audience (these stations include the NBC as well as the Telemundo owned and operated stations, as well as a station located in Puerto Rico). There are currently 1,340 commercial television stations licensed by the Commission. The percentage of these television stations owned by each of these networks is as follows: ABC owns less than 1%; CBS owns approximately 3%; Fox owns approximately 3%; and NBC owns approximately 2%.

433. Broadcast networks have lost market share in recent years to cable and DBS, and allowing them to achieve better economies of scale and scope may help them remain competitive in the marketplace. Further, given the rise in programming costs and increasing competition from non-broadcast national media, the economies of scale and scope made possible by network expansion of station ownership will contribute to the preservation of over-the-air television by deterring the migration of expensive programming, such as sports programming, to cable networks. Accordingly, the Commission modifies the national audience reach rule to impose a 45% cap.

434. Although the Commission affirms the finding in the *1984 Multiple Ownership Report and Order* that increased network ownership of stations will not harm either competition or diversity, the Commission's decision to retain a national ownership cap is a departure from its conclusion in 1984 that the national TV ownership rule should be repealed. In 1984, the Commission gave very limited consideration to the potential effects of the cap on localism. That attention was devoted to the quality and quantity of news and public affairs programming on group-owned versus individually-owned stations. In this R&O, by

contrast, the Commission expanded its "localism" measures to include the important consideration of program selection by local stations. The 1984 decision did not address the balance of power between networks and affiliates and how that affects program selection. It is this factor that is the central factor in our decision to retain a national cap.

435. *UHF Discount*. In the NPRM, the Commission invited comment on the relevance and continued efficacy of the 50% UHF discount, which is intended to recognize the deficiencies in over-the-air UHF reception in comparison to VHF reception. The NPRM explained that the discount was enacted because UHF stations were competitively disadvantaged by weaker signals and smaller household reach than VHF stations. In light of greater carriage of UHF stations on MVPDs since enactment of the UHF discount in 1985, the Commission sought comment on the continued need for the UHF discount.

436. The Commission concludes that the UHF discount continues to be necessary to promote entry and competition among broadcast networks. VHF signals typically reach between 72 and 76 miles, while UHF signals reach approximately 44 miles. This signal disparity results in a significantly smaller household reach of UHF signals compared with VHF signals. Fox, NBC and Viacom submitted data showing that, in markets where they own both a UHF and a VHF station, the UHF station reaches between 56% and 61% of the service area of their VHF stations. Similarly, Paxson Communications states that in eight cities where it owns UHF stations, its stations reach between 35.7% and 78.2% of the homes reached by VHF stations in those markets.

437. This diminished UHF signal area coverage affects UHF stations' ability to compete with VHF stations in two ways. First, although cable and DBS operators serve 86% of U.S. households, the Commission recently determined that roughly 30% of television sets are not connected to MVPD service and receive exclusively over-the-air broadcast stations. UHF stations reach far fewer of these broadcast-only viewers as VHF stations. Second, weaker UHF signals make it more difficult for a UHF station to qualify for cable and DBS carriage. Commission regulations require a local television station to place a Grade B signal over the cable or DBS headend in order to qualify for carriage. Alternatively, if a station does not place a Grade B signal over the headend, it may pay for an alternative method of delivering its signal to the headend, such as a fiber optic connection. Non-carriage on a cable system will, as a

practical matter, make the UHF station unavailable to homes in the MVPD's service area.

438. In addition to diminished signal coverage, UHF stations require between 1.5 and 3 times greater electricity costs to operate than VHF stations. UHF stations also require more expensive transmitters than VHF stations. These factors, along with the signal coverage disparity, appear to diminish the ability of UHF stations to compete in the delivered video programming market. According to a 1997 study provided by Paxson Communications, VHF affiliates of the top four broadcast networks had approximately 50% higher ratings than UHF affiliates of the top four networks. Paxson then replicated this study with 2002 ratings information and determined that the ratings disparity between UHF and VHF stations had actually increased between 1997 and 2002. Paxson's filing shows that, in November of 2002, network-affiliated VHF stations received approximately 57% higher ratings than network-affiliated UHF stations, compared with 50% in 1997. Thus, even after controlling for factors such as programming and market size, UHF stations continue to experience a competitive handicap compared with VHF stations. This disparity translates into reduced advertising revenues for UHF stations. Thus, the Commission does not believe that the UHF handicap has largely been eliminated by greater cable and DBS carriage of UHF signals.

439. In addition to strengthening competition between UHF and VHF stations, the UHF discount promotes entry by new broadcast networks. Paxson asserts that UHF discount enhanced its ability to launch a new broadcast network because it could own more UHF stations than VHF stations. Paxson states that the additional ownership of stations permitted by the UHF discount provides a significant financial incentive for new networks to enter and compete with established networks. This is because ownership of stations, as opposed to affiliation with separately-owned stations, enables a network such as Paxson's to earn both national and local advertising revenues. Univision Communications also states that the UHF discount has enabled it to enter the market with programming tailored to Hispanic audiences. Univision explains that its entry as a broadcast network is particularly beneficial to Hispanic audiences because they rely disproportionately on over-the-air broadcast channels.

440. Finally, the Commission observes that the established broadcast networks generally have not sought to

take advantage of the UHF discount to gain greater national reach through local stations. The four most established broadcast networks collectively own 67 stations, 12 of which are UHF stations. Instead of replacing their VHF stations with UHF stations and owning up to 70% national coverage, they have retained their VHF stations and sought elimination of the national ownership cap. By contrast, Paxson, a recent entrant into the broadcast network business, owns 61 stations, all of which are UHF. Absent the UHF discount, Paxson's audience reach would be 61.8% of the nation's television households. This data indicates that the UHF discount plays a meaningful role in encouraging entry of new broadcast networks into the market. For these reasons, the Commission retains the UHF discount.

441. The Commission has previously said it will issue a notice of proposed rulemaking proposing a phased-in elimination of the discount when DTV transition is near completion. At this point, however, it is clear that the digital transition will largely eliminate the technical basis for the UHF discount because UHF and VHF signals will be substantially equalized. Therefore, the Commission will sunset the application of the UHF discount for the stations owned by the top four broadcast networks (*i.e.*, CBS, NBC, ABC and Fox) as the digital transition is completed on a market by market basis. This sunset will apply unless, prior to that time, the Commission makes an affirmative determination that the public interest would be served by continuation of the discount beyond the digital transition. For all other networks and station group owners, it will continue to examine the extent of competitive disparity between UHF and VHF stations as well as the impact on the entry and viability of new broadcast networks. In a subsequent biennial review, the Commission will determine whether to include stations owned by these other networks and station group owners in the sunset provision it has established for stations owned by the top four broadcast networks.

B. Dual Network Rule

442. The dual network rule provides: "A television broadcast station may affiliate with a person or entity that maintains two or more networks of television broadcast stations unless such dual or multiple networks are composed of two or more persons or entities that, on February 8, 1996, were 'networks' as defined in § 73.3613(a)(1) of the Commission's regulations (that is, ABC, CBS, Fox, and NBC)." 47 CFR 73.658(g).

Thus, the rule permits common ownership of multiple broadcast networks, but prohibits a merger between or among the "top-four" networks, *i.e.*, ABC, CBS, Fox, and NBC. In the R&O, the Commission concludes that the dual network rule is necessary in the public interest to promote competition and localism.

443. The original dual network rule, which prohibited any entity from maintaining more than a single radio network, was adopted over sixty years ago. The rule was later extended to television networks. The Commission believed that an entity that operated more than one network might preclude new networks from developing and affiliating with desirable stations because those stations might already be affiliated with the more powerful network entity. In addition, the Commission expressed concern that ownership of more than one network could give the owner too much market power. The rule, therefore, was intended to serve the Commission's competition and diversity goals.

444. In the 1996 Act, Congress directed the Commission to amend the rule, which it did, to permit common ownership of two or more broadcast networks, but not a merger among ABC, CBS, Fox, or NBC, or between one of these top-four networks and UPN or WB. In 2001, the Commission further modified the rule to permit a top-four network to merge with or acquire UPN or WB. The Commission found that: (1) Competition in the national advertising market would not be harmed; (2) greater vertical integration was potentially an efficient, pro-competitive response to increasing competition in the video market; and (3) program diversity would not be harmed because the two combined networks would have economic incentives to diversify their program offerings.

445. The restrictions in the current rule apply only to combinations of the top-four networks. All existing network organizations, and all new network organizations, may create and maintain multiple broadcast networks. Thus, the current rule permits common ownership of multiple broadcast networks created through internal growth and new entry.

446. Under section 202(h), the Commission considers whether the dual network rule continues to be "necessary in the public interest as the result of competition." In determining whether the rule meets this standard, the R&O addresses whether the rule promotes competition, localism, and diversity.

447. *Competition.* The R&O summarizes the complex roles played by broadcast networks. Broadcast

networks acquire a collection of programs from program producers. The programs are selected based on their ability to attract audiences that can be sold to advertisers. These programs—with advertisements embedded—are then made available to television audiences through the broadcast network's owned and operated broadcast television stations ("O&Os"), and also through contractual arrangements with affiliated broadcast television stations. Thus, a broadcast network serves many roles. It is an intermediary between local broadcast stations and advertisers and program producers. Because the top-four broadcast networks are participants in the program acquisition market and the national advertising market, mergers among them can affect competition in each of these markets.

448. Given the level of vertical integration of each of the top-four networks, as well as their continued operation as a "strategic group" in the national advertising market, a top-four network merger would give rise to competitive concerns that the merged firm would be able to reduce its program purchases and/or the price it pays for programming. As a result, the Commission concludes that the dual network rule remains necessary in the public interest to foster competition.

449. *Program Acquisition Market.* The top-four networks are the broadcasting components of vertically-integrated firms, which compete against each other to acquire programming that will attract the largest national audiences. Competition in the program acquisition market is important because networks compete with each other to acquire new, diverse, and innovative programming. A top-four network merger would give rise to competitive concerns that the merged firm would restrict the consumption of programming by using its market power to limit competitors' access to sources of programming. In addition, the merged network could use its market power to control the price it pays for programming or to raise competitors' costs of acquiring programming. In concentrated markets, viewers have access to fewer programming choices if the number of national, independent purchasers of programming decreases due to limited access to programming and higher programming costs.

450. NASA argues that a merger of two or more of the top-four networks would result in a less competitive program acquisition market, evidenced by lower output, fewer choices, and less technological progress. CCC argues that the top-four networks represent a distinct and important resource for

viewers because only they are able to consistently distribute both news and entertainment programming to a mass audience, using their cable subsidiaries and local broadcast affiliates. Fox, on the other hand, argues that the rule actually undermines the Commission's competition policy by discouraging broadcast investment to the detriment of consumers of free over-the-air television. Fox also argues that the program acquisition market is only moderately concentrated, having an HHI of approximately 1120. In support of this argument, Fox asserts that the program acquisition market is characterized by a large number of purchasers of exhibition rights, including broadcast networks, broadcast stations, cable networks, DBS operators, premium cable networks, pay-per-view providers, and distributors of video cassettes and DVDs. NASA counters that the major broadcast networks do not compete with the cable networks for mass-audience, prime-time programs, and that the only avenue of distribution for such programs is the television broadcast networks. By NASA's estimate, which is based on an analysis of Fox's Economic Study E, Table E2, the top-four networks account for over 87 percent of programming expenditures by broadcasting networks, and the video entertainment program acquisition market has an HHI of approximately 2100, a result considered "highly concentrated" under the DOJ/FTC Merger Guidelines. NASA therefore asserts that only the major broadcasting networks should be considered in an analysis of concentration in the purchase of national video programming.

451. The Commission agrees with Fox and NASA that the context for analyzing the program acquisition market is to consider the shares of expenditures on video entertainment programming. The Commission concludes, however, that a more accurate assay of the market includes the shares of broadcast networks, broadcast stations, basic cable networks, pay cable networks, and pay-per-view networks. The Commission rejects NASA's narrow definition because it provides no evidentiary reason to exclude other video programming purchasers and it dismisses the range of programming choices available to viewers over the air, via cable and via satellite. The Commission does not agree with Fox's more expansive definition, specifically the inclusion of home video, as that requires additional action on the part of individual viewers, such as purchasing a DVD player, driving to a video rental

store, and renting a DVD. The Commission concludes that using broadcast networks, broadcast stations, basic cable networks, pay cable networks, and pay-per-view networks in its analysis accurately represents the market participants, and their role in delivering programming to large, passive audiences. In order to examine the effect of mergers among broadcast television networks subject to this rule, the Commission constructs hypothetical merger scenarios, building on the scenario developed in the national cap section. In the absence of actual figures for the network companies' broadcast station expenditures, the Commission examines the effects of mergers amongst the networks (*i.e.*, without their complement of O&Os, but including the cable networks they own). For the same reason, the Commission can only calculate the change in the HHI, not the "base level" HHI. So, for example, if Fox merged with GE and Disney merged with Viacom, the HHI would increase by almost 767 points. Then, if these two companies merged with each other, the HHI would increase by 2.246 points. Either of these changes in the HHI would be scrutinized under DOJ Merger Guidelines. Since these networks own television stations, the change in the HHI would actually be higher than in these examples.

452. Accordingly, the Commission concludes that a merger between or among any of the top-four networks would harm competition in the program acquisition market. As noted, the Commission determines in its analysis of the national ownership cap that an increase in the cap would not harm the program acquisition market, principally because networks would be enhancing their owned and operated distribution base. The Commission's analysis of a merger between two or more of the top-four broadcast networks, however, indicates a significant potential for harm to this market. In addition to acquiring an entire group of owned and operated stations and all of the affiliation agreements of the stations aligned with the network, a merger would also entail the acquisition of significant program purchasing power by the vertically integrated merging networks. The vertically integrated networks would limit competitors' access to programming by denying remaining networks access to the production output of the merged network. Currently, one network studio may produce programming that is ultimately purchased by another network. In addition the merged firm can raise the price paid by those competitors for

programming created and produced by the merged network's program production assets. The rule, therefore, remains necessary to promote competition in the program acquisition market.

453. *National Advertising Market.* Networks sell national advertising by creating large national audiences for their programming and delivering those audiences to advertisers. Sellers in the national advertising market include national broadcast networks, cable networks, and syndicators. Network O&Os, network-affiliated stations, and independent stations sell national spot advertising time, which is advertising sold on a market-by-market basis to national advertisers. National spot advertising time provides a competitive alternative to national advertising time to a certain extent. These sellers compete against each other not only based on the price they charge for advertising spots, but also based on their ability to deliver the largest number of viewers to their advertisers. If a merger were to reduce competition for advertising dollars, networks would have less incentive to compete against each other for viewers, which would lead them to pay less attention to viewers' needs and to produce less varied, lower quality, and less innovative programming.

454. In the discussion above of the necessity of maintaining the national TV ownership rule, the Commission concludes that the networks compete with each other and with cable networks for national advertising revenues and that the current ownership cap was not necessary to ensure competition in the national advertising market. However, while the Commission finds that the top-four networks do not possess market power today, that would change if two or more of them were to merge with each other. Moreover, as explained in the *Dual Network Order*, the top-four networks comprise a "strategic group" within the national advertising market. A strategic group refers to a cluster of independent firms within an industry that pursue similar business strategies. For example, the top-four networks supply their affiliated local stations with programming intended to attract mass audiences and advertisers that want to reach such large, nationwide audiences. By contrast, the emerging networks target more specialized, niche audiences similar to cable television networks. When properly applied, the concept of a strategic group ordinarily implies that only a relatively few firms will be included within its boundaries so that competitive rivalry will be oligopolistic

in nature, although the number of firms actually populating the industry aggregated over all strategic groups may be quite numerous. The top-four networks compete largely among themselves for advertisers that seek to reach large, national, mass audiences—a significant portion of the national advertising market that provides the top-four networks with a significant portion of their profits. The Commission therefore concludes that a merger of two or more of the top-four networks would substantially lessen competition in the national advertising market, especially within the strategic group, with the concomitant harm to viewers described above. The Commission's analysis suggests that economic concentration within the strategic group for 2001, as measured by the HHI, is 2646. This is based on advertising revenue and on shares of the top-four broadcast networks.

455. The recent growth of cable and DBS does not alter this conclusion. Despite that growth, the top-four networks continue to provide the greatest reach of any medium of mass communications. The top-four networks attract much larger prime-time audiences in relation to advertisement-supported cable networks. For example, during the month of February, 2003 (1/27/03–2/23/03), CBS, NBC, ABC, and Fox delivered prime-time household ratings of 8.9, 8.1, 6.7, and 6.7, respectively, as compared to the top advertiser-supported cable network, TNT, which garnered a 1.8 share rating. (A rating point is equal to 1.067 million households.) Broadcasting's percentage share of advertising revenue continues to exceed its percentage share of viewing. Broadcasting's share of advertising revenue in 2001 was 71.5% whereas its audience share stood at 53.7%. In addition, the networks have been able to increase the quantity of advertising availabilities for sale by adding more commercial minutes per hour. Moreover, despite a decrease in audience share, the top-four networks continue to command increases in advertising rates, a further testament to the strength of broadcasting television as an advertising medium. The networks have raised prices for advertising on a cost per thousand ("CPM") viewers basis steadily. Prime-time broadcast network CPMs have increased from \$9.74 in 1990 to \$13.42 in 2000, an average annual growth rate of 3.8%.

456. The Commission agrees with NASA that despite the emergence of new media on cable, DBS, and the Internet, the top-four broadcast networks still have the largest concentration of viewers and television

economic power. A recent survey shows that each of the top twenty-five prime-time broadcast programs during the week of December 9–15, 2002, all of which were aired by CBS, ABC, NBC, or Fox, achieved considerably higher household ratings than any of the 25 highest ranked cable programs. The highest-ranked broadcast program had a rating larger than the top five cable programs' ratings combined. The Commission also agrees that as it becomes more difficult to reach a large number of viewers, television broadcasters that can still deliver a mass audience become more valuable.

457. The Commission further concludes, as it did in the *Dual Network Order*, that obtaining a sufficient number of affiliated stations remains a major obstacle to developing a new broadcast network capable of attracting national advertisers seeking to reach a mass audience. As long as mobility barriers (i.e. barriers to entry that deter the movement of a firm *within* a given industry from shifting from one strategic group to another) deter entry into the major network strategic group, the pricing of network advertising will be sensitive to the number of network competitors. The Commission therefore concludes that the current dual network rule is necessary to maintain competition in national advertising market.

458. *Localism*. The Commission concludes that the dual network rule also is necessary to retain the balance of bargaining power between the top-four networks and their affiliates. As noted in the national TV ownership rule section, the Commission concludes that affiliates play an important role in assuring that the needs and tastes of local viewers are served. Elimination of the dual network rule would harm localism by providing the top-four networks with increased economic leverage over their affiliates, thereby diminishing the ability of the affiliates to serve their communities.

459. The top-four networks have an economic incentive to promote the widest distribution nationwide of the programming that they produce and to assure that it is carried simultaneously across the country. To reach the most viewers, the top-four networks acquire their own stations ("O&Os"), usually in the largest television markets, and enter into affiliation agreements with station owners throughout the remainder of the country. Through affiliation, the networks benefit from the wide-area delivery of their programming. Network affiliates benefit, in turn, by gaining access to high-quality programming.

460. Affiliates have an economic incentive to tailor their programming to their local audiences. Affiliates can influence network programming decisions by joining forces with other network affiliates in collective negotiations to ensure that the programming provided by the network serves local needs and interests. The strength of an affiliate's influence with its network lies in its power as part of a "critical mass" to join forces with other network affiliates in collective negotiations to try to influence network programming. On an individual basis, affiliates may also decide to preempt network programming if other programming is available that better suits local needs.

461. As noted by NASA, because of the costs of programming and promotional expenses, network affiliation remains critical for the economic survival of most local television stations. NASA argues that if the dual network rule were eliminated, a top-four network merger would result in the networks gaining an unfair advantage over their affiliates, noting that a merger would reduce alternative choices of program providers for affiliates as the number of network owners decreases. As an example, NASA notes that if NBC and CBS were permitted to merge, a terminated CBS affiliate would no longer be able to turn to NBC for affiliation. The harm would be exacerbated if more than two of the top-four networks were to combine.

462. The Commission agrees with NASA that a top-four network merger would harm localism by providing the networks with undue economic leverage over their affiliates. While a top-four network merger may not result in fewer networks, it would result in fewer network owners. The Commission concludes that a top-four network merger would reduce the ability of affiliates to bargain with their network for favorable terms of affiliation, and would result in less influence of affiliates on network programming. As the number of network owners declines, affiliates lose the ability to use the availability of other top independently-owned networks as a bargaining tool with their own networks. In the same way, a combined top-four network's increased leverage could be used to overwhelm affiliate bargaining power with respect to programming issues. A top-four network merger would lead to fewer alternatives for affiliates, which would lead to reduced bargaining power of affiliates, and less influence of affiliates on network programming, including the ability to preempt network programming that affiliates find

to not serve their local communities. The Commission therefore concludes that the dual network rule remains necessary to foster localism.

463. *Diversity.* In the NPRM, the Commission sought comment on the dual network rule's effect on program diversity and viewpoint diversity. As noted in the national TV ownership rule section, the Commission concludes that the market for diversity is local, not national. As also noted, the Commission concludes that viewpoint diversity is the most pertinent aspect of diversity for purposes of our ownership rules. Nevertheless, since several commenters argue that elimination of the dual network rule would result in a diminution of program diversity, the R&O addresses their arguments.

464. Several commenters argue that elimination of the dual network rule would result in less diverse programming and that national viewpoints in news reporting would be diminished. AFL-CIO and AFTRA argue that recent mergers and consolidation in the industry have resulted in instances of reduced viewpoint diversity and program diversity in local markets. AFTRA also argues that elimination of the rule will quell new voices and diverse viewpoints, "as emerging networks are quashed in favor of more 'cost-effective' means of delivering content." CCC argues that because CBS is "repurposing" its original programming on UPN, diversity between the two networks is reduced. CCC also argues that WB, UPN, and the cable networks do not have the audience reach or the resources to fill the diversity void created if the national networks were reduced by elimination of the rule. Fox disagrees, arguing that the vast array of other media outlets will provide the public with sufficiently diverse information and views.

465. UCC argues that despite recent gains in the popularity of other forms of media, national broadcast television continues to be the public's most important source for national and international news. UCC argues that the average weekday reach of the evening newscasts of ABC, CBS and NBC is about 10 times the combined reach at 6:30 p.m. for Fox, CNN, CNN Headline News, MSNBC, and CNBC. Because network news on broadcast television is expensive to produce, UCC argues, a top-four network merger would result in the consolidation of news departments in order to achieve economic efficiency.

466. In the *Dual Network Order*, the Commission found that program diversity at the national level would not likely be harmed by the combination of an emerging network (*i.e.*, UPN or WB)

with one of the top-four networks. The Commission found it likely that a common owner would have strong incentives to produce a diverse schedule of programming for each set of local TV outlets in the same market. In this proceeding, the Commission addresses possible combinations among only the top-four networks, which are distinct from combinations between a top-four network and an emerging network. Also, the Commission finds in this proceeding that the market for diversity is local, not national. Further, as noted in the Policy Goals section above, the Commission finds that program diversity is best achieved by reliance on competition among delivery systems rather than by government regulation.

467. The Commission is unable to conclude that the dual network rule can be justified on program diversity or viewpoint diversity grounds. Although the Commission received conjectural statements regarding the repurposing of some programming, and stories of news operations being shared in a few markets, these reports do not evidence a systematic reduction in diversity as a result of media mergers. The record provides no evidence that, because some stations share news operations, viewpoint diversity is diminished. Further, even if a merger among ABC, CBS, or NBC would result in the loss of one weekday evening newscast, a substantial number of outlets that report national/international news would remain to provide diverse viewpoints throughout the day to the public. Finally, to the extent that the Commission considers programming diversity an issue, the record provides no evidence that the repurposing of programming on different networks results in a diminution of program diversity. In fact, the Commission found in the Dual Network Order that the repurposing of programming between two merged networks was likely to produce net benefits to viewers of network television.

468. Given the level of vertical integration of each of the top-four networks, as well as their continued operation as a "strategic group" in the national advertising market, a top-four network merger would give rise to competitive concerns that the merged firm would be able to reduce its program purchases and/or the price it pays for programming. These competitive harms would, in turn, harm viewers through reductions in program output, program choices, program quality, and innovation. The Commission further concludes that a top-four network merger would harm

localism by providing the networks with undue economic leverage over their affiliates, reducing the ability of affiliates to bargain with their network for favorable terms of affiliation, giving the networks greater power in program selection, and diminishing alternative choices of programming for affiliates. As a result, the Commission concludes that the dual network rule remains necessary in the public interest to foster competition and localism.

VII. Miscellaneous Requests

469. Numerous parties submitted comments on issues not specifically raised in the NPRM. The Commission dismisses most of these requests on procedural grounds because they fall outside the scope of this proceeding. The Commission does not review the merits of these requests. To the extent appropriate, parties are free to re-file these requests as petitions for rulemakings. The Commission denies others for the reasons discussed in this summary.

470. *Proposed Behavioral Rules.* Several parties ask that the Commission impose behavioral rules to achieve a number of alleged public interest goals. The Commission invited comment in the NPRM as to whether behavioral rules might render structural rules unnecessary to achieve our public interest goals of diversity, competition, and localism. The following proposals, however, relate to policy goals that are unrelated to those served by our structural rules and are therefore outside the scope of the NPRM.

471. *TV Viewing.* TV Turnoff Network requests that the Commission require all broadcast stations to run announcements reminding the viewing public that: (1) Excessive television viewing has negative health, academic, and other consequences for children; and (2) parents and guardians retain and should exercise their First Amendment right and ability to turn off their television sets and limit their children's viewing time. The Commission dismisses this request because it is outside the scope of this proceeding, which reviews our structural broadcast ownership rules pursuant to section 202(h). Indeed, the goals sought to be advanced by the proposal bear no relation to diversity, competition, or localism.

472. *PEG.* Alliance requests that the Commission promulgate behavioral regulations that guarantee public, educational, and governmental ("PEG") access on cable and direct broadcast satellite ("DBS") to ensure diversity of voices. Alliance argues that such federal regulations are necessary because PEG

access is not mandated by federal legislation, but rather derives from a statute that allows local communities to regulate it. The Commission dismisses Alliance's request as outside the scope of this proceeding and our authority, generally. The Commission once had access requirements of the type suggested by Alliance, but the Supreme Court struck them down as beyond our statutory authority. Congress did not authorize the Commission, however, to implement, enforce, or oversee the broad local access requirements advocated by Alliance. Although DBS is required to set aside 4% of capacity for public interest ("non-commercial, educational, and informational") programming pursuant to section 335 of the Act, the Commission does not have authority to adopt the broader rights advocated. The Commission notes, however, that noncommercial educational television stations may request mandatory carriage on cable systems and also have satellite carriage rights in markets where DBS provides local-into-local service pursuant to the "carry-one-carry-all" requirements under section 338 of the Act.

473. *Payola*. Future of Music Coalition alleges that a new form of payola exists in which record companies pay independent promoters to ensure that the companies' records are played on the radio. The independent promoters, Future of Music Coalition alleges, then establish exclusive relationships with radio stations and pay these radio stations a large portion of the money received from the record companies in the form of "promotional expenses." Future of Music Coalition asks that the Commission ban this practice, thereby promoting diversity in radio programming. The Commission dismisses Future of Music Coalition's request because it is outside the scope of this proceeding.

474. *Ownership Issues Outside the Scope of the Proceeding*. Some parties request action regarding ownership or attribution issues that were not raised in the NPRM and that are therefore outside the scope of the proceeding. The Commission dismisses these requests.

475. *Alien Ownership*. CanWest suggests that the Commission's biennial review of media ownership rules and the multilateral trade in services negotiations underway in the World Trade Organization provide a timely occasion to review foreign ownership rules for broadcasting. The Commission declines to undertake such a review because it would be outside the scope of this proceeding. Moreover, to the extent that our foreign ownership

regulations are statutorily based, 47 U.S.C. 310, the Commission does not have the discretion to modify or repeal them in the biennial review process, pursuant to section 202(h).

476. *Attribution*. MMTC asks us to expand this proceeding to include review of the attribution rules. The Commission denies this request because the attribution limits are not properly reviewed in the biennial review process, except for review of radio joint sales agreements ("JSAs"), which the Commission addresses in the Local Radio Ownership section of the R&O. The attribution rules do not themselves prohibit or restrict ownership of interests in any entity, but rather determine what interests are cognizable under the ownership rules. The focus of the biennial review process is whether the ownership rules are necessary in the public interest as a result of competition. The attribution limits are set at the level the Commission believes conveys influence or control and, as these limits are not related to any changes in competitive forces, they are not reviewed biennially.

477. *LPFM*. REC Networks requests that the Commission refrain from changing our Low Power FM ("LPFM") rules relating to ownership caps and assignment of stations because these rules are consistent with our intentions in establishing LPFM. LPFM ownership and assignment rules are addressed in §§ 73.855, 73.858, 73.860, and 73.865 of the Commission's rules, and are not addressed in the context of this proceeding. These are non-commercial stations and therefore a consideration of ownership limits for these stations is outside the scope of this proceeding. REC also asks that the Commission impose new ownership restrictions on non-commercial educational stations. The Commission dismisses that request as such limits are outside the scope of this proceeding.

478. *Broadcast Auction Process*. Hodson recommends that the Commission modify the new entrant bidding credit in the broadcast auction process from the current percentages of 25 percent and 35 percent to 30 percent and 45 percent. Hodson also recommends, in its proposed 30 percent tier, that the Commission allow an attributable interest in five mass media facilities nationwide instead of the current three, with the condition that the winning bidder has no attributable interest in a broadcast presence already in the market the proposed broadcast station intends to serve. Finally, for entities eligible for Hodson's proposed 45 percent tier, Hodson recommends that the Commission establish a relaxed

payment plan for the winning bid balance that would include an extended payment schedule. Hodson's proposals go to the Commission's broadcast auction rules and process, not our ownership rules. These proposals are outside the scope of this proceeding. The Commission addressed the broadcast auction process in a prior rulemaking proceeding. In 1998, the Commission determined that it would fulfill its obligations under section 309(j) of the Communications Act of 1934, 47 U.S.C 309(j)(3)(B), to promote economic opportunity and competition for designated entities, including small businesses, by providing new entrant bidding credits. Changes to these bidding credits would require a separate rule making.

479. *Translator/Spectrum Issues Outside the Scope*. REC also makes other requests involving the Commission's rules applying to use of translators. REC claims that the current rules allow distant translators and discourage establishment of new local LPFM stations. Nickolas Leggett asks that the Commission provide alternative opportunities to small broadcasters including: (1) A frequency band for manually operated low-power commercial broadcasters; (2) a citizens broadcasting band; and (3) open-microphone neighborhood broadcasting supported by the consolidated broadcasters. The Commission denies requests to change its translator rules or afford spectrum to small broadcasters because they are outside the scope of the proceeding.

480. *Cable Ownership*. CCC requests that the Commission retain our 30% national cable system ownership limits. The Commission dismisses CCC's request because it is outside the scope of this proceeding and it relates to an issue that is the subject of a separate rulemaking.

481. *DTV*. USCCB asks the Commission to promulgate regulations that define digital television ("DTV") broadcasters' public interest obligations. The Commission dismisses USCCB's request because it is outside the scope of this proceeding. CST requests that the Commission amend or eliminate any of our rules that hinder the digital conversion of broadcasters, cable systems, and telephone systems, and that the Commission establish regulatory policies to encourage the introduction of digital technologies. The Commission dismisses CST's requests because they are outside the scope of this proceeding.

482. Further, CST proposes that all broadcast licensees and cable systems that expand their operations as a result

of rule relaxations be required to loan a percentage of their expansion revenues to a Digital Conversion Fund. The Commission declines to adopt CST's proposal because there is no basis for the Commission to directly fund industry's transition to digital television. When Congress established the framework for the digital television transition in the Telecommunications Act of 1996, it gave no indication that the Commission should directly fund industry transition costs for digital television. Even if CST's proposal fell within Congress's directives, the establishment of such a fund raises extraordinarily complex and controversial issues such as the measurement by the Commission of 'merger efficiencies' and how the fund would be administered. CST provides us with no meaningful basis to assess the viability or effectiveness of such a program. Finally, the Commission already has considered the relationship between local television consolidation and the transition to digital television. The Commission determined that the efficiencies from relaxing the local television ownership limit would likely promote the transition to digital television.

483. Some parties ask the Commission to undertake additional studies or delay taking action until after some future events. MMTC filed a motion requesting that the Commission postpone its vote on this R&O. MMTC argues that because our Electronic Comment Filing System ("ECFS") was overloaded with filings immediately prior to our June 2, 2003 vote, the record does not accurately reflect all comments received in this proceeding and, therefore, parties are unable to respond to the complete record. MMTC Motion for a Brief Postponement of the Vote (May 31, 2003). The Commission denies the motion. The reply comment period closed Feb. 3, 2003, more than four months ago. Nonetheless, in the interests of assembling a full record, the Commission has continued to accept comments, and more than 500,000 comments were filed in this proceeding, many of which were filed at the last minute. Given the large volume of last minute filings, it is inevitable that a small percentage would not be placed on our ECFS system or be available in the public reference room in sufficient time for replies. Nonetheless, the record is complete, and MMTC's failure to file its comments or requests in a timely fashion is no excuse to delay the proceeding. Nicholas Leggett asks us to engage in detailed political science analysis of the impact of removal of

ownership caps on the legitimacy of government and business. The Commission denies this request because it is unclear and declines to delay action in this proceeding. The Commission's statutory obligation is to review the rules biennially; it has no discretion to willfully deviate from that schedule.

484. *IBOC-DAB*. VCPP requests that there be no relaxation on ownership restrictions until several years after 100% rollout of In Band On Channel Digital Audio Broadcasting ("IBOC-DAB"), arguing that this technology will destroy competition. The Commission denies VCPP's request. The courts require the Commission to base our ownership decisions on today's marketplace and the facts presently before it. It is not free to adopt a "wait and see" approach. The impact of IBOC-DAB on diversity, competition, and localism in local media markets will be accounted for in future biennial reviews.

485. SBA asks the Commission to issue a Further Notice of Proposed Rulemaking in this proceeding, claiming the NPRM is not specific enough to comply with the Administrative Procedure Act or the Regulatory Flexibility Act. The Commission disagrees with SBA and denies its request. Contrary to the implication of SBA, the actual rules at issue in this proceeding are specifically identified in the NPRM and well known to all interested parties—they are our current broadcast ownership rules. Congress has directed us to review those rules every two years to determine whether those exact rules remain necessary in the public interest. That the Commission has done in this proceeding in accordance with the NPRM. Further, Congress directed the Commission to eliminate or modify any of its broadcast ownership rules that no longer are necessary. Again, it was explicit in the NPRM that we might eliminate any rule that could not be justified in light of the current media marketplace. To the extent that the Commission has eliminated rules in this R&O, therefore, there has been no failure of notice. With respect to those rules that, having been found unnecessary, have been modified herein, the question is the familiar one—were the modifications a "logical outgrowth" of the issues identified in the NPRM. The Commission concludes that this R&O and its accompanying rules are a logical outgrowth of the questions posed in the NPRM. The modifications made herein are consistent with the issues and questions posed in the NPRM, and take account of the full record in this proceeding. Finally, we take seriously the mandate

of Section 202(h) to review our broadcast ownership rules every two years. It would be impractical to complete such a Herculean task, in this case, to review six different rules, and to complete that review in time to start another review, if we issued a separate notice detailing modifications to rules and initiated another comment period.

486. Children Now asks that the Commission reserve our decision-making on media ownership until its research on the effects of media consolidation on children is complete and can be incorporated into our record. Laura Smith requests that we expand the scope of our public hearings on media ownership and that we conduct additional research before concluding this proceeding. The Commission declines to further delay this proceeding. The public, industry, and government agencies alike have an interest in finality, economy, and the avoidance of unnecessary delay. The public is not served by bureaucratic inaction; industries suffer when rules that restrain behavior without cause continue in force; and agencies fail in their responsibility when they commit public resources to meaningless exercises of no decisional significance. As a corollary, agencies should not refrain from acting on an issue once a robust record has been developed. It is the agency's responsibility, in the first instance, to determine when that point has been reached. *United States v. FCC*, 652 F.2d 72, 90-91 (D.C. Cir. 1980) (en banc).

487. In this case, the Commission sees no overriding need to augment the record, nor do we believe that the expenditure of additional time and resources in an effort to do so will provide us with a significantly more accurate or current assessment of the media markets. To the contrary, the record in the current proceeding is one of the most factually complete and thorough ever assembled in a Commission rulemaking. In addition, the court in *Fox Television* made it quite clear that regulatory delay in the biennial ownership review process is causing hardship to the parties and should not be tolerated. Accordingly, the Commission denies the requests of Children Now and Laura Smith.

488. *Independent Production Rules*. The Coalition for Program Diversity ("CPD") asks the Commission to take "content neutral action" by "adopting a 25% Independent Producer Rule that will insure [sic] that the prime time programming aired by the four networks is as diverse as possible." In a similar vein, the Writers' Guild of America ("WGA") proposes a requirement that

broadcast and cable national program services purchase at least 50 percent of the entertainment for their prime time schedules from independent producers. In essence, CPD and WGA ask us to re-impose some version of our prior financial interest/syndication rules, first adopted by the Commission in 1970. The Commission rejects these requests (collectively, the "Fin/Syn Proposals").

489. To begin with, there is substantial doubt as to whether we have adequate notice to adopt the Fin/Syn Proposals. In the NPRM, the Commission invited comment on, among other issues, whether diversity could be better promoted by alternatives to structural regulation, such as behavioral requirements and, if so, what behavioral requirements would be recommended. The Commission also sought comment on whether "the effects of the 1996 change in the national ownership cap [can] be separated from the effects of the repeal of the fin/syn and [prime time access] rules?" The Commission asked commenters to identify those effects.

490. Although the Commission invited comment as to whether we should, in lieu of structural rules, adopt behavioral rules to serve our public interest goals, we did not propose a re-imposition of the fin/syn rules, or anything related. The Fin/Syn Proposals, therefore, are not squarely within the four corners of our NPRM. Moreover, to the extent that we asked general questions about the effect of the repeal of our former fin/syn rules, or whether some behavioral rules might obviate structural regulation, we did not intend, nor do we think the NPRM can be fairly read to suggest, that a fin/syn overlay would or could substitute for structural regulation as a means of protecting our desiderata—localism, competition, and diversity. Accordingly, the Commission does not believe that the Fin/Syn Proposals are responsive to the NPRM, or that the adoption of such rules could be thought to be a logical outgrowth of the NPRM.

491. In any event, the Commission is not inclined to adopt the Fin/Syn Proposals. The original fin/syn rules prohibited a television network (defined at the time to include only ABC, NBC, and CBS) from syndicating television programming in the U.S., or from syndicating outside the U.S. programming for which it was not the sole producer, or from having any option or right to share in the revenues from domestic or foreign syndication. These rules also prohibited a network from acquiring any financial or proprietary right or interest in the exhibition, distribution, or other

commercial use of television programming produced by someone other than the network for distribution on non-network stations. In 1983, the Commission proposed repealing the rules based on, *inter alia*: (i) A 44% increase in the number of TV stations available to the average viewer since 1970; (ii) the dramatic increase in the availability of cable television; and (iii) evidence of vigorous competition among the television networks.

492. In 1991, however, the Commission opted not to repeal the rules, but instead modified them. Among other things, the Commission imposed a new restriction on networks, which provided that "no more than 40 percent of a network's own prime-time entertainment schedule may consist of programs produced by the network itself." In 1992, the U.S. Court of Appeals for the Seventh Circuit vacated the rules. The Court criticized the Commission for not addressing earlier Commission findings, in 1983, that the networks lacked significant market power. The Court found that the development of cable, video recorders, and the advent of the Fox network buttressed the earlier findings.

493. In the proceedings on remand, the Commission decided to repeal, on a graduated basis, most of its fin/syn rules. In repealing the 40 percent cap, the Commission observed that the cap does not necessarily foster diversity. The Commission also noted that "the decline in network audience share, which largely explained the rule's relaxation in 1991, has continued unabated." On appeal, the Seventh Circuit affirmed that decision, stating that if the Commission ever decided to re-impose similar fin/syn restrictions on the networks, "it had better have an excellent, a compelling reason" to do so.

494. In 1995, the Commission removed the remaining fin/syn restrictions, finding that there was no "clear trend toward increased network ownership of [prime time entertainment programming] that is attributable to the relaxation of our fin/syn rules or that constitutes a cause for concern from a public interest standpoint." At the time, independent producers provided 80.97% of the prime time programming hours for ABC, CBS and NBC. Although there had been a decline in the number of packagers of programming included in the prime time schedules for ABC, CBS and NBC, the Commission believed that the decline could not be attributed to elimination of the fin/syn rules, but was "instead attributable to the inherent riskiness of prime time programming." Moreover, ABC, CBS, and NBC faced more, rather than less, competition in

broadcast television due to the emergence of FOX and two additional broadcast networks (United Paramount and Warner Brothers). The Commission also reaffirmed its finding in 1993 that alternative video delivery systems, such as DBS and wireless cable, provided sufficient competition to the broadcast networks to obviate fin/syn restrictions.

495. CPD now argues that, despite the growth of cable and DBS providers in the video programming distribution market, there still is a strong public interest supporting limitations on network programming because 43 million consumers receive only broadcast network television. CPD also points out that in 1992, 66.4 percent of the networks' prime time schedule consisted of programs produced and owned by independent producers. Today, they argue, only 24 percent of the four largest networks' prime time schedule is supplied by independent producers. CPD argues that the Commission should preserve 25 percent of the networks' prime time schedule for independent producers.

496. WGA asks that the Commission "adopt measures designed to insure [*sic*] that national program services on broadcast and cable television purchase at least 50% of their prime time programming from independent producers." WGA contends that consolidation in the market for video programming makes any appearance of diversity a mirage. Although there are 230 national cable programming networks, according to WGA, there are just 91 networks that can be considered major networks (defined by WGA as available in more than 16 million homes). Of these 91 networks, 80 percent (73) are owned or co-owned by 6 entities: AOL Time Warner, Viacom, Liberty Media, NBC, Disney and News Corporation.

497. Four major networks (ABC, CBS, FOX, and NBC, collectively the "Networks") filed a joint *ex parte* pleading opposing any cap on the amount of network programming a network may air during prime time. The Networks invoke much of the rationale that the Seventh Circuit used when it vacated the Commission's prior fin/syn rules. To those arguments, the Networks add that the broadcast networks' prime time audience share has dropped from 72 percent in 1993–1994 to 58.9 in 2001–2002. The Networks assert that CPD's argument ignores the fact that, whereas there were only three broadcast networks in 1970 when the Commission first adopted the fin/syn rules, there are now seven networks providing English language programming. The Networks also argue that the growth in use of the

DVD player, personal video recorder, and the Internet continues to add to the diversity in video programming and continues to undermine any rationale for fin/syn rules. Even accepting WGA's assertion that six companies own many of the major cable networks, the Networks argue that the market for video programming is more diverse today because six is double the number of companies that owned broadcast networks when the fin/syn rules were adopted.

498. Although CPD and WGA appear to be correct that fewer of the programs in the Networks' prime-time lineup are produced by independent producers than at times in the past, the evidence in the record does not address whether the decline in the number of independently-produced programs is attributable to changes in the regulatory environment (*i.e.*, the elimination of the fin/syn rules) or to other changes that have taken place in the media business in the intervening years that have increased the risk of producing prime time programming. "Whatever the pros and cons of the original financial interest and syndication rules, in the years since they were promulgated the structure of the television industry has changed profoundly." The Commission previously has questioned whether changes in the mix of programming on the prime time lineup can be attributed to regulatory changes or to business considerations.

499. Moreover, the reduction in independently produced prime time programming on a small subset of television networks is not, by itself, a public interest harm. Our concern is to promote the interests of consumers and viewers, not to protect the financial interests of independent producers. The record does not demonstrate that consumers and viewers are harmed as a result of network financial interests in the programming they carry, particularly in light of the quantity and variety of media outlets for programming in today's media marketplace.

500. In particular, the record does not convince us that an "access" rule for independent producers will advance viewpoint diversity. CPD's argument, for example, is premised on the notion that the Networks are gatekeepers; if they are not, there are other outlets for independently-produced fare and no basis to impose fin/syn restrictions. To the extent that the Networks actually are gatekeepers, however, fin/syn rules cannot logically advance viewpoint diversity because the Networks, as gatekeepers, can filter messages at the distribution stage just as they can at the

production stage. Adopting the Fin/Syn Proposals, therefore, is not likely to promote viewpoint diversity.

501. Even if the Commission were to adopt a broader definition of "diversity" to include general entertainment programming, a gatekeeper at distribution still may filter unwanted programming whether or not the programming is produced in-house. For example, if a network were to decide that its prime time lineup should consist only of "reality programming," or that it should target a particular audience demographic, there is no reason to believe that it could not give effect to those plans with independently-produced programming as easily as it could with programming produced by itself or an affiliated company—it simply would make known its programming intent and allow independent producers to fill the void. The Fin/Syn Proposals, therefore, cannot be justified on grounds of programming diversity.

502. Both CPD and WGA also fail to justify their definitions of the relevant market for purposes of their proposals. CPD, for example, has targeted its proposal only at the four major broadcast networks, and only at their prime time schedule. However, aside from conclusory allegations that "the prime time television programming marketplace is a narrow, unique market," CPD has provided no reason to exclude other video programming outlets and other day-times, were we inclined to adopt a fin/syn-like rule. Viewers today have more programming choices available to them over-the-air, through cable, satellite, or home video, than ever before. Indeed, WGA considers a much larger market for these purposes (although it, too, provides little in the way of support for its market definition), and other commenters have suggested that non-prime time broadcast hours should be included in any analysis relating to programming diversity. Lacking the foundation of a sustainable market definition, the Fin/Syn Proposals cannot stand.

503. Finally, to the extent that the Fin/Syn Proposals are based on an assertion that the quality of independently-produced entertainment programming is superior to that of the Networks, we find the record devoid of evidence to that effect. *Cf.* MOWG Study No. 5, Program Diversity and the Program Selection Process on Broadcast Network Television by Mara Einstein (Sept. 2002). The Commission has no means or methodology to measure the quality of entertainment programming, and were we to favor one type or genre of programming over another, we would

run squarely into the teeth of the First Amendment. To be considered content-neutral, regulations must have neutral means and ends. It is up to consumers and viewers to determine what programming they want to watch, and networks, as they compete for viewers, must be responsive to those demands. It is not for this agency to intervene in the decisions that determine the content of programming (absent obscenity or indecency concerns).

504. When the Seventh Circuit affirmed the Commission's decision repealing all of the fin/syn rules, it questioned whether the rules "ever had much basis" and cautioned that, if the Commission ever decided to re-impose similar restrictions, "it had better have an excellent, a compelling reason" to do so. *Capital Cities/ABC, Inc. v. FCC*, 29 F.3d 309, 316 (7th Cir. 1994). None appears on this record. Accordingly, the Commission rejects the Fin/Syn Proposals. Aside from these reasons, we reject WGA's proposal because it is far from clear that the Commission has jurisdiction over the programming carried on cable networks.

Administrative Matters

505. *Paperwork Reduction Act of 1995 Analysis.* This R&O contains new and modified information collections. The Commission, as part of its continuing effort to reduce paperwork burdens, will publish, as required by the Paperwork Reduction Act of 1995, Public Law 104-13, a separate notice in the **Federal Register** inviting the general public to comment on the information collections contained in this R&O and establishing a timeframe for accepting such comment.

506. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) of the estimated significant economic impact on small entities of the policies and rules adopted in the R&O. The analysis may be found in Appendix G of the full text of the R&O. This is a summary of the full FRFA. An Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking (NPRM) initiating this proceeding. This present FRFA conforms to the RFA.

A. Need for, and Objectives of the Report and Order (R&O)

507. The R&O is the culmination of the Commission's third biennial ownership review and addresses all six broadcast ownership rules. This review is undertaken pursuant to section 202(h) of the Telecommunications Act of 1996, which requires the Commission to

review its broadcast ownership rules every two years. The NPRM initiated review of four ownership rules; the national television multiple ownership rule, the local television multiple ownership rule, the radio television cross-ownership rule; and the dual network rule. The R&O: (1) Replaces the newspaper/broadcast and radio/television cross/ownership rules with a set of cross-media limits; (2) modifies the local television multiple ownership rule; (3) modifies the local radio ownership rule and its market definition; (4) modifies the national TV ownership rule by changing the 35% limit in the current rule to 45%; and (5) retains the current dual network rule. The Commission believes these actions are necessary not only to comply with its section 202(h) obligation, but to protect the Commission's chief goals in effectively regulating broadcasting, to promote diversity, localism, and competition.

508. The changes adopted in the R&O provide a new, comprehensive framework for broadcast ownership regulation. The march of technology has brought to homes, schools, and places of employment across America unprecedented access to information and programming, while the Commission's broadcast ownership rules continue to restrict who may hold radio and television licenses. The current rules inadequately account for the competition presence of cable, ignore the diversity-enhancing value of the Internet, and lack any sound basis for a national audience reach cap. Our current rules are, in short, a patchwork of unenforceable and indefensible restrictions that, while laudable in principle, do not serve the interests they purport to serve.

509. The adoption of the R&O is critical to the realization of the Commission's public interest goals in that it puts an end to any uncertainty regarding the scope and effect of our structural broadcast ownership rules. Most importantly, the rules discussed and adopted in the R&O serve the Commission's competition, diversity and localism goals in highly targeted ways and, working together, form a comprehensive framework that is responsive to today's media environment.

B. Legal Basis

510. This R&O is adopted pursuant to §§ 1, 2(a), 4(j), 303, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, and 310, and section 202(h) of the Telecommunications Act of 1996.

C. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

511. In addition to comments filed in direct response to the IRFA, the Commission received hundreds of thousands of comments, some of which concerned matters of particular interest to small entities. These comments are discussed in the section of this FRFA discussing the steps taken to minimize significant impact on small entities, and the significant alternatives considered. The Small Business Administration (SBA) filed comments in response to the IRFA in the NPRM and also in response to the IRFAs in Dockets 01-317 and 00-244. In both letters, SBA argues that the Notices of Proposed Rulemaking were not specific enough to comply with the Administrative Procedure Act or the Regulatory Flexibility Act., and that the IRFA did not fully discuss the possible impact of the proposed actions on small entities or offer alternatives that could minimize that impact. SBA contends that the general nature of the decisions made it difficult for small entities to file meaningful comments and so "frustrates the spirit of the RFA." Therefore, SBA asks us to issue a Further Notice of Proposed Rulemaking in this proceeding. We disagree with SBA and deny its request. Contrary to the implication of SBA, the actual rules at issue in this proceeding are specifically identified in the NPRM and are well-known by interested parties—they are our current broadcast ownership rules. Congress has directed us to review those rules every two years to determine whether those exact rules remain necessary in the public interest. That we have done in this proceeding and in accordance with the NPRM. Further, Congress has directed the Commission to eliminate or modify any of its broadcast ownership rules that no longer are necessary. Again, it was explicit in the NPRM that we might eliminate any rule that could not be justified in light of the current media marketplace. To the extent that we have eliminated rules in the Order, there has been no failure of notice. With respect to those rules that, having been found unnecessary, have been modified in the Order, the question is the familiar one—were the modifications a "logical outgrowth" of the issues identified in the NPRM. The Commission concludes that the R&O and its accompanying rules are a logical outgrowth of the questions posed in the NPRM. The modifications made in the R&O are consistent with the issues and questions posed in the NPRM, and take account of the full record in this proceeding. The

Commission takes seriously the mandate of section 202(h) to review our broadcast ownership rules every two years. It would be impractical to complete such a Herculean task, in this case, to review six different rules, and to complete that review in time to start another review, if we issued a separate notice detailing modifications to rules and initiated another comment period.

512. SBA's contentions that the general nature of the IRFA in the NPRM made it financially and practically difficult for small entities to file meaningful comments and that small entities have not had an opportunity to comment on the potential impact of the actions adopted in the R&O are belied by the hundreds of thousands of comments filed in this proceeding. Additionally, public hearings were conducted.

513. Hodson Broadcasting filed comments and reply comments in MM Dockets 01-317 and 00-244, recommending that the Commission modify the new entrant bidding credit in the broadcast auction process from the current percentages of 25 percent and 35 percent to 30 percent and 45 percent. Hodson also recommends, in its proposed 30 percent tier, that we allow an attributable interest in five mass media facilities nationwide instead of the current three, with the condition that the winning bidder has no attributable interest in a broadcast presence already in the market the proposed broadcast station intends to serve. Finally, for entities eligible for Hodson's proposed 45 percent tier, Hodson recommends that we establish a relaxed payment plan for the winning bid balance that would include an extended payment schedule. Hodson claims that its proposals would benefit small entities. Hodson's proposals go to our broadcast auction rules and process, not our ownership rules. These proposals are not a logical outgrowth of the NPRM and they are therefore outside the scope of this proceeding.

D. Description and Estimate of the Number of Small Entities to Which Rules Will Apply

514. The RFA directs agencies to provide a description of and, where feasible, an estimate of, the number of entities that will be affected by the rules. The RFA defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act, unless the Commission has developed one or

more definitions that are appropriate to its activities. A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

515. In this context, the application of the statutory definition to television stations is of concern. An element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimates that follow of small businesses to which rules may apply do not exclude any television station from the definition of a small business on this basis and are therefore over-inclusive to that extent. An additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

516. *Television Broadcasting.* The Small Business Administration defines a television broadcasting station that has no more than \$12 million in annual receipts as a small business. Business concerns included in this industry are those "primarily engaged in broadcasting images together with sound." According to Commission staff review of the BIA Publications, Inc. Master Access Television Analyzer Database as of May 16, 2003, about 814 of the 1,220 commercial television stations in the United States have revenues of \$12 million or less. We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations³⁷ must be included. Our estimates, therefore, likely overstate the number of small entities that might be affected by any changes to the ownership rules, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies.

517. *Radio Broadcasting.* The SBA defines a radio broadcast entity that has \$6 million or less in annual receipts as a small business. Business concerns included in this industry are those "primarily engaged in broadcasting aural programs by radio to the public.

According to Commission staff review of the BIA Publications, Inc., Master Access Radio Analyzer Database, as of May 16, 2003, about 10,427 of the 10,945 commercial radio stations in the United States have revenue of \$6 million or less. We note, however, that many radio stations are affiliated with much larger corporations with much higher revenue, and that in assessing whether a business concern qualifies as small under the above definition, such business (control) affiliations³⁸ are included.³⁹ Our estimate, therefore likely overstates the number of small businesses that might be affected by any changes to the ownership rules.

518. *Daily Newspapers.* The SBA defines a newspaper publisher with no more than 500 employees as a small business. According to the 1997 Economic Census, 8,620 of 8,758 newspaper publishers had less than 500 employees. The data does not distinguish between newspaper publishers that publish daily and those that publish less frequently, and the latter are more likely to be small businesses than the former because of the greater expense to publish daily. The new cross ownership limits apply only to daily newspapers. It is likely that not all of the 8,620 small newspaper publishers are affected by the current rule.

E. Description of Projected Reporting, Recordkeeping, Other Compliance Requirements

519. The R&O generally relaxes or retains the existing broadcast ownership rules. The R&O does, however, adopt a paperwork and compliance requirement in connection with the local radio ownership rules. The R&O requires that parties with existing attributable Joint Sales Agreements (JSAs) covering radio stations located in Arbitron Metros file a copy of the JSA with the Commission within 60 days of the effective date of the R&O. Parties with JSAs for radio stations not located in Arbitron Metros will have to file JSAs within 60 days of the effective date of the Order. Additionally, we are modifying FCC Application Forms 314 and 315 to require applicants to file attributable JSAs at the time an application is filed. In addition, parties may be required to file a copy of Local Marketing

Agreements (LMAs) that have become attributable because of the decision to modify the market definition for radio stations.

520. Further, in connection with the local TV ownership rule, the R&O states that any licensee with a temporary waiver or pending waiver extension request must, by no later than 60 days after the effective date of the R&O, file either a statement describing how ownership of the subject station complies with the local TV ownership rule or an application for transfer or assignment of license for one of the stations that is subject of the waiver.

521. The R&O modifies the standards for rule waiver requests involving failed, failing, and unbuilt local television stations by removing the requirement to demonstrate that there is no reasonably available out-of-market buyer. It also provides guidelines for waiver of the top four-ranked restriction in markets of certain sizes, and addresses existing combinations that may not comply with the modified local television ownership rule. The R&O indicates that waiver applicants should supply: television ratings information for all the television stations in the market for the four most recent ratings periods; and information about current local news production for all stations in the local market and the effect of the proposed merger on local news and public affairs programming for the affected stations. Waiver applicants claiming that the merger is needed to facilitate the digital transition should provide data supporting this assertion. Applicants stating that the merger is needed to preserve a local newscast should document the financial performance of the affected news division. Applicants for waiver of our top four-ranked restriction must demonstrate that the proposed combination will produce public interest benefits. As in the context of the failing station waiver, the Commission will require that, at the end of the merged stations' license term, the owner of the merged stations must certify to the Commission that the public interest benefits of the merger are being fulfilled. This certification must include a specific factual showing of the program-related benefits that have accrued to the public. The Commission will consider waivers of our local TV ownership rule where a party can demonstrate that the signals of the stations in a proposed combination do not have overlapping Grade B contours and have not been carried, via DBS or cable, to any of the same geographic areas within the past year. The R&O also adopts a paperwork and compliance requirement in connection with parties who have a

³⁷ Concerns are affiliates of each other when one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. 13 CFR 121.103(a)(1).

³⁹ SBA counts the receipts or employees of the concern whose size is at issue and those of all its domestic and foreign affiliates, regardless of whether the affiliates are organized for profit, in determining the concern's size. 13 CFR 121(a)(4).

³⁷ Concerns are affiliates of each other when one concern controls or has the power to control the other or a third party or parties control or has to power to control both. 13 CFR 121.103(a)(1).

conditional waiver or a pending waiver request concerning newspaper/broadcast or television/radio cross-ownership situations. These parties must notify the Commission as to whether or not the combinations are in at-risk markets or whether the combinations would otherwise be prohibited pursuant to the Commission's Cross-Media Limits.

522. The R&O addresses issues relating to existing combinations that may not comply with the modified rules. The R&O grandfathers existing holdings. The R&O requires that parties come into compliance with the modified rules upon sale of the grandfathered combination, except when such transfers are made to, or by, "eligible entities." The R&O defines an eligible entity as a small business consistent with SBA standards for industry groupings. The R&O prohibits an eligible entity from selling a grandfathered combination acquired after the adoption date of the R&O unless it has held the combination for a minimum of three years. The R&O adopts processing guidelines for pending broadcast assignment and transfer of control applications. Applicants with pending long-form applications (FCC Forms 314 and 315) that require a multiple ownership showing may amend applications by submitting a new multiple ownership showing demonstrating compliance with the rules adopted in the R&O. Applicants may begin filing such amendments once notice has been published by the Commission in the *Federal Register* that OMB has approved the information collection requirements contained in such amendments. Applications pending as of the effective date of the rules adopted in the R&O will be processed under the new rules.

523. Finally, the R&O establishes a freeze on the filing of new broadcast assignment and transfer of control applications that require the use of FCC Form 314 or 315.

524. The freeze began on the adoption date of the R&O and ends on the date that notice has been published by the Commission in the *Federal Register* that OMB has approved the revised forms. The Commission will continue to process short-form (FCC 316) applications. The Commission is modifying and releasing revised forms 301, 314, and 315 based on the changes in the R&O, and these revised forms will be effective upon OMB approval.

F. Steps Taken To Minimize Significant Impact on Small Entities and Significant Alternatives Considered

525. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

526. Any discussion of alternatives which were available to the Commission in reviewing these broadcast ownership rules must begin with an understanding that section 202(h) mandates that the Commission review these rules to determine whether they remain "necessary in the public interest." Section 202(h) carries with it a presumption in favor of repealing or modifying the ownership rules if the Commission finds the rules are not "necessary in the public interest." Thus, the Commission has three chief alternatives available in analyzing each of these rules—to eliminate the rule, modify it, or, if the Commission determines that the rule is "necessary in the public interest," retain the rule. As discussed in paragraphs 10–16 of the R&O, the Commission in reviewing the broadcast ownership rules is acting under its legislative mandate and, guided by recent court decisions, finds that section 202(h) carries with it a presumption in favor of repealing or modifying the ownership rules. Given these limitations, the Commission is limited in the relief it can offer small entities.

527. The Commission received more than 500,000 brief comments and form letters from individual citizens. These commenters expressed general concerns about the potential consequences of media consolidation, including concerns that such consolidation would result in a significant loss of viewpoint diversity, and affect competition from all entities, including small entities. The Commission shares these concerns and believes that the rules adopted in the R&O serve our public interest goals, take account of and protect the vibrant media marketplace, including the continued viability of small entities, and comply with our statutory responsibilities and limits.

528. The decisions made in the R&O reduce or remove regulatory restrictions for all entities, including small entities. The Commission also adopts waiver processes that will enable licensees to seek relief from the impact of the rules in appropriate circumstances. Additionally, we are grandfathering existing combinations, both intra- and inter-media, that would not comply with the new regulations. This will prevent the harmful economic impact of forced divestiture at fire-sale prices that would have been burdensome to all affected licensees, including small entities. Also, the Commission generally elects to establish bright-line ownership rules rather than case-by-case determinations. This will reduce the delay, cost, and uncertainty that sometimes accompanies case-by-case reviews. This is of special interest to small entities as such costs could weigh disproportionately on small businesses if the subject matter of the proposed transaction is a substantial portion of the small business's total assets. Generally speaking, by adopting bright-line rules rather than a case-by-case approach, the Commission takes action that will benefit small businesses by lowering transaction costs and increasing regulatory certainty.

529. *Local TV Multiple Ownership Rule (Paragraphs 132–234)*. The R&O modifies the current local TV multiple ownership rule to permit an entity to have an attributable interest in two television stations in markets with 17 or fewer stations; and up to three stations in markets with 18 or more stations, provided that no more than one of the stations in the combination is ranked among the top four in terms of audience share. As a result of the top four-ranked standard, combinations in markets with fewer than five stations are not permitted. The R&O eliminates the provision of the current rule that permits combinations of two television stations that do not have overlapping signal contours. Because of mandatory carriage of television broadcast stations by multichannel video programming distributors, the geographic market in which a station competes is generally its Nielsen Designated Market Area (DMA), rather than its over-the-air service area. Therefore all proposed stations combinations will be subject to the restrictions described above, without regard to contour overlap.

530. Commenters proposing elimination or relaxation of the local TV multiple ownership rule argue that the rule is no longer "necessary in the public interest" because it prevents broadcasters from achieving efficiencies that will allow them to compete more

effectively with other media outlets and to provide improved services to the public. Several commenters contend that this is especially true for broadcasters in small and mid-sized markets. The Commission agrees that, by limiting common ownership of television stations in local markets where at least eight independently owned TV stations would remain post merger, the current rule prohibits mergers that would result in efficiencies that will benefit the public interest, especially mergers in small and mid-sized markets. The modifications to the rule adopted in the Order will permit broadcasters in more small and mid-sized markets, including small entities, to combine and thereby achieve such efficiencies. The modified rule accounts for the competitive realities faced by broadcasters in small and medium markets. Although the modified rule ensures that there will be at least six competitors in markets with 12 or more television stations, in markets with 11 or fewer television stations the R&O permits higher levels of concentration in light of the differences in the economics of broadcasting in smaller markets. The top four—ranked restriction of the modified local TV ownership rule also protects small entities by preventing the largest firms in a given local market from combining to achieve excessive market power. By prohibiting combinations involving stations with the largest audience shares, the restriction protects against potential harm to broadcasters with smaller market shares, including small entities.

531. The R&O also addresses competitive challenges faced by broadcasters in small markets through modified waiver standards. The R&O modifies the standards for rule waiver requests involving failed, failing, and unbuilt local television stations by removing the requirement to demonstrate that there is no reasonably available out-of-market buyer. The R&O further adopts two additional waiver standards. First, it provides for consideration of requests for waiver of the top four-ranked prohibition of the local TV ownership rule in markets with 11 or fewer TV stations where an applicant can show that the public interest benefits of a proposed combination outweigh potential harms to competition, diversity, and localism. In evaluating such waiver requests, the Commission also will account for the diminished reach of UHF stations by considering whether the proposed combination involves a UHF station. Reduced audience reach diminishes UHF stations' impact on diversity and

competition in local markets. Because this standard applies only in smaller markets, it may benefit smaller entities that would otherwise be unable to combine under the current rule. In addition, because it will account for competitive disparities faced by UHF stations, it will benefit small entities that may own such stations. The Order also provides guidelines for waivers for combinations involving stations that do not have overlapping signal contours and are not carried in the same geographic area by MVPDs.

532. The Commission received a proposal that, if the local TV multiple ownership rule is relaxed, the Commission require periodic certification by owners of same-market combinations that they are not engaged in certain types of anticompetitive conduct that would adversely affect smaller broadcasters in their markets. The Commission denies this proposal, on grounds that the modified local television ownership rule does not increase the likelihood that broadcasters will engage in anticompetitive conduct. The R&O notes that, if broadcasters engage in anticompetitive conduct that is illegal under antitrust statutes, remedies are available pursuant to those statutes. In addition, an antitrust law violation would be considered as part of the Commission's character qualifications review in connection with any renewal, assignment, or transfer of a license.

533. The Commission, as discussed in paragraphs 209–220 of the R&O, received several suggestions for modifying the local TV multiple ownership rule, but concludes that, as compared to the modified rule, the proposals advanced by commenters are more likely to result in anomalies and inconsistencies or will otherwise fail to serve our policy goals. Examining each proposal in turn, the R&O concludes that these proposals would permit unacceptable levels of concentration in local markets or would permit combinations among top four-ranked stations, which are likely to result in competitive harm, with no offsetting public interest benefits. One commenter, the National Association of Broadcasters (NAB) proposes a "10/10" alternative that would permit combinations where at least one of the stations has had, on average over the course of the year, an all-day audience share of 10 or less. NAB maintains that its proposal would provide needed financial relief for struggling stations in small and medium markets and those that are lower rated, and, by prohibiting combinations of leading stations, would effectuate the Commission's diversity

and competition goals. The Commission dismisses this proposal, finding that the proposal would permit mergers between financially strong stations, including top four-ranked stations, in a significant number of markets, and offers no justification for using 10 as a threshold. The R&O finds that, rather than allowing combinations involving top four-ranked stations as a general rule, consideration of waivers of the top four-ranked restriction in smaller markets on a case-by-case basis, as described above, will better effectuate its policy goals, and will address the concerns of broadcasters in smaller markets, including small entities operating in such markets.

534. *Local Radio Ownership Rule (Paragraphs 235–326)*. The local radio ownership rule limits the number of commercial radio stations overall and the number of commercial radio stations in a service (AM or FM) that a party may own in a local market. The Commission finds that the numerical limits in the current rule are "necessary in the public interest," but finds that the rule must be modified to change the method for defining radio markets and to count noncommercial stations in the market. The R&O thus modifies the rule by adopting a market definition that reflects more accurately the competitive impact of proposed radio station combinations, and by providing that the Commission will count non-commercial radio stations in calculating market size. The R&O also makes joint sales agreements (JSAs) attributable for purposes of determining compliance with the local radio ownership rule and adopts "grandfathering" rules and procedures to address any existing station ownership patterns or JSAs that may cause a party to be out of compliance with the modified rule. The Commission dismisses requests to repeal the local radio ownership rule. Commenters favoring repeal argue that, for example, the rule is unjustified because consolidation has resulted in efficiencies and has produced significant public interest benefits. While the Commission does not dispute that a certain level of consolidation of radio stations can improve the ability of a group owner to make investments that benefit the public, we seek to ensure that radio stations outside of the dominant groups, including small entities can remain viable and, beyond that, can prosper. Other commenters dispute these contentions, expressing concern that, in a concentrated market, dominant radio station groups can exercise market power to attract revenue at the expense of the small owner. As a

result, they argue, the small owner has greater difficulty obtaining the revenue it needs to develop and broadcast attractive programming and to compete generally against the dominant station groups. Although the Commission declines to pass on the competitive situation in any particular radio market in the context of this proceeding, the concerns raised by the latter commenters comport with the competition analysis that underlies this R&O and supports our decision not to repeal the local radio ownership rule.

535. The Commission decides not to require divestiture of existing combinations of broadcast stations that violate the modified multiple ownership rules adopted in the Order. The Commission determined that the alternative, requiring divestiture, would be too disruptive on the broadcast industry, which includes small broadcast owners. However, the Commission will require that combinations comply with the modified multiple ownership rules upon the assignment or transfer of control of the station group. The Commission rejected the alternative, allowing grandfathered combinations to be sold in perpetuity, because such a decision would dissuade our competition goals discussed in the Order. Any spin-offs that would be required upon sales of stations in a grandfathered group could afford new entrants the opportunity to enter the media marketplace. It could also give small station owners already in the market the opportunity to acquire more stations and take advantage of the benefits of combined ownership.

536. The Commission adopts an exception to the prohibition on the transfer of grandfathered combinations that violate the new rules. The Commission will allow transfers to "eligible entities." The Commission defines an eligible entity as a small business consistent with SBA standards for industry groupings. This exception was adopted to facilitate new entry by, and growth of, small businesses in the broadcast industry, and thereby further our goals of diversity of ownership, competition, and localism. The Commission will allow eligible entities to sell grandfathered combinations generally without restriction. The Commission believes that small businesses require greater flexibility than do larger entities for the disposition of assets. Restrictions on the sale of assets could disproportionately harm the financial stability of smaller firms, compared to that of larger firms that have other revenue streams. To prevent abuse of the policy, the Commission prohibits eligible entities

from selling grandfathered combinations acquired after adoption date of the Order unless it has held the combination for a minimum of three years.

537. Paragraphs 316–325 of the R&O discuss attribution of JSAs. In this regard, the Commission has the option, supported by some commenters, of maintaining its current policy of that JSAs are not attributable under the Commission's rules. Commenters supporting retention of this exemption argue that JSAs produce a public interest benefit. Although the Commission continues to believe that JSAs may have some positive effects on the local radio industry, the threat to competition and the potential impact on the influence over the brokered stations and requires attribution. As indicated in paragraph 319 of the R&O, the Commission recognizes that JSAs raise concerns regarding the ability of smaller broadcasters to compete, and may negatively affect the health of the local radio industry generally. Therefore, the R&O states that the Commission will now count such brokered stations toward the brokering licensee's attributable interest in one or more stations in a local radio market.

538. *Newspaper/Broadcast and Radio/Television Cross Ownership Rules.* (Paragraphs 327–481). Based on the extensive record in this proceeding, the Commission finds that neither the current nationwide prohibition on common ownership of daily newspapers and broadcast outlets in the same market, nor our cross-service restriction on commonly owned radio and television outlets in the same market, is "necessary in the public interest." With respect to both rules, the Commission concludes that the ends sought can be achieved with more precision and with greater deference to First Amendment interests by modifying the rules into a single set of cross media limits. The modified rules adopted in the R&O are, in sum, designed to protect against markets becoming highly concentrated, in a qualitative sense, for diversity purposes.

539. Although our conclusions pertain to markets of all sizes, newspaper-broadcaster combinations may produce tangible public benefits in smaller markets in particular. In this regard, West Virginia Media contends that the cross-ownership restriction impairs coverage of local news and public affairs in small markets by prohibiting combinations that would produce efficiencies and synergies particularly necessary in smaller markets. It argues that the rule may have the unintended effect of stifling local

news by prohibiting efficient combinations that would produce better output. We assume that the efficiencies cited by West Virginia Media can benefit small businesses with respect to the production of news and public affairs programming.

540. *National Ownership Rules* (Paragraphs 499–621). The R&O modifies the national TV ownership rule by raising the audience cap from 35% of the country's television households to 45%. The Commission received a significant amount of public comment in this regard and, based on the record, finds that, although retention of a national cap is necessary to limit the percentage of television households that an entity may reach through the station it owns, a cap of 35% is not necessary to preserve the balance of bargaining power between networks and affiliates and may have other drawbacks. The Commission believes that the current affiliate/network dynamic is beneficial to viewers and should be preserved and that eliminating the cap altogether would shift the balance of power with respect to programming decisions toward the national broadcast networks in a way that would disserve the Commission's localism policy. But the evidence suggests that 35% is overly restrictive and that the cap may safely be raised and the benefits of wider network station ownership achieved without disturbing either this balance or affiliates' ability to preempt network programming.

541. The R&O cites three primary reasons for settling on the 45% cap: (1) Given that the Commission is interested in finding a point at which the balance of bargaining power between networks and affiliates is roughly equal, a national audience reach cap of approximately half of all homes is appropriate; (2) because the Commission has some concern about allowing significant new aggregation of network power absent more compelling evidence regarding the possible effects of that aggregation above current limits and in light of the fact that Congress raised the ownership cap by ten percentage points in 1996, the Commission is inclined to take a similarly incremental approach; and (3) a 45% cap will allow some, but not unconstrained, growth for each of the top largest network owners. Permitting the networks a modest amount of growth will enable them to compete more effectively with cable and DBS operators and may help preserve free, over-the-air television by reducing the likelihood that networks will migrate expensive programming to their cable

networks. The R&O retains the 50% UHF discount when calculating a television station owner's national reach, which could benefit small businesses by encouraging the emergence of new broadcast networks. The R&O sunsets the application of the UHF discount for the stations owned by the top four broadcast networks when the digital transition is completed on a market by market basis.

542. The Commission retains the dual network rule, which permits common ownership of multiple broadcast networks, but prohibits a merger between or among the "top-four" networks, finding that the rule is "necessary in the public interest" to promote competition and localism. The R&O concludes that a top-four network merger would give rise to competitive concerns that the merged firm would be able to reduce its program purchases and/or the price it pays for programming, and that this would in turn harm viewers through reduction in program output, program choices, program quality, and innovation. Further, a top-four network merger would harm localism by providing the networks with undue economic leverage over their affiliates.

543. *Minority and Women Proposals (Paragraphs 46-52)*. MMTC proposes a dozen business and regulatory initiatives that "would go a long way toward increasing entry into the communications industry by minorities." MMTC's initiatives include: (1) Equity for specific and contemplated future acquisitions; (2) enhanced outreach and access to debt financing by major financial institutions; (3) investments in institutions specializing in minority and small business financing; (4) cash and in-kind assistance to programs that train future minority media owners; (5) creation of a business planning center that would work one-on-one with minority entrepreneurs as they develop business plans and strategies, seek financing, and pursue acquisitions; (6) executive loans, and engineers on loan, to minority owned companies and applicants; (7) enhanced access to broadcast transactions through sellers undertaking early solicitations of qualified minority new entrants and affording them the same opportunities to perform early due diligence as the sellers afford to established non-minority owned companies; (8) nondiscrimination provisions in advertising sales contracts; (9) incubation and mentoring of future minority owners; (10) enactment of tax deferral legislation designed to foster minority ownership; (11) examination of

how to promote minority ownership as an integral part of all FCC general media rulemaking proceedings; and (12) ongoing longitudinal research on minority ownership trends, conducted by the FCC, NTIA, or both; (13) sales to certain minority or small businesses as alternatives to divestitures.

544. These comments contain many creative proposals to advance minority and female ownership. Clearly, a more thorough exploration of these issues, which will allow us to craft specifically tailored rules that will withstand judicial scrutiny, is warranted. Therefore, we will issue a Notice of Proposed Rulemaking to address these issues and incorporate comments on these issues received in this proceeding into that proceeding.

545. We do, however, see significant immediate merit in MMTC's proposal regarding the transfer of media properties that collectively exceed our radio ownership cap. MMTC recommends that the Commission generally forbid the wholesale transfer of media outlets that exceed our ownership rules except where the purchaser qualifies as a "socially and economically disadvantaged business (SDB)." MMTC defines SDBs as the definition contained in legislation recently introduced by U.S. Senator John McCain. We agree with MMTC that the limited exception to a "no transfer" policy for above-cap combinations would serve the public interest. We agree with MMTC that the benefits to competition and diversity of a limited exception allowing entities to sell above-cap combinations to eligible small entities outweigh the potential harms of allowing the above-cap combination to remain intact. Greater participation in communications markets by small businesses, including those owned by minorities and women, has the potential to strengthen competition and diversity in those markets. It will expand the pool of potential competitors in media markets and should bring new competitive strategies and approaches by broadcast station owners in ways that benefit consumers in those markets.

546. In addition, MMTC proposes that we adopt an "equal transactional opportunity" rule similar in some respects to our EEO requirements. While such a rule is worthy of further exploration, we decline to adopt a rule without further consideration of its efficacy as well as any direct or inadvertent effects on the value and alienability of broadcast licenses. We see merit in encouraging transparency in dealmaking and transaction brokerage, consistent with business

realities. We also reiterate that discriminatory actions in this, and any other context, are contrary to the public interest. For these reasons, we intend to refer the question of how best to ensure that interested buyers are aware of broadcast properties for sale to the Advisory Committee on Diversity for further inquiry and will carefully review any recommendations this Committee may proffer. As soon as the Commission receives authorization to form this committee we will ask it to make consideration of this issue among its top priorities.

547. Report to Congress. The Commission will send a copy of the R&O, including this FRFA, in a report to be sent to Congress pursuant to the SBREFA. In addition, the Commission will send a copy of the Order, including the FRFA, to the Chief Counsel for Advocacy of the SBA.

Document Availability

548. This document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-863-2893, facsimile 202-863-2898, or via e-mail qualexint@aol.com. This document is available in accessible formats (computer diskettes, large print, audio recording, and Braille) to persons with disabilities by contacting Brian Millin in the Consumer & Governmental Affairs Bureau at 202-418-7426, TTY 202-418-7365, or at bmillin@fcc.gov.

Ordering Clauses

549. Pursuant to the authority contained in §§ 1, 2(a), 4(i), 303, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, and 310 and section 202(h) of the Telecommunications Act of 1996, this *Report and Order* in MB Docket No. 02-277 and MM Docket Nos. 01-235, 01-317, and 00-244 is adopted.

550. Part 73 of the Commission's rules is amended.

551. The Interim Policy set forth in the R&O is adopted.

552. The Motion for Revision of Procedural Dates, Expansion of the Scope of the Proceeding, and Inclusion of Additional Studies in the Record, filed on October 9, 2002 by Minority Media and Telecommunications Council and National Association of Black Owned Broadcasters, is denied in

part and granted in part to the extent described provided in the R&O; the Motion to Bifurcate and Repeal, filed on March 11, 2003 by Media General, Inc., is dismissed, and the Motion to Postpone, filed on May 31, 2003 by the Diversity and Competition Supporters, *et al.*, is denied.

553. Pursuant to the authority contained in §§ 1, 2(a), 4(i), 303, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, and 310 and section 202(h) of the Telecommunications Act of 1996, that the ownership requirements and rules adopted in this R&O shall become effective September 4, 2003, except for §§ 73.3555 and 73.3613 which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date. A separate notice will be published in the **Federal Register** soliciting public and agency comment on the information collections, and establishing a deadline for accepting such comment.

554. This action is taken pursuant to the authority contained in §§ 1, 2(a), 4(i), 303, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, and 310 and section 202(h) of the Telecommunications Act of 1996. If any section, subsection, paragraph, sentence, clause or phrase of this R&O or the rules adopted in the R&O is declared invalid for any reason, the remaining portions of the R&O and the rules adopted in the R&O shall be severable from the invalid part and shall remain in full force and effect.

555. The proceedings in MB Docket No. 02-277, MM Docket No. 01-235, MM Docket No. 01-317, and MM Docket No. 00-244 are terminated.

556. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of the Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 73

Radio, Reporting and recordkeeping requirements, Television.

Federal Communications Commission.
William F. Caton,
Deputy Secretary.

Rule Changes

■ For the reasons discussed in the preamble the FCC amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

§ 73.3555 [Amended]

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, and 336.

- 2. Amend § 73.3555 as follows:
 - a. Revise paragraphs (a) through (c);
 - b. Remove paragraph (d);
 - c. Redesignate paragraphs (e) and (f) as paragraphs (d) and (e);
 - d. Revise newly redesignated paragraph (d);
 - e. Revise Note 1 to § 73.3555;
 - f. Revise Note 2 to § 73.3555;
 - g. Revise Notes 4 through 7 to § 73.3555; and
 - h. Add Notes 11 and 12 to § 73.3555.

§ 73.3555 Multiple ownership.

(a)(1) *Local radio ownership rule.* A person or single entity (or entities under common control) may have a cognizable interest in licenses for AM or FM radio broadcast stations in accordance with the following limits:

(i) In a radio market with 45 or more full-power, commercial and noncommercial radio stations, not more than 8 commercial radio stations in total and not more than 5 commercial stations in the same service (AM or FM);

(ii) In a radio market with between 30 and 44 (inclusive) full-power, commercial and noncommercial radio stations, not more than 7 commercial radio stations in total and not more than 4 commercial stations in the same service (AM or FM);

(iii) In a radio market with between 15 and 29 (inclusive) full-power, commercial and noncommercial radio stations, not more than 6 commercial radio stations in total and not more than 4 commercial stations in the same service (AM or FM);

(iv) In a radio market with 14 or fewer full-power, commercial and noncommercial radio stations, not more than 5 commercial radio stations in total and not more than 3 commercial stations in the same service (AM or FM); provided, however, that no person or single entity (or entities under common control) may have a cognizable interest in more than 50% of the full-power, commercial and noncommercial radio stations in such market unless the combination of stations comprises not more than one AM and one FM station.

(2) [Reserved]

(b) *Local television multiple ownership rule.* (1) For purposes of this section, a television station's market shall be defined as the Designated Market Area (DMA) to which it is assigned by Nielsen Media Research or

any successor entity at the time the application to acquire or construct the station(s) is filed. Puerto Rico, Guam, and the U.S. Virgin Islands each will be considered a single market.

(2) An entity may have a cognizable interest in more than one full-power commercial television broadcast station in the same DMA in accordance with the following conditions and limits:

(i) At the time the application to acquire or construct the station(s) is filed, no more than one of the stations that will be attributed to such entity is ranked among the top four stations in the DMA, based on the most recent all-day (9 a.m.–midnight) audience share, as measured by Nielsen Media Research or by any comparable professional, accepted audience ratings service; and

(ii) (A) Subject to paragraph (b)(2)(i) of this section, in a DMA with 17 or fewer full-power commercial and noncommercial television broadcast stations, an entity may have a cognizable interest in no more than 2 commercial television broadcast stations; or

(B) Subject to paragraph (b)(2)(i) of this section, in a DMA with 18 or more full-power commercial and noncommercial television broadcast stations, an entity may have a cognizable interest in no more than 3 commercial television broadcast stations.

(c) *Cross-Media Limits.* Cross-ownership of a daily newspaper and commercial broadcast stations, or of commercial broadcast radio and television stations, is permitted without limitation except as follows:

(1) In Nielsen Designated Market Areas (DMAs) to which three or fewer full-power commercial and noncommercial educational television stations are assigned, no newspaper/broadcast or radio/television cross-ownership is permitted.

(2) In DMAs to which at least four but not more than eight full-power commercial and noncommercial educational television stations are assigned, an entity that directly or indirectly owns, operates or controls a daily newspaper may have a cognizable interest in either:

(i) One, but not more than one, commercial television station in combination with radio stations up to 50% of the applicable local radio limit for the market; or,

(ii) Radio stations up to 100% of the applicable local radio limit if it does not have a cognizable interest in a television station in the market.

(3) The foregoing limits on newspaper/broadcast cross-ownership do not apply to any new daily

newspaper inaugurated by a broadcaster.

(d) *National television multiple ownership rule.* (1) No license for a commercial television broadcast station shall be granted, transferred or assigned to any party (including all parties under common control) if the grant, transfer or assignment of such license would result in such party or any of its stockholders, partners, members, officers or directors having a cognizable interest in television stations which have an aggregate national audience reach exceeding forty-five (45) percent.

(2) For purposes of this paragraph (d):

(i) *National audience reach* means the total number of television households in the Nielsen Designated Market Areas (DMAs) in which the relevant stations are located divided by the total national television households as measured by DMA data at the time of a grant, transfer, or assignment of a license. For purposes of making this calculation, UHF television stations shall be attributed with 50 percent of the television households in their DMA market.

(ii) No market shall be counted more than once in making this calculation.

* * * * *

Note 1 to § 73.3555: The words "cognizable interest" as used herein include any interest, direct or indirect, that allows a person or entity to own, operate or control, or that otherwise provides an attributable interest in, a broadcast station.

Note 2 to § 73.3555: In applying the provisions of this section, ownership and other interests in broadcast licensees, cable television systems and daily newspapers will be attributed to their holders and deemed cognizable pursuant to the following criteria

(a) Except as otherwise provided herein, partnership and direct ownership interests and any voting stock interest amounting to 5% or more of the outstanding voting stock of a corporate broadcast licensee, cable television system or daily newspaper will be cognizable;

(b) Investment companies, as defined in 15 U.S.C. 80a-3, insurance companies and banks holding stock through their trust departments in trust accounts will be considered to have a cognizable interest only if they hold 20% or more of the outstanding voting stock of a corporate broadcast licensee, cable television system or daily newspaper, or if any of the officers or directors of the broadcast licensee, cable television system or daily newspaper are representatives of the investment company, insurance company or bank concerned. Holdings by a bank or insurance company will be aggregated if the bank or insurance company has any right to determine how the stock will be voted. Holdings by investment companies will be aggregated if under common management.

(c) Attribution of ownership interests in a broadcast licensee, cable television system or

daily newspaper that are held indirectly by any party through one or more intervening corporations will be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain and application of the relevant attribution benchmark to the resulting product, except that wherever the ownership percentage for any link in the chain exceeds 50%, it shall not be included for purposes of this multiplication. For purposes of paragraph (i) of this note, attribution of ownership interests in a broadcast licensee, cable television system or daily newspaper that are held indirectly by any party through one or more intervening organizations will be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain and application of the relevant attribution benchmark to the resulting product, and the ownership percentage for any link in the chain that exceeds 50% shall be included for purposes of this multiplication. [For example, except for purposes of paragraph (i) of this note, if A owns 10% of company X, which owns 60% of company Y, which owns 25% of "Licensee," then X's interest in "Licensee" would be 25% (the same as Y's interest because X's interest in Y exceeds 50%), and A's interest in "Licensee" would be 2.5% (0.1 x 0.25). Under the 5% attribution benchmark, X's interest in "Licensee" would be cognizable, while A's interest would not be cognizable. For purposes of paragraph (i) of this note, X's interest in "Licensee" would be 15% (0.6 x 0.25) and A's interest in "Licensee" would be 1.5% (0.1 x 0.6 x 0.25). Neither interest would be attributed under paragraph (i) of this note.]

(d) Voting stock interests held in trust shall be attributed to any person who holds or shares the power to vote such stock, to any person who has the sole power to sell such stock, and to any person who has the right to revoke the trust at will or to replace the trustee at will. If the trustee has a familial, personal or extra-trust business relationship to the grantor or the beneficiary, the grantor or beneficiary, as appropriate, will be attributed with the stock interests held in trust. An otherwise qualified trust will be ineffective to insulate the grantor or beneficiary from attribution with the trust's assets unless all voting stock interests held by the grantor or beneficiary in the relevant broadcast licensee, cable television system or daily newspaper are subject to said trust.

(e) Subject to paragraph (i) of this note, holders of non-voting stock shall not be attributed an interest in the issuing entity. Subject to paragraph (i) of this note, holders of debt and instruments such as warrants, convertible debentures, options or other non-voting interests with rights of conversion to voting interests shall not be attributed unless and until conversion is effected.

(f)(1) A limited partnership interest shall be attributed to a limited partner unless that partner is not materially involved, directly or indirectly, in the management or operation of the media-related activities of the partnership and the licensee or system so certifies. An interest in a Limited Liability Company ("LLC") or Registered Limited Liability

Partnership ("RLLP") shall be attributed to the interest holder unless that interest holder is not materially involved, directly or indirectly, in the management or operation of the media-related activities of the partnership and the licensee or system so certifies.

(2) For a licensee or system that is a limited partnership to make the certification set forth in paragraph (f)(1) of this note, it must verify that the partnership agreement or certificate of limited partnership, with respect to the particular limited partner exempt from attribution, establishes that the exempt limited partner has no material involvement, directly or indirectly, in the management or operation of the media activities of the partnership. For a licensee or system that is an LLC or RLLP to make the certification set forth in paragraph (f)(1) of this note, it must verify that the organizational document, with respect to the particular interest holder exempt from attribution, establishes that the exempt interest holder has no material involvement, directly or indirectly, in the management or operation of the media activities of the LLC or RLLP. The criteria which would assume adequate insulation for purposes of this certification are described in the Memorandum Opinion and Order in MM Docket No. 83-46, FCC 85-252 (released June 24, 1985), as modified on reconsideration in the Memorandum Opinion and Order in MM Docket No. 83-46, FCC 86-410 (released November 28, 1986). Irrespective of the terms of the certificate of limited partnership or partnership agreement, or other organizational document in the case of an LLC or RLLP, however, no such certification shall be made if the individual or entity making the certification has actual knowledge of any material involvement of the limited partners, or other interest holders in the case of an LLC or RLLP, in the management or operation of the media-related businesses of the partnership or LLC or RLLP.

(3) In the case of an LLC or RLLP, the licensee or system seeking insulation shall certify, in addition, that the relevant state statute authorizing LLCs permits an LLC member to insulate itself as required by our criteria.

(g) Officers and directors of a broadcast licensee, cable television system or daily newspaper are considered to have a cognizable interest in the entity with which they are so associated. If any such entity engages in businesses in addition to its primary business of broadcasting, cable television service or newspaper publication, it may request the Commission to waive attribution for any officer or director whose duties and responsibilities are wholly unrelated to its primary business. The officers and directors of a parent company of a broadcast licensee, cable television system or daily newspaper, with an attributable interest in any such subsidiary entity, shall be deemed to have a cognizable interest in the subsidiary unless the duties and responsibilities of the officer or director involved are wholly unrelated to the broadcast licensee, cable television system or daily newspaper subsidiary, and a statement properly documenting this fact is submitted to the Commission. [This statement may be

included on the appropriate Ownership Report.) The officers and directors of a sister corporation of a broadcast licensee, cable television system or daily newspaper shall not be attributed with ownership of these entities by virtue of such status.

(h) Discrete ownership interests will be aggregated in determining whether or not an interest is cognizable under this section. An individual or entity will be deemed to have a cognizable investment if:

(1) The sum of the interests held by or through "passive investors" is equal to or exceeds 20 percent; or

(2) The sum of the interests other than those held by or through "passive investors" is equal to or exceeds 5 percent; or

(3) The sum of the interests computed under paragraph (h)(1) of this note plus the sum of the interests computed under paragraph (h)(2) of this note is equal to or exceeds 20 percent.

(i) Notwithstanding paragraphs (e) and (f) of this note, the holder of an equity or debt interest or interests in a broadcast licensee, cable television system, daily newspaper, or other media outlet subject to the broadcast multiple ownership or cross-ownership rules ("interest holder") shall have that interest attributed if:

(1) The equity (including all stockholdings, whether voting or nonvoting, common or preferred) and debt interest or interests, in the aggregate, exceed 33 percent of the total asset value, defined as the aggregate of all equity plus all debt, of that media outlet; and

(2)(i) The interest holder also holds an interest in a broadcast licensee, cable television system, newspaper, or other media outlet operating in the same market that is subject to the broadcast multiple ownership or cross-ownership rules and is attributable under paragraphs of this note other than this paragraph (i); or

(ii) The interest holder supplies over fifteen percent of the total weekly broadcast programming hours of the station in which the interest is held. For purposes of applying this paragraph, the term "market," will be defined as it is defined under the specific multiple ownership rule or cross-media limit that is being applied, except that for television stations, the term "market," will be defined by reference to the definition contained in the local television multiple ownership rule contained in paragraph (b) of this section.

(j) "Time brokerage" (also known as "local marketing") is the sale by a licensee of discrete blocks of time to a "broker" that supplies the programming to fill that time and sells the commercial spot announcements in it.

(1) Where two radio stations are both located in the same market, as defined for purposes of the local radio ownership rule contained in paragraph (a) of this section, and a party (including all parties under common control) with a cognizable interest in one such station brokers more than 15 percent of the broadcast time per week of the other such station, that party shall be treated as if it has an interest in the brokered station subject to the limitations set forth in paragraphs (a) and (c) of this section. This limitation shall apply regardless of the source

of the brokered programming supplied by the party to the brokered station.

(2) Where two television stations are both located in the same market, as defined in the local television ownership rule contained in paragraph (b) of this section, and a party (including all parties under common control) with a cognizable interest in one such station brokers more than 15 percent of the broadcast time per week of the other such station, that party shall be treated as if it has an interest in the brokered station subject to the limitations set forth in paragraphs (b) and (c) of this section. This limitation shall apply regardless of the source of the brokered programming supplied by the party to the brokered station.

(3) Every time brokerage agreement of the type described in this Note shall be undertaken only pursuant to a signed written agreement that shall contain a certification by the licensee or permittee of the brokered station verifying that it maintains ultimate control over the station's facilities including, specifically, control over station finances, personnel and programming, and by the brokering station that the agreement complies with the provisions of paragraphs (b) and (c) of this section if the brokering station is a television station or with paragraphs (a) and (c) if the brokering station is a radio station.

(k) "Joint Sales Agreement" is an agreement with a licensee of a "brokered station" that authorizes a "broker" to sell advertising time for the "brokered station."

(1) Where two radio stations are both located in the same market, as defined for purposes of the local radio ownership rule contained in paragraph (a) of this section, and a party (including all parties under common control) with a cognizable interest in one such station sells more than 15 percent of the advertising time per week of the other such station, that party shall be treated as if it has an interest in the brokered station subject to the limitations set forth in paragraphs (a) and (c) of this section.

(2) Every joint sales agreement of the type described in this Note shall be undertaken only pursuant to a signed written agreement that shall contain a certification by the licensee or permittee of the brokered station verifying that it maintains ultimate control over the station's facilities, including, specifically, control over station finances, personnel and programming, and by the brokering station that the agreement complies with the limitations set forth in paragraphs (a) and (c) of this section.

* * * * *

Note 4 to § 73.3555: Paragraphs (a) through (c) of this section will not be applied so as to require divestiture, by any licensee, of existing facilities, and will not apply to applications for assignment of license or transfer of control filed in accordance with § 73.3540(f) or § 73.3541(b), or to applications for assignment of license or transfer of control to heirs or legatees by will or intestacy, if no new or increased concentration of ownership would be created among commonly owned, operated or controlled media properties. Paragraphs (a) through (c) will apply to all applications for new stations, to all other applications for assignment or transfer, to all applications for

major changes to existing stations, and to applications for minor changes to existing stations that implement an approved change in an FM radio station's community of license or create new or increased concentration of ownership among commonly owned, operated or controlled media properties. Commonly owned, operated or controlled media properties that do not comply with paragraphs (a) through (c) of this section may not be assigned or transferred to a single person, group or entity, except as provided in this Note or in the *Report and Order* in Docket No. 02-277, released July 2, 2003 (FCC 02-127).

Note 5 to § 73.3555: Paragraphs (b) and (c) of this section will not be applied to cases involving television stations that are "satellite" operations. Such cases will be considered in accordance with the analysis set forth in the *Report and Order* in MM Docket No. 87-8, FCC 91-182 (released July 8, 1991) in order to determine whether common ownership, operation, or control of the stations in question would be in the public interest. An authorized and operating "satellite" television station may subsequently become a "non-satellite" station under the circumstances described in the aforementioned *Report and Order* in MM Docket No. 87-8. A cognizable interest in such "non-satellite" television stations may be retained by the existing interest-holder even if that interest would be impermissible under § 73.3555(b) or (c). However, such "non-satellite" station may not be transferred or assigned to a single person, group, or entity except as provided for by § 73.3555(b) and (c).

Note 6 to § 73.3555: For purposes of paragraph (c) of this section a daily newspaper is one that is published four or more days per week, is in the dominant language of the market in which it is published, and is circulated generally in the community of publication. A college newspaper is not considered as being circulated generally.

Note 7 to § 73.3555: The Commission will entertain applications to waive the restrictions in paragraph (b) of this section (the local television multiple ownership rule) on a case-by-case basis. We will entertain waiver requests as follows:

(1) If one of the broadcast stations involved is a "failed" station that has not been in operation due to financial distress for at least four consecutive months immediately prior to the application, or is a debtor in an involuntary bankruptcy or insolvency proceeding at the time of the application.

(2) If one of the television stations involved is a "failing" station that has an all-day audience share of no more than four percent; the station has had negative cash flow for three consecutive years immediately prior to the application; and consolidation of the two stations would result in tangible and verifiable public interest benefits that outweigh any harm to competition and diversity.

(3) If the combination will result in the construction of an unbuilt station. The permittee of the unbuilt station must demonstrate that it has made reasonable

efforts to construct but has been unable to do so.

(4) If the signals of the stations in a proposed combination: (a) do not have overlapping Grade B contours; and (b) have not been carried, via DBS or cable, to any of the same geographic areas within the past year.

(5) For paragraph (b)(2)(i) of this section only (the top four-ranked restriction), if the stations in a proposed combination are in a market with 11 or fewer full-power television stations, we will consider waivers pursuant to criteria described in the *Report and Order* in MB Docket No. 02-277, released July 2, 2003 (FCC 03-127).

* * * * *

Note 11 to § 73.3555: For purposes of paragraph (c) of this section: (1) For radio/newspaper combinations, the Cross-Media Limit is triggered when the newspaper's community of publication is completely encompassed by: (i) for AM radio stations, the predicted or measured 2mV/m contour computed in accordance with § 73.183 or § 73.186 of the Commission's rules; (ii) for FM stations, the predicted 1 mV/m contour computed in accordance with § 73.313 of the Commission's rules; and (2) for television/newspaper combinations, the Cross-Media Limit is triggered when the newspaper's community of publication is located within the same Nielsen Designated Market Area to which the television station is assigned.

Note 12 to § 73.3555: For purposes of paragraph (c) of this section, for television/radio combinations, the rule is triggered when the radio station's community of license is located within the Nielsen Designated Market Area to which the television station is assigned.

■ 3. Section 73.3613 is amended by revising paragraphs (d) and (e) to read as follows:

§ 73.3613 Filing of contracts.

* * * * *

(d)(1) *Time brokerage agreements (also known as local marketing agreements):* Time brokerage agreements involving radio stations where the

licensee (including all parties under common ownership) is the brokering entity, the brokering and brokered stations are both in the same market as defined in the local radio multiple ownership rule contained in § 73.3555(a), and more than 15 percent of the time of the brokered station, on a weekly basis is brokered by that licensee; time brokerage agreements involving television stations where the licensee (including all parties under common control) is the brokering entity, the brokering and brokered stations are both licensed to the same market as defined in the local television multiple ownership rule contained in § 73.3555(b), and more than 15 percent of the time of the brokered station, on a weekly basis, is brokered by that licensee; time brokerage agreements involving radio or television stations that would be attributable to the licensee under § 73.3555 Note 2, paragraph (i). Confidential or proprietary information may be redacted where appropriate but such information shall be made available for inspection upon request by the FCC.

(d)(2) *Joint sales agreements:* Joint sales agreements involving radio stations where the licensee (including all parties under common control) is the brokering entity, the brokering and brokered stations are both in the same market as defined in the local radio multiple ownership rule contained in § 73.3555(a), and more than 15 percent of the advertising time of the brokered station on a weekly basis is brokered by that licensee. Confidential or proprietary information may be redacted where appropriate but such information shall be made available for inspection upon request by the FCC.

(e) The following contracts, agreements or understandings need not be filed but shall be kept at the station

and made available for inspection upon request by the FCC; subchannel leasing agreements for Subsidiary Communications Authorization operation; franchise/leasing agreements for operation of telecommunications services on the television vertical blanking interval and in the visual signal; time sales contracts with the same sponsor for 4 or more hours per day, except where the length of the events (such as athletic contests, musical programs and special events) broadcast pursuant to the contract is not under control of the station; and contracts with chief operators.

■ 4. Section 73.5007 is amended by revising paragraphs (b)(2)(i), (b)(2)(ii), (b)(2)(iii), and (b)(3)(i), (b)(3)(ii), and (b)(3)(iv) to read as follows:

§ 73.5007 Designated entity provisions.

* * * * *

(b) * * *

(2) * * *

(i) AM broadcast station—principal community contour (*see* § 73.24(i));

(ii) FM Broadcast station—principal community contour (*see* § 73.315(a));

(iii) Television broadcast station—television Grade B or equivalent contour (*see* § 73.683(a) for analog TV and § 73.622(e) for DTV);

* * * * *

(3) * * *

(i) AM broadcast station—principal community contour (*see* § 73.24(i));

(ii) FM broadcast station—principal community contour (*see* § 73.315(a));

* * * * *

(iv) Television broadcast station—television Grade B or equivalent contour (*see* § 73.683(a) for analog TV and § 73.622(e) for DTV).

* * * * *

[FR Doc. 03-19106 Filed 7-29-03; 12:43 pm]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 03-130; FCC 03-127]

Definition of Radio Markets for Areas Not Located in an Arbitron Survey Area

AGENCY: Federal Communications Commission

ACTION: Notice of proposed rulemaking.

SUMMARY: This document is designed to solicit comment on proposals to define radio markets outside of the Arbitron defined areas. The Commission replaced the current contour-overlap methodology for defining radio markets with a geography-based market definition. For areas of the country covered by Arbitron Metro markets, we adopted the Metro market as the relevant radio market for purposes of determining compliance with the local radio ownership rule. Metro markets, however, do not cover a significant portion of the country. We initiate this rulemaking proceeding to define radio markets for those areas.

DATES: Comments are due on or before September 4, 2003 and reply comments are due September 19, 2003.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. See **SUPPLEMENTARY INFORMATION** for filing instructions.

FOR FURTHER INFORMATION CONTACT: Amy Brett, Media Bureau at (202) 418-2703.

SUPPLEMENTARY INFORMATION: 1. This is a summary of the Commission's *Notice of Proposed Rulemaking* (NPRM) MB Docket No. 03-130, FCC 03-127, adopted June 2, 2003, and released July 2, 2003. The complete text of the NPRM and the Initial Regulatory Flexibility Analysis is available on the Commission's Internet site, at <http://www.fcc.gov>, and is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC. The text may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., CY-B4202, Washington, DC 20554 (telephone 202-863-2893).

2. In the Local Radio Section of the final rule in this proceeding (published in the final rule section of this **Federal Register**), we replaced our current contour-overlap methodology for defining radio markets with a geography-based market definition. 47

CFR 73.3555(a)(2). For areas of the country covered by Arbitron Metro markets, we adopted the Metro market as the relevant radio market for purposes of determining compliance with the local radio ownership rule. A significant portion of the country, however, is not covered by Metro markets. We initiate this rulemaking proceeding to define radio markets for those areas.

3. We seek comment on how to draw specific market boundaries in areas of the country not located in Arbitron Metros. What factors should we consider in grouping radio stations into markets? We propose that radio markets be county-based, as Arbitron Metros are. We seek comment on that proposal. In the western United States, counties are significantly larger. We seek comment on whether we should, like Arbitron, divide counties into separate radio markets in certain circumstances. We also propose that radio stations be assigned to radio markets based on the location of their communities of license. We seek comment on this proposal.

4. We seek comment on whether we should rely on any pre-existing market definitions in delineating radio markets for non-Metro areas. As indicated in the Local Radio Section, Arbitron traditionally has based its Metro definitions on the Metropolitan Area (MA) definitions developed by OMB. Should we also do the same for non-Metro areas? OMB recently released new MA definitions based on the results of the 2000 Census.¹ The 935 new MAs, moreover, cover a greater portion of the country. Previously, MAs were defined only for urban areas with a population of 50,000.² The new MA definitions cover areas with a population of 10,000 to 50,000 (known as Micropolitan Statistical Areas), which should greatly increase the number of radio stations located in MAs.³ If we rely on MAs, how should we address future changes to MA definitions, and the creation of a new, or the deletion of an existing, MA⁴ In addition, even with the expanded

¹ See OMB Bulletin No. 03-04, <http://www.whitehouse.gov/omb/bulletins/b03-04.html>. In 2000, OMB revised its procedures for defining MAs. In addition, it adopted the more generic term Core Based Statistical Area (CBSA) to cover both traditional Metropolitan Areas and the new Micropolitan Statistical Areas. See generally Standards for Defining Metropolitan and Micropolitan Statistical Areas, 65 FR 82228 (2000). Although less accurate, we will use former term—i.e., MAs—to avoid confusion.

² See U.S. Census Bureau, Cartographic Boundary Files, http://www.census.gov/geo/www/cob/ma_metadata.html (visited May 30, 2003).

³ See 65 FR 82236-37 for a detailed description of the standards OMB uses to define MAs.

⁴ See *id.* at 82237 for the rules governing future updates to MAs.

reach of the new MAs, there will be areas that they do not cover. How should the radio market be defined in those areas if MAs are used? One possible method is to establish geographic markets based on the location, distribution, and density of populated areas.⁵ Because population clusters are likely to indicate areas of economic and social interaction, the location and distribution of the centers of population should give us a reasonable indicator of the boundaries of the relevant geographic market in which radio stations compete. Because the geographic areas involved generally will be low-density and rural areas of the country, moreover, we believe that population data could provide a fairly reliable and easily determinable market definition. We seek comment on this and any other methods.

5. Another possibility is to treat Cellular Market Areas (CMAs) as the relevant geographic market for radio. CMAs were developed in the mid-1980s to be the geographic basis for licensing cellular spectrum. CMAs consist of MAs (as they were defined after the 1980 census) and Rural Service Areas (RSAs),⁶ which the Commission delineated for areas of the country not located in MAs.⁷ Although CMAs were not developed in the context of radio broadcasting, they were designed to follow "natural social and economic communities" through "multi-county groupings drawn along county boundaries."⁸ Are CMAs a reasonable proxy for radio markets in non-Metro areas of the country? We seek comment on this issue.

6. For any market definition we establish, how should we address situations in which that market overlaps an Arbitron Metro. If we use MAs or CMAs, there will be existing areas of overlap. Even if we define radio markets around existing Arbitron Metros, Metro boundaries may change, or Arbitron may create or delete a Metro. We seek comment on how to address the possibility of a market overlap (or in the case of a deleted Metro, the possibility of an undefined market).

7. The goal of this rulemaking proceeding is to generate a map or a list of markets for radio stations across the entire country, using Arbitron Metros where available and a Commission-

⁵ Population data is available over the Internet from the Census Bureau.

⁶ See *Amendment of the Commission's Rules for Rural Cellular Service*, 1985 WL 260366, FCC 85-646, ¶1 (rel. Dec. 17, 1985).

⁷ *Amendment of the Commission's Rules for Rural Cellular Service*, 60 Radio Reg. (P&F) 1029, ¶1 (1986).

⁸ *Id.* at ¶11.

endorsed market definition everywhere else. We therefore encourage parties to use this opportunity to submit specific information that would assist in properly delineating the boundaries of the local radio markets in which they are interested.

8. *Comments and Reply Comments.* Pursuant to applicable procedures set forth in sections 1.415 and 1.419 of the Commission's rules,⁹ interested parties may file comments on the *Notice of Proposed Rulemaking* on September 4, 2003 and reply comments are due September 19, 2003. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

9. Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket, which in this instance is MB Docket No. 03-130. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, "get form <your e-mail address>." A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistrionix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's

Secretary, Office of the Secretary, Federal Communications Commission.

10. Parties must also serve either one copy of each filing via e-mail or two paper copies to Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or e-mail at qualexint@aol.com. In addition, parties should serve one copy of each filing via e-mail or one paper copy to Amy Brett, Media Bureau, 445 12th Street, SW., 2-C134, Washington, DC 20554. Parties should serve one copy of each filing via e-mail or five paper copies to Linda Senecal, 445 12th Street, SW., 2-C438, Washington, DC 20554.

11. *Availability of Documents.* Comments, reply comments, and ex parte submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY-A257, Washington, DC 20554. Persons with disabilities who need assistance in the FCC Reference Center may contact Bill Cline at (202) 418-0267, (202) 418-7365 TTY, or bcline@fcc.gov. These documents also will be available electronically at the Commission's Disabilities Issues Task Force Web site: <http://www.fcc.gov/df>, and from the Commission's Electronic Comment Filing System. Documents are available electronically in ASCII text, Word 97, and Adobe Acrobat. Copies of filings in this proceeding may be obtained from Qualex International, Portals II, 445 12th Street, SW., Room, CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via e-mail at qualexint@aol.com. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at 202-418-0531 (voice), 202-418-7365 (TTY).

12. *Ex Parte Rules.* This proceeding will be treated as a "permit-but-disclose" proceeding, subject to the "permit-but-disclose" requirements under section 1.1206(b) of the Commission's rules.¹⁰ Ex parte presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, ex parte or otherwise, are generally prohibited. Persons making oral ex parte presentations are reminded that a memorandum summarizing a presentation must contain a summary of

the substance and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required.¹¹ Additional rules pertaining to oral and written presentations are set forth in section 1.1206(b) of the Commission's rules. Parties submitting written ex parte presentations or summaries of oral ex parte presentations are urged to use the ECFS in accordance with the Commission rules discussed above. Parties filing paper ex parte submissions must file an original and one copy of each submission with the Commission's Secretary, Marlene H. Dortch, at the appropriate address as shown above for filings sent by either U.S. mail, overnight delivery, or hand or messenger delivery. Parties must also serve either one copy of each ex parte filing via e-mail or two paper copies to Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or e-mail at qualexint@aol.com. In addition, parties should serve one copy of each ex parte filing via email or one paper copy to Amy Brett, Media Bureau, 445 12th Street, SW., 2-C134, Washington, DC 20554. Parties should serve one copy of each ex parte filing via email or five paper copies to Linda Senecal, 445 12th Street, SW., 2-C438, Washington, DC 20554.

13. *Initial Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act (RFA),¹² the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this Notice of Proposed Rulemaking ("NPRM"). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM.

14. The Commission will send a copy of the NPRM, including this IRFA to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

A. Need for, and Objectives of, the Proposed Rules

15. Section 202(h) of the Telecommunications Act of 1996 (1996 Act) requires the Commission to review all of its broadcast ownership rules

¹¹ See *id.* § 1.1206(b)(2).

¹² See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601 *et seq.*, has been amended by the Contract With America Advancement Act of 1996, Pub. L. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

⁹ 47 CFR 1.415 and 1.419.

¹⁰ 47 CFR 1.1206(b).

every two years commencing in 1998 ("Biennial Review"), and to determine whether any of these rules are necessary in the public interest as the result of competition. The 1996 Act also requires the Commission to repeal or modify any regulation it determines to be no longer in the public interest. In the 2002 Biennial Report and Order, the Commission concluded that the numerical limits in the local radio ownership rule are necessary in the public interest to protect competition in local radio markets. We also concluded that the rule in its current form did not promote the public interest as it relates to competition, in part, because the current methodology for defining radio markets is conceptually flawed as a means to protect competition in local radio markets. Thus, the Commission revised the present method of determining the dimensions of radio markets and/or of counting the stations available in those markets. The new geographic based approach better serves the public interest, reflects true markets in which radio stations compete, and better effectuates Congressional intent when it adopted the radio ownership limits in 1996. In the 2002 Biennial Report and Order, the Commission adopted a geography-based approach using Arbitron-defined markets. However, the Commission found that the current record provides insufficient information about appropriate boundaries for areas located outside of Arbitron defined areas. This NPRM is designed to solicit comment on proposals to define radio markets outside of Arbitron defined areas.

B. Legal Basis

16. This NPRM is adopted pursuant to sections 1, 2(a), 4(i), 303, 307, 309, 310, of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, 310, and section 202(h) of the Telecommunications Act of 1996.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

17. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.¹³ The RFA defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental entity under Section 3 of the Small Business Act."¹⁴

In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.¹⁵ A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.¹⁶

18. In this context, the application of the statutory definition to radio stations is of concern. An element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific radio station is dominant in its field of operation. Accordingly, the estimates that follow of small businesses to which rules may apply do not exclude any radio station from the definition of a small business on this basis and are therefore over-inclusive to that extent. An additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

19. The SBA defines a radio broadcast entity that has \$6 million or less in annual receipts as a small business.¹⁷ Business concerns included in this industry are those "primarily engaged in broadcasting aural programs by radio to the public."¹⁸ According to Commission staff review of the BIA Publications, Inc., Master Access Radio Analyzer Database, as of May 16, 2003, about 10,427 of the 10,945 commercial radio stations in the United States have revenue of \$6 million or less. We note, however, that many radio stations are affiliated with much larger corporations with much higher revenue, and that in assessing whether a business concern qualifies as small under the above definition, such business (control)

definition of a small business applies, "unless an agency, after consultation with the Office of Advocacy of the SBA and after opportunity for public comment, establishes one or more definitions of the term where appropriate to the activities of the agency and publishes the definition(s) in the Federal Register."

¹³ *Id.*

¹⁴ 15 U.S.C. 632.

¹⁵ See OMB, North American Industry Classification System: United States, 1997, at 509 (1997) (Radio Stations) (NAICS code 513111, which was changed to code 515112 in October 2002).

¹⁶ *Id.*

affiliations¹⁹ are included.²⁰ Our estimate, therefore likely overstates the number of small businesses that might be affected by any changes to the ownership rules.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

20. The NPRM proposes to modify the definition of radio markets outside of Arbitron defined areas. The action, depending on the definition ultimately adopted, would modify the instructions and the multiple ownership showing currently required for the following forms: (1) FCC Form 315, Application for Consent to Transfer Control of Entity Holding Broadcast Station Construction Permit or License; (2) FCC Form 314, Application for Consent to Assignment of Broadcast Station Construction Permit or License; and (3) FCC Form 301, Application for Construction Permit For Commercial Broadcast Stations. The impact of these changes will be the same on all entities. Whether compliance will take more, less, or the same amount of time and money, will depend on the definition adopted.

E. Steps Taken To Minimize Significant Impact on Small Entities, and Significant Alternatives Considered

21. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.²¹

22. We are directed under law to consider alternative means to achieve our stated objectives.²² In the 2002 Biennial Report and Order, the Commission considered and rejected alternatives to defining radio markets through the rulemaking process. Specifically, the Commission found that

¹⁹ "Concerns are affiliates of each other when one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both." 13 CFR 121.103(a)(1).

²⁰ "SBA counts the receipts or employees of the concern whose size is at issue and those of all its domestic and foreign affiliates, regardless of whether the affiliates are organized for profit, in determining the concern's size." 13 CFR 121(a)(4).

²¹ 5 U.S.C. 603(c).

²² 5 U.S.C. 603(b).

¹³ 5 U.S.C. 603(b)(3).

¹⁴ *Id.* section 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. 632). Pursuant to the RFA, the statutory

determining radio markets on a case-by-case basis would create significant regulatory uncertainty and impose substantial burdens on small-market radio broadcasters, many of which are small businesses. The Commission concluded that the better course is to develop radio market definitions for non-Metro areas through the rulemaking process. The Commission found that this would be the most expeditious way to define local radio market boundaries for the entire country. Defining radio markets also would give all interested parties, including small businesses, clear guidance about how the Commission will analyze a proposed radio station combination in non-Arbitron areas.

23. The NPRM invites comment on how to modify the current methodology for determining radio markets for areas of the country outside of Arbitron defined areas. The Commission has a number of alternatives on which it invites comment. We particularly invite comment on how the various alternatives might impact on small businesses and on alternatives outside the NPRM which might minimize any burden on small businesses.

24. The Commission seeks comments on how to draw specific market boundaries in areas of the country not located in the Arbitron Metros and on what factors should we consider in grouping radio stations into markets. The Commission proposes that radio markets be county-based. One alternative, if that proposal is adopted, would be to use a different standard in the western United States where

counties are significantly larger. The Commission could also divide counties into separate radio markets in certain circumstances. Small businesses should benefit from a county-based system because county boundaries are clear, stable, and well-known, and are commonly used for market definition purposes (see next paragraph).

25. The Commission also seeks comment on whether to rely on any pre-existing market definitions in delineating radio markets for non-Metro areas. For example, the Commission could base its Metro definitions on the Metropolitan Area (MA) definitions developed by OMB. The Commission asks how the radio market should be defined in areas that MAs do not cover, and notes one possible alternative would be to establish geographic markets based on the location, distribution, and density of populated areas. The Commission could also treat Cellular Market Areas as the relevant geographic market for radio. Both of these potential market definitions are county-based. We do not believe that the selection of one pre-defined market definition over another generally will have an impact on small business. We invite comment on this question.

26. The market definition we establish would result in small business owners being subject to a market definition that is different than the one to which they currently are subject. As a result, the number of radio stations that they may own, and the number of radio stations that their competitors may own, under the local radio ownership rule may change. We encourage parties to use this

opportunity submit specific information that would the Commission in properly delineating the boundaries of the local radio markets in which they are interested.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

27. None.

28. *Authority.* This *Notice of Proposed Rulemaking* is issued pursuant to authority contained in Sections 4(i), 303, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303, and 307, and Section 202(h) of the Telecommunications Act of 1996.

29. Pursuant to the authority contained in sections 1, 2(a), 4(i), 303, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152(a), 154(i), 307, 309, and 310 and section 202(h) of the Telecommunications Act of 1996, this Notice of Proposed Rulemaking in MB Docket 03-130 is adopted.

30. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 03-19091 Filed 7-29-03; 12:43 am]

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Federal Register

Tuesday,
August 5, 2003

Part III

**Department of
Health and Human
Services**

Food and Drug Administration

21 CFR Part 172

**Food Additives Permitted for Direct
Addition to Food for Human
Consumption; Olestra; Final Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2000F-0792]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to remove the requirement for the label statement prescribed specifically for savory snack products that contain olestra. This action is in response to a petition filed by the Procter and Gamble Co.

DATES: The regulation is effective August 5, 2003. Submit written objections and requests for a hearing by September 4, 2003.

ADDRESSES: Submit written objections to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3102.

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I. Subject of Petition

In a notice in the **Federal Register** of March 3, 2000 (65 FR 11585-11586), FDA announced that a food additive petition had been filed by the Procter & Gamble Co., 6071 Center Hill Ave., Cincinnati, OH 45224 (P&G, the petitioner) proposing that the food additive regulations be amended in § 172.867 *Olestra* (21 CFR 172.867) to remove the requirement for the label statement prescribed in § 172.867(e).

II. Background

In the **Federal Register** of January 30, 1996 (61 FR 3118, "the 1996 final rule") FDA announced the approval of olestra for use as a fat substitute in prepackaged ready-to-eat savory snacks. Olestra is the common name for a mixture of substances formed by chemical combination of sucrose with six, seven, or eight fatty acids. The fatty acids, bound to sucrose by ester bonds, are derived from edible fats and oils.

Olestra is essentially not absorbed or metabolized and passes unchanged through the gastrointestinal (GI) system (61 FR 3118 at 3125-3127). Therefore, olestra has the potential to affect GI physiology and function. Additionally, because of olestra's physical properties, fat-soluble nutrients present in olestra-containing foods¹ or other foods in the GI tract at the same time as olestra can partition into olestra and pass through the GI tract without being absorbed by the body. Therefore, FDA required the addition of fat-soluble vitamins A, D, E, and K, to savory snacks containing olestra to compensate for any inhibition of absorption by olestra (§ 172.867(d)).

At the time of the 1996 final rule, FDA concluded that, to avoid being misbranded within the meaning of sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n) and 343(a)(1)), olestra-containing foods would need to bear a label statement to inform consumers about possible effects of olestra on the GI system. The label statement also would clarify that the added vitamins were present to compensate for any nutritional effects of olestra, rather than to provide enhanced nutritional value. Therefore, the 1996 final rule required that foods containing olestra be labeled with the following statement in a boxed format: "THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added." (§ 172.867(e)(1)). FDA included the term "other nutrients" because any nutrient that is as lipophilic as these vitamins would also be affected, although there was no known basis for adding such nutrients back. The agency also required that the statement be made in a standardized format that specifies, among other things, type style and type size, and that

¹ Olestra has only been approved for use as a fat substitute in savory snacks. Throughout this document, we refer to olestra-containing foods to include those savory snacks made with olestra as well as other olestra-containing foods used in the preapproval studies for olestra.

the label statement be surrounded by a box to ensure proper prominence. This requirement was established under section 409(c)(3)(B) of the act (21 U.S.C. 348(c)(3)(B)), which prohibits approval of a food additive if the proposed use would result in misbranding of food (61 FR 3118 at 3160). The legal authority and scientific basis that underlaid the requirement for this label statement are reviewed in detail in the next section of this document.

A. Basis for Requiring the Label Statement—1996 Decision

1. Legal Authority for the 1996 Label Statement

Under section 403(a)(1) of the act, a food is deemed to be misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act amplifies what is meant by "misleading." Section 201(n) of the act states that in determining whether labeling is misleading, the agency shall take into account not only representations made or suggested about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations or material with respect to consequences which may result from use under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual (see 21 CFR 1.21). Thus, the omission of such material fact from the label or labeling of a food causes the product to be misbranded within the meaning of sections 201(n) and 403(a)(1) of the act.

2. GI Issues Associated With Olestra

As noted, olestra is not digested or absorbed, and it passes through the GI tract intact. The petitioner conducted a number of studies to address issues of potential concern with respect to the effect of olestra as it passes through the GI tract (61 FR 3118 at 3152–3159). For example, during studies designed primarily to assess potential effects of olestra on absorption of fat-soluble dietary components present in the gut at the same time, the petitioner also assessed the potential for olestra to elicit GI symptoms such as cramping, bloating, loose stools, and diarrhea-like symptoms by collecting reports from participants in the studies. In two human nutritional studies² (88 and 100 subjects respectively), the entire diet of

the subjects was controlled during the length of an 8-week study period. The studies were parallel, double-blind, and placebo-controlled, with olestra dosages of 0 (placebo), 8, 20, and 32 grams per day (g/d).³ The diets were formulated so that the total digestible fat (triglyceride) content was the same for all treatment groups. Triglyceride was added into the diets in the form of butter, margarine, or vegetable oil to compensate for the amount of fat replaced by olestra in the olestra-containing foods. Olestra was added to various food items by substituting olestra for triglyceride in recipes or in cooking oils. Therefore, the total amount of lipid-like material (digestible triglyceride plus olestra) increased with increasing olestra dose. Each meal contained olestra or the corresponding placebo (triglyceride). Subjects were questioned daily about changes in their health, including GI symptoms. To facilitate collection of GI symptom data, a questionnaire provided a list of common GI symptoms along with general definitions of each and was completed by each subject to capture data about the type, severity, and duration of symptoms experienced. As noted in the 1996 final rule (61 FR 3118 at 3152), the petitioner stated that the two 8-week studies were not intended to examine GI symptoms under real-life consumption conditions where snacks are not consumed every day with every meal and where people may moderate intake if they experience GI symptoms.

FDA's analysis of the data from the two 8-week studies (61 FR 3118 at 3152–3154) showed that there was a dose-response effect for olestra with respect to two endpoints, reported diarrhea/loose stools and fecal urgency. Reporting of diarrhea was based on subjects' perception of diarrhea. FDA found no evidence that study subjects experiencing olestra-related symptoms described as "diarrhea" also experienced significant fluid or significant electrolyte loss. The effect of olestra on stool consistency is similar to that produced by liquid petrolatum, which softens fecal contents. FDA recognized that the effect observed was not diarrhea in the clinical sense, but used that term in the 1996 final rule, and is using that term here, because it is the term used in the study report. FDA also found that these GI symptoms cease soon after olestra is no longer consumed.

The petitioner also conducted a study, the Fecal Parameters Study, designed to

examine fecal composition of stools from subjects who reported diarrhea when consuming olestra (61 FR 3118 at 3155). The study consisted of two phases, a screening phase and a study phase. The screening phase was conducted to identify subjects who reported GI symptoms from olestra consumption. During the study phase, the identified subjects ate different amounts of olestra, and GI symptoms were recorded and fecal measurements were made. From the initial screening phase, eighteen subjects reported an increase in the frequency, severity, or duration of GI symptoms during the olestra period, relative to the placebo period. These 18 subjects were selected to take part in the study phase, and 15 completed the study. The study phase was a crossover, placebo-controlled, single-blind (subject) design with three treatment groups, 0, 10, and 20 g/d olestra. Each subject received each treatment for 7 days. The treatment periods were separated by 7-day washout periods. Subjects ate all treatment meals under supervision at the clinical site, and ate their habitual diets at home during the washout periods. Study subjects recorded GI symptoms daily. Total fecal collections were made the last 3 days of each treatment period. Daily stool collections were measured for wet weight, volume, and density, and the pooled three day samples were analyzed for water concentration, dry weight, olestra content, sodium (Na), potassium (K), chloride (Cl), total and individual bile salts, free fatty acids, triglycerides, and total lipids.

Measurements of the concentration of stool water and electrolytes (Na, K, and Cl) suggested that these parameters did not differ in the stools of persons reporting "diarrhea" during the olestra 20 g/d period from those in the nondiarrheal stools (during the placebo period) of the same persons. However, it was not possible to analyze stool electrolyte values by individual stools or by individual days because the stools were pooled from the 3-day collection period, as is normally done when measuring fecal parameters. FDA noted that there appeared to be an increased weight of stools in those subjects reporting "diarrhea" when eating 20 g/d olestra that is not completely accounted for by the presence of olestra in the stools. FDA concluded that the results of this study indicated that there is no difference in stool composition (e.g., water and electrolyte content) when subjects consumed olestra versus placebo (61 FR 3118 at 3155).

FDA found that the number of subjects in the Fecal Parameters Study

² In evaluating olestra's nutritional effects, the petitioner conducted two 8-week clinical studies, the 8-week clinical dose response study (8-week DR), and the 8-week clinical vitamin restoration study (8-week VR)(61 FR 3118 at 3133–3134). In this document, when discussing the combined results of these studies, they will be called the two 8-week studies.

³ By comparison, FDA concluded that the estimated lifetime-averaged daily intake at the 90th percentile of olestra consumption would be 7.0 grams per person per day (g/p/d) (61 FR 3118 at 3124).

who reported diarrhea increased with increasing dose of olestra (*i.e.*, 3 subjects (20 percent) in the placebo, 6 subjects (40 percent) who consumed 10 g of olestra, and 11 subjects (69 percent) who consumed 20 g of olestra). In addition, both the mean number of reported diarrheal bowel movements per subject reporting any diarrhea, and the severity of the reported diarrhea, increased with increasing olestra consumption. Although there was an increase in the number of subjects reporting loose stools with increasing olestra dose, this increase was not statistically significant. FDA concluded that these results were qualitatively similar to the results of the 8-week studies.

The agency concluded, based upon its evaluation of the data and information available at the time, that consumption of olestra causes GI effects such as loose stools, abdominal cramping, and diarrhea-like symptoms. Additionally, the agency concluded that while olestra caused these GI symptoms, there was no evidence that these effects represented adverse health consequences.

At the time of approval, the agency did not have information about the potential GI effects from usual or customary consumption of olestra in savory snacks. Nonetheless, FDA considered it prudent to rely on the available data in deciding whether a label statement about olestra's potential effects on the GI tract was necessary. Olestra had the potential to be consumed in relatively large quantities by every segment of the U.S. population. Additionally, because olestra had never before been available in the marketplace, consumers had no experience with it and were not familiar with it or its potential to cause GI effects. The agency believed that providing consumers label information about olestra's GI effects would preclude unnecessary concerns about the origin of GI effects, were they to be observed, and might also prevent unnecessary or inappropriate medical treatment of those symptoms (61 FR 3118 at 3161). Based on the weight of the evidence about olestra's potential to cause GI effects, as well as the agency's belief that consumers lacked familiarity with olestra and its potential to cause such effects, FDA concluded at the time of olestra's approval that the relationship between GI symptoms and consumption of foods containing olestra is a fact that is material in light of the consequences of consuming olestra, and therefore a label statement was required.

3. Nutritional Issues Associated With Olestra

FDA concluded that olestra inhibits the absorption of the fat-soluble components of the diet when these components are present in the GI tract simultaneously with olestra (61 FR 3118 at 3132-3147). Such components include the fat-soluble vitamins A, D, E, and K, and the lipophilic carotenoids. Based on the data from the nutritional studies, FDA concluded that addition of the four fat-soluble vitamins (A, D, E, K) to foods containing olestra would compensate for any decreased absorption due to the action of olestra, thus ensuring that consumption of an olestra-containing food would not alter the amount of vitamin available for absorption (61 FR 3118 at 3144-3147). The amounts of the vitamins to be provided are prescribed to ensure safe use (§ 172.867(d)). As required under section 403(i) of the act, these vitamins are declared in the ingredient listing.

The added vitamins were not to be considered in determining nutrient content of the food for the nutritional label or for any nutrient claims, expressed or implied. This is because the added vitamins simply compensate for the transient impaired absorption of vitamins A, D, E, and K, *i.e.*, they are added to ensure no change (neither increase nor decrease) in vitamin availability. Thus, the vitamins added to olestra do not contribute significant amounts of these nutrients to the diet (61 FR 3118 at 3161).

Labeling may be considered misleading not only if it fails to reveal facts that are material in light of consequences that may result from use of a food, but also if the labeling fails to reveal facts that are material in light of representations made. Therefore, to set the context for why vitamins A, D, E, and K were added, FDA required a label statement providing information both that vitamins A, D, E, and K had been added and that olestra inhibits the absorption of vitamins. Because FDA believed that consumers who see vitamins A, D, E, and K in the ingredient listing might incorrectly believe that the food was fortified with these vitamins, the agency required an explanatory statement on the label of olestra-containing foods to inform consumers that olestra-containing foods were not an enhanced source of vitamins A, D, E, and K. The statement indicated that olestra inhibits the absorption of vitamins and other nutrients to explain why they were added. FDA included the term "other nutrients" because any nutrient that is as lipophilic as these vitamins would

also be affected, although FDA concluded that there was no basis for adding back nutrients other than vitamins A, D, E, and K. In this way, FDA sought to make clear to consumers the reason for the presence of vitamins A, D, E, and K in the ingredient listing.

Carotenoids are fat-soluble components in the diet, the majority of which are derived from fruits and vegetables. Data from the petitioner's two 8-week studies demonstrated that consumption of olestra inhibits absorption of carotenoids as measured by a decrease in serum carotenoid levels (61 FR 3118 at 3147-3149). Co-consumption of olestra and a carotenoid-containing food allows the greatest interaction between olestra and the carotenoid, thereby maximizing the potential for interfering with absorption of the carotenoid from the GI tract.

Beta-carotene is a provitamin A carotenoid that is a dietary source of vitamin A; provitamin A carotenoids are converted in the body into vitamin A. At the time of the 1996 final rule, FDA concluded that supplementing olestra-containing foods with vitamin A would compensate for olestra's effects on the provitamin A function of carotenoids.

In evaluating whether there is a scientific basis to require the addition of any carotenoids to olestra-containing foods, FDA consulted with scientists at the National Cancer Institute of the National Institutes of Health (NIH) and the National Eye Institute (NEI) of the NIH (61 FR 3118 at 3148-3149), and the agency's Food Advisory Committee (FAC) (61 FR 3118 at 3121). At the 1995 FAC meeting on olestra, experts with a range of views discussed whether carotenoids themselves have beneficial health effects, or whether it is some other substance in fruits and vegetables that provides the claimed health effects, in which case the carotenoids are serving solely as markers for fruit and vegetable consumption. Five different conferences or reviewing groups preceding the 1995 FAC meeting had examined the relationship between carotenoids and disease. All of these groups had concluded that there was insufficient evidence to recommend consumption of carotenoids, except to encourage the consumption of fruits and vegetables (61 FR 3118 at 3148). Although epidemiological studies showed an association between diets rich in fruits and vegetables (including those that contain carotenoids) and decreased cancer risk, there was no direct evidence that carotenoids themselves were responsible for or contributed in a significant way to that protective benefit. Therefore, at the time of the approval of olestra, the agency

concluded that the available data did not establish any identifiable nutritional or prophylactic benefits for carotenoids, either individually or collectively, aside from the provitamin A function (61 FR 3118 at 3147-3149).

Thus, FDA found no scientific basis for requiring the addition of any carotenoid to olestra-containing foods. The agency also found that the actual magnitude of olestra's effects on carotenoid absorption was likely to be within the range of the normal variation of such absorption due to diet and bioavailability, providing additional assurance that the effect of olestra on the absorption of carotenoids did not raise concern. Accordingly, FDA concluded that there was no basis for requiring a statement about carotenoids on the label of olestra-containing food.

B. Opportunity for Comment and Consideration of New Data

1. Request for Comments on the Label Statement Required by the 1996 Final Rule

Because section 409 of the act prohibits, among other things, approval of a food additive if doing so would cause misbranding, the agency concluded that the olestra label statement should be imposed as a requirement as part of the food additive petition process (§ 172.867(e)). The agency acknowledged, however, that the specific wording had not been tested or subject to an opportunity for comment. Thus, the agency requested comments on the label statement from interested persons on such issues as the need for labeling, the adequacy of its content, and the agency's current word choices (61 FR 3118 at 3160).

After the publication of the 1996 final rule, the agency received timely comments on the label statement,⁴ as well as objections to the 1996 final rule.⁵

2. P&G's Commitment To Further Studies

In a letter to the agency dated January 24, 1996, the petitioner stated its intention to conduct focus group testing

⁴ The comments received by April 1, 1996, included the results of P&G's consumer focus group studies on the label statement. Frito-Lay also submitted consumer perception studies on the olestra label statement. These studies are discussed in section III.F.1 of this document. The agency continued to receive comments on the label statement after April 1, 1996. In this document, FDA addresses comments received on the label statement regardless of whether the comments were received by April 1, 1996.

⁵ Timely objections were to be filed by February 29, 1996. FDA's response to these objections and requests for hearing is published elsewhere in this issue of the *Federal Register*.

of the required olestra label statement, to establish a postmarket surveillance system, to conduct additional studies of olestra exposure (both amounts consumed and patterns of consumption), and to conduct additional studies regarding the effects of olestra consumption (61 FR 3118 at 3160 and 3168). FDA responded that P&G was to conduct the studies it had identified in its letter to FDA, consistent with the timetables identified in that letter (61 FR 3118 at 3168).

P&G did carry out the surveillance and studies outlined in its letter of commitment, and performed additional studies not mentioned in the January 1996 letter. After the publication of the 1996 final rule, P&G carried out its commitment to establish a system of passive surveillance to collect spontaneous reports of possible effects that consumers associated with the consumption of olestra-containing snacks. This system included establishing an outside panel of medical experts to review reports, followup on reports of serious illness, and provide FDA information about reports received.

P&G also carried out its commitment to conduct studies on the exposure and effects of olestra. The active surveillance program that P&G sponsored was designed to examine the impact of olestra consumption on endpoints such as serum concentrations of carotenoids and vitamins, olestra consumption patterns (including frequency and amounts), and GI symptoms.

These data and information were presented to the FAC in June 1998, and were eventually incorporated into the petition that is the subject of this rulemaking.

3. FDA's Commitment To Convene an FAC Meeting

In the 1996 final rule, FDA committed to review and evaluate any new data and information bearing on the safety of olestra and to present such information to the agency's FAC within 30 months of the approval of the use of olestra in savory snacks (61 FR 3118 at 3168-3169; § 172.867(f)).

FDA convened a meeting of its FAC within 30 months of the approval of the use of olestra in savory snacks. At an open public meeting, held June 15-17, 1998, new data and information concerning olestra, obtained since the 1996 approval were presented (Ref. 1). These new data, which comprise the majority of material that P&G subsequently submitted in its petition, are discussed in section III of this document. FDA, P&G, the Center for Science in the Public Interest (CSPI), and other interested members of the

public made presentations to the Committee. After presentation of the new data, the FAC discussed the label statement specified in § 172.867(e). The complete set of transcripts of the June 1998 FAC meeting ("the transcript" or "transcript") is publicly available through FDA's Division of Dockets Management and through FDA's Internet site.⁶

4. P&G's Petition To Remove the Requirement for the Label Statement

P&G submitted a food additive petition, dated December 1, 1999, to amend the food additive regulations in § 172.867 *Olestra* by removing the requirement for the label statement prescribed in § 172.867(e). This petition incorporated the studies and information that were performed after the publication of the 1996 final rule. As noted, much of that material was discussed by the FAC in 1998.

5. Comments Received

FDA received approximately 80 letters, each containing one or more comments, on the olestra label statement.⁷ Some of the comments were submitted in response to FDA's request in the 1996 final rule for comments on the olestra label statement. Other comments were submitted in response to the January 24, 1996, announcement of the approval of olestra for use in savory snacks. Because all of these comments addressed P&G's original petition, which was granted in 1996, in this document FDA refers to these comments as comments "to the 1996 final rule." Comments were also submitted in response to publication in the *Federal Register* of the filing notice for the current petition (65 FR 11585, March 3, 2000); in this document, FDA refers to these comments as comments "to the current petition."

Comments were submitted by P&G, Frito-Lay, Inc. (Frito-Lay), and other members of the food industry, as well as from individual consumers, consumer organizations, academia, trade associations, and a member of Congress. Several comments were filed by CSPI. Several parties, including Frito-Lay and

⁶ The Internet site is located at <http://www.fda.gov/ohrms/dockets/ac/cfsan98t.htm#FoodAdvisoryCommittee> (choose June 15, 16, and 17).

⁷ FDA notes that one of the objections submitted by CSPI concerns the label statement required by the 1996 final rule.

⁸ Although not part of the petition being considered in the current rulemaking, FDA reviewed comments regarding labeling that were addressed to the 1998 FAC. These comments raised no substantive issue that was not already considered as part of the current food additive petition.

CSPI, submitted comments to both the 1996 final rule and the current petition.

Although section 409 of the act establishes no comment period for food additive petitions, and the agency generally does not solicit comments in notices announcing the filing of a food additive petition, it is FDA's practice to consider any relevant comments submitted prior to the agency's decision on a petition.⁹ In this document, FDA separately discusses data from telephone surveys and passive surveillance regarding GI effects, new studies regarding GI effects, and active surveillance and other information regarding nutritional effects of olestra. As part of its discussion of these areas, FDA describes and responds to comments relevant to the topic. FDA discusses and responds to comments on other topics (such as the wording of the label statement, the prominence and placement of the label statement, and the need for a label statement) in a separate section (see section V of this document). In responding to the submitted comments, FDA has considered all of the data and information available in the record that bear on the olestra label statement, including the data and information in the 1996 final rule as well as the new information in the current petition.

III. Data and Information Since the 1996 Final Rule

A. Introduction

Olestra-containing snacks were introduced into test markets in April 1996, and national marketing began in February 1998. P&G established a system of passive surveillance to collect reports of possible effects that consumers associated with eating olestra-containing snacks. This surveillance system was in place when test marketing began. P&G has submitted reports to the agency, as well as analyses of such reports. P&G also established its program for active surveillance to monitor, among other things, possible nutritional impacts of olestra consumption.

P&G conducted studies concerning possible GI effects from consuming olestra-containing snacks in "real-life" situations. Specifically, P&G conducted four controlled studies concerning possible GI effects in humans and submitted reports about those studies to FDA.¹⁰ The four controlled studies are described as follows:

- An Acute Consumption Study,
- A Six-Week Consumption Facilitated *Ad Lib* Study (also called the Home Consumption Study),
- A Rechallenge Study, and
- A Stool Composition Study.

In the current petition, P&G also submitted the following data and information:

- Reports and analyses of data collected through consumer focus group and perception studies,
- Surveys regarding GI symptoms,
- Updated literature reviews on carotenoids and disease, and
- A report and analysis of the first year of data collected in an Active Surveillance Study.

CSPI also submitted reports from individuals who attributed an effect to the consumption of an olestra-containing food (Docket No. 87F-0179). In some cases, CSPI obtained medical records from consumers and forwarded them to FDA for analysis.

Below, FDA describes in detail the studies and information submitted in support of this petition, comments to the 1996 final rule that discuss the labeling of olestra-containing foods, comments to the current petition, and other relevant information.

B. Surveys and Postmarket Passive Surveillance Regarding GI Effects

1. Telephone Surveys Regarding GI Complaints

a. *P&G*. P&G sponsored two telephone surveys to investigate the frequency and severity of GI complaints, to investigate the frequency of consumption of foods that consumers believe cause GI symptoms, and to determine knowledge about reported GI symptoms from olestra-containing foods. Both of these surveys were performed before olestra-containing foods were available for sale in those markets. The first survey was done in February 1997 in Indiana (in Marion County, where Indianapolis is located), which was later a test-market for olestra-containing foods. This survey also served as a pilot study for the second survey, which was a national survey of the U.S. population completed in September 1997. National marketing of olestra-containing foods began in February 1998.

The petitioner acknowledged limitations in the design of the first survey completed in Indiana. For example, because the first survey was also the pilot study, the study

instrument had not yet been validated.¹¹ Also, the sample size was small and not shown to be representative of the general population surveyed. Despite these limitations, the petitioner concluded from the survey that GI symptoms were very common among the adult respondents polled. Asked about the previous three month period, respondents reported most frequently the GI symptoms of gas (34.6 percent), diarrhea (33.2 percent), and abdominal cramps (25.8 percent). Of those respondents who experienced one or more GI symptoms, 14 percent reported seeking medical attention because of the symptom. More than half of those who experienced a GI symptom said it was of moderate to severe intensity. The other result noted by the petitioner in this study was that there are a number of common foods (e.g., beans, onions, spicy foods) that respondents said caused them to have GI symptoms, but more than 80 percent of these respondents said they continued to eat these foods. Approximately half of the respondents had heard of olestra and among that group, 18 to 28 percent associated olestra with a GI symptom such as abdominal cramping or diarrhea.

The second survey was a larger, national survey that was designed with a reliability check, and a portion of the survey was designed to be a truly random sample of respondents. In this survey, 40.5 percent of respondents reported having one or more GI symptoms in the previous month. Of those respondents reporting a GI symptom, 21.8 percent had abdominal pain or discomfort, and 26.9 percent reported diarrhea or loose stools. More than 65 percent of respondents rated each of their symptoms as moderate to severe in intensity, and 14 percent consulted physicians about their symptoms. When asked about specific foods, respondents reported having GI symptoms after eating foods such as beans (22 percent) or spicy foods (34.4 percent). Despite symptoms, approximately 80 percent continued to consume these foods. The petitioner also found that women were more likely than men to report GI symptoms, and that abdominal pain, discomfort, and bloating were more commonly reported by women. There was little difference between males and females for reports of diarrhea. More than half the respondents in this study had heard of olestra, and of those, a varying number associated olestra with different GI

⁹ See discussion of comments in the filing notice for this petition (65 FR 11585-11586, March 3, 2000).

¹⁰ A copy of the petition submitted by P&G, as well as copies of the studies, surveys, and other

supporting materials listed here, can be found at the Division of Dockets Management, Docket No. 00F-0792.

¹¹ Data obtained from the first survey was used to validate the study instrument for use in the second survey.

symptoms (diarrhea (33 percent), loose stools (4 percent), cramps (11 percent), other GI problems (23 percent)).

FDA notes that in both these surveys, the percent of individuals reporting a GI symptom was high. FDA also notes that while the great majority of respondents in both surveys indicated that they consumed foods that caused them GI symptoms, the survey did not obtain information about the severity of these symptoms (Ref. 2).

b. CSPI. In 1996, CSPI commissioned a telephone survey in cities where olestra-containing foods were test marketed (Cedar Rapids, IA, Eau Claire, WI, and Grand Junction, CO), and submitted a report of the results to FDA.¹² The purpose of CSPI's survey was to determine how many people in the test market had tried olestra-containing snacks, and of those who had eaten olestra-containing snacks, how many had experienced GI symptoms. A random digit dialing sampling system was used, until a total of 506 telephone interviews were conducted in June and July 1996. CSPI said that 27 percent of individuals surveyed had tried the newly marketed olestra-containing chips, and of those, 20 percent reported experiencing GI symptoms characterized by CSPI as an adverse GI effect. Respondents characterized these events as mild (58 percent), moderate (23 percent), or severe (9 percent). CSPI also found that the majority of respondents (78 percent) had seen negative reports in the press about olestra, although only 28 percent said they were concerned about these possible effects. Based on this telephone survey, CSPI predicted that a large number of adverse events would be caused by the national marketing of olestra-containing foods. CSPI performed a separate survey of the original respondents who had not eaten olestra-containing chips but ate other chips to assess the frequency of GI events associated with consumption of conventional savory snacks and found that only 0.5 percent associated an adverse GI effect with eating a triglyceride savory snack.

CSPI commissioned a second survey, which was conducted in April and May 1997 in the Indianapolis area where olestra-containing foods were test-marketed. The purpose of the survey was to ascertain the consumption of olestra-containing foods and possible rate of adverse effects. CSPI submitted a report of the results to FDA.¹³ CSPI

reported that the majority of respondents said they had eaten savory snacks in the past 8 weeks (68.8 percent), and that a smaller portion of respondents (32.7 percent) said they had eaten olestra-containing foods. CSPI said that when respondents were asked whether they had eaten a specific brand of chips that contain olestra, they said yes, but when asked whether they had eaten olestra, these consumers responded that they had not eaten olestra. Of the group of respondents who had eaten an olestra-containing food, 8.3 percent reported experiencing what was characterized as an adverse effect after eating the olestra-containing food.

In its review of the data and information submitted by CSPI, FDA found that the studies provided information about the prevalence of use of olestra-containing foods, awareness of GI symptoms associated with olestra, and sources of information that consumers were using to learn about GI symptoms associated with olestra. FDA disagreed, however, that these studies could provide information about the cause of these GI symptoms. FDA found that the study design was inadequate to determine the cause of GI symptoms. Additionally, it is known from food-borne illness outbreaks that attribution biases can influence consumers and lead to the erroneous attribution of symptoms to a particular food. CSPI's survey does not allow for the evaluation of erroneous attribution of GI symptoms to consumption of olestra-containing chips, *i.e.*, other plausible causes for illness reports were not considered (Ref. 3).

2. Postmarket Passive Surveillance by P&G

P&G established a system of passive surveillance to collect consumer reports associated with the consumption of olestra-containing foods. Passive surveillance refers to the collecting of spontaneous, voluntary reports about a product. In its petition, P&G presents an overview of both the utility and limitations of data obtained from spontaneous, postmarket consumer reports. P&G characterized postmarket passive surveillance as a means of identifying and characterizing potential issues, including safety issues, once a product has entered the marketplace and been utilized by the population at large. The population experience with a product will be much broader than that derived during premarket testing because the number of individuals participating in premarket testing is necessarily limited. A reporting rate may be calculated based on the total

amount of product sold and the number of reports received. P&G notes, however, that there are a number of limitations with passive surveillance reporting. For example, these data do not lend themselves to assessment of causality because of the lack of controlled conditions and various confounding factors, such as a high background incidence of reported GI effects. Voluntary reporting, such as that obtained in P&G's passive surveillance system, is also subject to a number of biases including the level of attention the subject is receiving in the news media. Because reporting is voluntary and subject to interpretation, and because the total number of "exposures" can only be estimated, a true incidence rate cannot be calculated from passive surveillance.

Reports to P&G under its passive surveillance program for olestra were, for the most part, collected via calls made by consumers to a toll-free telephone number displayed on olestra-containing foods. Such calls were taken directly by P&G via its own toll-free telephone number. Calls were also forwarded to P&G by other snack food manufacturers (specifically, Frito-Lay). In some cases, information from such calls (but not the calls themselves) was forwarded to P&G by other snack manufacturers. Information was collected from callers as to the product used, specific product code information (where available), amount consumed, the nature of the complaint, symptom onset and duration, recurrence, characteristics and treatment, concomitant medications, and physician or other health professional involvement. Where physician contact was involved, or a medically significant event was reported, the petitioner attempted to obtain more detailed information including release of medical records for evaluation.

Consumer reports were reviewed by trained medical affairs staff at P&G. Additionally, the petitioner established a committee (Olestra Postmarketing Surveillance Committee) of medical experts outside of P&G whose membership included specialists in GI disease (both adult and pediatric GI), epidemiology, and pharmacology to review the reports received, and to make recommendations about the implications, if any, of these reports on the safety of olestra. The petitioner submitted reports to FDA of complaints associated with olestra consumption beginning in April 1996 with the test marketing of snacks made with olestra.

The petitioner reported that there were peaks in the number of reports received after the test marketing and

¹² CSPI submitted this report to Docket No. 87F-0179.

¹³ CSPI submitted this report to the Docket No. 87F-0179.

national introduction of olestra-containing foods. The petitioner found that while the absolute number of reports increased when olestra-containing foods were first introduced into test markets, the reporting rate (reports per amount of product sold) declined over time. The petitioner also found that over time the absolute number of reports declined and eventually reached a plateau. The greatest number of reports the petitioner received over a four month period was 4,951 in 1998 at the national introduction of olestra-containing snacks. The petitioner stated in its initial reports on passive surveillance that it is common to receive calls and complaints for products. At the start of national marketing the reporting rate was one report for approximately 100,000 servings sold, and 2 years later the reporting rate was one report for approximately 1 million servings sold.

The petitioner analyzed the data from its passive surveillance efforts and found no trend toward increased symptoms with increased consumption; no trend towards increased severity with increased consumption; and no difference in severity by age group or gender. The petitioner's Olestra Postmarketing Surveillance Committee reviewed reports using an algorithm developed to assess the likelihood that an effect was caused by olestra. Using this algorithm, P&G's committee concluded that many reports were not likely to be related to olestra and no serious reports could be attributed to olestra (Docket No. 00F-0792, submission dated March 3, 2000). Based on the nature of the complaints received, the petitioner designed subsequent studies to address, in part, issues arising from consumers' anecdotal reports after eating olestra-containing foods.

In the 1996 final rule, FDA determined that the use of olestra was safe based on results from the preapproval safety studies. FDA stated in the 1996 final rule (61 FR 3118 at 3168) that P&G's plans to continue to study the consumption and effects of olestra were both prudent and responsible. FDA expected, based on results of the preapproval studies, that some reports concerning GI upset, such as loose stools and abdominal cramping, would be collected through a system of passive surveillance. FDA also considered that postmarket passive surveillance had the potential to detect low frequency and unexpected events because postmarket passive surveillance involves the entire population that consumes a product.

FDA reviewed the reports of effects attributed to olestra and found that the majority of reports received concern GI effects such as loose stools and abdominal cramping. Other symptoms were reported at lower frequencies.

FDA recognizes that passive surveillance data such as those collected by P&G have utility but are limited in that they do not allow for the determination of a causal association between the product consumed (*i.e.*, olestra-containing foods) and effects reported. Such reports can, however, lead to hypothesis generation about why specific effects are occurring. This may then result in the development of studies used to test these hypotheses (Ref. 4).

FDA reviewed reports of effects associated with ingestion of olestra that led consumers to seek medical attention. Where possible, the agency reviewed medical records that were obtained directly from individuals who reported the effect or that were obtained through P&G and CSPI (Refs. 5 and 6). At the 1998 FAC meeting, FDA presented its analysis of the medical reports received up to that time. Among the reports discussed was a case where a consumer had undergone an appendectomy and associated this with consuming an olestra-containing food. The pathology diagnosis at the hospital noted that there were minimal inflammatory changes. FDA obtained a medical release from the patient in order to examine the pathology slides from the appendectomy, which were read independently by four FDA pathologists, all of whom confirmed the presence of inflammatory cells throughout the wall of the appendix meriting a diagnosis of acute appendicitis.¹⁴ In many other of the medical records reviewed, physicians attributed patient symptoms to an etiology other than olestra, or did not provide an etiology. There were cases where physicians did attribute symptoms to olestra, but the limitations of passive surveillance make it difficult, if not impossible, to draw definitive conclusions about causality based on the review of individual medical records.

3. Postmarket Surveillance Reports From CSPI

CSPI has periodically submitted to FDA reports of effects allegedly associated with the consumption of olestra (Docket No. 87F-0179). The complaints were gathered initially in test markets by calls to an advertised toll-free telephone line, and gathered

subsequently through CSPI's Internet site.

FDA analyzed the reports from CSPI and compared the information and analysis to the information and analysis of the reports submitted to FDA by P&G. FDA noted that the reports received by CSPI were very similar in nature, type of complaint, and amount consumed as the reports by P&G.¹⁵ As discussed previously, passive surveillance has limited utility in determining causality.

4. Comments Regarding Consumer Reports

FDA received comments about reports of effects that consumers attributed to olestra. FDA considered these comments and responds in the following section of this document.

(Comment 1) One comment from an individual consumer to the current petition reported that a family member who had Addison's disease suffered gastric cramps and diarrhea, laid down, went into an Addisonian crisis, and died after consuming olestra-containing potato chips. The comment did not provide any further information regarding the death mentioned. CSPI forwarded to the agency the medical record of an Addison's disease patient who had reportedly consumed olestra-containing potato chips prior to death. The patient who died was diagnosed as having Addison's disease (adrenocortical insufficiency) and hypothyroidism in 1989. FDA believes, based on several factors, that the comment and medical record provided by CSPI refer to the same person.

FDA reviewed the medical record forwarded by CSPI. This patient collapsed suddenly after experiencing a bout of gastroenteritis, and reportedly consumed olestra-containing chips prior to the bout of gastroenteritis. An autopsy showed that the adrenal glands could not be identified and noted a finding of Hashimoto's thyroiditis. The medical record did not provide any information regarding the gastroenteritis experienced prior to death.¹⁶ Due to the lack of information contained in the medical record, the agency was unable to determine whether the ingestion of olestra had any role in this patient's illness or death (Ref. 5).¹⁷

¹⁵ Transcript, vol. 1, pp. 258-270.

¹⁶ The Certificate of Death lists acute cardiorespiratory arrest as the immediate cause of death with autoimmune adrenocortical deficiency syndrome as the underlying cause leading to the immediate cause of death. Other significant conditions contributing to death but not resulting in the underlying cause include mitral valve prolapse and Hashimoto's thyroiditis.

¹⁷ FDA investigated the death mentioned in the comment. As part of the investigation, FDA spoke with the patient's spouse and the patient's co-

¹⁴ Transcript, vol. 1, pp. 271-276.

(Comment 2) A comment from CSPI to the current petition asserted that FDA has never conducted in-depth investigations (beyond reviewing the medical records of a few individuals) of any of the anecdotal reports, including those reports involving rectal bleeding, hospitalization, and death. The comment further asserted that the agency has ignored all of the anecdotal reports and has said that there is no proof that any of the reports were due to olestra. The comment also stated that in some reports, a patient's physician attributed his/her symptoms to olestra. The comment also quoted FDA review memoranda (Refs. 6 and 7) stating that olestra may have been responsible for some of the effects reported.

FDA does not agree that it has ignored anecdotal reports. Nor does it agree that it must conduct further investigation of the anecdotal reports. FDA regularly reviews the reports forwarded to the agency by P&G and CSPI. The reports are analyzed and summarized using criteria such as sex, age, symptoms reported, duration of symptoms, and amount of olestra-containing food consumed. The agency also reviews any medical records forwarded with the reports. CSPI provided no evidence to support its allegation that anecdotal reports have been ignored. Nor has CSPI provided any reason to suspect that serious adverse health effects could have been caused by olestra. The agency will continue to monitor reports as they are forwarded to the agency.

As stated in the memoranda cited by the comment, some of the effects reported may have been caused by olestra. These reports were collected using passive surveillance. As noted previously, passive surveillance is useful in that it can lead to hypothesis generation about why specific effects are occurring. These hypotheses can then be tested in controlled clinical trials. For example, the reports received from consumers attributing their symptoms to olestra served as a basis for some of the hypotheses tested in the petitioner's most recent controlled clinical studies. However, while passive surveillance data have utility, such data are limited in that they do not allow for the determination of a causal association between the product consumed and effects reported. Thus, based on the passive surveillance data alone, it is not possible to determine whether the effects reported were caused by consumption of an olestra-containing food.

workers about the events leading up to the patient's death.

The agency has reviewed all of the medical records that it has received from CSPI and P&G about consumers who saw a physician for an effect attributed to the consumption of an olestra-containing food. In fact, FDA has conducted an investigation into the death mentioned in the previous comment. FDA has also obtained and examined the pathology slides of a patient who had undergone an appendectomy that the patient associated with consumption of an olestra-containing food. The agency has not found sufficient evidence to conclude that olestra is likely to have caused the symptoms that led the consumers to see a physician.¹⁸

(Comment 3) A comment from CSPI to the current petition stated that letters and electronic mail messages sent to P&G describing GI symptoms have not been included in reports that P&G submitted to the agency; therefore, the agency has not received all of the symptom-related reports. The comment recommended that the agency investigate whether it had received all reports.

FDA recognizes that not every report from a consumer will provide enough information for FDA to determine whether an effect was possibly related to olestra and that some judgement is needed in compiling data. In light of this limitation, the agency recognizes that P&G may not forward all reports it receives, such as those reports containing incomplete information, to the agency. While this may mean that less than 100 percent of reports are collected, the agency has no reason to believe that the complaints not forwarded to the agency constitute a unique data set or raise an issue not previously considered. Indeed, the reports gathered and forwarded independently to the agency by P&G and CSPI are consistent in terms of the nature of the complaints and the amounts of olestra consumed. CSPI's comment provides no specific information that would lead the agency to conclude that it has not received an accurate and representative sample of the effects reported to P&G or that such reports raise an issue not already considered. Thus, the agency finds that there is no basis for concluding that it should obtain and evaluate each and every report that P&G receives.

(Comment 4) A comment from CSPI to the current petition stated that the agency should obtain and disclose to the public the number of consumers (without identifying any particular individuals) who attributed their

symptoms to olestra and reached an out-of-court settlement with the petitioner. The comment also asked for the number of consumers who, after attributing their symptoms to olestra, received or were offered reimbursement for their medical expenses. The comment requested that the agency consider this information in its rulemaking.

FDA does not agree that it should obtain and disclose to the public the number of consumers who attributed their symptoms to olestra and reached an out-of-court settlement with the petitioner. Importantly, the comment does not demonstrate the relevance of the requested information to the question at issue: *i.e.*, whether FDA should continue to require special labeling for olestra-containing foods. Moreover, settlement of lawsuits may be reached for a variety of reasons, including improved public relations or avoidance of unnecessary conflict, and do not address any factual issues regarding whether olestra is capable of causing the effects claimed.

C. Studies Regarding GI Effects

1. Rechallenge Study

The petitioner submitted a report of a study designed to test whether individuals who complained of a GI effect after consuming olestra-containing snacks would have the same experience with subsequent exposure (Refs. 8 and 9). This test was designed to show whether the GI effect is consistently associated with consumption of the olestra-containing snack. The petitioner's study was a randomized, double-blind, placebo-controlled, four-period, within-subject crossover study. Subjects were recruited from consumers who had voluntarily called the snack manufacturer and reported GI symptoms associated with consumption of olestra-containing snacks. Each subject made four visits to the study site, at least 1 week apart, and was provided with 2 ounces (oz) of either potato chips containing olestra (olestra chips) or potato chips containing conventional triglyceride¹⁹ (triglyceride chips). At each visit, subjects were to consume as much as they could of the 2 oz serving. Each participant was randomly assigned to receive olestra chips at two visits and triglyceride chips at two visits. Participants were contacted after each visit and asked whether they had

¹⁹ In the various reports submitted by the petitioner, the terms triglyceride, full-fat, regular, and conventional were all used to describe the oil used in savory snacks. These terms mean the same thing. For consistency in this document, we use the word triglyceride.

¹⁸ Ref. 5 and Transcript, vol. 1, pp. 271-276.

experienced any GI symptoms within the week after eating the potato chip product.

The study was completed with 98 participants, the majority of whom had initially called to report that they had experienced diarrhea, loose stools, and/or abdominal cramping (61 percent, 16 percent, and 64 percent respectively). Approximately 48 percent of the participants described the symptoms that prompted their original call as severe. For nearly three-quarters of the participants, the amount of olestra chips consumed in the study was comparable to, or greater than, the amount associated with their initial call.

The petitioner found that during the study there were no significant differences following consumption of olestra chips, compared with consumption of triglyceride chips, in the frequencies of abdominal cramping (12 percent with olestra, 9 percent with triglyceride), diarrhea or loose stools (11 percent with olestra, 15 percent with triglyceride), gas (7 percent with olestra, 5 percent with triglyceride), or any other GI symptom (28 percent with olestra, 26 percent with triglyceride). Overall symptom severity ratings for all subjects were similar after consumption of olestra and triglyceride chips. The petitioner concluded that this study provided evidence that an episode that was initially reported to be an olestra-related effect was in all likelihood not olestra-related, and that there was no evidence of a population or subpopulation with a sensitivity to olestra. The petitioner suggested that these results indicate that initial calls made to the toll-free telephone line may reflect false attribution of symptoms to products made with olestra.

FDA found this study was adequately representative of the population who called the postmarketing surveillance system in terms of severity of initial symptoms and amount of olestra reportedly consumed prior to the initial symptom episode. FDA noted that while 98 participants were enrolled in the study, only 92 completed all 4 visits. The six dropouts were unrelated to olestra-related effects. Based on an analysis of the data in the study, FDA concluded that under the conditions of the study (two exposures of up to 2 oz of olestra-containing chips separated by at least a week), subjects eating olestra-containing chips were no more likely to report having had loose stools, abdominal cramps, or any other GI symptom compared to subjects eating an equivalent amount of triglyceride chips (Refs. 10 and 11).

2. Acute Consumption Study

P&G sponsored²⁰ a study to determine whether there was a difference in the nature or frequency of GI symptoms experienced by subjects eating olestra chips compared to those eating triglyceride chips, ad libitum on a single eating occasion (Ref. 12). The study was a randomized, placebo-controlled, double-blind study in which 1,092 adults and teenagers who were provided with a 13 oz bag of potato chips (either olestra chips or triglyceride chips) in a plain, unlabeled white bag, consumed as many chips as they desired while viewing a movie. Participants were also provided a 32-oz soft drink of their choice. Participants were told prior to the test that they might experience temporary dry mouth, thirstiness, or digestive symptoms (such as gas, cramping, or loose stools), as they might with salty or high fiber foods.

Participants were instructed to be seated in the theater at least one seat apart from other participants, to eat and drink as much or as little of their chips and beverage as they desired, and not to share with anyone else. The theaters were monitored by several study staff during the movies. At the conclusion of the movie, participants clipped their bags of chips shut; noted the approximate amount of beverage consumed; and completed a brief questionnaire about product acceptance, satiety, and sensory attributes. Participants turned in the completed questionnaires and bags with uneaten chips and were given a toll-free telephone number to call if they had any questions or problems. Bags of chips were subsequently weighed to determine the amount consumed by each subject.

Trained telephone interviewers contacted study participants and administered a recall questionnaire to collect information on any effect experienced since the movie. All subjects were specifically asked if they had experienced any GI symptoms during or since the movie, and to specify those symptoms including the severity and timing of any such symptoms. The study protocol specified that participants be contacted within 2 to 4 days of viewing the movie. The petitioner reported that 85 percent were contacted within 2 to 4 days and a total of 97 percent were contacted within a week of viewing the movie.

The petitioner reported that the median consumption of olestra chips

was approximately 2.1 oz (approximately 16 g of olestra)²¹ compared to about 2.7 oz of triglyceride chips. Overall chip consumption was similar across age groups, but males generally consumed more chips than females (median of 2.8 versus 2.1 oz, $p < 0.01$). The overall palatability of the triglyceride chips was rated slightly higher than the olestra chips, with a mean score of 6.4 versus 5.6 on a 9-point preference scale ($p < 0.01$). Regarding satiety, there were no significant differences between the groups as indicated by mean satiety scores of 5.9 versus 5.7 for triglyceride chips and olestra chips, respectively, on a 9-point scale, with 9 being "extremely full" ($p = 0.07$). Nor were any differences seen in beverage consumption, choice of beverage, or time since last meal prior to the movie between the two groups.

The petitioner attributed the lower chip consumption in the olestra group to the slightly lower preference for olestra chips reported by study participants. The petitioner stated, however, that the median consumption (2 oz) was more than a typical single-serving snack size bag of chips, and that approximately 100 participants ate more than 4 oz of olestra chips (approximately 32 g of olestra).

The petitioner reported that the proportion of subjects who reported GI symptoms after consuming olestra chips was not different from that after consuming triglyceride chips (15.8 percent and 17.6 percent respectively). There were no differences between the olestra and triglyceride groups in the frequencies for 14 different self-reported GI symptoms (gas, diarrhea, pain, cramping, upset stomach, loose stools, nausea, bloating, indigestion, aftertaste, eructation, constipation, vomiting, bloody stool), overall symptom severity for any GI event, nor time to onset or duration of symptoms. The petitioner also reported that consumption levels did not correlate with the rate of symptom reporting in either the olestra or triglyceride group.

The petitioner planned to have 1,400 participants in the study and anticipated symptom reporting to be 10 percent for the triglyceride group and 15 percent for the olestra group. Using these assumptions, the study would provide 80 percent power for detecting

²⁰The principal investigator for the study was Dr. L. Cheskin, Dept. of Gastroenterology, Johns Hopkins School of Medicine.

²¹In 1996, FDA estimated the probable life-time averaged intake of olestra at the 90th percentile to be 7.0 g/p/d. To evaluate subchronic conditions, FDA estimated that a "high" acute consumer of olestra (everyday for 12 weeks) would consume 20 g/p/d, equivalent to eating a 2 oz bag of potato chips every day, and the 99th-percentile single-day intake of olestra for the group consuming the highest level of savory snacks to be 45 g/d (61 FR 3118 at 3124).

a 5 percent difference in the proportions of symptoms between the olestra and triglyceride groups. The final number of participants to complete the study was 1,092,²² which was fewer than planned. The rate of symptom reporting in the triglyceride group was 17.6 percent, which was higher than planned. Given the actual number of participants, and the actual rate of reports of symptoms in the triglyceride control group, FDA found that the study had an 80 percent chance of detecting a 7 percent difference between the test groups ($p=0.05$) (Ref. 13).

FDA observed that 962 participants completed a post-movie interview within the 2 to 4 days goal of the study. Of the remaining 130 participants who were contacted, 124 participants were contacted in 5 to 10 days, 3 on the day of the movie, 1 within a day, and 2 within 23 days. FDA noted that P&G included data from these 130 participants in its analysis to enhance the sensitivity of its analysis.

FDA noted that in both the olestra and triglyceride groups, the most frequently reported GI symptoms were abdominal pain, diarrhea, and flatulence. These symptoms are also the symptoms most commonly reported to P&G's passive surveillance program. FDA agrees with the petitioner that in this study, there was no difference in the rate or severity reported for loose stools or abdominal cramps between subjects who ate olestra-containing chips and subjects eating triglyceride chips. FDA examined the percent of subjects reporting at different levels of chip consumption and found that reports of diarrhea increased for both the olestra and triglyceride groups with increasing consumption of chips, but there was no difference in the rate of reporting between the groups (Refs. 10 and 13).

3. Home Consumption Study

The Home Consumption Study²³ was designed to measure, under market use conditions, the effect of eating chips made with olestra on GI symptoms in adults and children over an extended period of time (Ref. 14). This double-blind placebo-controlled trial represented 1,138 households (3,181 individuals, ages 2 to 89) randomly assigned to either the olestra group or the control group. To be enrolled, at least half the members of the household had to have eaten corn or potato chips

at least four times in the previous month and all members of the household had to be willing to participate in the 6-week long study. A contact for each household was identified and was required to return to the study site once a week for 6 consecutive weeks. During each visit, the contact could choose from a selection of potato chips and tortilla chip products labeled as containing either olestra or triglyceride. The selection of snacks used in the study were products available in the marketplace presented in typical packaging. To encourage snack consumption, up to eight bags of chips (varying in weight from 5.5 to 9 oz) could be selected each week. For the households in the olestra group, the olestra-labeled packages contained olestra chips, but for the control group, the olestra-labeled packages contained triglyceride chips. For both groups, the triglyceride-labeled packages contained triglyceride chips. All olestra-labeled products displayed the olestra label statement.

At each weekly visit, the contact would also provide daily records kept by each member of the household regarding GI symptoms. The household contact assisted and/or completed the form for children. The record consisted of a check list of eight specific GI symptoms²⁴ as well as a field to write in any other symptoms. On each day a GI symptom was recorded, the subject was to rate the effect of those symptoms on daily activity using a scale ranging from "noticed but did not affect" to "missed all day at work/school." Medication use and physician visits were also to be recorded.

There were 1,620 subjects from 568 households in the olestra group and 1,561 subjects from 570 households in the control group. The groups were similar with respect to age, sex, and race. Subjects ate chips frequently throughout the study. The median number of days on which a subject consumed an olestra-labeled chip was 20 days of a possible 42 days for the olestra group and 21 of a possible 42 days for the control group. The length of the study and the large number of individuals per group resulted in a collective period of more than 30,000 "eating" days, making it possible to detect small differences in the reporting of GI symptoms. The median total amount of olestra-labeled chips eaten over the course of the study by the olestra group (25.2 oz) was slightly less

than that eaten in the control group (27.6 oz). During the 42-day study, subjects whose consumption was in the top 10 percent of the olestra group ate more than 59 oz of chips, while in the control group, the top 10 percent of the group ate more than 70 oz of chips. The petitioner presented data to show that the rates of olestra consumption achieved were beyond customary snacking by comparing the intake of olestra at the 90th percentile of consumption in this study (13.3 g/d) to Market Research Corp. of America (MRCA) preapproval estimates (6.4 g/d), and to data collected regarding "real-world" olestra consumption in the Active Surveillance Study (2.1 g/d). The petitioner concluded that the rates of consumption achieved in this study for both the olestra and triglyceride groups were higher than usual snack consumption.

The petitioner reported that for its original planned analysis for the study, which examined the percentage of eating days where GI symptoms were reported within 2 days, olestra-containing chips resulted in an increase ($p<0.05$) in the GI symptoms of more frequent bowel movements, loose stools, and gas. There was no increase in reports of abdominal cramping or any of the other individual or total GI symptoms. The petitioner decided that this analysis could not be clearly interpreted because olestra labeled chips were eaten on numerous days of the study and therefore a particular GI event would be associated with 2 or 3 eating days.

The petitioner presented data from an analysis that compared the occurrence and frequency of GI symptoms between the olestra and control groups. The primary response variable was the percentage of individuals reporting a GI event. For all subjects who consumed olestra-labeled products, the petitioner found that there was no difference in the total percentage of subjects reporting a GI symptom between the olestra and control groups. Of the eight GI symptoms evaluated, the only difference was an increased number of reports of nausea for the control group. For those subjects who reported a GI event, the number of symptom days was also compared. When the petitioner examined the data by days on which subjects reported symptoms, there was a small increase in the olestra group in the number of days when more frequent bowel movements were reported (3.7 days for olestra compared to 2.8 days for controls; $p=0.04$). The petitioner calculated that this increase was about one symptom day out of the 42 days of the study. The petitioner reported that

²² Of the 1,742 individuals originally enrolled for the study, 1,123 kept their appointments. Thirty-one individuals could not be contacted for followup, leaving a total of 1,092 evaluable subjects.

²³ Dr. R. Sandler, Professor of Medicine, University of North Carolina, Chapel Hill, was the principal investigator for this study.

²⁴ The list of GI symptoms include the following descriptions: (1) Heartburn or indigestion, (2) nausea or queasiness, (3) vomiting, (4) gas, (5) bloating, (6) abdominal cramping or pains, (7) more frequent bowel movements, and (8) looser stool.

subjects' self assessments showed little or no impact of GI symptoms on subjects' daily life, and there was no increase in the percentage of reported severe impacts in the olestra group compared to the control group.

The petitioner also examined whether there were differences in the incidence of reported GI symptoms among the different age groups. The petitioner reported that there were no significant differences in total or specific GI symptoms between the olestra and triglyceride groups for children (2 to 12 years; n=885), teens (13 to 17 years; n=227), or the elderly (65 to 89 years; n=402), even among the highest consumers. This analysis showed that for adults (18 to 64 years; n=1667), there was an increased percentage in reporting the GI symptom gas in the olestra group compared to the control group. There was also an increase in the number of GI symptom days, and an increase in the number of more frequent bowel movement symptom days, among adult subjects eating olestra of approximately one symptom day out of the 42 days of the study.

Among adult females in the olestra group, compared to adult females in the control group, there was an increase of approximately one symptom day out of 42 days of the study with regard to more frequent bowel movements, gas, and any GI symptom. The only difference regarding reports of abdominal cramping was an increase in the control compared to the olestra group for adult males.

The petitioner concluded, based on the subjects' self assessments, that none of these reported increases in the number of symptom days were meaningful because there was no impact on subjects' daily activities. Based on its comparison of the percent of subjects who reported one or more GI events during the course of the study, P&G concluded that there were no meaningful or serious GI effects associated with eating olestra-containing chips.

At the end of the 6-week study, P&G asked participants which kind of chips they thought they were eating from the olestra-labeled bags. P&G reported that the percentage of subjects reporting GI symptoms was greater (approximately 50 percent) in those who believed they were eating chips made with olestra compared to those who thought they were eating triglyceride chips. This was true regardless of whether the participant was actually eating olestra or triglyceride chips.

FDA employed a number of statistical approaches to best address the different questions to be answered by the study,

and while such differing approaches may yield different answers, this varied approach provides a more complete picture of the study results. FDA analyzed both the temporal relationship between consumption and symptoms, and summation data for the study (Refs. 15 and 16).

Examination of temporal data is important for evaluating an association between olestra intake and GI symptoms. Such an analysis is also important because in a study of this length, subjects can modify their eating behavior based on their experience with a product. FDA found that subjects in both the olestra and triglyceride groups modified their intake of chips as a result of experiencing more frequent bowel movements. FDA was able to conclude that consumers modify their behavior based on their experience with olestra chips by examining the amount of chips consumed the day before, the day of, and the day after a report of more frequent bowel movements. Chip consumption decreased after experiencing more frequent bowel movements, although consumption of chips did not cease.

In order to understand the temporal relationship between olestra consumption and GI symptoms, FDA examined the frequency of GI symptoms for numerous different patterns of olestra consumption over a period of several days.²⁵ In all these analyses, FDA found that for men, olestra consumption resulted in an increase in any GI symptom, gas, and more frequent bowel movements, and a decrease in nausea. For women, olestra consumption resulted in an increase in any GI symptom, gas, looser stools, and more frequent bowel movements. On the day that chips were eaten, the difference in the percentage of occasions that more frequent bowel movements were reported for the olestra chips compared to the triglyceride chips was

²⁵ These included determining the percent of occasions for which GI symptoms occurred on the same day and the following 2 days of eating an olestra-labeled chip; comparing the frequency of occurrence of GI symptoms on days that olestra-labeled chips were eaten to days that chips were not eaten to determine a "same day of eating effect"; determining the percent of days on which GI symptoms were reported for all non-eating days in order to evaluate possible delayed or continuing effects of olestra; comparing the percent of days on which GI symptoms were reported to the number of consecutive days eating olestra-labeled chips in order to examine possible cumulative effects; for various GI symptoms analyzing the pattern of consumption of olestra-labeled chips for the days prior to the GI symptom in order to examine how the most recent day of eating and the frequency of eating is related to the GI symptom; for various GI symptoms, determining the amounts of olestra-labeled chips consumed on the day the GI symptom occurred (Ref. 16).

1.6 percent for males and 1.2 percent for females. These effects were seen on days of consumption of olestra chips but not on subsequent days on which olestra-containing chips were not eaten. When olestra chips were consumed on consecutive days there was some cumulative effect for the reports of these GI symptoms. This was particularly true for males. For example, the difference in the percentage of occasions that a report was made in the category "any GI symptom" for the olestra chips compared to the triglyceride chips increased from 0.9 percent on the first day to 1.7 percent on the second day, to 2.6 percent on the third consecutive day that chips were eaten and a complaint was recorded. There was also a trend for more frequent and recent consumption of olestra to result in a GI symptom. While increasing consumption of olestra and triglyceride chips both resulted in more symptoms, the effect of olestra was greater compared to triglyceride chips at all doses.

In examining the effect of olestra consumption on different age groups, FDA found that GI symptoms were primarily seen in the 18 to 64 age group. There were no olestra-related effects in the groups over 65 years or younger than 18 years.

In a separate statistical analysis, FDA focused on the sum total of symptom days and consumption of olestra-labeled chips over the course of the 42-day study (summation data). FDA analyzed the data for each GI symptom for both the entire study population, and for a population divided based on age and gender.

In the statistical analysis of the sum total of symptom days over the course of the 42-day study, FDA first examined the relationship between the reporting of particular GI symptoms and the consumption of olestra-containing foods by comparing the olestra group and the triglyceride group. FDA found that for all study subjects (males and females) over the course of the 42 day study, there was an increase of 0.28 more frequent bowel movement symptom days in the olestra group compared to the triglyceride group. FDA then examined the relationship between the reporting of particular GI symptoms and the consumption of olestra-containing foods by analyzing the olestra group and the triglyceride group separately by gender. FDA found for females in the olestra group, there was an increase in "any GI symptom" of 0.5 mean symptom days compared to the females in the triglyceride control. It was also observed that for females in the olestra group, there was an increase of 0.3 symptom days in more frequent bowel

movements over the course of the 42 day study compared to females in the triglyceride group. For males in the olestra group, the analysis showed an increase of 0.24 more symptom days for more frequent bowel movements compared to males in the triglyceride group.

FDA then examined the relationship between the amount of product consumed and symptoms reported for all study subjects (males and females), and found there were associations between olestra consumption and reports of "any GI symptom" ($p=0.03$), loose stools ($p=0.006$), and more frequent bowel movements ($p=0.002$). No such associations were observed between the consumption of the control chips (triglyceride chips labeled as olestra) and any measured symptom. When analyzed separately by gender, both sexes showed trends for an association between the consumption of olestra and loose stools (males $p=0.001$, females $p=0.018$), and more frequent bowel movements (males $p=0.001$, females $p=0.042$), but only males also showed a trend for an association between the consumption of olestra and "any GI symptom" ($p=0.001$).

FDA examined the relationship between the consumption of olestra-containing foods and reports of abdominal cramping. FDA found no difference in the frequency of reported abdominal cramping between the olestra group and the triglyceride group. FDA analyzed the olestra and triglyceride groups separately by gender for reports of abdominal cramping and found no difference between males or females in the olestra group as compared to the triglyceride group. FDA agrees with the petitioner that there was no observed difference in the incidence or association of reported abdominal cramps between the olestra group and the triglyceride group (Ref. 10).

4. Stool Composition Study

The Stool Composition Study was sponsored²⁶ by the petitioner as a followup to the preapproval Fecal Parameters Study (discussed previously in section II.A.2 of this document). The study was designed to establish whether consumption of olestra-containing foods is associated with changes in clinical measures of diarrhea (water and electrolyte loss), effects which may be harmful, or stool consistency alone, which may result from adding bulk to the stool and which is not harmful. In addition, the study was designed to determine the relationship between

objective measures of clinical diarrhea (e.g., stool water output and bowel movement (BM) frequency) and subjective reports of "diarrhea" from study subjects. The effects of olestra were compared to a placebo, triglyceride chips, and to sorbitol, an osmotically active sugar alcohol that was chosen as a positive control to ensure that the study methodology was adequately sensitive to detect increases in stool water output.

The study was a single-site, randomized, double-blind, placebo-controlled parallel clinical trial. Sixty-six subjects, ages 18 to 74, were housed on a metabolic ward for 12 days and consumed meals ad libitum. The meals conformed to the American Heart Association Step 1 diet guidelines (no more than 30 percent of calories from fat). Beverages were available ad libitum. All study subjects had to consume 5 oz of potato chips eaten as two afternoon snacks. A serving of potato chips was either olestra (test) or triglyceride (placebo). All subjects were also required to consume 1.5 oz of candy made either with sorbitol (test) or sucrose (placebo) as a morning snack. The first two days (study days 1 and 2) were a lead-in period during which subjects were acclimated to the living conditions and the diet, and consumed placebo snacks (triglyceride potato chips and sucrose candies). Stool samples were not collected during the lead-in period. The next 4 days (study days 3 to 6) comprised the baseline period, in which subjects continued to consume placebo snacks, and all stool samples, BM ratings, and GI symptoms were collected. For the final 6 days (study days 7 to 12), subjects consumed snacks according to their randomly assigned treatment group, and all stool samples, bowel movement ratings, and GI symptom reports were collected. There were two olestra test groups (20 g and 40 g olestra) and two control groups (positive control of 40 g sorbitol and placebo). The placebo group consumed two servings of placebo (triglyceride) potato chips and placebo (sucrose) candy. The positive control group consumed two servings of placebo potato chips and test candy (40 g sorbitol). The 20 g olestra test group consumed one serving of test potato chips (olestra), one serving of placebo potato chips, and placebo candy. The 40 g olestra group consumed two servings of test chips and placebo candy.

The petitioner noted that in the study the doses of olestra were threefold to sixfold more than the estimated daily intake, and 10 to 20 times more than the observed intake at the 90th percentile level in the Active Surveillance Study

(see section III.D.1 of this document). The high dose, 40 g/d, was higher than the highest dose used in the preapproval nutrition studies (32 g/d) described previously in section II.A.3 of this document, in which the high dose group experienced an increase in GI symptoms, specifically in reported diarrhea/loose stools. In that preapproval study, FDA concluded that the reported diarrhea was not diarrhea in the medical sense because there was no evidence of subjects experiencing significant fluid or electrolyte loss (hemoconcentration, electrolyte imbalance; 61 FR 3118 at 3152-3154).

The petitioner concluded that with regard to the critical parameters that are medically relevant in defining diarrhea, the objective measures showed that olestra did not meaningfully change either the total stool output or stool water output, while sorbitol produced large effects on both parameters. Compared to baseline, mean stool water output increased 9 g/d and 37 g/d for the 20 and the 40 g/d olestra groups respectively, and 325 g/d for the 40 g/d sorbitol group. Stool water output decreased 28 g/d for placebo. The measured mean stool water content for the sorbitol group was nearly 10 times greater than the group consuming the highest level of olestra and the number of watery BMs was 140 in the sorbitol group, one in the 40 g/d olestra group, none in the 20 g/d, and one in placebo. While sorbitol significantly increased the severity of abdominal cramping compared to placebo, olestra did not. The petitioner found that olestra consumption did not result in any clinically meaningful increases in objective measures of diarrhea, namely, total stool output, bowel movement frequency, and stool water and electrolyte output. The mean number of BMs for the olestra 40 g/d group was increased compared to placebo but was not increased compared to the olestra 20 g/d group. Subject reports of "watery, difficult to control diarrhea" did not necessarily correlate with measured viscosity of the stool. Olestra did increase stool weight in proportion to the amount eaten, and daily consumption of olestra gradually softened stool in a dose-responsive manner. The sponsor found that there was increased reporting of "diarrhea" in the olestra treatment groups during the treatment phase without an increase in total water output outside the normal range, i.e., the range observed during the baseline period and in the placebo group.

P&G concluded, based upon the study results, that the consumption of olestra

²⁶The GI consultant to the study was Dr. R. Gianella, University of Cincinnati.

does not cause diarrhea, but simply adds bulk and softening to the stool.

FDA reviewed the data from this study and agrees with the petitioner's analysis, although some of the agency's analytical strategies differed from those of the sponsor (Ref. 17). FDA concludes that both comparisons of the mean after treatment and of changes from baseline showed dose responsive increases in stool characteristics (total output, water output, consistency, frequency and increases in water content) that were not clinically significant (Ref. 18).

Using a 7-point scale to rate consistency of bowel movements (1 = watery, diarrhea; 4 = normal; 7 = hard, constipation), subjective ratings of stool consistency showed that subjects who ate 40 g/d olestra perceived their stools to be looser (mean rating 2.4) compared to those who ate 20 g/d olestra (mean rating 3.1). By comparison, placebo subjects had a mean score of 3.9 whereas those subjects in the 40 g/d sorbitol group had a mean score of 1.5 (mean scores determined for days subjects consumed snacks according to their randomly assigned treatment group). When stool consistency was measured by peak force value for extrusion, both olestra groups had a lower mean stool consistency than placebo and the 40 g/d olestra group was lower than the 20 g/d group. These dose responsive findings seen among subjects eating olestra resulted from gradual stool softening effects observed after several consecutive days of olestra consumption. Although subjects characterized these viscosity changes as "diarrhea," the changes were not associated with an increase in stool water.

FDA examined the percentage of symptom days for cramping and found that although the 40 g/d olestra group reported an increased incidence of abdominal cramping compared to those in the 20 g/d olestra group (35.8 percent compared to 9.8 percent), this difference did not rise to statistical significance. The percentage of subjects reporting abdominal cramping in the 20 g/d olestra group appeared to decrease when compared to baseline or placebo (9.8 percent compared to 20.5 percent or 18.3 percent). The 40 g/d sorbitol group had the highest percentage (69.8 percent) of reports of cramping. Subjects rated symptom severity on a scale of 0 to 5, with 0 representing none and 5 extreme. The severity of cramps reported by subjects in the olestra 40 g/d group was less severe than that reported by subjects in the 40 g/d sorbitol group (0.72 compared to 2.3). No significant olestra effects were found for GI symptom severity, although one

individual in the 20 g/d olestra group reported severe urgency at a rating higher than any other report in any of the other groups (Refs. 10 and 18).

5. Comments Regarding the GI Studies

FDA received comments about the new GI studies. FDA considered these comments and responds in the following paragraphs. Comments regarding the label statement for GI effects will be discussed in section V of this document.

(Comment 5) A comment from CSPI to the current petition criticized the Rechallenge Study. The comment stated that the study subjects were not screened for sensitivity to olestra, as was done in the preapproval Fecal Parameters Study. The comment also asserted that the Rechallenge Study contained a strong likelihood of bias because only 10 percent of those contacted agreed to participate in the rechallenge and those that did participate consumed olestra on only 2 days, at least 1 week apart, which reduced the sensitivity of the study. CSPI asserted that the Rechallenge Study also assumed that those sensitive to olestra would respond to it 100 percent of the time. The comment contended that those experiencing adverse reactions may only do so under certain circumstances, not 100 percent of the time.

FDA does not agree that the selection of study subjects biased the Rechallenge Study nor does CSPI provide such evidence. FDA has determined that the subjects who participated in the Rechallenge Study were adequately representative of those persons who contacted the postmarketing surveillance system in terms of severity of initial symptoms and amount of olestra reportedly consumed prior to the initial symptom episode (Ref. 11). Further, CSPI provided no basis for its assertion that additional subject screening is necessary to accomplish the objectives of the Rechallenge Study.

CSPI states that the sensitivity of the Rechallenge Study was reduced because participants consumed olestra on only 2 days, at least 1 week apart. The conditions of the study were designed to be similar to the conditions under which the subjects originally reported effects that they attributed to consuming an olestra-containing snack. FDA found that for nearly three-quarters of the subjects, the amount of olestra consumed in the study was comparable to, or greater than, the amount associated with their initial symptom episode (Ref. 11). In addition, more than three-quarters of the subjects reported that their initial symptom episode

occurred after a single eating occasion. Therefore, subjects were challenged with 2 oz of olestra chips on two occasions separated by a week, providing a dose and number of exposures comparable to, or greater than, those associated with many of the subjects' initial symptom episodes.

CSPI's comment did not reference where FDA or the petitioner assumed that those sensitive to olestra would respond to it 100 percent of the time, nor is FDA aware of anyone who has put forth such a position. Indeed, FDA agrees that even if an individual experiences a reaction to olestra, that individual may not experience such reaction after every exposure. The Rechallenge Study shows that subjects exposed to olestra containing-chips were no more likely to report GI symptoms than when exposed to an equal amount of triglyceride chips. Thus, the study subjects' reactions to olestra containing-chips are not so frequent that they can be distinguished from their reactions to regular chips under the conditions of the test.

(Comment 6) A comment from CSPI to the current petition criticized the Acute Consumption Study. CSPI's comment relies on its published letter²⁷ commenting on a published study (Ref. 12.) that reports data from the Acute Consumption Study. CSPI stated that the study may have failed to detect the true incidence of GI effects due to a lack of statistical power or inadequate controls. For example, with the incidence of "any GI event" of about 15 percent, 550 subjects in each group would have provided only about a 50 percent probability of detecting a 5 percent actual increase in the treatment group. Along the same lines, diarrhea and loose stools were increased less than 1 percent in the olestra group compared to baseline levels of 2.6 percent and 1.1 percent, respectively. The comment asserted that maintaining 80 percent power to detect a 1 percent increase over a 2 percent baseline requires about 4,000 subjects per group. The comment also contends that the darkened movie theater may potentially cause exposure misclassification (some "olestra eaters" may have eaten few or none of their chips; some "non-olestra eaters" may have eaten friends' olestra chips). The comment also stated that it took up to 10 days after consumption to assess symptoms. CSPI also pointed out that non-olestra eaters consumed one-third more chips than the olestra eaters.

The criticism by CSPI of the Acute Consumption Study does not negate the

²⁷ CSPI's published letter was included in the comment as an attachment (Ref. 19).

conclusion that FDA reached in its analysis of the study. The Acute Consumption Study was conducted to provide information relevant to whether olestra-containing foods should bear a label statement that informs consumers about the potential GI effects associated with olestra. FDA points out that the Acute Consumption Study was only one of several studies under consideration in this petition, and that the agency's decision on the petition is based on the totality of evidence in the record.

While the petitioner's Acute Consumption Study did not achieve the statistical power that P&G originally desired (80 percent power to detect a 5 percent difference between treatment groups), the study still provides meaningful information concerning the effect of olestra-containing foods on the GI system. FDA's scientific review determined that the study does have 80 percent power to detect a 7 percent difference between treatment groups (Ref. 13). The study showed that there was no difference in the rate or severity of loose stools or abdominal cramps between subjects who ate olestra-containing chips compared to those who ate triglyceride-containing chips.

The comment provides no evidence that the darkened theater or the method used to collect symptom data affected the outcome of the study. As discussed previously, the study protocol was designed to minimize the possibility of inaccurate measurements or subjects' sharing of chips. For example, study participants were instructed to be seated in the theater at least one seat away from other participants and not to share their chips or beverage with anyone else. The theaters were also monitored by several staff during the movie.

Similarly, the comment did not explain the effect on the study results, if any, from the 10-day period used to assess symptoms. After the movie, trained telephone interviewers contacted study participants and administered a recall questionnaire to collect information on any effects experienced since the movie. The study protocol specified that participants be contacted within 2 to 4 days of viewing the movie. The petitioner reported that 85 percent of study subjects (962 of the 1,092) were contacted within 2 to 4 days of viewing the movie, an additional 124 subjects were contacted in 5 to 10 days.²⁸

FDA agrees that the median chip consumption for the control group was greater than that for the olestra group.

As discussed previously, the Acute Consumption Study was designed to be an ad libitum study, allowing the investigators to examine the effects of customary or usual consumption. As an ad libitum study, it is possible that one group of subjects may consume more chips than the other. For example, the median consumption of chips made with olestra was 2.1 oz compared to 2.7 oz for chips made with conventional triglycerides. CSPI did not explain how the fact that one group of subjects ate more chips than the other affects the conclusions drawn from this study regarding the need for special labeling.

(Comment 7) A comment from CSPI to the current petition criticized the Home Consumption Study. CSPI's comment relies on its published letter²⁹ commenting on a published study that reports data from the Home Consumption Study (Ref. 14). The comment raises five issues: (1) The comment stated that some of the data relating to the highest decile of olestra consumers were overlooked; (2) the comment argued that it is important to focus on the small number of heavier consumers because most subjects ate relatively few olestra-containing chips; (3) the comment stated that in the highest decile of olestra consumers the incidence of more frequent bowel movements and loose stools was twice that of controls; (4) the comment stated that olestra consumers in the highest decile had symptoms on 18 percent of person-days, compared to 12 percent of person-days in the control group (table 4 in Ref. 14); and (5) the comment pointed out that olestra consumers missed some or all of their activities on 0.4 percent of days, compared to 0.2 percent in the control group.

Prior to publication of the article concerning the Home Consumption Study (Ref. 14), FDA conducted its own in-depth analysis of the raw data from the Home Consumption Study (Refs. 15 and 16) and described this analysis at the 1998 FAC meeting in which CSPI participated. FDA's analysis included an estimate of the extra symptom-days experienced by subjects in both the 90th and 95th percentile of olestra-containing chip consumption (Ref. 15). Subjects at the 90th percentile ate 64 oz of olestra-containing chips over the course of the study while those at the 95th percentile ate 83 oz of olestra-containing chips over the course of the study. Although CSPI alleges that the subjects in the study ate relatively few olestra-containing foods, the petitioner presented data to show that, in fact, the

rates of olestra consumption achieved in the study were beyond usual snack consumption.

As part of the Home Consumption Study, the investigators considered the effect of GI symptoms on subjects' daily activities. In its comment, CSPI points out that olestra consumers missed some or all of their activities on 0.4 percent of days, compared to 0.2 percent in the control group, implying that this is significant. FDA disagrees.

CSPI does not explain how it calculated the percentage of days on which subjects missed some or all of their activities, nor does CSPI provide statistical analyses to assess whether these differences occurred by random chance (e.g., illness unrelated to olestra). FDA was able to replicate the numbers that CSPI presented and performed tests of statistical significance on the data. The actual number of days on which subjects in the highest decile missed some or all of their activities is very small (9 of 2,226 days in the olestra group versus 5 of 2,646 days in the control group). Five subjects in the olestra group and four subjects in the control group missed some or all activities at least 1 day. The number of subjects missing activities and the number of days missed by these subjects are comparable for the olestra and control groups, except for one subject in the olestra group who missed some or all activities on 4 days (Ref. 21).³⁰ From these data, it cannot be concluded that for the highest decile of consumers olestra consumption resulted in an increase in days in which consumers missed some or all activities. FDA believes that the Home Consumption Study, designed to examine the effects of "real life" olestra consumption, provides useful information relevant to the labeling of olestra-containing foods. CSPI does not show how their analysis would change FDA's conclusions.

(Comment 8) A comment from CSPI to the current petition criticized the petitioner's Stool Composition Study. The comment stated that this study does not negate and should not supersede the two preapproval 8-week studies or the preapproval Fecal Parameters Study. In its comment, CSPI cites a 1995 FDA memorandum discussing the Fecal Parameters Study (Ref. 22) and asserts that the memorandum says that several

³⁰ Sophisticated statistical models are impractical for such a small number of cases. However, a Fisher's Exact test showed that the proportion of subjects in the olestra group who missed some or all activity at least 1 day was not significantly different (p-value of 0.73) from the proportion of subjects in the control group who missed some or all activity at least 1 day.

²⁸ Of the remaining subjects, three were contacted on the day of the movie, one within a day, and two within 23 days (Ref. 13).

²⁹ CSPI's published letter was included in its comment as an attachment (Ref. 20).

subjects in the study experienced high rates of water loss through their stool. The comment also stated that the definition of diarrhea used in the Stool Composition Study was too narrow and is not consistent with the definition used by the Centers for Disease Control and Prevention (CDC; three or more loose stools in a 24 hour period). The comment asserted that self-reporting is usually considered sufficient to conclude that people experience diarrhea regardless of demonstrated loss of electrolytes.

In contrast to the Acute Consumption Study, the Home Consumption Study, and the Rechallenge Study, the Stool Composition Study was designed to extend the understanding of olestra's effect on stool characteristics that would potentially represent a safety concern. For this reason, the Stool Composition Study was conducted under conditions most likely to elicit GI effects. The highest dose of olestra provided in the Stool Composition Study (40 g/d) was greater than the 32 g/d used in the preapproval 8-week studies which was shown to cause an increase in GI symptoms (specifically in reported diarrhea/loose stools) and was twice as high as the highest dose given in the preapproval Fecal Parameters Study (20 g/d). Additionally, subjects' stool samples were collected for all 6 days of the treatment period in the Stool Composition Study, compared to only three days of the 7-day treatment periods in the Fecal Parameters Study. The Stool Composition Study does not negate the preapproval studies, but the results of the preapproval studies must be considered in light of those from the Stool Composition Study.

The results of the Stool Composition Study show that olestra consumption does not result in any clinically meaningful increases in the objective measures of diarrhea. Importantly, the Stool Composition Study assessed the effects of olestra consumption using objective parameters such as total stool output, bowel movement frequency,³¹ and stool water and electrolyte output rather than a subject's subjective assessment of whether he or she experienced diarrhea. The use of objective measures of diarrhea is necessary to assess whether the "diarrhea" experienced by study subjects represents a safety concern.

³¹ FDA notes that the mean bowel movement frequencies in the olestra-consuming groups were less than three bowel movements per day. The mean bowel movement frequencies were 1.6 ± 0.2 BM/d (mean \pm standard error) in the 20 g/d olestra group and 2.0 ± 0.2 BM/d (mean \pm standard error) in the 40 g/d olestra group (Ref. 18).

FDA was concerned with the potential for olestra to cause diarrhea because diarrhea of medical significance is associated with excessive water loss and electrolyte loss, which may raise safety concerns. The Fecal Parameters Study memorandum cited by the comment states that the stool water concentration of subjects who reported having diarrhea during the olestra 20 g/d period did not differ from that of their nondiarrheal stools during the placebo period. The memorandum also states that although the percent of water in the stools may not have differed, it is possible that absolute water loss was greater in subjects reporting olestra-associated diarrhea because of the greater mass (weight) of stool passed. FDA concluded in the 1996 final rule that the loose stools experienced in the preapproval clinical studies were not diarrhea in the medical sense because they were not associated with loss of water or electrolytes (61 FR 3118 at 3159). The agency also stated that even those subjects in the 8-week studies who experienced loose stools or diarrhea continuously for several weeks during olestra consumption did not show any evidence of fluid loss such as hemoconcentration or electrolyte imbalance. Thus, the agency determined that olestra-related GI effects were not adverse health effects (61 FR 3159). The results of the Stool Composition Study confirm the agency's 1996 decision that the GI effects resulting from olestra consumption do not represent adverse health effects, regardless of the terminology (diarrhea or otherwise) used to describe these effects.

D. A Study Regarding Nutritional Effects—Active Surveillance

As discussed previously in section II of this document, olestra is neither digested nor absorbed, and as such, passes intact through the digestive tract where it can interact with fat-soluble dietary components present in the gut at the same time. Fat-soluble nutrients and components tend to partition or dissolve into the olestra, thereby reducing the absorption efficiency of these substances (61 FR 3118 at 3144–3149). Olestra does not interfere with the absorption of macro-nutrients (protein, carbohydrates, and fats) or water-soluble nutrients (61 FR 3118 at 3149–3152). The clinical studies conducted in support of the 1996 final rule examining the effect of olestra on fat-soluble components of the diet were performed under conditions that maximized the interaction of olestra with these dietary components, *i.e.*, olestra was incorporated into foods eaten at every meal. These studies were not designed

to examine effects from the usual or customary consumption of savory snacks made with olestra (*see* section II.A.3 of this document).

To compensate for the effect of olestra on the absorption of the fat-soluble vitamins A, D, E, and K, FDA required that these vitamins be added to olestra-containing foods. The level of addition was chosen to ensure that there would be neither a reduction in the absorption of fat-soluble vitamins from the diet, nor an increase in vitamin levels due to the presence of the added vitamins in the olestra-containing foods (see section II.A.3 of this document). Although FDA noted that olestra interferes with the absorption of carotenoids, FDA found no scientific basis for requiring the addition of any carotenoid to olestra-containing foods (61 FR 3118 at 3147–3149).

As outlined by the petitioner in its January 24, 1996, letter to the agency, P&G established a program of active surveillance. A report of this surveillance with results and analysis from the first year at the sentinel site was submitted to the agency on April 15, 1998. Additionally, the agency has continued to review and evaluate new data and information that bear on the safe use of olestra, such as new data and information on the health significance of carotenoids.

1. Active Surveillance Study by P&G

The petitioner provided funding to investigators at the Fred Hutchinson Cancer Research Center in Seattle, WA, to design and implement a multi-year, Active Surveillance Study to monitor patterns of use of olestra-containing savory snack products and to collect blood samples to measure nutrient status (Ref. 23). The study had three specific goals: (1) To monitor adoption and patterns of use of olestra-containing savory snack products in representative samples of the U.S. population; (2) to assess the association between the introduction of olestra-containing savory snacks and serum concentrations of carotenoids and fat-soluble vitamins in representative cross-sectional samples of the U.S. population; and (3) to assess the long-term association between consumption of olestra-containing savory snacks and serum concentrations of carotenoids and fat-soluble vitamins among a cohort of olestra consumers.

The study has three components corresponding to the three specific aims. The first component, called the population cross-section, was a telephone survey used to monitor the prevalence and patterns of olestra-containing savory snack consumption,

fruit and vegetable consumption, and triglyceride savory snack food consumption by consumers. Demographic information was collected as well. A telephone survey was conducted in each of the study sites before olestra-containing snacks were marketed. Subsequent yearly surveys were completed after olestra-containing snacks were introduced to the market.

A random sample of participants in each telephone cross-section sample was recruited into the second component, a clinical cross-section. The clinical cross-section was an investigation of the relationships among nutrient intake, olestra consumption, and serum nutrients. Study participants visited a clinic to provide further information, including dietary information, medical histories, and blood samples. Followup telephone interviews included questions about usual fruit, vegetable, and snack food use during the previous month, a 24-hour dietary recall to measure co-consumption of fruits and vegetables with savory snacks, health symptoms and status, and a short household food inventory.

Within the clinical cross-section, information on olestra intake was used to select olestra users from non-users to be recruited into the third component of the Active Surveillance Study, *i.e.*, the clinical cohort study. The clinical cohort study was an investigation of the relationships among nutrient intake, olestra consumption, and changes in serum nutrients over time. Participants in the clinical cohort are a subset of those people who participated in the Year 0 clinical cross-section and were monitored annually over the course of the Active Surveillance Study. The clinical cohort was designed to have an over-representation of consumers of olestra-containing snack food. The design for the clinic visit and the information gathered is the same as for the clinical cross-section.

The study was conducted in four U.S. cities. As of the publication of this document, data are available only from the sentinel site, Marion County, IN, where test marketing began in 1997.³² The study began one year later in the other cities, because national marketing of olestra-containing foods in those areas began later.

The first component of the active surveillance is the population cross-section. A random-digit-dial telephone survey of Marion County, IN, residents was completed before olestra-containing

foods were marketed in that area (February 1997). This survey (Year 0) included 1,962 adults, aged 18 years and over. The second telephone survey was completed after olestra-containing foods were introduced to the local market (between August 1997 and January 1998). This survey (Year 1) included 1,525 adults, aged 18 years and over. Based on the Year 1 data, which are weighted to be representative of the Marion County population, 15.5 percent of adults reported eating olestra-containing snacks one or more times per month with the median frequency being three times per month. Ninety percent of adults reported eating one or more servings of fruits and vegetables per day, thus providing a basis for assessment of any effects on dietary carotenoid absorption. Intake of fruits and vegetables and intake of total snacks did not change in the population cross-section between Year 0 and Year 1. Olestra-containing snack food introduction was not associated with an overall increase in savory snack consumption or with a decrease in fruit and vegetable intakes. There was a modest decrease in consumption of reduced- and non-fat savory snacks at Year 1 compared to Year 0.

Blood sera from study subjects, in both the cross-sectional and clinical cohorts, were analyzed for vitamins A, D, E, and K, total cholesterol, high density lipoprotein (HDL) and triglycerides, and the six major carotenoids that represent more than 90 percent of the circulating carotenoids (alpha and beta carotene, lycopene, lutein, zeaxanthin, and beta-cryptoxanthin). The study investigators then compared these serum measures based on olestra intake. Four olestra consumption groups were defined: (1) None; (2) low (less than 0.4 g/d of olestra, which is less than the 60th percentile of consumption); (3) medium (between 0.4 and 2.0 g/d of olestra, which is between the 60th and 90th percentiles of consumption); and (4) high (greater than 2 g/d, which is greater than the 90th percentile of consumption).

Results from the cross-sectional study comparing 1,252 subjects in year 0, and 1,164 subjects in year 1, show that with increasing olestra intake, there were significant trends for an increase in vitamin K levels ($p = 0.013$) and a decrease in serum cholesterol ($p < 0.05$). There were no significant differences or trends found for other vitamins or for total carotenoid or individual carotenoids that could be associated with olestra consumption.

For the clinical cohort (477 study participants), the sponsor reported that

for the entire cohort from year 0 to year 1, there was a decrease in mean serum concentrations of total carotenoids, as well as in concentrations of retinol, 25-OH vitamin D, lycopene, lutein, and zeaxanthin, and an increase in beta-cryptoxanthin. Tests of association between olestra consumption and changes in serum concentrations of fat-soluble vitamins and carotenoids were based on regression models that included variables to characterize the four levels of olestra consumption. However, these changes were not related to the amount of olestra consumed. A trend was observed for increased vitamin K, but the change did not reach statistical significance ($p = 0.087$). There were no changes observed for the other vitamins.

The petitioner cautioned that the results discussed previously reflect data from only the first year that olestra products were marketed, and that data were available from only a single site. With these caveats, the petitioner reached the tentative conclusion that it appeared that the consumption of olestra-containing foods in the marketplace had little, if any, effect on the status of fat-soluble vitamins and nutrients as measured by serum concentration.

FDA notes that survey results show that the co-consumption of savory snacks (made with or without olestra) with a fruit or vegetable was relatively rare. Overall, less than 15 percent of total carotenoids were consumed with any savory snack. Olestra's effect on the absorption of fat-soluble carotenoids is greatest when co-consumed with the source of the carotenoid. Interference with absorption of carotenoids diminishes and then disappears as the time between eating an olestra-containing food and a carotenoid-containing product increases.³³

In the clinical cross-sectional sample, 217 of 947 individuals reported eating at least one olestra-containing food in the previous month with a median intake of 8.1 g of olestra per month. The 90th percentile consumption level was 64 g of olestra per month. Of the 402 clinical cohort participants who were considered consumers of olestra, only 139 reported eating any olestra-containing foods in the previous month. The median frequency of eating olestra-containing foods for this group of consumers was 1.01 times per month with a median intake of 11.9 g of olestra per month. The 90th percentile

³² The other three cities in the Active Surveillance Study were Baltimore, MD, San Diego, CA, and Minneapolis, MN.

³³ The precise length of time olestra interferes with absorption varies with the dose of olestra, and also varies somewhat from individual to individual, as GI transit time is variable among individuals (61 FR 3118 at 3144).

frequency of eating olestra-containing foods was six times per month with a 90th percentile intake total of 70.6 g of olestra per month.

FDA notes the infrequent and small olestra ingestion reported in the study. These reports are drawn from participants' "real-life" use of snacks made with olestra. FDA evaluated whether there were changes in serum levels of carotenoids and fat-soluble vitamins from year 0 to year 1 in the clinical cohort. FDA also evaluated whether olestra consumption was associated with changes in serum carotenoid status and fat-soluble vitamins. FDA noted the various changes in serum measures (a drop in total serum carotenoids as well as in concentrations of vitamins A and D, lycopene, lutein, zeaxanthin, and an increase in beta-cryptoxanthin) seen in the clinical cohort group from year 0 to year 1. FDA also noted that there is a lack of association in the clinical cohort between olestra ingestion and any nutrient changes, and therefore, the changes are unlikely to be caused by olestra consumption (Ref. 24).

2. Comments Regarding the Active Surveillance Study

FDA received comments about the Active Surveillance Study. FDA considered these comments and responds in the following paragraphs.

(Comment 9) Comments from CSPI and academia to the current petition asserted that P&G's Active Surveillance Study showing that olestra consumption produced no change in carotenoid levels provides little useful data because the subjects consumed only small amounts of olestra. CSPI stated that study subjects consumed no more than 2 g of olestra/day (approximately one-fourth to one-fifth of a serving of an olestra-containing snack per day) and only about 15 percent of adults in the study ate at least one olestra-containing snack per month. The comment from academia stated that any assumption about the effects of olestra on blood carotenoid levels should be based on the strong likelihood that at least some individuals will consume 1 to 4 oz of olestra-containing potato chips on a daily basis, the effects of which are addressed in the preapproval studies.

The Active Surveillance Study is only one piece of information in the current petition. It was designed to assess the effects of olestra consumption on serum carotenoids and fat-soluble vitamins under customary or usual consumption conditions. As such, it complements the preapproval studies, which were conducted using consumption scenarios designed to assess the safety of olestra's

effects on serum carotenoids and fat-soluble vitamins. The highest dose of olestra consumed in the preapproval studies was 32 g/d, which is equivalent to eating approximately 4 oz of olestra-containing chips; in contrast to the Active Surveillance Study, in the preapproval studies olestra was consumed in a variety of foods for which it is not approved for use. FDA noted in the 1996 final rule that it was likely that olestra's effects on carotenoid absorption would be substantially less than those observed in the 8-week studies (61 FR 3118 at 3149). Under the conditions of the 8-week studies, which were designed to assess safety, FDA found supplementing olestra with vitamin A to compensate for the provitamin A function of beta-carotene addressed the possible safety concerns about carotenoid loss in olestra-containing foods. The comments provide no evidence to contradict FDA's 1996 conclusions.

FDA agrees that P&G's active surveillance did not identify high levels of olestra consumption. Importantly, however, the levels of olestra consumption identified in P&G's Active Surveillance Study provide information about customary or usual consumption which is relevant to the labeling issue raised by this petition.

E. Consultations and Literature Review Regarding Nutritional Effects

FDA considered data and information that became available after the 1996 decision in assessing whether the scientific understanding of the possible human health benefits of carotenoids has changed since FDA's 1996 decision, and whether new information should be reflected in the label statement.

The petitioner conducted a literature review of all peer-reviewed articles published between January 1996 (when the 1996 final rule was published) and May 1998, just prior to the FAC meeting, concerning possible health effects of carotenoids. This review included more than 200 references to carotenoids and their possible role in human health (Refs. 25 and 26). The petitioner's conclusion was that the reviewed data did not establish that consumption of carotenoids confers protection from disease.

FDA considered data and information discussed at the 1998 FAC meeting. The petitioner presented its review of the scientific literature on carotenoids and human health. The petitioner sponsored a study that was presented to the FAC that found no significant association between macular pigment density with olestra intake. The researchers testified that the relationship between the

carotenoid-rich macular pigment and the disease process was yet to be understood.³⁴

At the FAC, the petitioner called upon Dr. Gilbert Omenn³⁵ to present results from intervention studies with beta-carotene.³⁶ These studies indicated that there was an association between beta-carotene intake and increased risk for lung cancer within the study groups.

During the open public hearing portion of the FAC meeting, a number of individuals that the petitioner invited as experts spoke about the potential role carotenoids play in human health and expressed the view that carotenoids do not explain the cancer preventive effect of fruits and vegetables.³⁷

At the FAC meeting, CSPI, and the individuals they called upon as experts, asserted that a consensus had been developing among the scientific community that carotenoids are likely to reduce the risk of certain chronic diseases. For example, Dr. Graham Colditz of Harvard Medical School said that a low intake of carotenoids is associated with an increased risk of cardiovascular disease and certain cancers.³⁸

Most members of the FAC expressed the view that epidemiological data show a decreased risk for certain chronic diseases and cancer with increased intake of fruits and vegetables. The increased intake of fruits and vegetables is associated with an increased serum level of carotenoids (which are a component of fruits and vegetables), but it is yet to be determined what, if any, specific role carotenoids play, and at what level they may be required in the diet.³⁹

The Panel on Dietary Antioxidants and Related Compounds, Food and Nutrition Board, Institute of Medicine (IOM), National Academy of Sciences (NAS) published a report in 2000 (Ref. 27). The panel that produced the report considered dietary antioxidants and other compounds to assess the required daily intakes for these nutrients. The NAS panel noted that there is a considerable body of research relating blood levels of carotenoids with a lower risk for some chronic diseases. However, the NAS panel concluded that this evidence did not support a requirement for carotenoid intake because the observed effects may be due

³⁴ Transcript, vol. 2, pp. 197, 201, 210.

³⁵ At the time Dr. Omenn was Executive VP Medical Affairs and CEO, University of Michigan Health System and was a principal investigator for the CARET study.

³⁶ Transcript, vol. 2, pp. 154-160.

³⁷ Transcript, vol. 2, pp. 32-34, 42-44.

³⁸ Transcript, vol. 2, pp. 233-247.

³⁹ Transcript, vol. 3, pp. 102-174.

to other factors related to fruit and vegetable intake. Intervention studies designed to test whether carotenoids (specifically beta-carotene) had any direct protective benefits for health did not show any benefit compared to the control (placebo supplement), and indicated that there was an increased incidence in disease (lung cancer) for certain at-risk sub-populations (smokers). The panel did not propose establishing a dietary reference intake (DRI) for beta-carotene or any other carotenoid (Ref. 27).

FDA considered the NAS report on carotenoids and concluded that the evidence concerning carotenoids and the conclusions that could be drawn from the evidence about carotenoids and human health had not substantially changed since the 1996 decision. FDA acknowledges that investigations are continuing on carotenoids to better understand biochemical mechanisms and genetic controls of these substances, and what, if any, role carotenoids have in human health (Ref. 28).

In the fall of 2000, FDA consulted with the NEI for an update as to whether there had been a change in the understanding of the science regarding lipophilic carotenoids and eye health since FDA last consulted with NEI on this question prior to the 1996 final rule (Ref. 29). The NEI said that no specific vitamin or carotenoid had been established as protective against macular degeneration (Ref. 30). The NEI also said that the ongoing "Age-Related Eye Disease Study" (AREDS) includes a randomized clinical trial of an antioxidant combination (beta-carotene, Vitamins C and E) or zinc that is evaluating the effect of these nutrients on macular degeneration and cataracts.⁴⁰ Other investigations continue to explore the hypothesis that oxidative damage to the retina increases the risk of macular degeneration and that antioxidant nutrients and carotenoid pigments concentrated in the macula may protect against this damage (Ref. 30).

⁴⁰ Since FDA's consultation with the NEI in the fall of 2000, the ongoing AREDS study published a report of a randomized clinical trial of an antioxidant combination (beta-carotene, Vitamins C and E) or zinc evaluating the effect of these nutrients on macular degeneration and cataracts (Ref. 31). Results of the study showed that a combination of antioxidants (vitamin C, vitamin E, beta carotene) and zinc reduced the probability for the development of advanced age-related macular degeneration (AMD) in study subjects who were at high risk for developing AMD. The groups given only antioxidants, or only zinc, did not show this reduction in rates of at least moderate visual acuity loss.

F. Consumer Perception Studies of the Label Statement

P&G and Frito-Lay submitted data from studies designed to test consumer understanding of the label statement required by the 1996 final rule as comments to that final rule. Additional reports of testing, conducted after the original comment period for the label statement closed on April 1, 1996 (61 FR 3118 at 3160), were also submitted to the agency. These reports are discussed in the following paragraphs.

1. 1996 Consumer Studies

On April 1, 1996, P&G submitted consumer studies conducted on the label statement required on olestra-containing foods. These studies were completed before olestra-containing foods were available in the marketplace. The petitioner did both qualitative (focus group) and quantitative (small intercept, detailed questionnaire) testing. The objective of the qualitative research was to determine how consumers comprehended the required label statement and to develop potentially more informative label statement(s) for use in subsequent quantitative research. The objective of the quantitative research was to understand how the required label statement and alternative label statements communicate to consumers, to understand issues raised by the various label statements, and to understand how the label statements affect consumers' understanding of olestra-containing snack foods.

In the qualitative research, three focus group sessions were conducted in each of three cities (total of nine focus group sessions) among adults or teens. Participants saw a realistic product package and several possible versions of the olestra label statement, and were told that a version of these statements might appear on product packages. Participants discussed their impressions of the product and the various label statements in their own words. The group went through each label statement line by line.

In the quantitative research, a detailed questionnaire was presented to 1,726 respondents, adults and teens, recruited at shopping malls at 40 different sites around the country. Respondents were randomly assigned to a group to assess one of four conditions for wording or presentation of the label statement. Respondents were shown the assigned information statement on a realistic product package that included a nutrition facts panel, ingredient list, and other product information. They then answered questions about the product,

the information statement, and the effects of olestra.

The petitioner concluded from these studies that the required label statement did not communicate clear and understandable messages to consumers. The petitioner found that most participants in the studies were confused by label statements about both the GI effects and the nutrient effects.

The petitioner asserted that the data demonstrate that consumers, after reading the "vitamins added" portion of the required label statement, are left with the impression that eating olestra-containing foods will change their vitamin status. After reading the nutrient statements, some participants inappropriately concluded that olestra is not safe based on presumed vitamin effects. The petitioner stated that the qualitative research indicated that when participants understood that there are no net consequences on vitamins A, D, E, and K, the participants questioned the need for any statement or were suspicious of the statement. The petitioner stated that this study shows that consumers find the concept of nutritional effects and compensatory addition difficult to comprehend without extensive amounts of information. The petitioner concluded from the results of the quantitative studies that a simple label statement indicating that the vitamins in the ingredient statement do not provide a nutritionally significant source best communicates to consumers the fact that there would be no effect on their status of vitamins A, D, E, and K.

Also, the petitioner concluded that the term, "other nutrients," appears to provide no meaningful information to consumers. The petitioner reported that a majority of participants concluded that there were no effects on other nutrients regardless of whether the label statement cited effects on "other nutrients." For those participants who did notice the message, they incorrectly concluded that a variety of nutrients, some known not to be affected by olestra (for example, vitamins C and B) were, in fact, being affected.

The petitioner stated that results from the focus group study on the GI portion of the label statement showed that the currently required label statement may cause consumers to incorrectly attribute GI symptoms to the consumption of olestra, including GI symptoms that olestra does not cause and GI symptoms that are not listed on the label statement. The petitioner said that the research supports the conclusion that the label statement may cause consumers to wrongly attribute symptoms because participants

interpreted the label statement in the context of their experience with other foods that are not labeled. Because there are other foods that cause GI symptoms but are not labeled (e.g., psyllium,⁴¹ wheat fiber, and beans), consumers infer from the olestra label statement that olestra's effects must be worse. The petitioner characterized a typical participant reaction during the focus group testing to be, "If it's like my other experiences, then why does it have this label?"

The petitioner found that a label statement with an explanation of why olestra might cause GI effects ("Because olestra is not digested, it may cause intestinal discomfort or a laxative effect.") added significantly to participant understanding. When specific symptoms were mentioned, such as "loose stools" and "abdominal cramping," more participants responded that they would expect those GI symptoms, compared to panelists who viewed statements that did not mention specific symptoms. The petitioner also found that general GI symptom terms, such as "laxative effect" and "intestinal discomfort" communicate the same expectations in GI changes as the specific terms for other GI symptoms, especially for the range of symptoms related to stool changes.

The petitioner also investigated consumer reaction to the boxed configuration of the label statement, and concluded that statements not boxed had less connotation of harm.

Frito-Lay, an interested party and producer of olestra-containing snack foods, also submitted to the agency results from consumer studies on the label statement conducted prior to marketing of olestra-containing foods (sent as comments to Docket No. 87F-0179, dated March 28, 1996, and March 29, 1996). The purpose of these studies was to test the effect and communication value of the required label statement and alternative statements developed by Frito-Lay. The same type of methodology described above for the quantitative assay was used to obtain responses from 1,183 individuals from 5 sites around the country. Respondents were shown a label statement and then asked, based on this label statement, whether they believed that products containing

olestra were safe. Frito-Lay said that in response to all the tested label statements, including the required statement, most respondents were uncertain as to the safety of olestra (66 to 71 percent), or thought it unsafe (14 to 19 percent). Because none of the label statements Frito-Lay tested eliminated consumer misconception about safety (including a label statement declaring that olestra has been found safe for consumption by the FDA), Frito-Lay concluded that there should be no special label statement. Additionally, Frito-Lay found that 63 to 65 percent of respondents believed that some people would experience GI discomfort. About half of these respondents said that they would delay going to a doctor if they ate a product containing olestra and then experienced GI discomfort for which they would normally seek medical attention. Additionally, a majority of the respondents (68 to 71 percent) believed that olestra would decrease the level of vitamins A, D, E, and K in their bodies, and a majority believed that other nutrients are affected by olestra.

FDA reviewed the consumer perception studies submitted in 1996 by P&G and Frito-Lay (Ref. 32). FDA noted that the studies were an attempt to evaluate what the olestra label statement communicated to consumers regarding several issues. These issues include the following subjects: (1) The safety of olestra; (2) whether the portion of the label statement about GI effects communicates reasonable expectations about the severity, frequency and duration of potential symptoms, and whether alternate wording or presentations communicate more effectively; and (3) whether the portion of the label statement about the potential nutrient absorption effects of olestra effectively communicates the reason for the addition of vitamins A, D, E, and K, as well as the scope and potential severity of the consequences of eating olestra, and whether alternate wording or presentations communicate more effectively.

FDA found the mall intercept studies to be adequate in methodology and sample size to differentiate between the communication effectiveness of the statements tested, including such changes as alternate wordings, or separation of portions of the label statement. For example, in part of Frito-Lay's quantitative study, participants were asked about the safety of olestra before, as well as after, viewing the test label statement. This use of a question before viewing the label statement serves to measure the impact of the label statement on participants' opinions or whether that opinion was established

prior to viewing the label statement. However, the studies were limited to some extent by the choice and wording of questions. For example, P&G's quantitative study did not include, as a control, a "no information" statement, so the communication value of simply having a statement on the product package cannot be evaluated.

Regarding the safety of olestra, FDA found that the results of the consumer perception studies conducted by the petitioner and by Frito-Lay show that the label statement is misunderstood by respondents and thought to be a warning about possible health consequences of olestra consumption. FDA notes that Frito-Lay's data demonstrate that there was an increase in the level of concern about the safety of olestra after participants read a label statement. Specific wordings or presentations contributed little to the level of expressed concern. Only when a label statement included wording that FDA has found olestra to be safe for consumption was some of the concern alleviated. FDA also noted that when participants were given the opportunity to respond to the question of whether olestra is safe by opting for "uncertain," a majority chose this response to every label statement examined. When response options were limited to yes or no, the majority chose "no" (*i.e.*, not safe).

Regarding GI symptoms, FDA concluded that there was no indication from these studies that consumer expectations about the severity, frequency, or duration of GI symptoms was influenced by specific wording or qualifications on effects or by whether there were any directions about when to contact a physician. There also was no indication from these studies that consumers' expectations about the GI symptoms were influenced by whether the nutrient portion of the label statement was present. Participants tended to use the same words used in the label statement to describe potential symptoms (*i.e.*, loose stools, abdominal cramping), but alternate words to describe certain GI effects (loose stools, more frequent bowel movements, diarrhea) were all understood to mean the same thing. When asked what proportion of the population might experience symptoms, modifiers had little effect on respondents' answers.

Regarding the nutrient absorption portion of the label statement, FDA found that the results of the 1996 consumer perception studies show that the current label statement is not effective in explaining the rationale for and quantitative consequences of adding the four fat-soluble vitamins to

⁴¹ FDA assumes that the term "psyllium" refers to the soluble fiber component of the psyllium husk that is the subject of the agency's regulation in part 101 (21 CFR part 101) authorizing a health claim for soluble fiber from certain foods and coronary heart disease (§ 101.81). FDA considers both "psyllium seed husk" and "psyllium husk" to be common or usual names for this substance, but uses the term "psyllium" where it was used by the petitioner or comments.

olestra-containing foods. Respondents' knowledge about olestra's ability to interfere with the absorption of fat-soluble components of the diet was not tested directly, so it is not possible to assess the role that prior knowledge has in respondents' interpretation of the label statement.

The studies demonstrate that consumers do not understand that the addition of the vitamins was intended to produce no net effect in the body. The studies also show that respondents tended to believe that the statement about the inhibition of absorption applied to many other nutrients, including those on which olestra has no effect.

Without the absorption statement, somewhat fewer respondents believed that vitamin A, D, E, and K levels would be changed by consuming olestra, but fewer respondents were also aware that olestra reduced the absorption of these vitamins. Even without an absorption statement, substantial fractions of respondents believed that consuming olestra-containing foods would change both fat-soluble and fat-insoluble vitamin levels, presumably because of prior beliefs about olestra. Variations on the wording of the portion of the label statement regarding vitamin absorption and addition made consumers more aware of the vitamin absorption effect of olestra, but none remedied the miscommunication.

FDA concludes, based on this work, that neither the current label statement nor the alternative label statements tested on product packaging clearly communicate to consumers the effect of olestra on vitamin absorption. Without more detailed information or familiarity with olestra, consumers drew inappropriate inferences about the scope and magnitude of the additive's effect on vitamin absorption.

2. 1999 Consumer Studies

In 1998 and 1999, the petitioner conducted quantitative consumer research using a detailed questionnaire, and submitted the study to the agency on April 22, 1999 (Docket No. 00F-0792). The petitioner's stated purpose for this study was to obtain quantitative data on consumer perceptions of the required label statement. Participants were asked to respond to a series of questions regarding safety and GI effects after reading the required label statement.

The petitioner reported that 61 percent of participants thought that the products bearing the required label

statement were unsafe.⁴² The same percentage believed that the label statement was the government's way of telling them that the product was unsafe. A majority viewed the label statement as a warning, and not as an information statement. After reading the label statement, 83 percent of respondents believed that they could experience symptoms after eating a handful of chips, and approximately a quarter of these respondents would attribute extremely serious symptoms to olestra (severe diarrhea lasting several days, bloody stools, or vomiting lasting up to several days). The petitioner noted that extensive clinical data on olestra show that the additive does not cause such symptoms. The petitioner concluded from the results of this study that the label statement is misleading and conveys messages to consumers that are not consistent with the total body of clinical data on olestra or with FDA's intention in requiring the label statement.

P&G also sought to assess consumer perceptions about the current and alternative label statements. Twenty alternative label statements were tested and rated on a scale of 1 to 9 for the degree of safety perceived from the label statement (1 is "not at all safe," 9 is "very safe"). For the GI portion of the label statement, P&G reported that respondents' perception of the degree of safety of olestra-containing foods after viewing the alternative GI statements ranged from 3.8 to 6.8. Alternative GI statements that provided a familiar frame of reference (comparison to beans, or onions for example), or that stated that GI symptoms were not a likely consequence, resulted in a greater perception of safety than those statements that provided generalized GI symptom data or context to qualify or describe GI symptoms. In this study, P&G found that the statements that elicited the lowest perception of safety were statements that specified GI symptoms, including those that are in the current label statement. For the nutrient portion of the label statement, P&G reported that more than 80 percent of study participants who read an ingredient declaration statement in which the vitamins A, D, E, and K were marked with an asterisk and accompanied with an explanatory phrase ("not a nutritionally significant source") and that no longer had the phrase "other nutrients," believed that levels of vitamins A, D, E, and K and

⁴² By comparison, in the 1996 survey 45 percent of respondents, after viewing the required label statement, considered products containing olestra to be unsafe (Ref. 33).

other nutrients would not change after eating olestra-containing foods.

P&G also conducted research by a national tracking survey to measure consumer awareness of olestra and to determine whether consumers had concerns about olestra's potential GI effects (Docket No. 00F-0792). Survey results were obtained between January 1998 (just prior to the start of national marketing of olestra-containing foods) and May 1999. P&G reported that the results of the tracking survey showed that population awareness of olestra-containing foods increased substantially during this period (from 38 percent to well over 70 percent). The study also showed that respondents who were familiar with olestra-containing foods were quite concerned about possible GI effects. The percentage of "aware" consumers who were at least somewhat concerned about GI effects averaged 74 percent at the beginning of the tracking survey, and 70 percent after national marketing of olestra-containing food was fully underway.

Frito-Lay also conducted new studies on consumer perceptions of the olestra label statement to determine whether that statement was still capable of influencing consumer perception, as it did in 1996 (FAP 0A4708, exhibit 7 and August 13, 1999, Docket No. 00F-0792). Because the 1996 perception study was conducted shortly after FDA's approval of olestra but before availability of olestra in any product on the market, no participant in the 1996 study had eaten a product made with olestra. Frito-Lay therefore considers that the 1996 study showed the effect of the label statement on a "naive" population. Since the 1996 study, Frito-Lay points to numerous significant events involving olestra, including the nationwide availability of Frito-Lay products made with olestra, the FAC meeting held by FDA in 1998, and many national and local news stories about olestra. The new testing of the label statement was conducted with the protocol used in Frito-Lay's 1996 studies.

Frito-Lay reported that in its 1999 study, before seeing the required label statement, 64 percent of respondents were uncertain about safety, but only 6 percent said products made with olestra were unsafe. After viewing the label statement, the number of respondents who thought olestra products were unsafe more than doubled. No one who originally thought olestra products were unsafe changed their opinion after viewing the label statement. Frito-Lay presented results showing that only 24 percent of study participants concluded that products made with olestra do not affect the levels of vitamins in the body,

and an approximately equal distribution of participants concluded that olestra did or did not affect the absorption of other nutrients.

Frito-Lay concluded from these studies that the olestra label statement did influence consumer perception, much like it did in 1996. Frito-Lay also concluded that consumers still did not understand the various parts of the label statement and viewed it incorrectly as a warning.

FDA reviewed the consumer perception studies of the label statement submitted by P&G and Frito-Lay in 1999 and found them to be similar to the 1996 studies in methodology and types of questions asked (Ref. 33). This set of studies concentrated on the GI portion of the required label statement and perceptions of safety about products made with olestra. As with the 1996 studies, the studies were limited by choice and wording of questions and did not include, as a control, a "no information" statement. FDA notes that it is difficult, without careful controls, to distinguish whether a label statement miscommunicates information, is ignored, or is ineffective. Another important limitation to this study is the lack of measurement of initial attitudes toward olestra. Testing of initial attitudes and preconceptions is needed in order to identify the direction of the label statement's effect (*i.e.*, whether the consumer is more accurately informed or not informed).

FDA concludes that P&G's tracking study showed that consumers became more aware of olestra-containing snack foods as products were introduced nationally, and that increasing awareness was accompanied by concern about possible GI effects caused by these products. However, FDA also concludes that the tracking survey does not establish the role (if any) the required label statement plays in consumers' association of olestra-containing foods and GI effects. It cannot be determined from this study whether the rise in product awareness and association with GI effects was due to news reports, advertisements, promotions, or reading the label statement.

FDA concluded that the 1998 and 1999 studies reinforced conclusions from the 1996 studies and support several new conclusions. The new conclusions include the following scenarios: (1) Consumers became more concerned about the safety of olestra-containing products between 1996 and 1998, prior to the introduction of olestra-containing food into national distribution; (2) consumers familiar with olestra-containing snack food (Olean brand name) are very likely to

make an association between olestra and possible GI effects; and (3) consumers newly introduced to olestra-containing products by the introduction of Olean brand products into local stores and the accompanying advertising and promotion are just as likely to make the association between olestra and GI effects as those who already knew about Olean products.

FDA notes that the 1998 study gave respondents a choice of "I don't know" about safety. Given this option, 45 to 49 percent of participants in the 1998 study chose the response "I don't know" when asked about safety, and only 10 to 13 percent of participants in the 1998 study chose the response "unsafe." In contrast, in the 1996 survey, when participants did not have an option to choose "I don't know" when asked about safety, 38 to 61 percent of participants chose the response "unsafe."

G. 1998 FAC Discussion of the Label Statement

The FAC discussed the required label statement on the last day of the 3-day meeting (June 17, 1998), after new data and information concerning possible GI and nutritional effects were presented and discussed. The FAC was to consider whether, in light of the new data and information concerning the consumption of olestra, the label of olestra-containing products should be changed in any way. The FAC was also asked to consider what factual information, if any, regarding the consequences of consuming olestra-containing products should be disclosed on the product label. FDA began the session by discussing the scope of the agency's authority, under the act, regarding labeling. The sponsor (P&G) made presentations to the FAC, followed by Frito-Lay, and CSPI. The FAC asked questions at the end of each presentation. Following this portion of the meeting, each FAC member was polled regarding the label statement.

Polling the individual members of the FAC about whether the label statement should be changed revealed a wide variation in opinions on the labeling issue.⁴³ A majority of members, however, did agree that the label statement should be modified in some way in order to make its messages more clear to the consumer. Several members stated that some labeling information about olestra was needed, based in part on their view that olestra-containing foods were still relatively new products and that consumers were not entirely familiar with these products. Some

members of the FAC suggested there be a sunset clause on the label statement because after consumers became familiar with olestra, there would no longer be a need for a label statement.

Members made various suggestions for different wordings of the label statement to clarify to consumers the likelihood that olestra would cause GI effects and the nature of those effects. Other members expressed concern that consumers might confuse olestra's effect with more serious GI symptoms. Some members of the FAC concluded that olestra's GI effects did not warrant a special label statement, especially because consumers might mistakenly attribute more serious GI symptoms to the olestra. Other members thought a label statement should include information to tell the consumer to seek medical attention if symptoms persist. Several members said they believed that the current data did not support keeping the portion of the label statement on abdominal cramps.

A majority of the members of the FAC specifically agreed that the portion of the label statement regarding "vitamins added" should be removed and replaced with an asterisk following the vitamins in the ingredient listing and a footnote indicating that the added vitamins are not a nutritionally significant source or not nutritionally available. Both P&G and CSPI agreed that this approach was an acceptable and effective way to explain that the presence of the vitamins in the ingredient listing is not meant to imply that these foods are a source of these vitamins.⁴⁴

A majority of members of the FAC agreed that there is no basis, at this time, for adding back any carotenoid, and that the role carotenoids play, if any, in human health is not yet understood. Members did say that the sponsor and the agency should be aware of the evolving understanding of the health effects of carotenoids, and consider that information and its bearing on the use of olestra. Some members expressed reservations about not having any statement on the label about olestra's potential to interfere with the absorption of fat-soluble nutrients such as carotenoids, and suggested that the statement about "other nutrients," might be clarified by changing the phrase to "nutrients found in fruits and vegetables."

IV. FDA's Conclusions

A. The Applicable Legal Standard

Under section 409(c)(3) of the act, a food additive shall not be approved if

⁴³ Transcript, vol. 3, pp. 101-174.

⁴⁴ Transcript, vol. 3, pp. 92-93.

such approval would result in the misbranding of a food containing the food additive. Misbranding includes labeling that is misleading because it fails to reveal facts material with respect to consequences resulting from use of the additive under "customary or usual" conditions (sections 201(n) and 403(a)(1) of the act). Thus, the data and information of principal relevance to evaluating whether olestra must bear a label that discloses, for example, the possible GI effects of olestra, are those that evaluate the additive's effects when eaten at levels, and in patterns of consumption, that are customary or usual.⁴⁵ As the preceding discussion reflects, FDA has considered all of the evidence in the record and has considered the preapproval studies in light of the postapproval investigations reflecting customary or usual patterns of consumption.

FDA does not ordinarily require special labeling on a food that may have consequences of consumption (such as GI effects) when the available information shows that consumers are aware that such food cause the effects. Psyllium husk is an example of an ingredient that may cause GI effects. Consumers are aware of these potential effects because psyllium husk has been used as a laxative. However, FDA's health claim regulation for psyllium husk does not require a label disclosing these effects (§ 101.81). In those situations in which consumers understand the possible consequences of consuming a particular food, information describing those consequences is not new information for consumers and thus, such disclosure would not be material within the meaning of section 201(n) of the act. Thus, information about consumer knowledge of olestra and its potential to cause effects (such as GI effects) is relevant to determining whether labeling is required to prevent misbranding of olestra-containing food.

⁴⁵ This would be in contrast to the preapproval studies which were designed to assess safety.

In addition, it is critical to recognize that the issue presented by this petition is not whether olestra is safe for use in savory snacks; that issue was addressed in the 1996 final rule. Instead, the question before the agency is what labeling, if any, must be required for foods containing olestra to ensure that they are not misbranded (section 403(a)(1) of the act). Accordingly, the act's "reasonable certainty of no harm" safety standard in § 170.3(i) (21 CFR 170.3(i)), does not apply here.

B. FDA's Conclusions Regarding Gastrointestinal Effects

1. Basis of the 1996 Final Rule—GI Effects

a. *Abdominal cramping.* In 1996, the agency concluded that olestra had the potential to cause abdominal cramping. FDA's conclusion was based primarily on two 8-week studies designed to assess olestra's safety in terms of its potential nutritional effects. These 8-week studies maximized participants' exposure to olestra in order to maximize the additive's possible nutritional effects. Although FDA estimated an intake of 20 g/d for the "high" acute consumer of olestra (every day for 12 weeks) (61 FR 3118 at 3124), the highest dose used in these studies (32 g/d) well exceeded this estimate. In addition, in these preapproval studies, olestra was incorporated into savory snacks as well as a variety of foods for which it is not approved for use, and these foods were eaten at every meal for 56 consecutive days. Finally, diets in these studies contained all the ambient levels of fat with no adjustment for the olestra added to the diet. As such, the 8-week studies were not designed to address the effects of customary consumption of olestra-containing snack foods. Based on the information available in 1996, the agency found that there were no safety concerns with the use of olestra in savory snacks.

Although FDA determined in 1996 that the 8-week studies did not reflect conditions of use that are usual or customary for the consumption of savory snacks, there were no other data or information available reflecting the usual or customary use of olestra-containing snack foods. Thus, FDA concluded that it would be prudent to rely on the available data that indicated that under some circumstances olestra had the potential to cause abdominal cramps. Because snack foods containing olestra were new, the agency further concluded that consumers would not know to associate abdominal cramps with these foods. Accordingly, FDA required that products containing olestra bear a label statement indicating that olestra may cause abdominal cramps. The agency imposed the requirement for this label statement because it concluded that consumers were not familiar with the newly approved food additive, olestra, and a label statement would allow consumers to associate GI symptoms they might experience with olestra and preclude unnecessary concern about such effects (61 FR 3118 at 3161).

b. *Loose stools.* In 1996, the agency also concluded that olestra had the

potential to cause the GI effect "loose stools."⁴⁶ The studies on which this conclusion was based are the same studies discussed above on abdominal cramps, *i.e.*, the two 8-week studies. These studies were designed to measure the potential nutritional effects from consumption of olestra-containing foods, and were not designed to address potential GI effects from usual or customary consumption of olestra-containing savory snacks. Nevertheless, in the absence of more specific data, FDA relied on the data from the 8-week studies, which the agency concluded showed that at high doses, olestra increased the potential for loose stools. Accordingly, FDA required a label statement about the potential of olestra consumption to cause loose stools (61 FR 3118 at 3153). FDA believed that information on the label would enable consumers to associate olestra with any GI effects and preclude any unnecessary concerns about the origin of such effects. FDA evaluated the data available in 1996 and concluded that a label statement telling consumers that olestra may cause loose stools was necessary so that olestra-containing food products would not be misbranded within the meaning of section 201(n) of the act. In addition, FDA required the label statement about loose stools because at the time of the final rule, consumers were familiar neither with olestra itself, nor its potential to cause GI symptoms such as loose stools.

2. Data in the Current Petition—GI Effects

Three issues are relevant to determining whether the required statement concerning olestra's potential to cause loose stools and abdominal cramping should be modified: The additional data on olestra's association with these effects under customary or usual conditions of use; research concerning consumer understanding of this portion of the required label statement; and the evidence regarding the status of consumer knowledge of olestra and its potential to cause such effects.⁴⁷

⁴⁶ As noted previously, FDA concluded in 1996 that these effects are not adverse health effects.

⁴⁷ The agency also reviewed data from the petitioner's Stool Composition Study, which address the safety of olestra (*i.e.*, do the loose stools that olestra may cause constitute diarrhea that would be harmful from a health risk standpoint?). As noted, in 1996, FDA concluded that olestra was safe for use in savory snacks, specifically determining that loose stools caused by consumption of the additive were not "harm" within the meaning of the applicable safety standard (section 409(c) of the act; § 170.3(i)). The results of the Stool Composition Study confirm that

Continued

a. *Abdominal cramping.* In 1996, when FDA required the label of foods containing olestra to list the GI symptom "abdominal cramping," it did so on the basis of data generated under conditions that were not customary or usual for savory snack use (see section 201(n) of the act). Since then, FDA has received and reviewed new data and information designed to evaluate olestra's effects under the customary or usual conditions of use for savory snacks. These new data provide no evidence of an increased frequency of abdominal cramps due to the ingestion of olestra in savory snacks. This lack of association is consistently found in several well designed, double-blind, placebo-controlled studies.

Specifically, the Home Consumption Study was conducted under circumstances that more closely reflect the usual and customary conditions of use for savory snacks. As noted, in this study, there was no evidence of an increase in reported abdominal cramping among subjects who ate olestra-containing foods compared to those who ate triglyceride-containing foods. Importantly, the Home Consumption Study had sufficient power to detect differences in the frequency of reported GI effects between the olestra and the triglyceride consuming groups, but such an effect was not found for abdominal cramping. Likewise, results from the Acute Consumption Study showed no difference in the rate or severity of abdominal cramps for the group consuming olestra compared to the group consuming triglyceride. Although CSPI has raised questions about the power of the Acute Consumption Study, the agency believes that the results of that study provide meaningful information that corroborates the findings of the more powerful Home Consumption Study. In addition, these results are confirmed by the Rechallenge Study. That investigation used a population of consumers who had previously reported a GI effect that they associated with eating an olestra-containing snack; in their initial symptom episode, the majority claimed to have experienced abdominal cramps. As noted previously, in the Rechallenge Study, there was no difference in the frequency of reports of abdominal cramps after eating olestra-containing chips when compared to triglyceride-containing chips. Finally, the results of the Stool Composition Study are consistent with outcomes of the foregoing three studies. In this study,

olestra does not cause diarrhea but simply adds bulk and softens the stool.

although there was an increase in the percentage of symptom days for abdominal cramping, with increasing olestra dose, the difference was not significant. Accordingly, FDA concludes that consumers of olestra are no more likely to report abdominal cramping than are consumers of triglyceride chips under normal use conditions.⁴⁸

FDA has also evaluated information about whether the current olestra label statement communicates effectively to consumers (see section III.F of this document). In general, evidence from consumer perception studies shows that after reading the required label statement, a majority of consumer participants did not correctly understand the nature, severity, or frequency of possible GI effects as a result of consumption of an olestra-containing snack. Although FDA's purpose in requiring the label was to provide information to consumers, most of those surveyed viewed the label statement as a warning and thus drew inaccurate conclusions about olestra's safety. Accordingly, FDA concludes that the required label statement is not an effective means of communicating accurate information to olestra consumers.

The new data and information that the agency has received since the 1996 final rule provide no evidence of an increased frequency of abdominal cramps when olestra-containing foods are consumed under the customary or usual conditions of use for savory snacks (see section 201(n) of the act). As discussed previously, this lack of association is consistently found in several well designed, double-blind, placebo-controlled studies. Accordingly, FDA finds that there is no scientific basis to support a statement on the label of foods containing olestra that olestra consumption may cause "abdominal cramping."

b. *Loose stools.* As noted, prior to the approval of the use of olestra for savory snacks and their subsequent marketing, consumers had little knowledge of, and no experience with, olestra. Since the 1996 decision, the agency has received additional data about olestra and the nature and frequency of loose stools; these new data better reflect the conditions of use that are customary or usual for savory snacks. FDA has found that olestra may increase the frequency

⁴⁸FDA reviewed a number of reports from passive surveillance of olestra consumers. As noted in the previous discussion, passive surveillance cannot establish cause and effect, although such information may be useful in supporting hypothesis generation. FDA has not relied upon information from the passive surveillance in reaching its conclusions about the current label statement.

of loose stools and bowel movements but that the magnitude of the increase is minor and the severity and impact of these effects on daily activity are not different from other foods that may cause an effect such as loose stools. In addition, the record before the agency shows that consumers are now familiar with olestra's potential to cause loose stools.

In particular, the Home Consumption Study found that consumers of olestra-containing chips experienced a small but measurable increase in more frequent bowel movements and loose stools compared to those who ate triglyceride-containing chips. Because of the number of subjects enrolled (3,181), and the length of time for the study (42 days), the study was able to detect small differences in the frequency of symptoms. Importantly, the absolute incidence of these reports was low, especially relative to the background rate of reported symptoms. Analysis of the reported incidence of severity did not show any difference between the olestra and triglyceride groups. The study showed no increase in the use of medications or physician visits associated with olestra consumption. FDA's analysis of the study showed that consumers who reported a GI event moderated their consumption of chips. Assessments by participants of a symptom's effect on the ability to carry out normal activities showed little if any impact on the daily life of subjects. There was no increase in the percentages of reported severe impairment in performing daily activities in the olestra group compared to the control group. There was no evidence that these effects (loose stools, more frequent bowel movements) were more severe or had any different impact on consumers' daily activities than those associated with similar foods made with fat.

Results from the Acute Consumption Study and the Rechallenge Study are consistent with the results from the Home Consumption Study. Specifically, the Rechallenge Study showed that under the conditions of the study, the incidence of reports of diarrhea or loose stools after exposure to olestra or to triglyceride chips did not differ. The incidence of diarrhea was 6 percent for the olestra group, 8 percent for the triglyceride group; the incidence of reports of loose stools was 5 percent for the olestra group, 7 percent for the triglyceride group. Subjects who had previously reported a GI effect (including loose stools and abdominal cramps) after consuming olestra were no more likely to report GI symptoms after eating olestra chips than those eating

triglyceride chips. Similarly, the Acute Consumption Study showed no difference in the frequency, nature, or severity of GI complaints (including loose stools) between the placebo (triglyceride) and olestra groups after a single, ad libitum eating occasion.

At the time olestra was initially approved and first marketed, consumers had limited awareness of olestra and its potential to cause GI effects. In contrast, evidence gathered in the postapproval consumer perception studies and the tracking survey show that there is currently a high degree of awareness among the public about olestra, including a high degree of awareness of olestra's potential to cause GI effects. Results from a postapproval tracking survey show that consumers became more aware of olestra as products were introduced nationally.

FDA does not have evidence to draw conclusions about the role played by the label statement in creating consumer awareness about olestra's potential to cause GI symptoms. However, as with other products that may cause GI effects but are not so labeled, awareness of the potential to cause GI effects is maintained in the population based on common knowledge and consumer experience. Consumers are accustomed to regulating their diets based on this knowledge and experience. FDA has no reason to conclude that the case for olestra-containing foods would be different.

As previously noted, FDA has evaluated consumer perception studies conducted with the olestra label statement and has concluded that while FDA's purpose in requiring the label was to provide information to consumers, a significant number of consumers perceive the label statement as a warning about possible health consequences of olestra consumption and consider olestra-containing foods to be unsafe.⁴⁹ This is contrary to FDA's determination that olestra is safe for use in savory snacks. Thus, the agency believes that the current label does not accurately communicate information to consumers about olestra's potential to cause loose stools.

Since the 1996 final rule, additional data about olestra and the nature and frequency of loose stools have become available. This information does not supersede the previous information, but rather, extends FDA's understanding of olestra under customary conditions of use and its potential to cause loose

stools. FDA has found that olestra may increase the frequency of loose stools but the frequency of the increase is minor. FDA also has found that the severity and impact of this effect on daily activity are not different from other foods that may cause an effect such as loose stools.

In addition, the administrative record before the agency shows that consumers are now familiar with olestra's potential to cause loose stools. FDA believes that because there is currently an awareness among consumers about possible GI effects of olestra, and because the potential effects from customary or usual consumption of olestra-containing snacks are relatively insignificant, a label statement concerning loose stools for olestra-containing savory snacks is no longer needed to ensure that the product is not misbranded (sections 201(n) and 403(a)(1) of the act).

C. FDA's Conclusions Regarding Nutritional Effects

1. Basis of the 1996 Final Rule—Nutritional Effects

At the time of the 1996 final rule, FDA found that because olestra is a fat-like material that is not digested or absorbed, it may interfere with the absorption of fat-soluble components of the diet, including the fat-soluble vitamins A, D, E, and K. The agency had evaluated studies performed in humans and animals (61 FR 3118 at 3132-3252), and considered the available information concerning nutritional requirements for various fat-soluble components of the diet. FDA concluded that the addition of vitamins A, D, E, and K (§ 172.867(d)), to foods containing olestra would compensate for any inhibition of absorption of fat-soluble nutrients by olestra. The amount of vitamins added was intended to have no net effect (neither increase nor decrease) on vitamin status of olestra consumers. The agency required that the level of added vitamins be adequate to compensate for olestra's effects on absorption even if the olestra and fat-soluble vitamin are present in the gut simultaneously. Additionally, the agency set the amount of vitamins so that if there is no fat-soluble vitamin present in the gut with olestra, the level of added vitamin would not pose any safety concerns.

The added vitamins A, D, E, and K are required to be declared in the ingredient listing (section 403(i) of the act). In 1996, FDA concluded that this mandatory listing of vitamins A, D, E, and K could mislead consumers by implying that the food would provide significant amounts of these vitamins (61 FR 3118 at 3161).

Thus, FDA required a label statement to explain why these vitamins were added and why the food should not be considered fortified, so that olestra-containing food would not be misbranded (sections 201(n) and 403(a)(1) of the act).

FDA required that the label include the statement "Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added." FDA did not require a specific statement about carotenoids or any other fat-soluble components of the diet because such a statement could have falsely implied that their decreased absorption was known to be of significance.

2. Data in the Current Petition—Nutritional Effects

Three issues are relevant to determining whether the required statement as to olestra's effects on nutrient absorption should be modified: The additional data on absorption of the added vitamins A, D, E, and K obtained since the 1996 final rule; the current understanding of the nutritional importance of carotenoids and olestra's effect on their absorption; and the research evaluating consumer understanding of this portion of the required label statement.

As to the added vitamins A, D, E, and K, early data from the Active Surveillance Study confirm that, as the agency intended, there is no dietarily significant net loss or gain of vitamins A, D, E, and K due to the consumption of olestra-containing foods.⁵⁰

The early data from the Active Surveillance Study also provide important information regarding olestra and carotenoids. First, these data show that consumption levels of olestra-containing foods are below FDA's original estimates and further, that co-consumption of any savory snack with a carotenoid-containing food is relatively rare. Second, although there are changes in serum measures of certain carotenoids, these changes are unlikely to be the result of consumption of olestra-containing foods because the clinical cohort data reflect no association between the amount of olestra consumed and the changes in serum levels of carotenoids.

As noted, FDA has considered the recent scientific literature pertaining to carotenoids and human health and concluded that the decreased risk of cancer is associated with increased

⁴⁹ In fact, these studies show that many consumers attribute certain serious GI effects to olestra, even though there is no evidence of olestra's potential to cause such effects.

⁵⁰ There was some indication from the Active Surveillance Study cross-sectional data of a small increase in vitamin K levels in the highest olestra consumers.

consumption of fruit and vegetables generally and that at the present time no specific role of carotenoids (other than the provitamin A function) has been identified.⁵¹ The agency's conclusions are consistent with the recent NAS report (Ref. 27) that determined that there is no basis at present for setting dietary requirements for any carotenoid. Similarly, this conclusion is consistent with the results of recent intervention studies, which show no benefit from treatment with carotenoids over control.^{52, 53}

FDA acknowledges that research is continuing and that the scientific community's understanding of the role of carotenoids in human health may evolve as new data emerge. The agency will review new information about the role of carotenoids in human health relevant to olestra use in savory snacks, and if necessary, take appropriate action. At this time, however, FDA concludes that no direct evidence demonstrates that the association between the consumption of diets high in fruits and vegetables and a decreased risk of cancer is due to any single carotenoid or group of carotenoids. Accordingly, FDA has determined that there continues to be no basis to require any label statement about olestra's effects on carotenoids or any other fat-soluble nutrient.

As discussed previously, FDA has also evaluated information about the effectiveness of the current olestra label statement to communicate about olestra's potential nutritional effects to consumers. In general, the evidence from consumer perception studies shows that after reading the required label statement, a majority of consumer participants did not correctly understand olestra's effect on the absorption of fat-soluble nutrients or why vitamins A, D, E, and K would be added to olestra-containing foods. Accordingly, FDA concludes that the required label statement is not an effective means of communicating to olestra consumers.

Although the currently required label statement may be misinterpreted by consumers, FDA still believes that because the presence of the added vitamins must be disclosed as ingredients of olestra-containing foods (§ 101.4(a)(1)), consumers may be misled and believe that such snacks are

fortified with the added vitamins. Therefore, in order for olestra-containing foods not to be misbranded, the agency has determined that a statement about the presence of vitamins A, D, E, and K should be required. Accordingly, this final rule requires that the label of foods containing olestra use an asterisk following each of the added vitamins in the ingredient statement which would refer to a statement, "Dietarily insignificant." Such a statement directly addresses the presence of the vitamins in the ingredient statement and closely links the message to the particular vitamin affected.⁵⁴ This format and configuration are familiar to consumers because such a configuration has been used previously in the nutrition facts panel. Likewise, as noted, the required wording, "dietarily insignificant," is similar to wording used in other label statements, and thus, is familiar to consumers (§§ 101.60(c)(1)(ii), 101.61(b)(1)(ii), and 101.62(b)(1)(ii)).

FDA further concludes that there is no need for a contextual statement about olestra's effect on the absorption of the vitamins in order to avoid misbranding of olestra-containing foods. Indeed, information from consumer perception studies shows that the 1996 required label's contextual statement about "some vitamins and other nutrients" actually tends to mislead consumers and that contextual information is not necessary to understand that olestra-containing foods do not contribute significant amounts of vitamins A, D, E, and K to the diet. In addition, although olestra may affect the absorption of other fat-soluble components of the diet, such as carotenoids, there is no known basis for adding back carotenoids or nutrients other than vitamins A, D, E, and K to olestra-containing food. Finally, there is no representation made on the label about "other nutrients" that would require a specific statement about such nutrients. For these reasons, this final rule eliminates the requirement that the label for foods containing olestra include the sentence "Olestra inhibits the absorption of some vitamins and other nutrients."

In sum, having considered all of the evidence of record, FDA has determined that the olestra regulation, § 172.867, should be revised to require that vitamins A, D, E, and K listed in the ingredient statement be labeled with an asterisk (appearing as a superscript) following the listing of each of these vitamins, and that the asterisk reference

the phrase, "Dietarily insignificant," which shall appear immediately following the ingredient statement.

V. Response to Comments on the Label

In this section, FDA responds to comments not previously addressed in this document. FDA considered these comments and responds in this section of the document.

A. Label Statement for GI Effects

(Comment 10) In comments to both the 1996 final rule and the current petition, Frito-Lay recommended that the statement about the GI effects of olestra be eliminated. Frito-Lay based its recommendation on the results of studies, such as the petitioner's postapproval studies, showing that consumption of snack foods made with olestra produces no meaningful GI effects. Frito-Lay also cited a consumer perception study suggesting that consumers may attribute GI effects to olestra when their symptoms are caused by a more serious condition requiring medical attention. In that study, 58 percent of consumers said they would delay medical attention if GI changes occurred after eating products bearing the olestra label statement. A comment from P&G to the 1996 final rule argued that the label statement is inconsistent with data from the postapproval studies and has the potential to mislead consumers. P&G objected to the suggestion at the 1998 meeting of the FAC that the GI effects statement be amended and subject to a sunset clause, rather than dropped entirely, by arguing that discontinuing the GI effects portion of the label statement would be more consistent with the existing data and prevailing legal precedent.

In contrast, several comments to the 1996 final rule specifically stated that a GI effects statement was warranted but provided no factual evidence or rationale for their recommendation.

FDA agrees that the requirement for a label statement about olestra's potential to cause GI effects should be eliminated. As noted previously, P&G's postapproval studies show that customary or usual consumption of olestra in savory snacks causes only minor GI effects, and that the public is now aware of olestra's potential to cause GI effects. Therefore, the agency has no basis to require a label statement regarding olestra's potential to cause GI effects.

(Comment 11) A comment from CSPI to the current petition stated that instead of eliminating the label statement about GI effects, the statement should be amended to indicate that GI effects may occur in a "small percentage

⁵¹ The FAC reached the same conclusion in June 1998.

⁵² This is true with respect to the NIH/NEI ARES study, which showed no specific vitamin or carotenoid was protective of macular degeneration.

⁵³ Indeed, in at least one subpopulation (smokers), treatment with carotenoids was associated with an increased risk.

⁵⁴ This asterisk format is supported by P&G, CSPI, and a majority of the FAC members present at the 1998 FAC meeting.

of consumers." CSPI asserted that consumers need information on GI effects so that they can learn to associate olestra with possible symptoms and can avoid olestra in the future if such symptoms occur. CSPI also asserted that olestra's GI effects are material consequences that may result from customary consumption and that the label statement would be misleading without a statement about GI effects. CSPI asserts that P&G's two 8-week studies, together with a clinical study published in the *British Journal of Nutrition*⁵⁵ (Ref. 34), show an association between consumption of olestra (in the case of P&G) or sucrose polyester (in the case of the study published in the *British Journal of Nutrition*) and GI symptoms. CSPI also stated that the postmarketing studies provide some reassurance that no more than a small percentage of consumers experience GI symptoms.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that GI effects may occur in a small percentage of consumers. The standard for determining whether this information must be required on the label is whether the labeling fails to reveal facts that are material with respect to consequences which may result under the conditions of use prescribed in labeling or advertising or under such conditions that are customary or usual (section 201(n) of the act). The fact that olestra-containing foods can cause GI effects under conditions such as those in P&G's two 8-week studies and the study published in the *British Journal of Nutrition* must be considered in light of the data from studies addressing the GI effects associated with customary or usual olestra consumption. As with other foods, GI symptoms may occur in a small percentage of olestra consumers, but the available data show that customary or usual consumption of olestra-containing foods does not cause GI symptoms with a frequency, severity, or impact on daily activity that are different from those from triglyceride snacks. In addition, the agency has determined that consumer perception

studies and tracking surveys show that there is a high degree of public awareness concerning olestra and its potential effects. Based on the minor GI effects associated with customary or usual consumption of olestra-containing foods and the public's awareness of the potential for olestra to cause GI symptoms, the agency has concluded that olestra-containing foods should not be required to bear a label statement informing consumers of possible GI symptoms resulting from olestra consumption.

(Comment 12) Several comments to the current petition stated that the wording of the GI effects statement should be changed to indicate that symptoms may be "severe." Many of these comments were from consumers who reported having GI effects that they attributed to olestra. Another comment supported the suggested change by citing consumers' GI effects reported to CSPI.

Comments from CSPI, individual consumers, and manufacturers of baked, fat-free snacks to the 1996 final rule stated that the wording of the GI effects statement should be changed to describe a greater number of potential side effects⁵⁶ and to indicate that the side effects could be "severe." Several comments also suggested that the label statement should indicate that symptoms occur "commonly." Some comments cited reports submitted to CSPI and P&G that report severe GI effects after olestra consumption as the rationale for the suggested labeling. CSPI asserted that if all pertinent symptoms are not identified, consumers might continue to eat olestra-containing foods even when GI disturbances are occurring, because many consumers will not make the connection between consumption of the fat substitute and symptoms not specified on the label statement. CSPI reported the results of a telephone survey that showed that 7.4 percent of consumers experienced GI effects or headache after an average of 4.8 exposures to olestra over a 2-month period. CSPI also stated that P&G's two 8-week studies showed that half of the subjects experienced diarrhea or other symptoms during the study. The comment also reported data from a study conducted by Frito-Lay that showed a 9 percent increase in anal oil leakage associated with olestra

consumption.⁵⁷ CSPI compared the labeling for adverse effects caused by drugs to the labeling of olestra related effects, and argued that because olestra is consumed more widely, at greater amounts, and over longer periods of time than drugs, labeling for effects should be more complete and explicit.

In contrast, a comment to the 1996 final rule from P&G opposed a GI effects statement listing all GI symptoms that may possibly occur following olestra consumption. The comment stated that the clinical data show that the digestive effects of olestra are similar to the effects that consumers experience from eating certain other foods and food products (such as products that contain psyllium or wheat fiber) that are not specially labeled. The comment also stated that olestra's effects are similar to those of other foods that have no impact on daily activities and are not specially labeled.

FDA does not agree that olestra-related GI symptoms should be labeled as "severe." FDA has no basis for concluding that the GI symptoms caused by olestra are severe when olestra-containing snacks are consumed under customary or usual conditions. Moreover, these comments provide no evidence that any severe symptoms were actually caused by olestra. As noted earlier (section III.B of this document), the reports of the type cited in the comments cannot be used to draw conclusions about cause and effect. Furthermore, the Home Consumption Study and the Acute Consumption Study demonstrate that the GI symptoms caused by customary or usual olestra consumption are not severe. In fact, the petitioner's postapproval studies show that customary or usual consumption of olestra in savory snacks causes only a minor increase in the frequency of loose stools.

FDA does not agree that the wording of the label statement should disclose a greater number of potential side effects. As described above, the postapproval studies show customary or usual consumption of olestra-containing foods causes only a minor increase in the frequency of loose stools and bowel movements, and no increase in the frequency of abdominal cramps. The results of the studies do not provide evidence that there are other GI symptoms resulting from customary or usual consumption of olestra-containing foods that warrant special labeling.

⁵⁵ FDA notes that this study was a double-blind, placebo-controlled, randomized, cross-over trial in which subjects consumed 20 to 40 g sucrose polyester or triacylglycerol per day. Each treatment was administered for three months. The study included measurements of the effect of each treatment on GI symptoms and plasma carotenoid concentrations. The article does not state whether the sucrose polyester used meets the specifications for olestra. Sucrose polyester was incorporated into chips, beefburgers, meat pies, sausages, sausage rolls, fruit pies, milk, margarine, salad cream, fruit dessert, processed cheese, biscuits, peanut butter, cake, crisps, chocolate spread, and chocolate bars.

⁵⁶ In its comments, CSPI suggested that symptoms such as diarrhea, loose stools, increased bowel movements, fecal urgency, nausea, gas, cramps, bloating, anal leakage, yellow-orange underwear staining, greasy bowel movements, yellow-orange discoloration of stools, and oil in toilet appear on the label statement.

⁵⁷ FDA believes that CSPI is referring to a marketing study conducted by Frito-Lay. Frito-Lay informed FDA that the execution of the study was flawed. FDA relied on data from the petitioner's safety studies to address the issue of anal oil leakage (61 FR 3118 at 3154-3155).

Based on the results of the postapproval studies, reviewed in light of the preapproval investigations, FDA has determined that there is no longer a basis to require special labeling for loose stools, abdominal cramps, or any other GI symptom.

(Comment 13) P&G stated in a comment to the 1996 petition that the GI effects statement is inconsistent with FDA's handling of psyllium-containing foods. The comment stated that the digestive effects that occur after eating psyllium-containing foods at levels necessary to support the agency's health claim are the same as for olestra, softer fecal contents and more frequent bowel movements, but are likely more pronounced than those that occur after eating olestra-containing foods. The comment stated that no label information related to GI effects is required on psyllium-containing foods.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a statement about olestra's potential to cause GI effects. Therefore, whether the GI effects statement originally required in the olestra label is inconsistent with the labeling of psyllium husk-containing foods is no longer an issue.

(Comment 14) A comment from CSPI to the current petition objected to P&G's argument that the required labeling of olestra-containing foods is not consistent with the labeling of GI effects from psyllium-containing foods. CSPI argued that the GI effects of psyllium and olestra are different by citing FDA's published statements that psyllium would have no effect on the bowel other than to promote normal function by softening fecal contents and increasing fecal volume (63 FR 8103 at 8115, February 18, 1998) while olestra may cause bloating, loose stools, abdominal cramps, and diarrhea-like symptoms (61 FR 3118 at 3159). CSPI also states that psyllium's mild GI effects would not cause consumers significant discomfort, undue concern, or cause them to seek unnecessary medical treatment. CSPI points out that FDA does require disclosure of the material effects of psyllium consumption, the potential for esophageal blockage from not consuming adequate amounts of fluids. CSPI concludes that the requirement for disclosure of psyllium's material effects, the potential to cause choking, and the fact that disclosure of psyllium's nonmaterial mild bowel-normalizing effects, are not required to be disclosed is consistent with requiring disclosure of the material GI and carotenoid effects of olestra.

FDA determines the need for special labeling on a case-by-case basis. In this

case, FDA must consider not only whether the potential GI effects of olestra-containing foods rise to the level that warrant special labeling, but also whether consumers are aware of the potential GI effects associated with the consumption of olestra-containing foods. Customary or usual consumption of psyllium husk-containing foods may cause stool softening effects and increases in stool volume and frequency of bowel movements (63 FR 8103 at 8115). Products containing psyllium husk are not specially labeled for GI effects because FDA believes consumers are aware that psyllium husk is dietary fiber and consumers know the effects of dietary fiber. Therefore, the labels of psyllium husk-containing foods are not required to disclose the stool softening effects and increases in stool volume and frequency of bowel movements associated with customary or usual consumption of foods containing psyllium husk. Based upon data and information obtained since the 1996 final rule, FDA believes that the GI effects of customary or usual consumption of olestra-containing foods are not significantly different from the stool softening effects and increases in stool volume and frequency of bowel movements associated with the customary or usual consumption of psyllium husk-containing foods.⁵⁸ In addition, FDA believes that there is now a high degree of awareness concerning olestra and its potential to cause GI effects. Based on the nature of the GI effects caused by olestra-containing foods and the public's awareness of such effects, the agency does not believe that olestra's potential to cause GI effects warrants special labeling.

(Comment 15) A comment from CSPI to the current petition stated that the olestra label statement should advise consumers to contact a health professional if GI symptoms persist because such symptoms may represent a problem more serious than those associated with the consumption of olestra-containing foods.

FDA disagrees with this comment. While FDA agrees that consumers experiencing persistent GI symptoms should contact a health professional because such symptoms may represent a condition more serious than those caused by olestra, a food label is not the proper place to provide medical advice unrelated to the product (61 FR 3118 at 3162). FDA notes, however, that the

⁵⁸ The published statement about olestra's GI effects referenced in the comment by CSPI represents effects seen under the consumption conditions associated with the petitioner's preapproval studies that were designed to demonstrate the safety of olestra.

decision to delete the label statement requirement is consistent with the expressed concern that consumers may erroneously conclude that GI symptoms are related to olestra when, in fact, they are caused by something else.

(Comment 16) Assuming that the label statement would be retained, comments from P&G, Frito-Lay, academia, and several trade associations to the 1996 final rule stated that the wording of the GI effects statement should be changed to indicate that olestra causes a "laxative effect." Comments cited focus group studies showing that the current statement creates unwarranted alarm and implies that the product is harmful. A comment from P&G reported research demonstrating that the phrase "laxative effect" was able to communicate the idea of loose stools and was more effective in communicating the range of other possible symptoms than the phrase "loose stools." This comment also stated that the suggested changes are consistent with the views expressed by the FAC at its 1995 meeting. Other comments supported use of the term "laxative effect" by arguing that the current label statement is not consistent with the precedent set by the labeling of other food additives that cause similar effects, such as mannitol, sorbitol, and polydextrose.

In contrast, one comment opposed use of the term "laxative effect" because it puts olestra in the category of psyllium, and expressed the opinion that olestra does not belong in the same category as psyllium but provided no rationale for the opinion expressed. A comment from CSPI opposed a label statement indicating that olestra is similar to fiber because such a label statement would confuse the public. The comment asserted that although fiber and olestra cause similar GI symptoms, the appearance and disappearance of symptoms are so different that the label statement would be "highly deceptive."

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that olestra causes a "laxative effect." Use of the term "laxative effect" in a label statement was discussed in the 1996 final rule. The agency chose not to use the term "laxative effect" in the label statement because such use may imply the therapeutic use of olestra as a laxative (61 FR 3118 at 3162). These comments provide no basis for the agency to change its position on this matter. Moreover, given the results of the postapproval studies, FDA believes that there is no longer a basis for requiring special labeling about the potential GI effects associated with customary or usual consumption of

olestra-containing foods. Therefore, the specific characterization of these GI effects by terms such as "laxative effect" is no longer an issue.

(Comment 17) A comment from CSPI to the 1996 final rule stated that olestra causes diarrhea and the word "diarrhea" should appear in the label statement. CSPI stated that olestra-related diarrhea meets the criteria established for "clinical diarrhea" discussed at the 1995 meetings of the Olestra Working Group (OWG)⁵⁹ and FAC. In support of its comment, CSPI quotes portions of the FDA memorandum that discusses data from the preapproval Fecal Parameters Study (Ref. 22). CSPI quotes portions of the memo discussing subjects' ability to distinguish between "normal," "loose," and "diarrhea" stool as well as portions of the memorandum discussing water loss through diarrheal and nondiarrheal stools. CSPI states that one of the criteria for "clinical diarrhea" discussed at the 1995 meeting of the OWG and FAC was increased water content of diarrheal stool compared to normal or loose stool. CSPI also asserted that in the petitioner's preapproval Oil Loss Study, bowel movements exceeded 3/d for subjects in all the study groups who consumed olestra potato chips while no such increase was reported for subjects who consumed chips with triglyceride. CSPI also reports that some subjects in the preapproval study of patients with inflammatory bowel disease reported an increased frequency of bowel movements. CSPI states that bowel movement frequency exceeding three per day was a criteria for "clinical diarrhea" considered at the 1995 meetings of the OWG and FAC. CSPI also quotes an FDA memorandum that reviews a preapproval study of the effect of olestra on intestinal micro flora (Ref. 35). CSPI quotes a portion of the memorandum stating that the projected means for fecal volume for the olestra-fiber consuming groups⁶⁰ in the study indicate diarrhea at 24 g of olestra if the strict definition of diarrhea used by research gastroenterologists (200 g/d) is applied.

⁵⁹The OWG was a subcommittee of the 1995 FAC functioning as a special working group on olestra. The OWG was made up of several members of the FAC as well as consultants and in-depth review experts who represented scientific disciplines appropriate for the evaluation of a macro-ingredient fat substitute. The OWG met for 3 days (November 14-16, 1995) and reported its findings to the FAC in a meeting on November 17, 1995. The transcripts for the 1995 FAC meetings are available at the Division of Dockets Management (see ADDRESSES).

⁶⁰FDA notes that subjects in the study were fed breakfast meals daily containing 7 g or 24 g of fiber with 24 g of either olestra or triglyceride for 28 days.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that olestra causes diarrhea. FDA considered the evidence presented by CSPI during the agency's review of the original petition for the use of olestra in savory snacks. Upon evaluation of all of the data considered in the original petition, FDA concluded that the "diarrhea" reported by study subjects was not diarrhea in the medical sense because it was not associated with objective measures of diarrhea (*i.e.*, the loss of water or electrolytes) (61 FR 3118 at 3159). Moreover, as discussed previously, data from the petitioner's Stool Composition Study support FDA's 1996 decision that consumption of olestra does not cause medical diarrhea. Therefore, FDA has no basis to require a label statement indicating that olestra causes diarrhea.

(Comment 18) A comment from CSPI to the 1996 final rule stated the group's opposition to any use of the phrase "excessive consumption of olestra" in the label statement because P&G's data show that consumption of even modest amounts of olestra can cause GI disturbances. CSPI also opposed labeling indicating that olestra's GI symptoms were "usually minor," arguing that diarrhea is not a minor symptom and that some subjects experienced moderate or severe symptoms.

At the time of the 1996 final rule, FDA believed that it was prudent to rely on the data generated from the safety studies as a basis for requiring labeling to disclose potential GI effects of olestra-containing foods. The data generated from the safety studies did not provide a basis to characterize the frequency of GI symptoms or the consumption levels at which consumers would experience such effects under customary or usual consumption of savory snacks. Data and information obtained since the 1996 final rule examining the effect of customary or usual consumption of olestra-containing foods show that olestra causes only minor increases in the frequency of loose stools and bowel movements, and no increase in the frequency of abdominal cramps. Based on these findings, the agency believes that there is no longer a basis to require a label statement about the possible GI effects associated with the consumption of olestra-containing foods. Therefore, use of specific phrases such as "excessive consumption of olestra" and "usually minor" in the label statement are no longer at issue.

B. Label Statement for Nutritional Effects

(Comment 19) Comments from CSPI and Frito-Lay to the current petition suggested that the label statement regarding the addition of vitamins A, D, E, and K should be replaced with an asterisk and a phrase such as "Not nutritionally significant" because the current statement is confusing. Frito-Lay stated that the suggested labeling will ensure that consumers know the product has not been fortified to provide a nutritional benefit with respect to vitamins A, D, E, and K. Frito-Lay also stated that the vitamin statements should be eliminated from the olestra label because they are widely misunderstood and P&G's postapproval research shows that the added vitamins compensate for any absorptive effect of olestra.

Similarly, comments from P&G, Frito-Lay, trade associations, and academia to the 1996 final rule stated that the statements regarding added vitamins should be dropped from the label. Some of these comments asserted that the added vitamins should be labeled instead in the ingredient list with an asterisk directing consumers to a statement such as "Not a nutritionally significant source." Arguments presented in support of this recommendation were summarized briefly as follows: (1) Consumer studies submitted by P&G and Frito-Lay arguably show that the current label statement is difficult for consumers to understand; (2) quantitative research submitted by P&G shows that the suggested labeling (use of an asterisk and referencing language such as "Not a nutritionally significant source") best communicates the fact that olestra will have no net effect on the status of vitamins A, D, E, and K; (3) the suggested label statement is consistent with the views expressed by the FAC at the 1995 and 1998 meetings; and (4) consumers are accustomed to seeing the suggested-type of labeling on the nutrition label for skim milk and some fat-free products; therefore, they are more likely to understand it.

FDA agrees with these comments. As discussed previously, by this final rule, a label statement that explains olestra's potential effects on the absorption of fat-soluble vitamins and other nutrients is no longer required, and information that informs consumers that olestra-containing foods have not been fortified with vitamins A, D, E, and K will be provided through an asterisk and the statement "Dietarily insignificant" that will follow the ingredient list of olestra-containing foods.

(Comment 20) Some comments to the 1996 final rule suggested specific language changes to the vitamin statements because the statements in the label are too vague or misunderstood by consumers. All of the suggested language changes indicated that olestra interfered with the absorption of vitamins A, D, E, and K and that these vitamins were added to compensate for potential losses.⁶¹ A comment from P&G also suggested that, if the label statement is retained, it should explain why olestra has effects on vitamin absorption.

Based on consumer studies, FDA believes that the current label statement is not an effective means of communicating to consumers that olestra affects the absorption of fat-soluble vitamins or why vitamins A, D, E, and K are added to olestra-containing foods. As part of this rulemaking, the agency has concluded that a statement about olestra's effects on the absorption of fat-soluble vitamins is not needed in order to understand that olestra-containing foods do not contribute significant amounts of vitamins A, D, E, and K to the diet. Therefore, the agency believes that the label statement about olestra's effects on vitamin absorption should be eliminated, not simply reworded. The agency does, however, believe that the label of olestra-containing foods must communicate that the vitamins A, D, E, and K added to such foods will not change consumers' vitamin status. Accordingly, this final rule requires the use of an asterisk and short explanatory phrase, "Dietarily insignificant," a configuration that will communicate the intended message more clearly than the current statement. FDA notes that the petitioner concluded from consumer studies that the asterisk/statement configuration best communicates to consumers the fact that the vitamins A, D, E, and K added to olestra-containing foods would have no net effect on consumers' vitamin status. It is also a format and configuration familiar to consumers because it is used in the Nutrition Facts panel and is similar to language used in other label statements (§§ 101.60, 101.61, and 101.62).

(Comment 21) A comment from a trade association to the 1996 final rule stated that the vitamin statement should be eliminated because the statement is

a nutrient content claim for added vitamins and therefore violates §§ 101.13, 101.54, and 101.9(c)(8)(ii). The comment stated that to satisfy a nutrient content claim for added vitamins, the product must provide an additional 10 percent of the reference daily intake (RDI) compared to a reference food. The comment claimed that vitamin addition to olestra would not always contribute an additional 10 percent of the RDI for the added vitamins; therefore, the vitamin statement violates §§ 101.13 and 101.54. The comment also argued that the label statement violates § 101.9(c)(8)(ii) because any claimed nutrient must be included on the nutrition label. Under the current policy, the vitamins added to olestra are not included on the nutrition label.

Because the olestra label statement will no longer be required to appear on the package of olestra-containing foods, whether the label statement contains a nutrient content claim is no longer an issue.

(Comment 22) A comment from CSPI to the 1996 final rule recommended that the label statement advise consumers not to consume olestra with meals or vitamin supplements because such consumption would maximize nutrient loss. In contrast, a comment from P&G opposed such a label statement. In its comment, P&G cited preliminary data from its Active Surveillance Study showing that consumption of olestra-containing food does not result in any meaningful decrease in serum carotenoids. P&G also stated that the compensation levels of vitamins A, D, E, and K required by the agency are based on data reflecting worst-case consumption scenarios. P&G also noted that the majority of members of the FAC concluded in 1998 that there were no new data showing that olestra will adversely affect health by interference with the absorption of fat-soluble vitamins or other lipophilic substances.

FDA does not agree that olestra-containing foods should be required to bear a label statement advising consumers against consumption of olestra with meals or vitamin supplements. FDA required the addition of vitamins A, D, E, and K to compensate for the known effects of olestra and established compensation levels that would be adequate for those individuals who consume olestra-containing snacks at meals. For carotenoids, FDA concluded in the 1996 final rule that there was no basis to require compensation of olestra-containing foods with specific carotenoids (61 FR 3118 at 3147-3149). Moreover, in its comments, CSPI

provided no data to show that customary or usual consumption of olestra-containing snacks with meals or vitamin supplements causes nutrient losses that warrant a statement advising consumers not to consume olestra-containing snacks with meals or vitamin supplements.

(Comment 23) A comment from CSPI to the 1996 final rule stated that the olestra label statement should include information directed toward those using coumarin derivatives to control blood clotting because there are no clinical data in the olestra petition showing that the addition of vitamin K to olestra-containing foods would be safe and efficacious for people who use coumarin derivatives. The comment also suggested that the label statement include information directed toward those with hemophilia or "other blood diseases." A comment from academia also requested that the label statement provide information directed at those taking coumarin derivatives and cited an article in the *New England Journal of Medicine* (Ref. 36) as support for a warning label statement. The comment asserted that olestra's inhibition of vitamin K absorption could result in extreme elevation of prothrombin time and that patients taking this medication would need a careful and more frequent monitoring system to regulate and adjust drug administration. The comment also asserted that safety studies with olestra should be performed in patients taking coumarin derivatives. Another comment requested that the label statement indicate that olestra could cause blood clots, but provided no data or rationale to support this assertion.

One comment opposed the use of "hemophilia" in statements directed toward users of coumarin derivatives, stating that vitamin K status is not a factor in hemophilia. The comment also opposed use of the phrase "other blood diseases" in any statement directed toward users of coumarin derivatives because it is too vague. The comment also stated that the routine monitoring by physicians of patients taking coumarin derivatives will result in alterations in drug dosing if major and persistent alterations of vitamin K-compensated olestra-containing food intakes are found to influence drug efficacy.

FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward those using coumarin derivatives to control blood clotting. FDA concluded in 1996 that consumption of olestra would not significantly influence the rate or extent of absorption of drugs (61

⁶¹ Two examples of wording suggested by the comments are: "Because olestra interferes with your body from absorbing certain nutrients and the vitamins A, D, E, and K, these essential vitamins have been added to this product." and "Olestra reduces the absorption of some nutrients, and vitamins A, D, E, and K have been added to compensate."

FR 3118 at 3132). Further, FDA stated that it did not expect olestra consumption to have a significant effect on the absorption of Coumadin, the most commonly prescribed form of coumarin (61 FR 3118 at 3132). As part of the 1996 final rule, FDA required olestra-containing foods to be compensated with 8 micrograms vitamin K₁/g olestra so that consumption of vitamin K-compensated foods will have no net effect on vitamin K status (61 FR 3118 at 3167). FDA also concluded in 1996 that any change in vitamin K status due to consumption of vitamin K-compensated olestra would likely be within the normal range of dietary variation (61 FR 3118 at 3147). The comments do not provide the agency with any evidence that vitamin K-compensated olestra would cause changes in vitamin K status beyond the normal range of dietary variation or that olestra would affect the absorption of coumarin derivatives. Thus the agency has no basis to require labeling directed to those individuals using coumarin derivatives to control blood clotting.

(Comment 24) A comment from Frito-Lay to the current petition as well as comments from P&G, Frito-Lay, and academia to the 1996 final rule stated that the phrase "other nutrients" should be eliminated from the label because the health benefits associated with consumption of fruits and vegetables have not been specifically attributed to carotenoids and consumer perception studies show that consumers are confused as to its meaning. One comment added that current evidence does not show that inhibition of carotenoid absorption has any nutritional significance. One comment stated that this phrase creates a misperception of a lack of safety and serves no purpose because carotenoids are neither specifically mentioned nor added back. P&G and Frito-Lay both reported that data from consumer studies show that the phrase "other nutrients" is not informative and may be misinterpreted.

A comment from academia to the 1996 final rule criticized the focus group study submitted by P&G, stating that the participants were not adequately informed about the depletion of blood carotenoids and the evidence relating low blood carotenoids to risks of serious major health outcomes; therefore, this comment concluded that the results of the focus group study are "specious."

FDA agrees that the phrase "other nutrients" should be eliminated from the label statement. Information from consumer perception studies shows that the label's contextual statement about

"some vitamins and other nutrients" tends to mislead consumers and the contextual information is not necessary to understand that olestra-containing foods do not contribute significant amounts of vitamins A, D, E, and K to the diet.

In the 1996 final rule, FDA did not require a specific statement on carotenoids because doing so could falsely imply that their decreased absorption is known to be of significance (61 FR 3118 at 3161). FDA determined in the 1996 final rule that the data and information available to the agency do not establish any identifiable nutritional or prophylactic benefits for carotenoids, with the exception of their provitamin A effects (61 FR 3118 at 3149). Thus, FDA does not agree that the results of the focus group studies are "specious" because participants were not informed of possible health consequences of decreased levels of blood carotenoids.

(Comment 25) A comment from CSPI to the current petition asserted that the olestra label statement should indicate that olestra consumption may reduce the absorption of carotenoids and that carotenoids may protect against certain chronic illnesses. Alternatively, the comment stated that FDA should require fortification of olestra-containing foods with the relevant fat-soluble carotenoids. The comment asserted that olestra's effect on carotenoid levels is a material consequence that may result from customary consumption and that the olestra label statement would be misleading without a statement about carotenoid loss. The comment cited P&G's two 8-week studies as well as two published articles describing human studies⁶² conducted with sucrose polyester and asserted that all of these studies showed substantial decreases in serum carotenoids associated with olestra consumption. CSPI quotes statements from the two published studies conducted with sucrose polyester indicating that the effects of sucrose polyester on carotenoids are undesirable. CSPI also quotes from an invited commentary on one of the

⁶² One of the articles cited by CSPI is described in section VI.A (Ref 34). The other article cited by CSPI describes two studies (Ref. 37). The first study was a double-blind, placebo-controlled crossover study in which subjects received, through margarine, zero or 12.4 g of sucrose polyester per day for 4 weeks. The second study was a double-blind, placebo-controlled parallel comparison study in which subjects received, through margarine, zero or 3 g of sucrose polyester per day for 4 weeks. Both studies measured the effect of the treatments on plasma carotenoid concentration. The article does not include information (such as specifications) to determine the similarity between the sucrose polyester tested and olestra.

studies. The commentary states that the deleterious effects of sucrose polyester should be studied further before it is widely available for long-term consumption (Ref. 38). CSPI also stated that there is growing evidence that carotenoids provide a health benefit, citing studies reviewed by Dr. Graham Colditz at the 1998 FAC meeting and three other research articles submitted to the docket by another comment (Refs. 39 through 41). CSPI added that consumers need information concerning carotenoid absorption because they cannot monitor depletion of their carotenoids, and detection of health changes caused by carotenoid depletion may occur only after irreversible damage has taken place. Finally, CSPI stated that the agency should base its decision on the potential nutritional effects of daily consumption of olestra, as documented by the preapproval clinical studies.

Similarly, in its comments to the 1996 final rule, CSPI suggested that the phrase "other nutrients" should be expanded to advise consumers that olestra has been shown to decrease blood levels of carotenoids. The comment also stated that the label statement should include statements about the types of conditions that carotenoids may help prevent, such as cancer and blindness. The comment reported that the majority of carotenoid experts contacted by CSPI agreed that depletion of carotenoids is likely to pose hazards or risk of harm to health. The comment also cites the 1995 edition of the "Dietary Guidelines for Americans" issued on January 2, 1996, jointly by the Department of Agriculture and the Department of Health and Human Services. CSPI stated that the guidelines say that antioxidants such as carotenoids are of interest because they may have a beneficial role in reducing the risk of cancer and certain other chronic diseases. CSPI asserts that if evidence of carotenoids' value in protecting health is sufficient to warrant such a statement by the Department of Health and Human Services, it should be sufficient for FDA to inform consumers that olestra depletes carotenoids. CSPI also argued that depletion of carotenoids is a side effect that the public cannot monitor and the public needs information on side effects in order to decide whether to buy olestra-containing foods.

In contrast to CSPI's comments, a comment to the 1996 final rule specifically opposed use of the words "causing cancer or blindness" on the label statement because the words put olestra in the category of cigarettes and expressed the opinion that olestra did

not belong in the same category as cigarettes, but provided no factual information or rationale in support of the opinion expressed.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that consumption of these foods may reduce the absorption of carotenoids and that carotenoids may protect against certain diseases, nor does FDA agree that it should require addition of specific carotenoids to olestra-containing foods. Current evidence supports the connection between the consumption of fruits and vegetables (many of which contain carotenoids) and reduced risk for certain diseases. The available data do not, however, establish any identifiable nutritional or prophylactic benefits specifically for carotenoids, either individually or collectively (61 FR 3118 at 3149) other than their provitamin A function. This position is consistent with the conclusions of the 2000 report of the IOM Panel on Dietary Antioxidants and Related Compounds which found no basis for establishing a DRI for beta-carotene or other carotenoids.⁶³ The 1995 "Dietary Guidelines for Americans" recommend healthy dietary habits, including eating fruits and vegetables, but do not present any new scientific information related to possible beneficial health effects specifically attributed to the consumption of carotenoids. Based on the lack of an identifiable nutritional or prophylactic benefit for carotenoids (other than their provitamin A activity), FDA has no basis at this time to require a label statement about carotenoids and their potential health effects or to require the addition of specific carotenoids to olestra-containing foods.⁶⁴

FDA determined in its 1996 final rule that, based on the existing scientific evidence, including the 8-week studies examining the nutritional effects of daily olestra consumption, that there was no justification or need to require compensation of olestra-containing foods with specific carotenoids (61 FR 3118 at 3149). The data and information obtained since the time of the 1996 final rule do not change the agency's 1996 conclusion.

The issue of olestra's effect on carotenoids was discussed by the FAC in both 1995 and 1998. Most members of the FAC agreed in 1995 that the effect

of olestra on the bioavailability of carotenoids is not a fact that is material in light of the consequences that may result from consumption of olestra-containing foods and therefore the effect does not warrant disclosure on the label of such foods (61 FR 3118 at 3162). Subsequently, in 1998, a majority of the FAC expressed the view that there were no new data to show that the potential effect of olestra on carotenoids represents a public health concern.⁶⁵

(Comment 26) A comment from academia to the current petition stated that the issue of olestra, carotenoids, and chronic disease should be considered by an impartial body such as the NAS to determine whether there is reasonable certainty that reductions in carotenoid levels will not increase the risk of various diseases. The comment states that the approval process for olestra was flawed because in the first review, the committee did not include cancer or nutritional epidemiologists or other experts who are qualified to review the issue of carotenoid intake and its effect on risk of chronic disease. The comment also stated that in the second review, the committee did not consider evidence considered by the first committee, but only considered new evidence.⁶⁶ The comment asserted that since the June 1998 FAC meeting, there have been a substantial number of publications indicating that low carotenoid status may be linked to increased risk for certain diseases and included copies of three published articles on carotenoids.⁶⁷ The comment also states the results of a 1996 survey of 13 members of the NAS Committee on Diet, Nutrition, and Cancer who authored the 1982 review of Diet, Nutrition, and Cancer.⁶⁸ The survey asked the following questions: (1) "Are you reasonably certain that carotenoids contained in fruits and vegetables are not related to the apparent benefits of these foods in reducing cancer risk?" and (2) "Are you reasonably certain that reductions in blood levels of carotenoids will not increase the risk of cancer?" The comment stated that seven members answered "no" to both questions and that not one member could affirm that they could be reasonably certain that reductions in

blood carotenoids would not increase cancer risk. Based on the results of the survey, the comment concluded that the FDA's conclusion of olestra's "reasonable certainty of no harm" is not supported by expert scientific opinion. The comment asserted that the effects of carotenoids are poorly understood and we cannot be reasonably confident that reduction in blood carotenoid levels will cause no harm. The comment also stated that the logic that we cannot be certain whether it is the carotenoids in fruits and vegetables that are protective against disease violates the precautionary principle and FDA's guideline of reasonable certainty of no harm because the burden of proof should be on the petitioner to show that carotenoids are not the protective factors in fruits and vegetables.

This comment raises the issue of whether olestra's use in savory snacks is safe (section 409(c) of the act), given the potential effects of olestra consumption on serum carotenoids levels. This issue is beyond the scope of the petition before FDA which concerns labeling. FDA notes that even if the comment is correct that olestra's use in savory snacks is unsafe due to the additive's effect on serum carotenoids, such lack of safety cannot be rectified through labeling. Indeed, as noted, in the 1996 final rule, FDA concluded that olestra is safe for use in savory snacks, a conclusion reached after a review of the evidence in the record concerning carotenoids and human health. If the comment wishes to have FDA consider this safety issue, they must file a citizen petition requesting such consideration, 21 CFR 10.30, not raise it as a collateral issue in this proceeding. FDA addresses the issue of labeling for olestra's effect on carotenoids in its response to the previous comment. FDA addresses the issues raised about the 1995 meeting of the OWG and FAC and the 1998 meeting of the FAC in response to comment 43 of this document.

C. Labeling for Special Populations

(Comment 27) Some comments to the current petition stated that the olestra label should include a statement that olestra-containing foods should not be given to children. One comment stated that olestra should be marketed in childproof containers or the food label should include the statement "Keep out of reach of children." One comment expressed concern that there is a lack of testing and evaluation of olestra in young children, and that even small packages may be a relatively high dose in children when considered on the basis of grams of olestra per kilogram of body weight. Two comments reported

⁶⁵ Transcript, vol. 3, pp. 101-174.

⁶⁶ FDA assumes that the first review referred to by the comment is the 1995 meeting of the OWG and FAC and that the second review referred to by the comment is the 1998 meeting of the FAC.

⁶⁷ The publications submitted with the comment are the same as those discussed in the previous comment (Refs. 39 through 41).

⁶⁸ The survey was conducted in May 1996 by Drs. Walter Willett and Meir Stampfer of the Department of Nutrition, Harvard School of Public Health.

⁶³ FDA notes that in its report, the panel considered the 1999 research articles referred to by CSPI (Refs. 39 through 41).

⁶⁴ FDA notes that the addition of vitamin A to olestra-containing foods compensates for any provitamin A losses caused by the inhibitory effect of olestra on carotenoid absorption.

GI reactions of a child who had consumed an olestra-containing food.

CSPI submitted comments to the 1996 final rule requesting that the olestra label contain statements directed toward certain populations of consumers. In particular, CSPI stated that the label statement should contain special notification for children and for the elderly because olestra is poorly studied in children and there are inadequate data regarding the possible hazards of olestra consumption over both the long and short terms. The comment also quoted a 1995 FDA review memorandum of the petitioner's preapproval Fecal Parameters Study which expresses concern for two populations not represented in the study, the elderly and young children, because of the potential for increased water loss through the stool of subjects reporting olestra-associated diarrhea (Ref. 22). CSPI also stated that the label of olestra-containing foods should include statements directed toward pregnant women because there are inadequate data regarding the safety of olestra for use by pregnant women. CSPI suggested that the label statement indicate that those with inflammatory bowel diseases, irritable bowel diseases, and malabsorption disorders should contact a physician before eating olestra-containing foods because, in CSPI's opinion, the study of inflammatory bowel disease patients was too small and too brief to determine conclusively that olestra is safe for people with these illnesses.

FDA does not agree that the agency should require olestra-containing foods to bear a label statement directed toward special populations. In the 1996 final rule (61 FR 3118 at 3156-3157), the agency stated its conclusion that olestra was safe for use by children. Three studies submitted in support of the original petition reported GI symptoms in the young. FDA noted that GI symptoms seen in children were similar to those seen in the 8-week studies of adults. FDA concluded that the safety of olestra for use by children could be addressed by extrapolating the GI effects in adults to the young. This approach was fully consistent with the expert views provided by the OWG and the members of the FAC. Further, the petitioner's Home Consumption Study submitted in support of the current petition shows no olestra-related effects in the group of subjects younger than 18 years (Ref. 15). The comments provide the agency with no new data to show that olestra-containing foods should not be consumed by children, or should be specially labeled or packaged for children.

Similarly, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward the elderly. The agency is not aware of any safety issues specific to olestra-consumption by the elderly, nor does the comment provide evidence of such issues. Since submission of this comment, the agency has received several postapproval studies from the petitioner that have included subjects over the age of 65. These studies have not identified any concerns specific to the elderly that would require specialized labeling.

FDA does not agree with CSPI's conclusion that the agency's memorandum (Ref. 22), should drive the overall conclusion about the effects of consumption of olestra-containing food on children and the elderly. The agency considered this memorandum in its analysis of the original food additive petition on olestra (61 FR 3118 at 3155). In the 1996 final rule, FDA concluded that the Fecal Parameters Study showed there is no difference in stool composition (e.g., water and electrolyte content) between those olestra-consuming subjects who reported diarrhea and those who did not (61 FR 3118 at 3155). In its overall conclusions on the effects of olestra on the GI tract, the agency stated that even those olestra-consuming subjects in the preapproval studies who experienced loose stools continuously for several weeks did not show any evidence of fluid loss, such as hemoconcentration or electrolyte imbalance (61 FR 3118 at 3159). Since publication of the 1996 final rule, P&G submitted the Stool Composition Study, which examined the effect of olestra on the water content of stools. The Stool Composition Study used a dose of olestra that was greater than the highest dose used in the Fecal Parameters Study and collected stools from study subjects for a longer period of time. As discussed previously, based upon the agency's evaluation of the Stool Composition Study, FDA has concluded that the GI effects observed are not clinically significant (Ref. 18), and that the stools study subjects characterized as "diarrhea" were not associated with an increase in stool water (Ref. 10).

In addition, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward pregnant women. FDA concluded in 1996 that olestra is safe for its intended use in savory snacks (§ 172.867). FDA has no basis to conclude that there are consequences associated with the consumption of olestra that are specific to pregnant women. Importantly, the comment

provides no information to demonstrate that olestra-containing foods present a unique risk to pregnant women.

Finally, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward those with inflammatory bowel disease, irritable bowel disease, or malabsorption disorder. Once again, the comment provides no evidence to establish that there are consequences of olestra consumption specific to patients with inflammatory bowel disease, irritable bowel syndrome, or malabsorption disorder, that warrant special labeling. Moreover, FDA considered data regarding inflammatory bowel disease at the time of the 1996 final rule. In particular, P&G conducted a study to address concerns as to whether the presence of olestra in the GI tract exacerbates the disease state of patients with inflammatory bowel disease. FDA acknowledged that the study of inflammatory bowel disease patients was limited in size and duration (61 FR 3118 at 3155-56). The study does, however, provide reassurance that consumption of 20 g olestra/d for up to 31 days did not cause an observable effect in populations with inflammatory bowel disease. In addition to this human study, the petitioner conducted studies to assess the potential for increased absorption of olestra in guinea pigs with compromised GI tracts containing lesions similar to those seen in ulcerative colitis and Crohn's disease. The studies showed that the absorption of intact olestra is no greater in guinea pigs with compromised GI tracts than in guinea pigs with normal GI tracts (61 FR 3118 at 3126-3127).

(Comment 28) One comment from an individual consumer to the 1996 final rule expressed concern that it is important for diabetics to know that sucrose is part of the olestra molecule.

FDA disagrees with this comment. As discussed in the 1996 final rule, olestra is a chemical combination of sucrose with six, seven, or eight fatty acids (61 FR 3118 at 3118). While olestra is made from nutritive ingredients, only a minuscule amount of olestra is absorbed by the body (61 FR 3118 at 3120 at 3126-3127), and therefore, most of the sucrose present in olestra is not biologically available. Similarly, FDA noted that rats administered the formulation of olestra proposed for human consumption absorbed only 0.14 percent of the administered dose (61 FR 3118 at 3126). Thus, at most, only trivial amounts of sucrose could be obtained from the ingestion of olestra. FDA concluded in 1996 that all safety issues regarding olestra had been addressed

adequately and that the use of olestra in savory snacks is safe (61 FR 3118 at 3168). The comment provides no evidence that the small amount of sucrose potentially obtained from olestra is hazardous to diabetics or warrants disclosure on the food label. Therefore, FDA concludes that there is no basis for the agency to require that the label of olestra-containing foods disclose that olestra is made from sucrose.

D. Label Statement in Its Entirety

(Comment 29) Frito-Lay and P&G submitted comments stating that the olestra label should be eliminated in its entirety and that the added vitamins should be labeled in the ingredient list with an asterisk and a statement such as “*Not a nutritionally significant source.” The comment from P&G to the 1996 final rule reported the findings of an expert panel it convened to examine whether the label statement should be maintained. The comments from both Frito-Lay and P&G provided arguments for the elimination of the GI and nutritional effects statements. FDA responded to these arguments in the previous sections discussing comments on the GI and nutritional effects statements. Both comments argued that the current scientific evidence does not support retention of the label statement and that the label is misleading. Frito-Lay also pointed out that the sentence “This product contains olestra.” is not needed in the label statement because olestra is listed in the ingredient statement, and manufacturers that use olestra generally place the logo of the olestra brand name, Olean, on the front panel of olestra-containing foods.

In contrast, a comment from CSPI to the current petition supported the retention of a label statement. In its comment CSPI proposed the following label statement enclosed in a box:

THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools in a small percentage of consumers. If you experience adverse effects that may be caused by olestra, call 1-800-OLESTRA. If your symptoms persist or are severe, contact a health professional. Frequent consumption of olestra may reduce your body's absorption of fat-soluble nutrients (carotenoids). Carotenoids, found in fruits and vegetables, may protect you against certain chronic illnesses.⁶⁹

⁶⁹ FDA notes that since the 1996 final rule, CSPI has submitted several versions of a suggested label statement. The version presented is CSPI's most recent version. Previous versions are generally characterized as including a greater number of possible GI symptoms, statements about olestra's effect on the absorption of vitamins A, D, E, and K, statements that loss of carotenoids may increase the risk of certain health conditions, and statements

CSPI argued that a nondescript declaration of the word “olestra” in the ingredient listing does not inform consumers of the side effects of consuming olestra, and unless consumers are aware of the potential side effects, they would have no reason to consult the ingredient list to determine if a food contains olestra. CSPI asserted that a similar concern was raised about the use of the terms “pasteurized” or “unpasteurized” in the preamble to the final rule requiring warning label statements for unpasteurized juices (63 FR 37030, July 8, 1998). CSPI pointed out that the final rule stated that some consumers do not know the significance of pasteurization and therefore would not be able to make an informed decision on whether to purchase and consume the products and that use of the term “pasteurized” or “unpasteurized” alone would not give consumers information about the risks presented by untreated juices (63 FR 37030 at 37034). CSPI noted that the final rule for labeling of unpasteurized juices argues that the presence of some pathogens that have been responsible for recent outbreaks of food borne illnesses associated with untreated juice products is a relatively new phenomenon. Therefore, consumers do not associate such pathogens and the risks they present with the consumption of untreated juice (63 FR 37030 at 37032-33). CSPI asserted that label statements for olestra are necessary to inform consumers of the unexpected, potential consequences of consuming foods that have long been consumed without adverse effects and that simply disclosing the presence of olestra in the ingredient statement does not inform consumers of olestra's potential side effects.

FDA agrees with the comments from Frito-Lay and P&G that olestra-containing foods should no longer be required to bear a label statement. FDA concluded in the 1996 final rule that olestra was safe for its intended use in savory snacks. As part of the 1996 final rule, FDA required a label statement to appear on olestra-containing foods. The label statement was required to inform consumers of the potential for olestra to cause GI effects and because consumers had no experience with this food ingredient. The label was also required in order to prevent consumers from erroneously concluding that the vitamins added to olestra-containing foods would contribute significant amounts to their diet when, in fact,

directed toward special populations (such as children, patients taking Coumadin, and those with bowel disorders).

these vitamins were added to offset any vitamin losses caused by the consumption of olestra-containing foods. The rationale used in the labeling of untreated juice products cannot be directly applied to the labeling of olestra-containing foods because untreated juice products were labeled to warn consumers of potential health hazards such as serious illness, while olestra-containing foods were labeled to inform consumers of potential effects that do not represent health hazards.

In determining the wording of the warning statement for unpasteurized juices, FDA determined from focus group research that most participants had a good understanding of what pasteurization was, but a significant number of participants did not (63 FR 37030 at 37034). The agency also concluded that use of the terms “pasteurized” or “unpasteurized” alone would not give consumers information about the risks presented by untreated juices (63 FR 37030 at 37034). In contrast, as discussed previously, postapproval consumer perception studies and tracking surveys show that there is currently a high degree of awareness about olestra and its ability to cause GI effects. Indeed, it appears that consumers are more likely to overestimate rather than underestimate the potential for olestra to cause GI effects. FDA does not typically require label statements for products that may cause GI symptoms when consumers are aware that such foods may cause such effects. As noted in the response to previous comments, FDA does not believe that the label of olestra-containing foods should be required to contain information about the effect of olestra on serum carotenoid levels. FDA will require that vitamins A, D, E, and K added to olestra be labeled in the ingredient list with an asterisk and the phrase “Dietarily insignificant” to prevent consumers from being misled to believe that the added vitamins contribute significant amounts to the diet.

(Comment 30) Many comments to the current petition specifically stated that olestra-containing foods should bear a label statement. Most of these comments were from consumers who reported experiencing GI reactions that they associated with consuming olestra-containing foods. One comment stated that the label statement was important in identifying the cause of their GI symptoms. Another comment expressed concern that there is insufficient knowledge about olestra. Another comment stated that a side effect such as severe abdominal cramping and diarrhea should be made known to

people who consume olestra, because such symptoms can have significant clinical effects on patients with many different medical conditions.

In addition, some comments to the 1996 final rule specifically stated that olestra-containing foods should bear a special label statement. One comment stated that the label statement required by the 1996 final rule is clear and should be retained. One comment supported the need for labeling by citing reports from a number of constituents who had consumed olestra-containing foods and had experienced severe GI reactions that they believe were caused by olestra. Other comments requested that olestra-containing foods bear a label statement so that these products can be avoided.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement. FDA does not agree that it should require special labeling for olestra-containing foods on the basis that consumers are not familiar with olestra and the potential GI symptoms it may cause. In reaching its decision on this food additive petition, FDA considered the public's awareness of olestra's potential to cause GI effects. As stated previously, the postapproval consumer perception studies and the tracking surveys show that there is currently a high degree of awareness about olestra and its potential to cause GI effects. FDA does not typically require special labeling of products that may cause GI symptoms when consumers are aware that such foods may cause such effects. FDA notes that, even in the absence of the label statement, consumers who wish to avoid olestra will still be able to identify olestra-containing foods because olestra is required to be declared in the ingredient list of such products.

The agency concluded in 1996 that olestra was safe for use in savory snacks and that olestra's GI effects were not adverse health effects (61 FR 3118 at 3159). The comments reporting GI reactions provide no basis to conclude that the GI symptoms reported are actually caused by olestra. The new data and information submitted by the petitioner show that customary or usual olestra consumption causes no increase in the frequency of abdominal cramps and only a minor increase in the frequency of loose stools and bowel movements and that these effects do not have a meaningful impact on daily activity. Moreover, the petitioner's most recent studies show that the label statement could be misleading and cause consumers of olestra to attribute

serious problems to olestra when this is unlikely to be the case.

(Comment 31) Some comments from individual consumers to the current petition stated that olestra-containing foods should bear a label statement because the public has a right to know about the potential side effects of olestra-containing foods.

FDA notes that the act does not provide the agency with the authority to require labeling simply because consumers appear to want such information. (*See Stauber v. FDA*, 895 F. Supp 1178, 1193 (N.D.Wisc. 1995); *Alliance for BioIntegrity v. Shalala*, 116 F. Supp 166, 179 (DDC Sept. 29, 2000).) FDA could require the suggested labeling if, without such labeling, the product labeling failed to reveal facts that are material in light of the consequences which may result from the conditions of use prescribed in the labeling or under conditions of use that are customary or usual.

(Comment 32) A comment from Frito-Lay to the 1996 final rule stated that the label statement should contain only a message directing consumers to a telephone number for more information instead of the current label statement. The Frito-Lay comment cited a consumer study showing that none of the label statements evaluated in the study eliminated consumer misperception and that consumers interpreted the current label statement as a safety warning. The comment concluded that this type of labeling, however worded, has a strong negative effect on the consumer's perception of the safety of olestra-containing foods. In a comment to the 1996 final rule, P&G stated that as an alternative to the nutritional effects statement or the labeling of the added vitamins in the ingredient list with an asterisk, the agency could consider requiring manufacturers to provide a telephone number for consumers to obtain nutritional information. In its comments to both the current petition and the 1996 final rule, CSPI stated that the label statement should include a telephone number for consumers to obtain more information or to report adverse effects.

FDA does not agree that it should require the labeling of olestra-containing foods to include a telephone number. As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement and that vitamins A, D, E, and K required to be added to olestra-containing foods should be labeled in the ingredient list with an asterisk that refers to the statement "Dietarily insignificant." FDA is requiring this labeling to ensure consumers

understand that such foods do not contribute significant amounts of the vitamins A, D, E, and K to the diet. FDA does not agree that it should require manufacturers to provide a telephone number in place of this information. FDA believes that there is no basis to require that the label for olestra-containing foods include a telephone number for consumers to obtain more information or report adverse effects, nor do the comments explain why such a number is necessary to prevent the misbranding of these foods. FDA recognizes that some firms voluntarily include telephone numbers on their food labels. For those products that do not contain a telephone number, consumers may obtain more information or report adverse effects by contacting the company using the company's name and address, both of which are required to appear on the food label in accordance with § 101.5.

E. Data and Information Considered in This Rulemaking

(Comment 33) A comment from CSPI to the current petition stated that the postapproval studies should be considered, but they should not supersede or override the preapproval studies. The comment asserted that the postapproval studies are not a reason to reject all the previous evidence that olestra can cause GI symptoms. The comment also asserted that the lack of adverse effects reported during P&G's postapproval studies may be due to the small doses of olestra consumed, relative to the preapproval studies, and that rules should be based on the possibility that a greater number of olestra-containing foods would be consumed more frequently in the future. CSPI also stated that the postapproval studies cannot disprove that olestra-containing foods cause adverse effects in a small percentage of consumers.

In deliberations on this petition, FDA has considered all evidence of record (including both preapproval and postapproval studies). The agency notes that the petitioner's postapproval studies are meant to complement, not supersede, the preapproval studies. The preapproval studies were designed to address safety while the postapproval studies were, with the exception of the Stool Composition Study, designed to address labeling.

FDA's 1996 decision to require special labeling of olestra-containing foods was based on preapproval studies which were designed to address the safety standard for food ingredients—reasonable certainty of no harm under the intended conditions of use (§ 170.3(i)). These studies examined the

effect of conditions of use that did not reflect expected intake and thus, do not provide information about the effects of olestra consumption under customary or usual conditions. In contrast, the petitioner's recent Acute Consumption Study, Home Consumption Study, and Rechallenge Study more closely address the factual predicate of the legal standard for requiring special labeling—facts that are material with respect to consequences which may result under the conditions of use prescribed in labeling or advertising or under such conditions of use that are customary or usual (section 201(n) of the act). Thus, FDA concludes that the petitioner's preapproval studies should be considered, but they must be considered in light of the postapproval studies which more directly address whether olestra-related effects warrant special labeling.

During FDA's review of P&G's petition for the use of olestra in savory snacks, FDA assumed that olestra-containing foods may be consumed more frequently than they are presently. For example, when estimating daily intake of olestra from savory snacks, the agency assumed that all savory snacks consumed would be olestra-containing savory snacks (61 FR 3118 at 3125). Such conservative assumptions are likely to over-estimate consumption.

Olestra is currently approved for use as a fat substitute only in ready-to-eat savory snacks. Any additional use will require agency approval through the food additive petition process in accordance with § 171.1 (21 CFR 171.1). When considering the approval of olestra for additional uses, FDA will consider consumers' cumulative exposure to olestra through the currently approved uses (savory snacks) as well as through any additional uses requested.

The question raised by this petition is not simply whether olestra causes GI effects, but whether customary or usual olestra consumption causes GI effects that warrant special labeling. As mentioned previously, while no study can rule out the possibility that olestra may cause GI effects in a small percentage of consumers, the petitioner's postapproval studies do show that customary or usual consumption of olestra-containing savory snacks does not cause GI symptoms with a frequency, severity, or impact on daily activity that warrant special labeling.

(Comment 34) A comment from CSPI to the current petition cited a study (Ref. 42) showing that consumption of 40 g olestra/day resulted in levels of fecal fat commonly observed in patients with

steatorrhea caused by malabsorption syndrome. CSPI quoted the researchers' concerns that physicians may suspect malabsorption syndrome in patients who consume olestra and subject them to unnecessary diagnostic tests. CSPI stated that while the results of the study alone may not warrant label statements they should be factored in with studies demonstrating olestra's effects on nutrient levels and GI symptoms.

Consideration of the study cited by CSPI does not change the agency's decision on this food additive petition. CSPI does not explain how the study should be considered in the context of labeling or why the results warrant special labeling of olestra-containing foods. CSPI provides no reason to believe that customary or usual olestra consumption has resulted in patients having to undergo unnecessary diagnostic tests for malabsorption syndrome or that malabsorption syndrome has been incorrectly diagnosed because of customary or usual olestra consumption.⁷⁰ FDA notes that the study cited in the comment serves to alert physicians to the potential effects of olestra consumption on the measurement of fecal fat so that such misdiagnoses may be avoided.

(Comment 35) A comment from CSPI to the current petition addressed a statement that P&G made in its petition that the First Amendment, which includes the right not to speak, may bar the requirement of anything other than material information or information deemed essential under the act to appear on the food label. In its comment, CSPI stated that consumers must be informed of the possible side effects of olestra-containing foods so that they can avoid needless medical treatment or avoid the possibility of suffering side effects altogether. CSPI also stated that the disclosure of potential side effects provides material information and is "reasonably related" to the agency's interest in preventing misleading food labels. Therefore, in CSPI's view, the label statement does not violate the First Amendment right

⁷⁰ Subjects in the study cited by CSPI were fed 40 g olestra per day for 6 days. Based on the agency's preapproval estimate of olestra consumption, this level of olestra consumption is unlikely to be achieved under customary or usual consumption conditions. FDA's preapproval estimate of chronic daily olestra intake was 7 g/p/d at the 90th percentile snack eater and 20 g/p/d for short-term "high" consumption consumers (61 FR 3118 at 3124-3125). The estimate of chronic daily olestra intake assumes that olestra will be consumed at this level every day. FDA estimated that a "high" short-term consumer would consume olestra at a level equivalent to eating a 2 oz bag of olestra chips each day for 12 weeks (61 FR 3118 at 3124-25).

not to speak, as asserted by the petitioner.

FDA did not rely on the petitioner's First Amendment argument in concluding that olestra-containing products should no longer be required to bear the label statement required by the 1996 final rule. The issue raised by the current petition and the comment is whether olestra-related side effects are consequences of customary or usual olestra consumption that require disclosure in labeling. As stated previously, the agency has concluded that olestra-related side effects do not warrant required labeling because these effects are not consequences of customary or usual olestra consumption, and the comment provides no such data or information to demonstrate the contrary.

(Comment 36) A comment from CSPI to the current petition pointed out that the petition states that FDA may decline to require disclosure of material information when to do so would crowd other important information or confuse consumers. CSPI argued that a label statement revised for increased clarity would not confuse consumers, and snack food packages are large enough to provide a label statement without crowding other important information.

As noted, this final rule requires that the label of olestra-containing foods list vitamins A, D, E, and K in the ingredient statement followed by an asterisk and the phrase "Dietarily insignificant." FDA has determined that, for the remainder of the label statement required by the 1996 final rule, the underlying factual basis no longer exists and thus, is removing the relevant requirement from § 172.867. These changes in the requirements for labeling of olestra-containing foods render moot the issue of "label crowding."

F. Safety of Olestra

(Comment 37) Several comments from individual consumers to the current petition stated that olestra-containing foods should no longer be sold. One comment stated that olestra-containing foods should no longer be sold because even a more prominent label statement would not prevent illness in those who ingest such products in situations where the products are served in unlabeled containers. These comments relayed GI reactions that were attributed to olestra. A comment from CSPI stated that other countries have not approved petitions for the use of olestra and that such decisions not to approve olestra should provide some guidance as to how a substance like olestra should be regulated.

A comment from CSPI to the 1996 final rule suggested that the label should include a statement indicating that the long-term effects of olestra consumption are not known. The comment expressed concern that the human studies were too brief compared to the length of time people will be eating olestra-containing foods and stated that the problems observed in the human and animal studies warrant a broader advisory about the possible long-term effects of olestra consumption. CSPI also stated that labeling should be complemented with point-of-purchase health-hazard information and mass media consumer information campaigns. Comments from manufacturers of baked snacks expressed concern that without clear labeling consumers will believe that olestra-containing foods are as safe as baked snacks.

In comments to the 1996 final rule, CSPI and an individual consumer requested that the label statement be placed on restaurant menus so that diners will not unknowingly consume olestra at a restaurant.

FDA disagrees with these comments. FDA concluded in the 1996 final rule that the use of olestra in savory snacks meets the safety standard for food additives, reasonable certainty of no harm (61 FR 3118 at 3167). The label statement required by the 1996 final rule was never intended to prevent illness or warn against conditions of use that may be harmful as the agency concluded in 1996 that olestra is safe for its intended use in savory snacks even without the label statement. FDA required that olestra-containing foods bear the label statement to provide information about the presence of the vitamins listed in the ingredient statement and about potential nutrient and GI effects of olestra. FDA determined that these statements were necessary at the time to ensure that olestra-containing foods are not misbranded within the meaning of the act (61 FR 3118 at 3168).

Because olestra-containing foods are safe even in the absence of the label statement, olestra-containing foods served in unlabeled containers or in a restaurant do not represent a health risk. FDA has no evidence to confirm that there is a group of individuals who are so sensitive or intolerant to olestra when it is consumed under customary or usual conditions that such consumption presents a health concern or warrants special labeling. In fact, the petitioner's Rechallenge Study shows that when consumers who reported effects that they attributed to olestra, were rechallenged with olestra chips, they were no more likely to report GI

symptoms compared to when they were challenged with triglyceride chips.

G. Allergenicity of Olestra or Olestra-Containing Foods

(Comment 38) A comment from CSPI to the current petition stated that while there is no reason to think that olestra itself causes allergic reactions, the agency or the petitioner should conduct tests to determine whether a contaminant in olestra, or another ingredient in olestra-containing chips, causes allergic reactions because allergic responses were reported. The comment added that FDA cannot design an accurate label statement until such studies have been conducted.

FDA does not agree that allergenicity testing of olestra or olestra-containing foods must be conducted before ruling on this petition. The agency addressed the potential allergenicity of olestra in the 1996 final rule (61 FR 3118 at 3166). Food allergens are generally known to be protein or glycoprotein in nature. Olestra, composed of six, seven, or eight fatty acids esterified to sucrose, is neither a protein nor a glycoprotein and does not contain these substances even as minor constituents. The comment provides no basis to alter FDA's original conclusion that olestra is unlikely to cause allergic reactions.

FDA acknowledges that some reports allege that unspecified allergic reactions or symptoms of allergic reactions were caused by an olestra-containing food. The comment provides no evidence or reason to conclude that the effects reported were caused by olestra. FDA notes that a published article reports that when individuals who reported an allergic reaction to olestra were rechallenged, none of the individuals were found to have a positive response to olestra upon eating olestra-containing potato chips or when given a skin prick test with olestra (Ref. 43).

FDA notes that olestra-containing foods, like non-olestra-containing foods, contain other ingredients that may be allergens to some individuals. Consumers are informed of the presence of such potential food allergens through the product ingredient statement, as is the case for products containing potentially allergenic substances like milk and eggs.

H. Nutrition Labeling and Claims

(Comment 39) A comment from CSPI to the current petition asserted that the amount of olestra contained in snacks should be declared in the Nutrition Facts label. The comment stated that the amount of total fat per serving should be listed with an asterisk pointing to a note stating, "This product contains x grams

of olestra, which is not digested by the body. These figures have been adjusted to reflect that reduced availability." The comment states that the amount of available fat, saturated fat, and polyunsaturated fat would be listed. Alternatively, the comment stated that if the Nutrition Facts label states "Fat 0 g" an asterisk should reference the statement, "Contains x grams of olestra, which is not absorbed by the body."

In a related comment to the 1996 final rule, P&G stated that the amount of olestra per serving should not be included on the label because the presence of olestra is already declared in the ingredient statement and because the position of olestra within the ingredient statement will reflect its predominance based on weight in the food. P&G's comment also stated that there is no precedent for requiring the declaration of the amount of an ingredient on the food label, and that many manufacturers offer consumers access to phone numbers from which they could obtain quantitative information about ingredients.

These comments on the information that should appear on the Nutrition Facts panel of olestra-containing foods fall outside the scope of this document. As stated in the notice of filing, this petition proposed to amend the food additive regulations by removing the requirement for the label statement prescribed in § 172.867(e), the requirement for which is found only in paragraphs (e)(1) through (e)(3).

FDA notes, however, that the current regulation on ingredient labeling (§ 101.4) requires food ingredients to be declared by their common or usual names in the ingredient statement of the food. Accordingly, olestra-containing foods must declare olestra as an ingredient of the food. Olestra's placement in the declaration of ingredients is determined by its predominance based on weight in the food. In addition, § 101.4(e) provides manufacturers with a uniform method to voluntarily declare the percentage of each ingredient in their product (58 FR 2850 at 2865, January 6, 1993).

(Comment 40) A comment from CSPI to the current petition stated that olestra-containing food should not be allowed to use the phrase "fat-free." The comment stated that olestra is a fat; therefore, the term "fat-free" on the label of olestra-containing foods is inaccurate. Instead of using the phrase "fat-free," CSPI suggested that olestra-containing food could declare "no calories from fat" or "contains x grams of olestra." This type of labeling statement would help to differentiate baked snacks from olestra-containing

snacks. The comment stated that an ounce of baked chips provides an ounce of carbohydrate and protein, whereas an ounce of olestra-containing chips provides only two-thirds to three-fourths an ounce of carbohydrate and protein.

A comment from a potato chip manufacturer to the 1996 final rule stated that olestra-containing foods should not be allowed to declare "fat-free" and "low fat" because the fat content of olestra-fried chips is equal in quantity to that of any standard chip; therefore, the comment concluded that the label statement is misleading.

These comments on the declaration of "fat-free" on olestra-containing foods fall outside the scope of this document. As stated in the notice of filing, this petition proposed to amend the food additive regulations by removing the requirement for the label statement prescribed in § 172.867(e). The requirement for the label statement is found only in § 172.867(e)(1) through (e)(3). These comments relate to a requirement found in § 172.867(e)(5).

FDA notes that the agency previously concluded that olestra shall not be considered to be a source of fat or calories for purposes of nutrition labeling or nutrient content claims because olestra is neither a triglyceride nor is it absorbed or metabolized like a fat (§ 172.867(e)(5)).

I. Appearance of the Label Statement

(Comment 41) Comments to both the current petition and the 1996 final rule addressed the appearance of the label statement. Comments from individual consumers and CSPI requested that the label statement be larger, printed in bold type, and placed on the principal display panel of the package to increase its prominence. CSPI stated that many of those who used CSPI's telephone line to report reactions did not see the label statement prior to consumption, and several comments from consumers stated this as well. In its comments to the 1996 final rule, CSPI requested that the label statement be placed far enough from the edges of the container to provide a flat unobscured surface for the wording, that there be sufficient white space around the box to set off the wording within the box, that the label statement be black on a white background, that the size of the text increase as the package size increases, that a prefatory word such as "Notice" precede the label statement, and that the box around the label statement be retained because boxed statements increase the likelihood that consumers will read the statement.

Comments from a trade association to the 1996 final rule stated that the olestra label statement should use general food labeling typography (as described in §§ 101.2, 101.3, and 101.105), like that used for labels on products containing mannitol, sorbitol, and polydextrose. Frito-Lay argued that the appearance requirements of the olestra label should be aligned with those of other substances with similar effects and levels of concern. The comment pointed out that label statements for food additives that are proven to cause serious health problems, such as sulfites (21 CFR 130.9), do not have the stringent requirements for labeling prominence that are required of olestra, which has been determined to be safe. Comments from P&G and a trade association stated that the box around the label statement should be eliminated because it increases concern about the safety of the product. P&G stated that boxed statements are appropriate only when death or very serious illness is a possible outcome of customary or usual use.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear the label statement required by the 1996 final rule. Therefore, the appearance of the label statement is no longer an issue. The label for olestra-containing foods will be required to provide information about the added vitamins A, D, E, and K through an asterisk, in the list of ingredients, referencing the statement "Dietarily insignificant." The prominence and placement of the phrase "Dietarily insignificant" will follow customary practice for other food products (such as §§ 101.60, 101.61, and 101.62) and will appear prominently and conspicuously as specified in § 101.2(c).

J. Labeling for Single-Serving Packages

(Comment 42) Comments from Frito-Lay and a trade association to the 1996 final rule stated that single serving packages of olestra-containing foods should be exempt from the requirement to bear a label statement because the small package of such containers is not compatible with the label statement, and because the portion contained in such packages is so small that the label statement may not disclose a material fact. Frito-Lay recommended that instead of the label statement required on larger packaging, single-serving packages include the statement, "For information on olestra call 1-800-XXX-XXXX."

In contrast, CSPI stated that single-serving packages should be required to bear the label statement because studies

by P&G show that the amount of olestra contained in such packages is sufficient to increase the incidence of GI disturbances.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement that informs consumers about the potential GI effects of these products. Therefore, whether single-serving containers should be required to bear the label statement is no longer an issue. FDA does not believe that single serving packages should be exempt from the required labeling of added vitamins A, D, E, and K with an asterisk and the phrase "Dietarily insignificant", nor do the comments provide a basis for such an exemption.

K. 1995 and 1998 FAC Meetings

(Comment 43) A comment from CSPI to the current petition criticized the 1995 and 1998 FAC meetings held by FDA. CSPI asserted that the 1995 FAC did not provide objective advice to FDA regarding the approval of olestra.⁷¹ CSPI also stated that the committee did not contain a single expert on carotenoids and that 9 of the 17 committee members who concluded that olestra meets the safety standard of "reasonable certainty of no harm" were affiliated with industry.

CSPI also stated that the conclusions of the 1998 FAC must be considered in light of the fact that the committee did not consider studies conducted prior to January 30, 1996, including those studies that CSPI stated prove that olestra can cause gastrointestinal symptoms and reduce serum carotenoid levels. CSPI also pointed out that the 1998 FAC did not consider the Fecal Parameters Study even though it was provided to FDA after the 1995 FAC meeting. CSPI also stated that reports of GI symptoms such as diarrhea, cramps, and nausea were downplayed at the 1998 FAC because they were not "unexpected" problems and the committee was asked only to consider whether there were any "unexpected" problems associated with olestra.

FDA does not agree that the 1995 FAC provided biased advice. CSPI raised this issue previously and FDA responded in the 1996 final rule (61 FR 3118 at 3164). As stated in the 1996 final rule, FAC members are screened prior to each meeting to determine if they have a conflict of interest with the material to be discussed at the meeting. Committee members are also expected to provide an objective opinion on the information presented. FDA believes that the committee was fairly balanced as

⁷¹ In its comment CSPI cites Ref. 36.

required by the Federal Advisory Committee Act (FACA). FDA also believes that there is no basis to conclude that the 10 nutrition experts at the FAC meeting were not able to understand the views and information presented on carotenoids (61 FR 3118 at 3164).

As part of the 1996 final rule, FDA announced its intention to review and evaluate all data and information bearing on the safety of olestra received by the agency within the first 30 months after the approval of olestra and to present an evaluation of the data to the agency's FAC (§ 172.867(f)). Consistent with its obligation, in 1998 FDA presented to the FAC an evaluation of the data and information obtained since the 1996 approval of olestra. The purpose of the presentation was to receive advice from the Committee on whether there continued to be reasonable certainty that use of olestra is not harmful. Specifically, the 1998 FAC was asked to evaluate whether data and information obtained since the approval of olestra raised safety concerns regarding any GI effects that were not anticipated at the time of olestra's approval and whether any newly available data showed that consumption of olestra-containing foods had a significant adverse health effect due to olestra's interference with absorption of fat-soluble vitamins or other lipophilic substances.⁷² The committee was also asked whether the label statement should be changed in light of new data and information. Because the FAC was asked if there were any new issues raised since the approval of olestra, the committee was asked to consider only the data and information obtained since the approval of olestra. Much of the new data focused on the effects of "real life" consumption of olestra-containing foods (*i.e.*, the Rechallenge Study, the Acute Consumption Study, and the Home Consumption Study). The studies conducted prior to the approval of olestra, such as the Fecal Parameters Study, examined the effects of olestra when consumed under conditions designed to assess safety and were previously considered by FDA in its review of the petition for the use of olestra in savory snacks. Although the 1998 FAC did not consider the petitioner's Fecal Parameters Study, the committee did consider the Stool Composition Study. Like the Fecal Parameters Study, the Stool Composition Study was designed to examine olestra's effect on objective stool characteristics but tested a higher

dose of olestra and collected stool samples on a greater number of days than was done in the Fecal Parameters Study. The committee also considered FDA's analysis of the reports collected through passive surveillance by P&G and CSPI, which include reports of GI symptoms such as diarrhea and abdominal pain.⁷³ Upon review of the data and information received since the 1996 final rule, a majority of the FAC concluded that there continues to be reasonable certainty of no harm concerning the use of olestra in savory snacks.⁷⁴ FDA believes that the data and information considered by the 1998 FAC were appropriate for the objective of the meeting, to determine whether the data and information obtained since the approval and marketing of olestra raise any issue not anticipated at the time of approval.

VI. Summary

In its petition, P&G requested that FDA amend the food additive regulations in § 172.867 *Olestra* by removing the requirement for the label statement prescribed in § 172.867(e). Based on its analysis of data and information in the petition, as well as data and information in FAP 7A3997 (which resulted in the establishment of § 172.867(e)), FDA has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers of possible GI symptoms from consumption of olestra. FDA also has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers of possible effects of olestra on the absorption of some vitamins and other nutrients. Finally, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers that vitamins A, D, E and K have been added. Instead, the listing of the vitamins in the ingredient statement of olestra-containing foods will now be followed by an asterisk that is linked to the statement "Dietarily insignificant."

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

⁷³ Transcript, vol. 1, pp. 258-270.

⁷⁴ Transcript, vol. 3, pp. 101-174.

VIII. Inspection of Documents

In accordance with § 171.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (*see ADDRESSES*) by appointment with the information contact person. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

Additionally, a copy of P&G's December 1999 petition and additional supporting material that P&G supplied are publically available at the Division of Dockets Management (Docket No. 00F-0792).

IX. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (*see ADDRESSES*) written or electronic objections by (*see DATES*). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (*see ADDRESSES*) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Transcript of the meeting of the Food Advisory Committee (vols. 1-3), Reston, VA, June 15 through 17, 1998.

2. Memorandum from K. C. Klontz, FDA to M. Ditto, FDA, February 13, 1998.

⁷² Transcript, vol. 1, pp. 22-25.

3. Memorandum from A. S. Levy, FDA to H. Thorsheim, FDA, August 20, 1996.
4. Memorandum from D. A. Street, FDA to M. Ditto, FDA, October 23, 2000.
5. Memorandum from K. C. Klontz, FDA to M. Ditto, FDA, February 23, 2000.
6. Memorandum K. C. Klontz and E. F. Barker, FDA to H. Thorsheim, FDA, March 26, 1997.
7. Memorandum K. C. Klontz, FDA to H. Thorsheim, FDA, August 8, 1996.
8. Zorich, N. L., D. Biedermann, K. A. Riccardi, et al., "Randomized, Double-Blind, Placebo-Controlled, Consumer Rechallenge Test of Olestra Salted Snacks," *Regulatory Toxicology and Pharmacology*, 26:200-209, 1997.
9. Zorich, N. L., D. Biedermann, K. A. Riccardi, et al., "Follow-Up to the Study: A Randomized, Double-Blind, Placebo-Controlled Consumer Rechallenge Test of Olestra Salted Snacks," *Regulatory Toxicology and Pharmacology*, 27:2, 1998.
10. Memorandum from K. C. Klontz, FDA to M. Ditto, FDA, May 25, 2000.
11. Memorandum from K. C. Klontz, FDA, to M. Ditto, FDA, April 13, 1998.
12. Cheskin, L. J., R. Miday, N. Zorich, et al., "Gastrointestinal Symptoms Following Consumption of Olestra or Regular Triglyceride Potato Chips: a Controlled Comparison," *Journal of the American Medical Association*, 279:150-152, 1998.
13. Memorandum from P. V. McCarthy, FDA, to M. Ditto, FDA, August 26, 1998.
14. Sandler, R. S., N. L. Zorich, T. G. Filloon, et al., "Gastrointestinal Symptoms in 3181 Volunteers Ingesting Snack Foods Containing Olestra or Triglycerides. A 6-Week Randomized, Placebo-Controlled Trial," *Annals of Internal Medicine*, 130:253-261, 1999.
15. Memorandum from S. J. Chirtel, FDA to B. Timbo, FDA, July 16, 1998.
16. Memorandum from C. Barton, FDA to B. Timbo, FDA, May 7, 1999.
17. Memorandum from C. Barton, FDA to M. Ditto, FDA, May 7, 1999.
18. Memorandum from H. E. Gallo-Torres, FDA, June 5, 1998.
19. Jacobson, M. F., M. A. Brown, and E. B. Whorton, "Gastrointestinal Symptoms Following Olestra Consumption," *Journal of the American Medical Association*, 280:325-326, 1998.
20. Jacobson, M. F., "Olestra Snacks Compared with Regular Snacks," *Annals of Internal Medicine*, 131:866, 1999.
21. Memorandum from C. Barton, and S. Chirtel, FDA to M. Ditto, FDA, March 27, 2003.
22. Memorandum K. C. Klontz, FDA to H. Thorsheim, FDA, December 26, 1995.
23. Kristal, A. R., R. E. Patterson, M. L. Neuhaus, et al., "Olestra Postmarketing Surveillance Study: Design and Baseline Results from the Sentinel Site," *Journal of the American Dietetic Association*, 98: 1290-1296, 1998.
24. Memorandum from T.G. Wilcox, FDA to M. Ditto, FDA, November 22, 2000.
25. Cooper, D. A., A. L. Eldridge, and J. C. Peters, "Dietary Carotenoids and Lung Cancer: a Review of Recent Research," *Nutrition Reviews*, 57:133-145, 1999.
26. Cooper, D. A., A. L. Eldridge, and J. C. Peters, "Dietary Carotenoids and Certain

Cancers, Heart Disease, and Age-Related Macular Degeneration: a Review of Recent Research," *Nutrition Reviews*, 57:201-214, 1999.

27. Institute of Medicine (U.S.), Panel on Dietary Antioxidants and Related Compounds, "Beta-Carotene and Other Carotenoids," *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids: A Report of the Panel on Dietary Antioxidants and Related Compounds, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine*, pp. 325-382, Washington, DC: National Academy Press, 2000.

28. Memorandum of Meeting, August 31, 2000.

29. Letter from A. Rulis, FDA, to J. McLaughlin, NEI, September 15, 2000.

30. Letter from J. McLaughlin, NEI, to A. Rulis, FDA, October 17, 2000.

31. Age-Related Eye Disease Study Research Group, "A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation with Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss," *Archives of Ophthalmology*, 119:1417-1436, 2001.

32. Memorandum from A. S. Levy, FDA to H. Thorsheim, FDA, July 30, 1996.

33. Memorandum from A. S. Levy, FDA to M. Ditto, FDA, November 16, 2000.

34. Kelly, S. M., M. Shorthouse, J. C. Cotterell, et al., "A 3-Month, Double-Blind, Controlled Trial of Feeding with Sucrose Polyester in Human Volunteers," *British Journal of Nutrition*, 80:41-49, 1998.

35. Memorandum from R. Pertel, FDA to N. Beru, FDA, September 6, 1995.

36. Blackburn, H., "Sounding Board: Olestra and the FDA," *New England Journal of Medicine*, 334:984-986, 1996.

37. Westrate, J. A. and K. H. van het Hof, "Sucrose Polyester and Plasma Carotenoid Concentrations in Healthy Subjects," *American Journal of Clinical Nutrition*, 62:591-597, 1995.

38. Lawton, C. L., "Regulation of Energy and Fat Intakes and Body Weight: the Role of Fat Substitutes," *British Journal of Nutrition*, 80:3-4, 1998.

39. Giovannucci, E., "Tomatoes, Tomato-Based Products, Lycopene, and Cancer: Review of the Epidemiologic Literature," *Journal of the National Cancer Institute*, 91:317-331, 1999.

40. Chasan-Taber, L., W. C. Willet, J. M. Seddon, et al., "A Prospective Study of Carotenoid and Vitamin A Intakes and Risk of Cataract Extraction in U.S. Women," *American Journal of Clinical Nutrition*, 70:509-516, 1999.

41. Brown, L., E. B. Rimm, J. M. Seddon, et al., "A Prospective Study of Carotenoid Intake and Risk of Cataract Extraction in U.S. Men," *American Journal of Clinical Nutrition*, 70:517-524, 1999.

42. Balasekaran, R., J. L. Porter, C. A. Santa Ana, et al., "Positive Results on Tests for Steatorrhea in Persons Consuming Olestra Potato Chips," *Annals of Internal Medicine*, 132:279-282, 2000.

43. Burks, A. W., L. Christie, K. A. Althage, et al., "Randomized, Double-Blind, Placebo-Controlled, Food Allergy Challenge to Olestra Snacks," *Regulatory Toxicology and Pharmacology*, 34: 178-181, 2001.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.867 is amended by revising paragraph (e) to read as follows:

§ 172.867 Olestra.

* * * * *

(e)(1) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(i) An asterisk shall follow vitamins A, D, E, and K in the listing of ingredients;

(ii) The asterisk shall appear as a superscript following each vitamin;

(iii) Immediately following the ingredient list an asterisk and statement, "Dietarily insignificant" shall appear prominently and conspicuously as specified in § 101.2(c) of this chapter;

(2) Olestra shall not be considered as a source of fat or calories for purposes of §§ 101.9 and 101.13 of this chapter.

* * * * *

Dated: July 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-19508 Filed 8-1-03; 4:00 pm]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1987F-0179]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of requests for a hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests for a hearing it has received on the final rule that amended the food additive regulations to provide for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a replacement for fats and oils in savory snacks. After reviewing the objections to the final rule and the requests for a hearing, FDA has concluded that the objections do not raise any issue of material fact that justifies a hearing or otherwise provides a basis for revoking the regulation.

FOR FURTHER INFORMATION CONTACT: Mary Ditto, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3102.

SUPPLEMENTARY INFORMATION:

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I. Background and Procedural History

In a notice published in the *Federal Register* of June 23, 1987 (52 FR 23606), FDA announced that a food additive petition (FAP 7A3997) had been filed by the Procter & Gamble Co., 6071 Center Hill Rd., Cincinnati, OH 45224-1703 (P&G, the petitioner), proposing the issuance of a food additive regulation providing for the safe use of sucrose esterified with medium and long chain fatty acids as a replacement for fats and oils. The common name for this additive is olestra. Subsequently, the petitioner amended the petition to limit the intended use of the additive to a 100 percent replacement for conventional fats in the preparation of savory snacks (i.e., snacks that are salty or piquant but not sweet, such as potato chips, cheese puffs, and crackers).

FDA reviewed the data and information in the olestra food additive petition to determine whether the additive is safe (see section 409(c)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)), for use in savory snacks. As part of this review process, FDA held public meetings of the agency's Food Advisory Committee (the FAC) and a working group of the FAC, the Olestra Working Group (the OWG) to provide for a scientific discussion of FDA's evaluation of the safety data in the petition.

On January 30, 1996, FDA issued a final rule in the *Federal Register* authorizing the use of olestra in place of fats and oils in prepackaged ready-to-eat savory snacks (61 FR 3118, January 30, 1996) (§ 172.867 (21 CFR 172.867)). In the preamble to the final rule, FDA concluded that all safety issues regarding olestra had been addressed adequately and that there is a reasonable certainty that no harm will result from the use of olestra in savory snacks. The 1996 olestra regulation requires that the fat-soluble vitamins A, D, E, and K be added to olestra-containing foods to compensate for any inhibition of absorption of these vitamins caused by olestra. The 1996 regulation also requires that foods containing olestra be labeled with the following information statement:

THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added. (§ 172.867(e)(1)).

Consistent with section 409(f) of the act (21 U.S.C. 348(f)), the preamble to the final rule advised that objections to

the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by February 29, 1996)¹ (§ 171.110 (21 CFR 171.110) and 21 CFR 12.22(a).) On February 29, 1996, CSPI filed six objections to the final rule and requested a hearing on all six objections.² CSPI had substantially participated in the November 1995 OWG/FAC meeting and had also filed multiple sets of comments with FDA prior to issuance of the final rule.

In the preamble to the 1996 final rule (61 FR 3118 at 3169), FDA advised that it would publish in the *Federal Register* notice of the objections that it received or lack thereof.³ This document fulfills the agency's obligation to publish such a notice. The only timely, substantive objections FDA received were from CSPI.

II. Standard for Granting a Hearing

Under § 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Specific criteria for determining whether a hearing has been justified are set forth in § 12.24(b). Under the regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (1) There is a genuine and substantial issue of fact for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester; a hearing will be denied if the data and information

¹ In addition to notifying the public of the opportunity to submit objections and hearing requests, FDA requested comments on the olestra label requirement on such issues as the need for such a label, the adequacy of its content, the agency's word choice, and the configuration of the label. In the *Federal Register* of March 3, 2000 (65 FR 11585), FDA announced that a food additive petition (FAP 0A4708) had been filed by P&G proposing to amend § 172.867 by removing the requirement for the label statement prescribed in § 172.867(e). Elsewhere in this issue of the *Federal Register*, FDA is issuing a final rule that responds to FAP 0A4708. In that final rule, the agency responds to comments received regarding the label statement.

² In addition, FDA received several letters within the 30 day objection period, all of which expressed general opposition to olestra, identified no substantive question to which the agency can respond, and did not request a hearing. These letters will not be discussed further.

³ The January 30, 1996, final rule includes a more detailed background statement.

submitted are insufficient to justify the factual determination urged, even if accurate; and (4) resolution of the factual issue in the way sought by the requestor is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested, (e.g., if the action would be the same even if the factual issue were resolved in the way sought).

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." (See *Costle v. Pacific Legal Foundation*, 445 U.S. 198, 214-215 (1980), *reh. den.*, 446 U.S. 947 (1980), citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-621 (1973).) An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. (See *Georgia-Pacific Corp. v. U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982).) If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there is no genuine issue of material fact, and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (§ 12.28).

A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. (See *Pineapple Growers Association v. FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982).) Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. (See *Dyestuffs and Chemicals, Inc. v. Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).) FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States v. Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971).) In other words, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." (See *Pactra Industries v. CPSC*, 555 F.2d 677 (9th Cir. 1977).) Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc. v. FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.*

v. FPC, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).)

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity. (*Retail Clerks Union, Local 1401, RCIA v. NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972).) (See also *Costle v. Pacific Legal Foundation, supra* at 1106, and *Pacific Seafarers, Inc. v. Pacific Far East Line, Inc.* 404 F.2d 804 (D.C. Cir. 1968).)

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence presented must be adequate to resolve the issue as requested and to justify the action requested.

III. Objections and Supporting Documents Submitted by CSPI

In a document dated February 29, 1996, entitled "Objections and Request for Hearing" (CSPI obj.), CSPI submitted to the Division of Dockets Management, its objections to the approval of the use of olestra as a food additive in savory snacks. CSPI submitted six objections to the 1996 final rule, and requested a hearing on issues raised by each objection. CSPI raised one general objection to the 1996 final rule, asserting that FDA improperly concluded that the use of olestra in savory snacks meets the safety standard of reasonable certainty of no harm. CSPI also raised five specific objections, asserting that: (1) Olestra's potential to deplete carotenoids may present a risk of harm to health, which precludes a finding of reasonable certainty of no harm; (2) FDA's decision to require compensation with vitamin K may not solve health problems that depletion of vitamin K may cause; (3) the potential GI disturbances that olestra may cause are adverse health effects that preclude a finding of reasonable certainty of no harm; (4) the label statement required on an interim basis by the 1996 final rule is insufficient to protect the public against adverse effects associated with consumption of olestra; and (5)

problems with procedure and process tainted FDA's review of, and decision-making process for, the food additive petition for olestra to the detriment of FDA's consideration of the public health concerns raised by CSPI and others. In support of its objections and hearing requests, CSPI filed 18 exhibits (CSPI exh. 1 through 18).⁴

IV. Analysis of Objections and Response to Hearing Requests

As noted in section III of this document, CSPI raised one general objection and five specific objections to the 1996 final rule. In this document, FDA addresses each of CSPI's objections, as well as the data and information filed in support of each, comparing each to the standards for granting a hearing in § 12.24(b). Because several of the issues in the general objection overlap with the five more specific objections, FDA addresses CSPI's five specific objections first (CSPI obj. 2 through 6), followed by the general objection (CSPI obj. 1).

A. Carotenoids

In its second objection and request for a hearing, CSPI states that there are two questions central to a discussion of the depletion of carotenoids by consumption of olestra. First, are carotenoids beneficial to health? Second, if carotenoids are beneficial to health, does consumption of olestra cause depletion of carotenoids such that there would be an absence of a reasonable certainty of no harm? CSPI claims that FDA did not answer either of these questions accurately and requests a hearing on both factual issues.

1. Are Carotenoids Beneficial to Health?

In its objection and request for a hearing, CSPI asserts that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids except the provitamin A function of beta-carotene.

In analyzing this objection, it is important to recognize that FDA's position on carotenoids (as articulated in the 1996 final rule) has two parts. First, although FDA concluded that there is no demonstrated association between carotenoids per se and health

⁴ In a letter dated August 26, 1996 (Docket No. 1987F-0179), CSPI requested that certain documents submitted to the agency after February 29, 1996, be considered part of their objections. As noted previously, February 29, 1996, was the final day allowed under section 409(f)(1) of the act for submission of objections and hearing requests, including supporting material. Accordingly, the material submitted in August 1996 was not timely filed and thus, has not been considered in evaluating the CSPI objections and hearing requests.

benefits, the agency agrees that epidemiological studies show an association between diets rich in fruits and vegetables and decreased cancer risk (61 FR 3118 at 3149).⁵ As shown in this section, all of the evidence and opinions cited by CSPI to support this objection is consistent with an association between fruit and vegetable consumption and health benefits. Second, FDA concluded that the variation in serum levels of carotenoids associated with olestra consumption is within the normal range, given diet variations and the bioavailability of carotenoids. CSPI's objection does not directly address this second issue.⁶

CSPI offers essentially two arguments to support its view that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids except the provitamin A function of beta-carotene. First, CSPI asserts that FDA's position on carotenoids is a minority view.⁷ To support this challenge, CSPI relies on statements of Drs. Regina Ziegler (CSPI exh. 10), Walter Willet (CSPI exh. 13), and Jerianne Heimendinger (CSPI exh. 8) to demonstrate that FDA's position is not well-founded. Importantly, Drs. Ziegler and Willet both state that fruits and vegetables, not carotenoids per se, are associated with reduction of the risk of cancer. (CSPI exh. 13, p. 1; CSPI exh. 10, letter dated October 23, 1995, p. 1, and letter dated January 21, 1996, p. 2.) Similarly, Dr. Heimendinger asserts merely that evidence is "increasing that * * * carotenoids may play important roles" in reducing cancer risk (emphasis added). (CSPI exh. 8, Heimendinger letter, p. 2). Thus, none of these statements support CSPI's claim that carotenoids have been demonstrated to have a significant beneficial health role.⁸ Accordingly,

⁵ Indeed, CSPI itself concedes that there may be "substances in fruits and vegetables for which carotenoids are markers" that are beneficial to health (CSPI obj. at 19).

⁶ Although not strictly relevant to the objections lodged by CSPI, it is important to note that in its 1996 final rule, FDA acknowledged the growing body of data and information regarding carotenoids and committed to reviewing such information within 30 months of olestra's initial approval (61 FR 3118 at 3168 and footnote 94). In June 1998, FDA presented the accumulated data and information to the FAC.

⁷ Although CSPI asserts that FDA's view is a minority view, the final rule noted that five different conferences or reviewing groups have examined the relationship between carotenoids and disease and concluded that there was insufficient evidence to recommend specifically the consumption of carotenoids, except to encourage the consumption of fruits and vegetables (61 FR 3118 at 3148). CSPI does not challenge this fact.

⁸ CSPI's objection and hearing request on this point also refer to an article published by Dr. Edward Giovannucci addressing the association

FDA is denying CSPI's request for a hearing on this issue because the information identified in the objection is insufficient to justify the factual determination urged by CSPI (§ 12.24(b)(3)).⁹

CSPI also relies on the dietary guidelines issued by the Department of Health and Human Services (DHHS), 4th edition, to support its assertion that FDA's position on carotenoids is a minority view. Careful reading of the guidelines establishes that, once again, the evidence identified in the objection does not support the position urged by CSPI because the guidelines do not identify carotenoids per se as beneficial to human health.

Consumption of these foods [fruits and vegetables] is associated with a substantially lower risk of many chronic diseases, including certain types of cancers. (CSPI exh. 11, p. 13.)¹⁰

Elsewhere the guidelines describe the role of carotenoids in health as yet-to-be established.

The antioxidant nutrients found in plant foods (e.g., vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their *potentially beneficial* role in reducing the risk for cancer and certain other chronic diseases. Scientists are also trying to determine if other substances in plant foods protect against cancer. (CSPI exh. 11, p. 13, emphasis added.)

Because the information regarding the DHHS dietary guidelines is insufficient to establish CSPI's claim regarding the role of carotenoids in human health, FDA is denying a hearing on this issue (§ 12.24(b)(3)).

As a third basis to show that FDA's position regarding carotenoids is a minority view, CSPI cites correspondence between FDA and two different institutes of the National Institutes of Health (NIH).¹¹ CSPI

examined the relationship between carotenoids and disease and concluded that there was insufficient evidence to recommend specifically the consumption of carotenoids, except to encourage the consumption of fruits and vegetables (61 FR 3118 at 3148). CSPI does not challenge this fact.

⁸ CSPI's objection and hearing request on this point also refer to an article published by Dr. Edward Giovannucci addressing the association between high intake of tomato products and reduced incidence of prostate cancer and claims that Dr. Giovannucci opposes the approval of olestra because of the additive's potential to deplete carotenoids, citing CSPI exh. 8. Although CSPI exh. 8 contains numerous letters from individuals opposing olestra's approval, there is no identifiable communication from Dr. Giovannucci in that exhibit. In the absence of specifically identified evidence demonstrating Dr. Giovannucci's position, FDA is denying CSPI's objection and hearing on this point (§ 12.24 (b)(2)). In addition, CSPI's reliance on the Giovannucci article is misplaced because, even as described by CSPI, the paper does not support CSPI's claim that carotenoids themselves have been shown to have distinct health benefits. Accordingly, FDA is denying CSPI's claim on this point (§ 12.24(b)(2) and (b)(4)).

⁹ CSPI also relies on its White Paper (CSPI exh. 1) and exhibits 3 through 7 to the White Paper.

challenges FDA's reliance on the letter from the NEI because it only addresses the role of beta-carotene, not lutein or lycopene. Even if CSPI's claims on this issue are correct, FDA is denying its request for a hearing because the assertion that lutein and lycopene have a beneficial role in eye health is not supported by specifically identified factual evidence. Accordingly, CSPI's allegations are mere speculation, which is not an adequate basis for a hearing request (§ 12.24(b)(2)).

With respect to the NCI, CSPI claims that there are conflicting views in the record from NCI and that FDA should determine, on the record, the "official" NIH position. Specifically, CSPI believes that Dr. Ziegler's views are significantly different from the views expressed by the then Director of the Division of Cancer Prevention and Control, NCI, NIH, Dr. Peter Greenwald.¹² CSPI does not demonstrate why such a determination is necessary, the authority under which it would be done, or how it would alter the outcome of this proceeding. Accordingly, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(2) and (b)(4)).

Finally, CSPI asserts that FDA staff, the OWG, and the FAC failed to acknowledge and accept data from in vitro, animal, and epidemiologic studies that all point to a protective role for carotenoids. In support of this portion of its second objection, CSPI cites two articles (CSPI obj. at p. 20, footnote 19).¹³ This portion of CSPI's objection is without foundation because the information specifically cited is not adequate to establish the factual issue urged by CSPI¹⁴ (§ 12.24(b)(3)). In particular, the first article cited (Garewal, H., "Antioxidants in Oral Cancer Prevention," *American Journal of Clinical Nutrition*, 62:1410S-1416S, 1995, at 1413S.) concludes that the reported results do not themselves demonstrate a reduction in human

¹² In fact, CSPI's own documents demonstrate that there is no conflict as to the official statements of the NCI regarding carotenoids because Dr. Ziegler acknowledges that she does not speak on behalf of the NCI (even though her two letters are written on NCI letterhead). (CSPI exh. 10, letter dated January 21, 1996, p. 1).

¹³ These articles are the only specific data identified by CSPI to support its second objection.

¹⁴ CSPI claims that FDA, the OWG, and the FAC ignored certain data on carotenoids. Importantly, however, the two journal articles cited by CSPI were published in a supplement to the December 1, 1995, issue of the *American Journal of Clinical Nutrition*. The FAC/OWG meeting was held November 14 through 17, 1995, and CSPI presents no evidence that these articles were even available at the time of the meeting. In fact, these two articles were not submitted to FDA until December 22, 1995.

cancer risk,¹⁵ and CSPI does not identify any other potential health benefit of carotenoids established by this article. Similarly, the second publication (Bertram, J. S. and H. Bortkiewicz, "Dietary Carotenoids Inhibit Neoplastic Transformation and Modulate Gene Expression in Mouse and Human Cells," *American Journal of Clinical Nutrition*, 62:1327S-1336S, 1995, at 1328S.), notes that the investigators' results simply provide "a possible mechanistic basis for the activity of carotenoids as chemopreventive agents (emphasis added)." Moreover, citing this second publication, CSPI asserts that "carotenoids affect intercellular communications" (CSPI obj. at p. 20, footnote 19). However, CSPI does not demonstrate how the effect of carotenoids on intercellular communications supports its assertion that carotenoids are beneficial to health.¹⁶ Accordingly, FDA is denying CSPI's hearing request on this issue (§ 12.24(b)(3)).¹⁷

CSPI's second argument to support its position that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids, except the provitamin A function of beta-carotene, is that the agency wrongly insisted on randomized trials to establish the role of carotenoids in health. CSPI bases this allegation on the fact that FDA quoted Dr. Alvan Feinstein in the preamble to the 1996 final rule. CSPI implies that FDA relied on Dr. Feinstein and thus, ignored evidence in the record that establishes a beneficial role of carotenoids in human health. In addition, CSPI claims that Dr. Feinstein

is a "debunker" and he, and his views, lack credibility.

These allegations are not adequate to justify a hearing on this issue for three reasons. First, CSPI quotes Dr. Feinstein out of context. Contrary to CSPI's claim, Dr. Feinstein did not "insist" on randomized trials. Instead, Dr. Feinstein described certain limitations of epidemiologic studies (studies such as those cited by another witness, Dr. Meir Stampfer), including the fact that it is difficult to draw conclusions about cause and effect relationships from such studies (61 FR 3118 at 3147 to 3148), a conclusion not directly challenged by CSPI. Thus, FDA is denying CSPI's hearing request on this point because a hearing will not be granted where the information to support the factual conclusion urged is unreliable (§ 12.24(b)(2)). Second, CSPI asserts that Dr. Feinstein failed to acknowledge that the test methods he advocated might not be meaningful for dietary carotenoids. Because CSPI offers no evidence to suggest that these methods are not appropriate and does not show how, if at all, prevailing on this factual issue would change the outcome of the rulemaking, FDA is denying a hearing on this issue (§ 12.24(b)(2) and (b)(4)). Finally, in reaching its position on carotenoids, FDA considered all the comments, data, and information that the agency had received on carotenoids, including information from epidemiological studies (61 FR 3118 at 3149). FDA's position on the carotenoids issue is not inconsistent with the findings of the epidemiological studies relied upon by CSPI (61 FR 3118 at 3149). Thus, even if Dr. Feinstein's views were shown to be incorrect and CSPI prevailed on this issue, the outcome of the ruling would not be altered. Therefore, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(4)).

2. Does Consumption of Olestra Cause a Harmful Depletion of Carotenoids?

In its second objection and request for a hearing, CSPI asserts that consumption of olestra likely would cause major depletions of serum levels of carotenoids and that this depletion could be harmful because carotenoids have beneficial properties.¹⁸ CSPI also asserts that even a 5 to 10 percent

reduction in serum levels of carotenoids could be harmful. CSPI offers several arguments to support this portion of its objection.¹⁹

First, CSPI asserts generally that the amounts of olestra consumed are sufficient to cause major depletions of carotenoids, referring to "the section [above] on consumption estimates." (CSPI obj. at p. 24.) However, there is no such section in CSPI's submission.²⁰ Moreover, CSPI's objection did not offer any facts to contradict FDA's conclusion in the final rule that the magnitude of olestra's effects on carotenoid absorption are likely to be within the range of normal variation (61 FR 3118 at 3149). Accordingly, FDA is denying CSPI's challenge to the agency's determination that any depletion of carotenoids by olestra consumption would be minor because a hearing on a factual issue will not be granted in the absence of specifically identified, available evidence to support the requestor's position (§ 12.24(b)(2)).

CSPI also challenges FDA's conclusion on the magnitude of carotenoid depletion by asserting that patterns of consumption of olestra will not prevent such depletion. In particular, CSPI asserts that P&G's depletion studies only measured the status of beta-carotene and thus, the full impact of olestra consumption on carotenoids was not assessed. However, CSPI did not submit or otherwise specifically identify evidence to establish that olestra's effect on beta-carotene was not representative of the additive's effect on carotenoids generally. Moreover, CSPI does not demonstrate how resolving this particular issue in its favor will alter the outcome of this proceeding. Accordingly, FDA is denying CSPI's objection and hearing request (§ 12.24(b)(2) and (b)(4)).

CSPI also claims that FDA erroneously relied on data presented by P&G on patterns of consumption when the agency concluded that olestra's effects on carotenoid absorption would not be harmful. CSPI did not present

¹⁹It is important to note that depletion of serum carotenoid levels is relevant only if carotenoids themselves are shown to have human health benefits. As discussed in the previous section, CSPI's objection and hearing request fails to establish any genuine issue of material fact regarding FDA's conclusion that there is no demonstrated health benefit of any carotenoid except the provitamin A function of beta-carotene. Thus, this portion of CSPI's objection and hearing request is also denied because resolution of this issue in CSPI's favor would not alter the outcome of this proceeding (§ 12.24(b)(4)).

²⁰It is possible that CSPI intended to reference the discussion in its White Paper (CSPI exh. 1) on consumption estimates, but no such reference was given (§ 12.24(b)(2)).

¹⁵CSPI states that "carotenoids reverse oral leukoplakia in rats." (CSPI obj. at p. 20, footnote 19.) However, the Garewal article cited by CSPI in support of this statement presents no data on the reversal of oral leukoplakia in rats.

¹⁶As noted previously, in the 1996 final rule, FDA concluded that the variation in serum levels of carotenoids associated with olestra consumption is within the normal range, given diet variations and the bioavailability of carotenoids, a conclusion not addressed directly by CSPI. In view of this unchallenged conclusion, the Bertram and Bortkiewicz paper, id. at 1333S-1334S, appears to support a finding of no harm from olestra's effects on carotenoid levels of consumers of olestra-containing food. "Our demonstration that dietary carotenoids can inhibit neoplastic transformation and modulate the expression of gene products in both human and mouse cells implies that these ubiquitous compounds have hitherto unknown properties. Moreover, these effects were produced at micromolar concentrations that are within the physiological range * * *"

¹⁷Indeed, the paper by Bertram and Bortkiewicz is consistent with FDA's conclusion that the available evidence demonstrates an association between a diet rich in fruits and vegetables and reduction in the risk of certain diseases. "Many epidemiologic studies have shown a consistent inverse correlation between consumption of foods rich in carotenoids * * * and future risk of cancer." (Id. at 1327S.)

¹⁸To the extent that CSPI contends that there is a lack of reasonable certainty of no harm from olestra's depletion effect on carotenoids, CSPI's hearing request is denied because whether a food additive is safe for its intended use (i.e., whether there is a reasonable certainty of no harm) is a question of law to be decided based on the facts established in the record. Under § 12.24(b)(1), a hearing will not be granted on issues of policy or law.

any specific information to dispute P&G's consumption pattern data; instead, CSPI simply asserted that other consumption patterns were likely.²¹ Mere allegations of this type do not require that a hearing request be granted (§ 12.24(b)(2)). Moreover, although the petitioner did present information on snack consumption patterns and their effects on carotenoid depletion, FDA did not rely on this information in its safety determination (61 FR 3118 at 3149 at footnote 51). Accordingly, even if CSPI were to prevail on this factual issue, the outcome of this rulemaking would not be altered and thus, FDA is denying this portion of CSPI's objection and hearing request (§ 12.24(b)(4)).²²

Finally, CSPI relies on the proceedings of a January 1996 workshop at the Harvard School of Public Health to support its view that olestra's depletion of carotenoids will be harmful.²³ In particular, CSPI cites estimates of the possible impact on the public health that would allegedly result from the wide-spread use of olestra in snack foods, which estimates were presented at the Harvard meeting (CSPI exh. 13). CSPI contends that if FDA had correctly understood the Harvard meeting estimates regarding carotenoid depletion, it is doubtful that olestra would have been approved²⁴ (CSPI obj. at 28).

²¹ For example, CSPI claims that the "great popularity of tomato-based salsa in recent years suggests that many consumers would consume tortilla, corn, or potato chips with this carotenoid-rich dip, with or between meals." (CSPI obj. at p. 24.) Similarly, CSPI asserts that "consumption of savory snacks is likely to increase if olestra snacks become generally available." (CSPI obj. at p. 25.) CSPI does not identify any particular information or evidence in the record to support either assertion (§ 12.24(b)(2)).

²² In questioning the petitioner's evidence on consumption patterns, CSPI also challenges the hypothesis of Dr. Penny Kris-Etherton, a P&G consultant, that consumption of olestra-containing foods between meals has no effect on carotenoid depletion. Importantly, however, CSPI fails to identify any credible data or information to support its assertion that this hypothesis is "unproven and doubtful." (CSPI obj. at p. 25.) Thus, FDA is denying CSPI's request for a hearing on this point (§ 12.24(b)(2)).

²³ CSPI raises two spurious arguments regarding carotenoids, neither of which is adequate to justify a hearing on this issue. Specifically, CSPI criticizes the agency because no one from FDA's "senior level" attended the meeting, and faults the summary prepared by the FDA staffer who did attend the meeting. In addition, CSPI claims that Dr. Stampfer was given only a limited period to speak during the November 1995 FAC meeting and that his schedule precluded him from staying for the afternoon session when he could have expanded his comments. Neither of these arguments raises a material question of fact that requires a hearing (§ 12.24(b)(1)).

²⁴ CSPI also asserts that at the Harvard meeting, P&G employee Dr. Keith Triebwasser "stated that he could not assume that depletion of carotenoids was harmless," citing a letter from Dr. Alberto Ascherio

FDA is denying CSPI's request for a hearing on this point because the data and information submitted are insufficient to establish that olestra's depletion of carotenoids will be harmful (§ 12.24(b)(3)). First, the comments of those preparing the estimates undermine their validity. In particular, in their letter transmitting the estimates, Drs. Willett and Stampfer readily acknowledge that the estimates are not based on an established cause and effect relationship and are speculative in that they are based on a number of assumptions (CSPI exh. 13, pp. 1, 3, and 4). Moreover, in the preamble to the final rule, FDA outlined several considerations to be addressed in determining whether olestra's effect on carotenoids will be harmful, including the other factors that influence carotenoid utilization (carotenoid stability, bioavailability, and absorption) and whether serum carotenoid levels are an adequate indicator of carotenoid availability (61 FR 3118 at 3148 to 3149). Neither CSPI nor the scientists who prepared the Harvard estimates addressed these considerations. Accordingly, the Harvard estimates in and of themselves are not adequate to demonstrate that olestra's effect on carotenoid levels will be harmful.

B. Vitamin K

In its third objection and request for a hearing, CSPI challenges FDA's conclusion that supplementation of olestra with vitamin K will offset the additive's effect on vitamin K and thereby prevent adverse health effects associated with vitamin K depletion in olestra consumers. CSPI claims that FDA's decision on this point is erroneous for two reasons. First, CSPI asserts that a decision on olestra's safety should not have been made in the absence of a study of the interaction between Coumadin (a widely used anti-coagulant) and olestra. Importantly, however, CSPI did not specifically identify any available data or information in the record to demonstrate why data from a study of olestra's effects on Coumadin therapy are necessary.²⁵ Accordingly, FDA is

(CSPI exh. 15). Importantly, however, Dr. Ascherio does not directly quote or even paraphrase Dr. Triebwasser; instead, the letter contains Dr. Triebwasser's characterization of what Dr. Triebwasser said. (Dr. Ascherio stated: "The responses of the gentleman from Procter & Gamble made it clear that there is no scientific evidence to support [a conclusion that depletion of carotenoids will not harm people's health.]" Again, the information tendered by CSPI is insufficient to justify the factual conclusion urged and thus, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(3)).

²⁵ In fact, this concern was raised at the November 1995 FAC meeting and addressed in the

denying CSPI's request for a hearing on this question because it is merely an unsupported allegation (§ 12.24(b)(2)). Second, CSPI asserts that olestra supplemented with vitamin K may have adverse effects on bone formation. Once again, CSPI fails to specifically identify any data or information that could be used to resolve this question. Accordingly, FDA is denying CSPI's objection and hearing request on this point (§ 12.24(b)(2)).

C. GI Effects

In its fourth objection and request for a hearing, CSPI asserts that in a significant proportion of individuals olestra causes GI disturbances, including diarrhea, that these disturbances are adverse health effects, and that these GI disturbances are of sufficient concern to warrant a finding that there is no "reasonable certainty of no harm." CSPI also asserts that FDA's analysis of the data from two 8-week studies obscured the detection of trends between olestra consumption and GI symptoms reported.

1. Are the Observed GI Symptoms Adverse Health Effects?

In its objection and request for a hearing, CSPI asserts that FDA erred by concluding that certain GI effects of olestra (such as anal leakage, underwear staining, and oil-in-the-toilet) are not relevant to the question of the safety of olestra.²⁶ In particular, CSPI asserts that these olestra-related effects can have an "adverse effect on people's lives and interfere with their daily activities" and thus implies that FDA should have considered them in determining olestra's safety. In support of this objection, CSPI relies heavily on the proceedings before the OWG and the FAC (such as the testimony of Dr. Ian Greaves and Ms. Rosie Schwartz.)²⁷

At its core, CSPI's fourth objection concerns the meaning of the statutory standard of "safe," section 409(c)(3)(A) of the act, and, specifically, what is

preamble to the final rule. One witness, Dr. John Suttie, testified that vitamin K intake can vary from day-to-day by three or four-fold and that diet is not usually a primary factor of concern with anti-coagulation therapy. Accordingly, he concluded that changes due to consumption of vitamin-K compensated olestra would likely be within the normal range of dietary variation (61 FR 3118 at 3147).

²⁶ In its fourth objection, CSPI also claims that consumption of olestra causes diarrhea, which CSPI claims is an adverse health effect. However, CSPI does not further address diarrhea in this objection.

²⁷ As part of their objections, CSPI criticizes a P&G market research study, and the OWG's alleged reliance on it. FDA told the OWG that the agency had not used data from the market research study in its analysis. Moreover, FDA did not rely on the study in determining that olestra is safe. CSPI concedes as much (CSPI obj. at p. 33).

"harm" for purposes of that standard.²⁸ CSPI has not demonstrated that FDA wrongly decided any genuine and substantial issue of fact concerning the GI effects of olestra. Rather, CSPI disagrees with FDA's application of the statutory safety standard, alleging that FDA ignored certain effects of olestra consumption that CSPI claims preclude a finding of safety.²⁹ In the absence of a genuine and substantial issue of fact, a hearing need not be granted because a hearing is not needed to settle issues of law (§ 12.24(b)(1)).

2. Did FDA Err in Pooling Certain GI Data for Analysis?

In its objection and request for a hearing, CSPI asserts that FDA's analysis of two 8-week studies was inappropriate because the analysis pooled the data from both studies.³⁰ CSPI asserts that pooling these data was inappropriate because different formulations of olestra were used in the two studies. CSPI also objects to pooling the data because it would allegedly diminish the ability to detect trends in one study.³¹

FDA is denying CSPI's request for a hearing on this issue because the organization failed to identify specifically any reliable evidence to support either of its factual allegations. That is, CSPI did not identify any data or information to support its claim that different olestra formulations precluded the pooling of the data from the two 8-week studies³² (§ 12.24(b)(2)). Moreover, even if the data from the two studies should have been analyzed separately, as asserted by CSPI, that analysis would

not have changed the outcome of this proceeding because the results would be the same whether analyzed separately or pooled (61 FR 3118 at 3153 to 3154). Accordingly, FDA is denying CSPI's hearing request on this point (§ 12.24(b)(4)).

D. Adequacy of Olestra's Label Statement³³

In its fourth objection and request for a hearing, CSPI challenges the label statement required by the 1996 final rule, claiming that it is not sufficient to protect the public from adverse effects associated with consumption of olestra. CSPI also claims that the portion of the label statement regarding the nutritional effects of olestra consumption is inadequate. CSPI offers several specific criticisms in support of these general allegations. As shown in the following sections D.1 and D.2, none of CSPI's specific allegations raises a question of material fact that requires a hearing. In analyzing CSPI's objection regarding the olestra label statement, it is critical to recognize that FDA did not require the statement to ensure olestra's safe use (61 FR 3118 at 3160). Instead, the label statement was designed to prevent olestra-containing foods from being misbranded.

1. Label Statement Regarding GI Effects

CSPI alleges that the GI effects portion of the olestra label statement is not adequate for three reasons. First, CSPI claims that the word "laxative" should be used to describe olestra's GI effects. Second, CSPI asserts that all GI effects of olestra should be disclosed, including diarrhea, underwear staining, oil-in-toilet, and anal leakage because they "might distress" consumers of olestra-containing snacks. Third, CSPI claims that the GI portion of the olestra label statement ought to advise consumers to seek medical treatment if the effects of olestra consumption do not subside within 48 hours of consumption. Importantly, CSPI does not dispute any facts that underlie FDA's decision regarding the label statement. Fundamentally, CSPI's allegation in this instance is that olestra-containing foods are misbranded in the absence of these three pieces of information. Whether foods that bear the olestra label statement set out in § 172.867 are misbranded is a question of law. Thus, FDA is denying CSPI's hearing request on this point because a hearing will not be granted on issues of law

(§ 12.24(b)(1)). Moreover, even if such questions are questions of fact, CSPI did not specifically identify any data or other information to support its position. Thus, on this basis, FDA is denying this hearing request (§ 12.24(b)(2)).

2. Label Statement Regarding Absorption of Nutrients

CSPI also challenges that portion of the olestra label statement that relates to absorption of nutrients. CSPI asserts that this portion of the olestra label statement has several deficiencies. Specifically, CSPI claims that the word "compensation" should be substituted for "added," that carotenoid depletion resulting from olestra consumption should be disclosed, that consumers should be advised that there are "no data" about the vitamin K repletion, and that the statement should begin with the word "warning" and appear on the front of the package. Again, in presenting this portion of the fifth objection, CSPI fails to identify specifically any underlying factual dispute that could be resolved by a hearing. The question of whether olestra-containing foods that bear the required label statement are misbranded is a question of law. Accordingly, FDA is denying CSPI's request for a hearing on this point because a hearing will not be granted on issues of law (§ 12.24(b)(1)).

E. Alleged Procedural Problems in the Olestra Proceeding

In its fifth objection and hearing request, CSPI claims that there were a number of problems with the procedures utilized by FDA to reach a decision about the safety of olestra. CSPI raises the following six complaints: (1) Its White Paper was not provided promptly enough to the members of OWG and FAC, (2) the presentation by FDA's staff to OWG did not adequately address carotenoids, (3) the 1996 final rule unfairly described support for olestra and discounted letters from CSPI members opposing olestra's approval, (4) the petitioner engaged in a letter writing campaign to gain olestra's approval, (5) FDA discounted the opinions of CSPI's experts and ignored the "scientific information" in the letters from these experts, and (6) members of OWG and FAC were biased. As is the case with its fourth objection and hearing request, CSPI specifically identifies no factual issue underlying any of its six procedural complaints. In such circumstances, a hearing is not

²⁸ As noted in the preamble to the final rule, "safe" means "proof of a reasonable certainty of no harm," a standard drawn from the legislative history of section 409 of the act; harm in this context means "hazardous to the health of man or animal." (61 FR 3118 at 3119 to 3120.) FDA concluded that "an effect is harmful if it affects health, not if it is simply an undesirable or unexpected effect that has no adverse health consequences." (61 FR 3118 at 3120.)

²⁹ Contrary to CSPI's assertions, FDA's evaluation of the evidence in the record did address a broad range of GI symptoms, including loose stools, cramping and bloating, fecal urgency, oil-in-the toilet, and anal leakage (61 FR 3118 at 3152 to 3159). In applying the statutory standard of "safe," FDA concluded that none of these effects is harmful to health (61 FR 3118 at 3159). CSPI's objection identifies no factual evidence to contradict this conclusion.

³⁰ FDA explained that pooling the data from the two studies increased the number of study subjects, thereby increasing the power of the data to detect trends (61 FR 3118 at 3153).

³¹ In its first objection, CSPI alludes to the pooling issue but does not elaborate on or support its challenge to pooling data (CSPI obj. 1 at p. 16).

³² In fact, although the two formulations of olestra differed in the degree of stiffness, each was within the range of stiffness permitted by the 1996 final rule (§ 172.867(b)(14)).

³³ In fact, although the two formulations of olestra differed in the degree of stiffness, each was within the range of stiffness permitted by the 1996 final rule (§ 172.867(b)(14)).

required (§ 12.24(b)(1)). Accordingly, FDA is denying CSPI's fifth objection.³⁴

F. Alleged Absence of Reasonable Certainty of No Harm

As noted, CSPI filed six objections to FDA's decision to approve olestra, including a general objection (CSPI obj. 1) that asserts that the additive does not meet the statutory standard of "reasonable certainty of no harm."³⁵ Many of the assertions of CSPI's general objection mirror the allegations of the more specific objections (CSPI obj. 2 through 5), which FDA has considered previously and denied.³⁶ Even standing alone, however, CSPI's first objection must be denied for several reasons.

Second, although CSPI's first objection is the longest of the six, it is almost exclusively a series of allegations³⁸ without any specifically identified and available evidence to support them.³⁹ That is, CSPI did not cite specific data or other factual information in the record to demonstrate the validity of its challenges to FDA's conclusions (CSPI

obj. at pp. 8 through 18). Thus, CSPI's first objection is denied for a second, separate reason because a hearing will not be granted on the basis of mere allegations (§ 12.24(b)(2)).⁴⁰

Third, CSPI asserts that the quality of certain studies relied upon by FDA is "spotty at best," and claims that these tests were "critical" to the safety evaluation of olestra (CSPI obj. at p. 13). In support of this claim, CSPI cites parts of the 1996 final rule and supporting memoranda discussing the limitations of certain studies.⁴¹ (CSPI obj. at p. 12, footnote 8). Importantly, however, CSPI does not demonstrate how the outcome of this proceeding would have been different if, due to these alleged quality problems, FDA had not been able to rely on these "certain studies" in determining the safety of olestra. Thus, FDA is denying CSPI's first objection because a hearing will not be granted on factual issues that are not determinative of the action requested⁴² (§ 12.24(b)(4)).

Fourth, CSPI challenges FDA's conclusion that the GI effects seen in P&G's 8-week studies are not harmful health effects. As part of this challenge, CSPI criticizes the size of the two 8-week studies and asserts that a larger study would likely have shown statistical significance at the 8 grams/day (g/d) dose, citing the comments of David Allison, Ph.D., a statistician and consultant to FAC (CSPI obj. at pp. 13 through 14 and footnote 11). CSPI fails to note that Dr. Allison concluded his statement by saying that whether "to make a great deal of argument on is, there or isn't there an effect at the 8 g dose is really a misleading kind of argument because it seems almost certain that there is but, rather, is it an important effect, an effect that is clinically meaningful * * * (transcript of FAC meeting, November 16, 1995, at p. 52). In the same footnote, CSPI claims that Dr. Marvin

Schneiderman performed a trend test which demonstrated an increase in incidence of "gastrointestinal disturbances above the placebo level at 8 g/day." In fact, Dr. Schneiderman's analysis concerned only anal leakage, not all GI effects (CSPI exh. 14 at p. 2). FDA found that anal leakage is not a health hazard (61 FR 3118 at 3154), a fact not disputed by CSPI in its objections and hearing requests. Accordingly, FDA is denying CSPI's objection on this point because a hearing will be denied where the data and information submitted are insufficient to justify the factual determination urged (§ 12.24(b)(3)).

Finally, CSPI disputes FDA's conclusion that the "diarrhea" experienced by olestra consumers is not clinical diarrhea and thus, not an adverse health effect.⁴³ In particular, CSPI asserts that "weight and water content of diarrheal stools was increased over those of loose and normal stools in subjects eating 20 g/day of olestra." (CSPI obj. at p. 16). Importantly, however, CSPI does not cite a reference to support this conclusion. In the absence of specifically identified and available evidence to support a disputed fact, a hearing must be denied (§ 12.24(b)(2)). Moreover, CSPI does not explain how a finding of increased stool weight among olestra consumers would alter FDA's conclusion that olestra's GI effects are not harmful to health.⁴⁴ Thus, FDA is denying a hearing on this issue because it is not determinative of the question at issue (§ 12.24(b)(4)). Likewise, although FDA concluded that increased water content of stools could be an indicator of true diarrhea (61 FR 3118 at 3158), FDA concluded that in the study in question, the data "regarding stool water concentration—expressed as a percent of stools by weight—suggests that the stool water concentration of subjects having diarrhea during the olestra 20 g/d period did not differ from that of their nondiarrheal stools during the placebo period" (61 FR 3118 at 3171; Ref. 88). Thus, even if CSPI intended to rely on Ref. 88 to support this allegation, the memorandum does not establish that

³⁴ In fact, CSPI raised most of these complaints in comments to FDA prior to olestra's approval, and the agency addressed each such complaint in the preamble to the final rule (61 FR 3118 at 3163 to 3165). CSPI's fifth objection and hearing request does not dispute FDA's resolution of these challenges in the final rule.

³⁵ The act prohibits FDA from approving a food additive if it has not been shown to be "safe" for its intended use, section 409(c)(3) of the act; FDA's regulation, relying on the legislative history of the Food Additives Amendment of 1958, defines "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance." (§ 170.3(i) [21 CFR 170.3(i)].)

First, CSPI's first objection challenges FDA's finding that olestra is safe for use in savory snacks.³⁷ As noted, resolving the question of olestra's safety requires the application of the legal standard ("safe") as defined by FDA's regulations ("reasonable certainty of no harm") to a set of facts. As such, the question of whether olestra is safe for its intended use is a question of law, not fact. Accordingly, FDA is denying CSPI's first objection because a hearing will not be granted on issues of policy or law (§ 12.24(b)(1)).

³⁶ In these circumstances and for reasons of economy, FDA does not restate its analysis and basis for denial of the specific objections.

³⁷ CSPI asserts that FDA's approval of olestra is "arbitrary and capricious" and thus erroneous (CSPI obj. at p. 12). In fact, the standard of review for a food additive approval is "a fair evaluation of the entire record * * * (section 409(g)(2) of the act). CSPI provides no evidence that FDA did not conduct a fair evaluation of the entire record.

³⁸ For example, in its discussion of the "Inadequate Safety Base" for olestra, CSPI notes Dr. Klish, a witness at OWG, testified that at 1 year, children's GI tracts are the same as adults and therefore, data from adults can be extrapolated to children. On this subject CSPI simply asserts, "Life experience, however, does not support that view. After all, why do one- and two-year-olds experience 'toddlers' diarrhea' * * * ?" (CSPI obj. at p. 8.)

³⁹ In the carotenoids portion of its first objection, for example, CSPI refers to a "selection of letters from noted scientists opposing the approval of olestra" (CSPI exh. 8.) Notably, however, CSPI does no more to identify the specific facts these experts dispute or to specify the data and other information on which these experts rely (§ 12.24(b)(2)).

⁴⁰ It is not surprising that CSPI's allegations are unsupported because, in some cases, the allegations are clearly false. For example, CSPI claims that "the FDA staff declined to consider" certain data regarding carotenoids (CSPI obj. at p. 6). In fact, FDA devoted a significant amount of attention to the carotenoids issue (61 FR 3118 at 3147 to 3149 and 3161), but ultimately reached a different conclusion than that urged by CSPI.

⁴¹ In particular, CSPI quotes excerpts from the 1996 final rule in which FDA identified certain limitations of these studies of olestra. Identifying such limitations is consistent with FDA's obligation to make a "fair evaluation of the data" in the record when determining olestra's safety (section 409(c)(4) of the act).

⁴² For example, CSPI offers several criticisms of a P&G marketing study which the company presented to illustrate consumption patterns for savory snacks (CSPI obj. at p. 13, footnote 10). In fact, as CSPI noted (CSPI obj. at p. 33), FDA told OWG that FDA had not relied on data from this study in its safety evaluation (Transcript of the FAC meeting, November 16, 1995, at p. 55).

⁴³ CSPI refers to a December 26, 1995, memorandum of Karl Klontz, M.D., erroneously describing it as Ref. 87 to the final rule (CSPI obj. at p. 16, footnote 14). In fact, Dr. Klontz's December 26, 1995, memorandum is Ref. 88 of the final rule (61 FR 3118 at 3171).

the subjects' stool water content increased when they consumed olestra. Thus, FDA is denying CSPI's hearing on this point (§ 12.24(b)(3)).

V. Summary and Conclusion

The act requires that a food additive be shown to be safe prior to marketing under section 409 of the act. Under § 170.3(i), a food additive is "safe" if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the agency's January 30, 1996, final rule approving olestra, FDA concluded that the studies conducted to establish the

safety of this additive demonstrate that olestra is safe for its intended use in savory snacks.

The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Nevertheless, once FDA makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co. v. FDA*, 606 F.2d 1307, 1314-1315 (D.C. Cir. 1979)).

Despite its many allegations, CSPI has not established that FDA overlooked significant information in the record in reaching its conclusion that olestra is

safe. In such circumstances, FDA has determined that the objections do not raise any genuine, and substantial issue of fact that would justify an evidentiary hearing on any of the objections raised (§ 12.24(b)). Accordingly, FDA is overruling CSPI's objections and is denying CSPI's requests for a hearing in their entirety.

Dated: July 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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Federal Register

Tuesday,
August 5, 2003

Part IV

Department of Education

**National Institute on Disability and
Rehabilitation Research; Alternative
Financing Mechanism Program and
Access to Telework Fund Program;
Inviting Applications for New Awards for
Fiscal Year (FY) 2003; Notices**

DEPARTMENT OF EDUCATION

RIN 1820 ZA30

National Institute on Disability and Rehabilitation Research

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed priorities and change to the application process.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services is providing notice of a proposed priority for the Alternative Financing Mechanisms Program (AFP) under title III of the Assistive Technology Act of 1998 (AT Act) that is administered by the National Institute on Disability and Rehabilitation Research (NIDRR). The Assistant Secretary is also providing notice of a proposed priority for the Access to Telework Fund Program (Telework) under section 303(b) of the Rehabilitation Act of 1973, as amended (Rehab Act), that is administered by the Rehabilitation Services Administration (RSA). In addition, the notice contains changes to the application process that NIDRR and RSA will use for these competitions.

DATES: We must receive your written comments on or before September 4, 2003.

ADDRESSES: Address all comments about this priority to Carol Cohen, U.S. Department of Education, 400 Maryland Avenue, SW., room 3420, Switzer Building, Washington, DC 20202-2645. Fax: (202) 205-8515. If you prefer to send your comments through the Internet, use the following address: carol.cohen@ed.gov.

FOR FURTHER INFORMATION CONTACT: Carol Cohen. Telephone: (202) 205-5666.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205-4475 or via the Internet: carol.cohen@ed.gov.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: During and after the comment period, you may inspect all public comments about these priorities in room 3420, Switzer Building, 330 C Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Invitation to Comment

We invite you to submit comments regarding these proposed priorities. To ensure that your comments have maximum effect in developing the notice of final absolute priorities, we urge you to be specific about any recommended changes.

Assistance to Individuals With Disabilities in Reviewing the Comments

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

We will announce the final priorities in a notice in the *Federal Register*. We will determine the final priorities after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use these proposed absolute priorities, we invite applications through a notice in the *Federal Register*.

SUPPLEMENTARY INFORMATION: The Assistant Secretary may use these priorities for competitions in fiscal year (FY) 2003 and later years.

Eligibility for an AFP Grant

States that receive or have received grants under section 101 of the AT Act are eligible for an AFP grant. Under section 3(a)(13)(A) of the AT Act, State means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Eligibility for a Telework Grant

States as defined in the AT Act and governing bodies of American Indian tribes located on Federal and State reservations consistent with section 7(19)(B) of the Rehab Act are eligible for a Telework grant. Consortia of States and American Indian tribes are also eligible for a Telework grant.

Joint Administration of Grants

States may jointly apply for and administer an AFP grant and a Telework grant. States that submit one application for the two priorities must meet the

requirements for each priority and will compete separately under each priority.

Proposed Priority 1: Alternative Financing Mechanism Program

Note: Public comment is limited to those portions of the proposed AFP priority not specifically addressed by the AT Act. We have provided citations to the AT Act where appropriate.

Background

The purpose of title III of the AT Act is to maximize independence and participation in society by individuals with disabilities through the establishment of the AFP. Title III authorizes a Federal program to pay a share of the cost of establishment or expansion, and administration of programs that fund alternatives to the traditional payment options of public assistance and self-financing so that individuals with disabilities can acquire assistive technology devices and services (hereinafter referred to as AT).

Most individuals with disabilities do not have the private financial resources to purchase the AT they need. Currently, major service programs such as Medicaid, Medicare, and vocational rehabilitation cannot meet the growing demand for AT. The AFP offers individuals with disabilities attractive options that significantly enhance their access to AT in a way that underscores independence and inclusion.

The Assistant Secretary may award one-year grants or cooperative agreements to States to establish or maintain an AFP to increase access to AT for individuals with disabilities. NIDRR made AFP grants to six States in FY 2000 and to 14 States in FY 2001. In addition, NIDRR funded one AFP Technical Assistance project to assist States to apply for AFP grants and to assist recipients to develop and implement the AFP program in their States.

On August 13, 2002, NIDRR published a notice in the *Federal Register* inviting comments on the AFP (67 FR 52838). NIDRR received 17 comments by the deadline. The proposed AFP priority contains provisions suggested by the commenters. In addition, in response to the comments, NIDRR is planning on making changes to its application process for AFP awards.

An AFP grantee may implement one or more types of alternative financing mechanisms to allow individuals with disabilities and their family members, guardians, advocates, and authorized representatives to purchase AT devices and services. The statute requires

grantees to place all funds that support their AFP grant, including those repaid during the life of the program, in a permanent and separate account (Sec. 303(b)(5)(A)).

The following is a discussion of important issues that an applicant for an AFP grant should consider in developing an application.

(1) *Nature of the Match:* As established in the Fiscal Year 2002 Appropriations bill that supercedes the AT Act's statutory requirement, the State:Federal match requirement ratio is 1:3 (Department of Education Appropriations Act, 2002, Public Law 107-116). Thus, the State match share is 25 percent.

In the past, the biggest hurdle to States submitting a fundable application for an AFP grant has been meeting the requirement in section 303(b)(1) to match the Federal award with cash. NIDRR received comments on this issue urging that "cash" be defined as broadly as possible, including allowing "in-kind" contributions to qualify as a match of the Federal funds. NIDRR has concluded that the statute does not allow for this interpretation. The statutory language is clear: the State matching funds must be cash. Thus, the match cannot be "in-kind" contributions such as personnel costs, rent, equipment or other program supports.

State matching funds must come from State, local or private sources (Sec. 303(b)(1)). State matching funds may not be other Federal or previously obligated State funds, or funds made available by a financial or lending institution for direct loans that are not maintained in the required permanent separate account. The proposed priority includes a provision establishing that applicants must identify the source of their matching funds.

The State matching funds cannot supplant funds that have been used to support AFP mechanisms (e.g., title I or existing title III funds)(Sec. 303(b)(4)). However, a State may use its AFP award to expand an existing AFP.

(2) *Permanence of the Program:* The AFP awards have a 12-month funding period (Sec. 303(b)(2)). However, the project period for an AFP remains in effect for as long as the program originally funded by the AFP award is in operation. NIDRR received comments asking for clarification of the statutory language that refers to the permanence of the AFP. The proposed priority includes a provision that addresses what is meant by a State's obligation to implement its AFP grant on a permanent basis. This obligation goes

well beyond a project's 12-month funding period.

(3) *Responsibilities of the Grantee During the First Budget Period:* During the first 12-month budget period, the statute requires a grantee to submit policies and procedures to NIDRR that will be used to administer the AFP grant (Sec. 305). The proposed AFP priority includes provisions specifying when during the first 12-month budget period these policies and procedures must be submitted to NIDRR. In addition, the proposed AFP priority includes provisions requiring the grantee to undertake two additional statutory activities during the first 12-month budget period: (1) depositing its matching funds and its Federal award funds into a permanent separate account (Sec. 303(b)(5)), and (2) entering into a contract with a community-based organization (CBO), ensuring that the CBO has entered into a contract with commercial lending institutions or organizations or State financing agencies (Sec. 304).

(4) *Closing out an AFP Grant with Funds Remaining:* The proposed AFP priority includes a provision that establishes how much a State must return to NIDRR when it terminates its AFP grant and how to address outstanding loans in that calculation. When the AFP grant ceases, voluntarily or involuntarily, as part of the grant closeout process, the grantee has 90 days after the end of the funding year to return the Federal share of the remaining funds.

(5) *Use and Control of Funds:* One of the assurances that applicants must submit involves the use and control of the AFP grant funds, including funds generated through interest-bearing accounts and investment income (Sec. 303(b)(6)). The proposed AFP priority includes a provision that clarifies that the assurance regarding the use and control of funds applies to all funds derived from the AFP grant including the original Federal award, the State matching funds, AFP funds generated by either interest bearing accounts or investments, and all principal and interest paid by AFP borrowers who are extended loans directly from the permanent separate account.

(6) *Contract with CBO:* Grantees are required to contract with a community-based organization (CBO) to administer the AFP grant (Sec. 304). NIDRR strongly encourages a State to identify this CBO in their application and include a letter of participation from the organization. Further, States are encouraged to take a competitive and inclusive approach to selecting the CBO.

(7) *Indirect Costs:* The statute provides that the percentage of funds made available through the grant that is used for indirect costs may not exceed 10 percent (Sec. 303(b)(7)). The proposed AFP priority includes a provision that requires the grantee to recalculate annually the maximum allowable indirect cost rate, which may not exceed 10 percent of the amount of funds in the permanent and separate account and the amount of loans outstanding from that account.

(8) *Eligibility of Employers:* NIDRR received comments requesting clarification whether employers are eligible to assist individuals with disabilities through an AFP grant. The proposed AFP priority includes language stating that an employer is eligible to serve as an authorized representative of an individual with a disability.

(9) *Responsibilities of Employers under the Americans with Disabilities Act (ADA):* NIDRR received comments on whether an AFP grant affects an employer's responsibility to provide reasonable accommodations to qualified employees with disabilities. An employer's obligations under the ADA are not affected by the existence of an AFP grant, which is a voluntary program for individuals with disabilities. However, there is nothing in the ADA or in the AT Act that would prohibit an individual with a disability from choosing to have an employer serve as an authorized representative to obtain AT on behalf of the employee by using AFP grant support even if the employer already has a responsibility under the ADA to provide the AT. At the same time, an employer may not require an employee to designate the employer as an authorized representative under the AFP grant nor may an employer require an employee to use the AFP grant to purchase AT.

(10) *Personal Grants:* NIDRR received comments inquiring whether an AFP grantee could provide direct financial assistance to qualified individuals for AT. The statutory language of the AFP is unequivocal: AFP funds cannot be used as outright grants to eligible individuals. Individuals who participate in an AFP grant are expected to pay for the purchase of the AT.

Proposed Priority

The purpose of these proposed requirements is to increase the funding for and provision of AT (Sec. 2(b)(1)(A)). The AFP will: (1) Achieve the program's short-term goal of purchasing AT through alternative financing mechanisms for individuals with disabilities, and other eligible parties;

and (2) achieve the program's long-term goals of establishing a nationwide network of permanent State AFPs that promote independence and choice.

States that receive or have received grants under section 101 of the AT Act are eligible to compete for an AFP (Section 303(a)). In its application, a State must identify and describe one or more of the following types of AFP programs that the State will implement:

- (1) A low-interest loan fund;
- (2) An interest buy-down program;
- (3) A revolving loan fund;
- (4) A loan guarantee or insurance program;
- (5) A program operated by a partnership among private entities for the purchase, lease, or other acquisition of AT devices or AT services; or
- (6) Another mechanism that meets the requirements of title III and is approved by the Secretary (Sec. 301(b)).

According to section 301(a) of the AT Act, the AFP is designed to allow individuals with disabilities and their family members, guardians, advocates, and authorized representatives to purchase AT. The terms "AT devices" and "AT services" are defined in section 3(a) of the AT Act. When family members, guardians, advocates, and authorized representatives (including employers who have been designated by an individual with a disability as an authorized representative) receive AFP support to purchase AT, the purchase must be on behalf of an individual with a disability, i.e., the AT that is purchased must be solely for the benefit of that individual.

In addition, an applicant must submit the following assurances:

(1) *Nature of the Match*: An assurance that the State will provide the non-Federal share (25 percent) of the cost of the AFP in cash, from State, local, or private sources (Sec. 303(b)(1)). An applicant must identify the amount of Federal funds the State is requesting and the amount of cash that the State is going to generate as a match as well as the source of the cash.

(2) *Permanence of the Program*: An assurance that the AFP will continue on a permanent basis (Section 303(b)(2)).

A State's obligation to implement the AFP program consistent with all of the requirements, including reporting requirements, continues throughout the project period until there are no longer any funds available to operate the AFP and all outstanding loans have been repaid.

If a State decides to terminate its AFP while there are still funds available to operate the program, the State must return the Federal share of the funds remaining in the permanent separate

account to NIDRR (e.g., 75 percent if the original State:Federal match was 1:3) except for funds being used for grant purposes, such as loan guarantees for outstanding loans. However, before closing out its grant, the State must also return the Federal share of any principal and interest remitted to it on outstanding loans and any other funds remaining in the permanent separate account, such as funds being used as loan guarantees for those loans.

(3) *Consumer Choice and Control*: An assurance that, and information describing the manner in which, the AFP will expand and emphasize consumer choice and control (Section 303(b)(3)).

(4) *Supplement Not Supplant*: An assurance that the funds made available through the grant to support the AFP will be used to supplement and not supplant other Federal, State, and local public funds expended to provide alternative financing mechanisms (Sec. 303(b)(4)).

(5) *Permanent Separate Account*: An assurance that the State will ensure that (A) all funds that support the AFP, including funds repaid during the life of the program, will be placed in a permanent separate account and identified and accounted for separately from any other fund; (B) if the organization administering the program invests funds within this account, the organization will invest the funds in low-risk securities in which a regulated insurance company may invest under the law of the State; and (C) the organization will administer the funds with the same judgment and care that a person of prudence, discretion, and intelligence would exercise in the management of the financial affairs of such person (Section 303(b)(5)).

During the first 12-month budget period, a grantee must deposit its matching funds and its Federal award funds in the permanent and separate account.

(6) *Use and Control of Funds*: An assurance that (A) funds comprised of the principal and interest from the account described in paragraph (5) will be available to support the AFP; and (B) any interest or investment income that accrues on or derives from such funds after such funds have been placed under the control of the organization administering the AFP, but before such funds are distributed for purposes of supporting the program, will be the property of the organization administering the program (Section 303(b)(6)).

This assurance regarding the use and control of funds applies to all funds derived from the AFP including the

original Federal award, the State matching funds, AFP funds generated by either interest bearing accounts or investments, and all principal and interest paid by borrowers of the AFP who are extended loans from the permanent separate account.

(7) *Indirect Costs*: An assurance that the percentage of the funds made available through the grant that is used for indirect costs will not exceed 10 percent (Section 303(b)(7)).

For each 12-month budget period, grantees must recalculate their allowable indirect cost rate, which may not exceed 10 percent of the amount of funds in the permanent and separate account and any outstanding loans from that account.

(8) *Contract With a Community-Based Organization*: An assurance that the State will enter into a contract with a community-based organization (including a group of such organizations) that has individuals with disabilities involved in organizational decision making at all organizational levels, to administer the AFP. The contract will: (1) Include a provision requiring that the program funds, including the Federal and non-Federal shares of the cost of the program, be administered in a manner consistent with the provisions of title III; (2) include any provision the Secretary requires concerning oversight and evaluation necessary to protect Federal financial interests; and (3) require the community-based organization to enter into a contract, to expand opportunities under title III and facilitate administration of the AFP, with commercial lending institutions or organizations or State financing agencies (Section 304(a) and (b)).

During the first 12-month budget period, a grantee must enter into the contract with a CBO and ensure that the CBO has entered into the contract with the commercial lending institutions or organizations or State financing agencies.

(9) *Administrative Policies and Procedures*: An assurance that the State and any community-based organization that enters into a contract with the State under title III, will submit to the Secretary the following policies and procedures for administration of the AFP: (1) A procedure to review and process in a timely manner requests for financial assistance for immediate and potential technology needs, including consideration of methods to reduce paperwork and duplication of effort, particularly relating to need, eligibility, and determination of the specific AT device or service to be financed through the program; (2) A policy and procedure

to ensure that access to the AFP shall be given to consumers regardless of type of disability, age, income level, location of residence in the State, or type of AT device or AT service for which financing is requested through the program; and (3) A procedure to ensure consumer-controlled oversight of the program (Section 305).

Grantees must submit the administrative policies and procedures required in this assurance within six months of the start of the grant.

(10) *Data Collection*: An assurance that the State will collect the following: (1) Information on the type of alternative financing mechanisms used by the State and the community-based organization with which each State entered into a contract, under the program (Section 307); (2) the amount of assistance given to consumers through the program (who shall be classified by age, type of disability, type of AT device or AT service financed through the program, geographic distribution within the State, gender, and whether the consumers are part of an underrepresented population or rural population) (Section 307); and (3) information on the program's short-term and long-term goals.

Grantees must enter the data requested in this assurance, and other data the Secretary may require, in the system developed by the Secretary. The Technical Assistance provider has developed a (voluntary) web-based data collection instrument to assist the AFP grantees for this purpose. For more information on the data collection system, products, and reports, see <http://www.resna.org/AFTAP/loan/index.html>. Grantees must enter the data elements contained in this form as well as specific information (to be determined) pertaining to the short-term and long-term goals.

Through the analysis of data collected under the following reporting requirements, the Secretary will assess grantee success in meeting the program's overall goals of: (1) Increasing access to alternative financing programs for the purchases of AT for individuals with disabilities; and (2) establishing a nationwide network of permanent State AFPs that promote independence and choice.

Performance measures used to determine whether the goals have been accomplished will include: (1) Number of loan applications; (2) number of loans; (3) amount and terms of each loan; (4) number of loan applications denied and the reasons for the denials; (5) number of individuals with disabilities who obtained AT; (6) purpose and type of the AT purchased;

(7) default rate and net losses; (8) number of States that have established new loan program or expanded existing loan programs; and (9) State loan capacity.

Grantee evaluation systems must be capable of collecting and analyzing this and any additional required information.

Proposed Priority 2: Access to Telework Fund

Eligibility for a Telework Grant

State agencies from the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands, are eligible for a Telework grant. For the purposes of this document, these entities will be referred to as States.

Governing bodies of American Indian tribes located on Federal and State reservations (and consortia of those governing bodies) consistent with section 7(19)(B) of the Rehab Act are also eligible for a Telework grant.

More than one agency within a State or tribe may receive a Telework grant, but there must be coordination and communication between these grantees.

Background

In February of 2001, the President introduced his *New Freedom Initiative* to help individuals with disabilities by increasing access to assistive technologies, expanding educational opportunities, increasing the ability of individuals with disabilities to integrate into the workforce, and promoting increased access into daily community life. In order to increase the participation of individuals with disabilities in the workforce, Telework was proposed as part of this initiative. Telework provides support for alternative financing mechanisms with the goal of expanding telework opportunities for individuals with disabilities.

Through the availability of telework and other alternative work options, barriers to employment such as inadequate transportation, fatigue, inaccessible work environments, and the need for personal assistance experienced by individuals with disabilities can be reduced or eliminated. While Telework does not relieve covered employers from their obligations under the Americans with Disabilities Act (ADA), it will provide individuals with disabilities an alternative mechanism to access computers and other needed equipment

not provided by an employer to enable them to establish telework and other alternative work environments. These work options will provide employment opportunities to many Americans who want or need a flexible work environment.

While computer technology and the Internet have tremendous potential to broaden telework options, including home-based self-employment, the computer and Internet revolution has not reached as many people with disabilities as the population without disabilities. Only 25 percent of individuals with disabilities own a computer, compared with 66 percent of U.S. adults without disabilities, and only 20 percent of individuals with disabilities have access to the Internet, compared with 40 percent of U.S. adults. The primary barrier to wider access to computer equipment is cost.

It is often very difficult for individuals with disabilities to save enough money to purchase computer and adaptive technology (e.g., screen readers, voice synthesizers, adaptive keyboards, and specialized software). Cash benefit programs do not provide sufficient funds for both living expenses and savings, and income support programs limit the amount of assets a person can accumulate. For a number of reasons, individuals with disabilities often find it difficult to access loans as a method to purchase necessary equipment. For example, they may have insufficient cash or collateral, lack an appropriate credit rating, or face attitudinal barriers. Telework addresses these barriers by assisting individuals with disabilities to obtain financing for computers and other equipment, so that they may work from home or other telework sites.

For the purposes of the proposed Telework priority, the term "telework" encompasses work that can be performed effectively from home or from other remote sites away from the office, such as work on the road or at a telework center. Successful applicants will develop programs that will enable individuals with disabilities to obtain computers and other equipment so that they can work as an employee or contractor or to become self-employed on a full-time or part-time basis from home or other remote sites.

On December 26, 2002 RSA published a notice of proposed priority and proposed application requirements in the *Federal Register* for Telework (67 Fed. Reg. 78790). RSA received 24 comments by the deadline. Twelve of the 24 commenters suggested allowing State grantees to jointly administer AFP and Telework, and six other

commenters suggested that AFP and Telework grantees collaborate closely.

We agree that it would be more efficient for AFP grantees that choose to apply for Telework to jointly apply for and administer the two grant programs. However, AFP grantees may also choose to separately apply for and administer a Telework grant.

In order to enable joint administration of the two programs, the Assistant Secretary has revised the December 26, 2002 proposed Telework priority to parallel the AFP statutory requirements. The major revision is that the application and program requirements contained in the December 26, 2002 proposed Telework priority are now addressed through a number of required assurances with accompanying timeframes for implementing the assurances.

Eligible State applicants for an AFP grant may apply for a Telework grant by submitting one application to jointly administer the two grant programs. These States must specify in their application the amount of their match that is devoted to each grant. However, section 303(b)(5)(A) of the AT Act requires that AFP funds be placed in a permanent separate account. Thus, while State grantees may jointly administer the AFP and Telework, the funds must be kept in permanent separate accounts.

There are two major differences between the AFP and the Telework. The match requirement for a Telework grant is 10 percent while the match requirement for an AFP grant is 25 percent.

The second difference between the AFP and Telework is that the two programs have different short-term and long-term goals. Telework will provide support to individuals with disabilities for the purpose of purchasing computers and other equipment, including adaptive equipment. Telework will: (1) achieve the program's short-term goal of increasing access to technology for disabled individuals through alternative financing mechanisms that are used to purchase computers and other equipment, including adaptive equipment, so that individuals with disabilities can telework from home or other remote sites; and (2) achieve the program's long-term goal of increasing employment opportunities and competitive employment outcomes for individuals with disabilities. The proposed priority would implement the Access to Telework Fund proposed by the President in his New Freedom Initiative.

Congress appropriated funds under section 303(b) of the Rehab Act to

provide RSA the funds necessary to administer Telework. The proposed priority supports this section by furthering the purposes of the Rehab Act, specifically by empowering individuals with disabilities to maximize employment.

Proposed Priority

In its application, a State or Indian tribe must identify and describe one or more of the following types of programs that the State will implement:

- (1) A low-interest loan fund;
- (2) An interest buy-down program;
- (3) A revolving loan fund;
- (4) A loan guarantee or insurance program;
- (5) A program operated by a partnership among private entities for the purchase, lease, or other acquisition of computers and other equipment, including adaptive equipment;
- (6) Another mechanism that meets the requirements and intent of this program and is approved by the Secretary.

In addition, an applicant must submit the following assurances:

(1) *Nature of the Match*: An assurance that the State or Indian tribe will provide the non-Federal share (10 percent) of the cost of Telework in cash, from State or Indian tribe, local, or private sources. An applicant must identify the amount of Federal funds it is requesting and the amount of cash that the State or Indian tribe is going to generate as a match as well as the source of the cash.

(2) *Permanence of the Program*: An assurance that Telework will continue on a permanent basis.

A State or Indian tribe's obligation to implement Telework consistent with all of the requirements, including reporting requirements, continues throughout the project period until there are no longer any funds available to operate Telework and all outstanding loans have been repaid.

If a State or Indian tribe decides to terminate its Telework grant while there are still funds available to operate the program, the State or Indian tribe must immediately return the Federal share of the funds remaining in the permanent separate account to RSA (e.g., 90 percent if the original State or Indian tribe: Federal match was 1:9) except for funds being used for grant purposes, such as loan guarantees for outstanding loans. However, before closing out its grant, the State or Indian tribe must also return the Federal share of any principal and interest remitted to it on outstanding loans and any other funds remaining in the permanent separate account, such as funds being used as loan guarantees for those loans.

(3) *Consumer Choice and Control*: an assurance that, and information describing the manner in which, Telework will expand and emphasize consumer choice and control.

(4) *Supplement Not Supplant*: an assurance that the funds made available through the grant to support Telework will be used to supplement and not supplant other Federal, State or Indian tribe, and local public funds to support similar services to individuals with disabilities.

(5) *Permanent Separate Account*: an assurance that the State or Indian tribe will ensure that (A) all funds that support Telework, including funds repaid during the life of the program, will be placed in a permanent separate account and identified and accounted for separately from any other fund; (B) if the organization administering the program invests funds within this account, the organization will invest the funds in low-risk securities in which a regulated insurance company may invest under the law of the State; and (C) the organization will administer the funds with the same judgment and care that a person of prudence, discretion, and intelligence would exercise in the management of the financial affairs of such person.

During the first 12-month budget period, a grantee must deposit its matching funds and its Federal award funds in the permanent and separate account.

(6) *Use and Control of Funds*: an assurance that (A) funds comprised of the principal and interest from the account described in paragraph (5) will be available to support Telework; and (B) any interest or investment income that accrues on or derives from such funds after such funds have been placed under the control of the organization administering Telework, but before such funds are distributed for purposes of supporting the program, will be the property of the organization administering the program.

This assurance regarding the use and control of funds applies to all funds derived from Telework including the original Federal award, the State or Indian tribe matching funds, Telework funds generated by either interest bearing accounts or investments, and all principal and interest paid by borrowers of Telework who are extended loans from the permanent separate account.

(7) *Indirect Costs*: An assurance that the percentage of the funds made available through the grant that is used for indirect costs will not exceed 10 percent.

For each 12-month budget period, grantees must recalculate their

allowable indirect cost rate, which may not exceed 10 percent of the amount of funds in the permanent and separate account and any outstanding loans from that account.

(8) *Administrative Policies and Procedures:* An assurance that the State or Indian tribe will submit to the Secretary the following policies and procedures for administration of Telework: (1) A procedure to review and process in a timely manner requests for financial assistance for immediate and potential needs, including consideration of methods to reduce paperwork and duplication of effort, particularly relating to need, eligibility, and determination of the specific device or service to be financed through the program; (2) A policy and procedure to ensure that access to Telework shall be given to consumers regardless of type of disability, age, income level, location of residence in the State or Indian tribe, or type of device or service for which financing is requested through the program; and (3) A procedure to ensure consumer-controlled oversight of the program.

Grantees must submit the administrative policies and procedures required in this assurance within six months of the start of the grant.

(9) *Data Collection:* An assurance that the State or Indian tribe will collect the following: (A) Information on whether the program is achieving its short-term goal of increasing access to technology for disabled individuals through the provision of loans that must be used to purchase computers and other equipment, including adaptive equipment, so that individuals with disabilities can telework from home and other remote sites; and (B) Information on whether the program is achieving its long-term goal of increasing employment opportunities and competitive employment outcomes for individuals with disabilities.

Grantees must enter the data requested in this assurance, and other data the Secretary may require, in the system developed by the Secretary.

Through the analysis of data collected under the following reporting requirements, the Secretary will assess grantee success in meeting the program's overall goals of: (1) Increasing access to technology for disabled individuals; and (2) Increasing employment opportunities and competitive employment outcomes for individuals with disabilities.

Performance measures used to determine whether the goals have been accomplished will include: (1) Number of loan applications; (2) number of loans; (3) amount and terms of each

loan; (4) number of loan applications denied and the reasons for the denials; (5) the types of equipment financed, including the total number of each type of equipment financed; (6) number of individuals who obtained telework employment as a result of Telework loans; (7) default rate and net losses; and (8) the total financial contribution to the project, including the Federal share and non-Federal matching contributions, and the source of the non-Federal share.

Grantee evaluation systems must be capable of collecting and analyzing this and any additional information as required by the Secretary.

In addition, each State applicant must provide the following assurance:

Contract with a Community-based Organization: an assurance that the State (note: Indian tribes are exempt from this requirement) will enter into a contract with a community-based organization (including a group of such organizations) that has individuals with disabilities involved in organizational decision making at all organizational levels, to administer Telework. The contract will: (1) Include a provision requiring that the program funds, including the Federal and non-Federal shares of the cost of the program, be administered in a manner consistent with the provisions of this priority; (2) include any provision the Secretary requires concerning oversight and evaluation necessary to protect Federal financial interests; and (3) require the community-based organization to enter into a contract, to expand opportunities under this priority and facilitate administration of Telework, with commercial lending institutions or organizations or State financing agencies.

During the first 12-month budget period, a grantee must enter into the contract with a CBO and ensure that the CBO has entered into the contract with the commercial lending institutions or organizations or State financing agencies.

Applicability of Education Department General Administrative Regulations (EDGAR) to AFP and Telework

In general, EDGAR applies to these two grants except to the extent it is inconsistent with the purpose and intent of title III of the AT Act, section 303(b) of the Rehab Act, or the requirements in this notice. Specifically, grantees are exempt from section 80.21(i) regarding interest earned on advances and the addition method in section 80.25(g)(2) applies to program income rather than the deduction

method in section 80.25(g)(1). Also, sections 75.560–75.564 do not apply to the extent that these sections of EDGAR are inconsistent with the AFP and Telework requirement that indirect costs cannot exceed 10 percent. Finally, section 75.125, which requires applicants to submit a separate application for each program, does not apply to this competition.

Changes in NIDRR's and RSA's Application Processes for AFP and Telework Awards

Based upon public comments made in response to the earlier **Federal Register** notices for the AFP and Telework, NIDRR and RSA are planning on making changes to the application process for the grant awards. These revised application procedures will assist applicants to prepare fundable proposals, simplify the information that is required in the application, and streamline the application review process. NIDRR and RSA expect to fund all applications that meet the requirements set forth in the proposed priorities.

In order to promote fundable applications, NIDRR and RSA will provide applicants with technical assistance on their proposals beginning with the publication of this notice and up until the deadline for submission of applications. Prior to the application deadline, NIDRR and RSA will answer questions, review draft proposals, and provide applicants with feedback in order to assist them to submit a fundable application. In addition, NIDRR's AFP Technical Assistance project will provide assistance to all entities that are interested in applying for an AFP or Telework award.

The application process will be simplified by requiring applicants to submit a number of assurances, and a limited amount of information related to those assurances. NIDRR and RSA will not require applicants to provide details in their applications concerning the policies and procedures they will use to administer their AFP or Telework grant. These policies and procedures will be submitted by grantees to NIDRR or RSA within the first year of the grant.

NIDRR and RSA will use an internal application review process to determine whether all the necessary assurances and required program information have been submitted. This will ensure that the same standards that are used to provide applicants with information and feedback during the application period will be applied to evaluate applications for funding.

The Notice Inviting Applications that accompanies the final priorities will ask

each applicant to identify the amount of the Federal award for which it is applying and can qualify. That amount is based on the amount of matching funds to be provided by the applicant. The size of each award will depend on the total number of fundable applications that NIDRR and RSA receive and the requests for Federal funding that are included in those applications.

Electronic Access to This Document

You may review this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/legislation/FedRegister>.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC, area at (202) 512-1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO access at: <http://www.access.gpo.gov/nara/index.html>.

(Catalog of Federal Domestic Assistance Number 84.224C, Alternative Financing Program and 84.235T, Access to Telework Fund Program.)

Program Authority: 29 U.S.C. 773(b) and 29 U.S.C. 3051-3056.

Dated: July 31, 2003.

Robert H. Pasternack,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 03-19844 Filed 8-4-03; 8:45 am]

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DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.224C and 84.235T]

Alternative Financing Mechanism Program and Access to Telework Fund Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003

Purpose of Program: This notice invites applications for two programs: the Alternative Financing Mechanisms Program (AFP) under title III of the Assistive Technology Act of 1998 (AT Act) that is administered by the

National Institute on Disability and Rehabilitation Research (NIDRR) and the Access to Telework Fund Program (Telework) under section 303(b) of the Rehabilitation Act of 1973, as amended (Rehab Act), that is administered by the Rehabilitation Services Administration (RSA).

It is the policy of the Department of Education not to solicit applications before the publication of final priorities. However, in this case it is essential to solicit applications on the basis of the notice of proposed priority, definitions, and application and project requirements published elsewhere in this issue of the **Federal Register**, because the Department's authority to obligate these funds will expire on September 30, 2003. Applicants should base their applications on the proposed priority, definitions, and application and project requirements. If changes are made in the final notice in response to public comments or other considerations, applicants will be given an opportunity to revise or resubmit their applications.

SUPPLEMENTARY INFORMATION: Funds under these competitions will be used to support projects in FY 2003.

States may jointly apply for and administer an AFP grant and a Telework grant. These States must meet the requirements for each priority and will compete separately under each priority. Alternatively, States may apply for either the AFP or the Telework grant, or both, to be administered separately. In addition, Indian tribes are eligible to apply for Telework grants.

Priorities

Absolute Priority 1—Alternative Financing Mechanism Program (84.224C)

For FY 2003, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet the priority, definitions, and application and project requirements.

The AFP will award grants to States to pay for the Federal share of the cost of the establishment and administration of, or the expansion and administration of, an AFP featuring one or more alternative financing mechanisms to allow individuals with disabilities and their family members, guardians, advocates, and authorized representatives to purchase AT devices and AT services.

Eligible Applicants: States that receive or have received grants under section 101 of the AT Act are eligible for an AFP grant. Under section 3(a)(13)(A) of the AT Act, State means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 80, 81, 82, and 85.

Selection Criteria

In evaluating an application for a new grant under this competition, we will determine if an applicant has submitted the required assurances.

Absolute Priority 2—Access to Telework Fund Program (84.235T)

For FY 2003, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet the priority, definitions, and application and project requirements.

The Access to Telework Fund Program will award grants to States and Indian Tribes to pay for the Federal share of the cost of the establishment and administration of an Access to Telework Fund featuring one or more alternative financing mechanisms to allow individuals with disabilities access to computers and other needed equipment not provided by an employer to enable them to telework from home or other remote sites.

Eligible Applicants: States as defined in the AT Act and governing bodies of American Indian tribes located on Federal and State reservations consistent with section 7(19)(B) of the Rehab Act are eligible for a Telework grant. Consortia of States and American Indian tribes are also eligible for a Telework grant.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 80, 81, 82, and 85

Selection Criteria

In evaluating an application for a new grant under this competition, we will determine if an applicant has submitted the required assurances.

ALTERNATIVE FINANCING MECHANISM PROGRAM AND ACCESS TO TELEWORK FUND PROGRAM CFDA NOS. 84.224C AND 84.235T

[Applications for FY 2003]

CFDA No. program name	Application available	Deadline for transmittal of applications	Estimated range of awards	Estimated number of awards*	Project period (months)
84.224C Alternative Financing Mechanism Program..	Aug. 5, 2003.	Sept. 4, 2003	\$500,000–2,000,000	24	As long as the program originally funded by the AFP award is in operation (section 303(b)(2) of the AT Act).
84.235T Access to Telework Fund Program..	Aug. 5, 2003.	Sept. 4, 2003 ...	\$250,000–1,000,000	40	As long as the program originally funded by the Telework award is in operation.

*The Department is not bound by any estimates in this notice.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794-1398. Telephone (toll free): 1-877-433-7827. FAX: (301) 470-1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1-877-576-7734.

You may also contact ED Pubs via its Web site: <http://www.ed.gov/pubs/edpubs.html>; or you may contact ED Pubs at its e-mail address: edpubs@inet.ed.gov.

If you request an application from ED Pubs, be sure to identify these competitions as follows: CFDA number 84.224C (AFP) and 84.235T (Telework).

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 3317, Switzer Building, Washington, DC 20202-2550. Telephone: (202) 205-8207. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service

(FIRS) at 1-800-877-8339. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

FOR FURTHER INFORMATION CONTACT: Carol G. Cohen. Telephone: (202) 205-5666 or via the Internet: carol.cohen@ed.gov.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205-4475.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Application Procedures

The application procedures for these priorities are found in the application package.

Electronic Access to This Document

You may view this document, as well as all other Department of Education

documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/legislation/FedRegister>.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC, area at (202) 512-1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.access.gpo.gov/nara/index.html>.

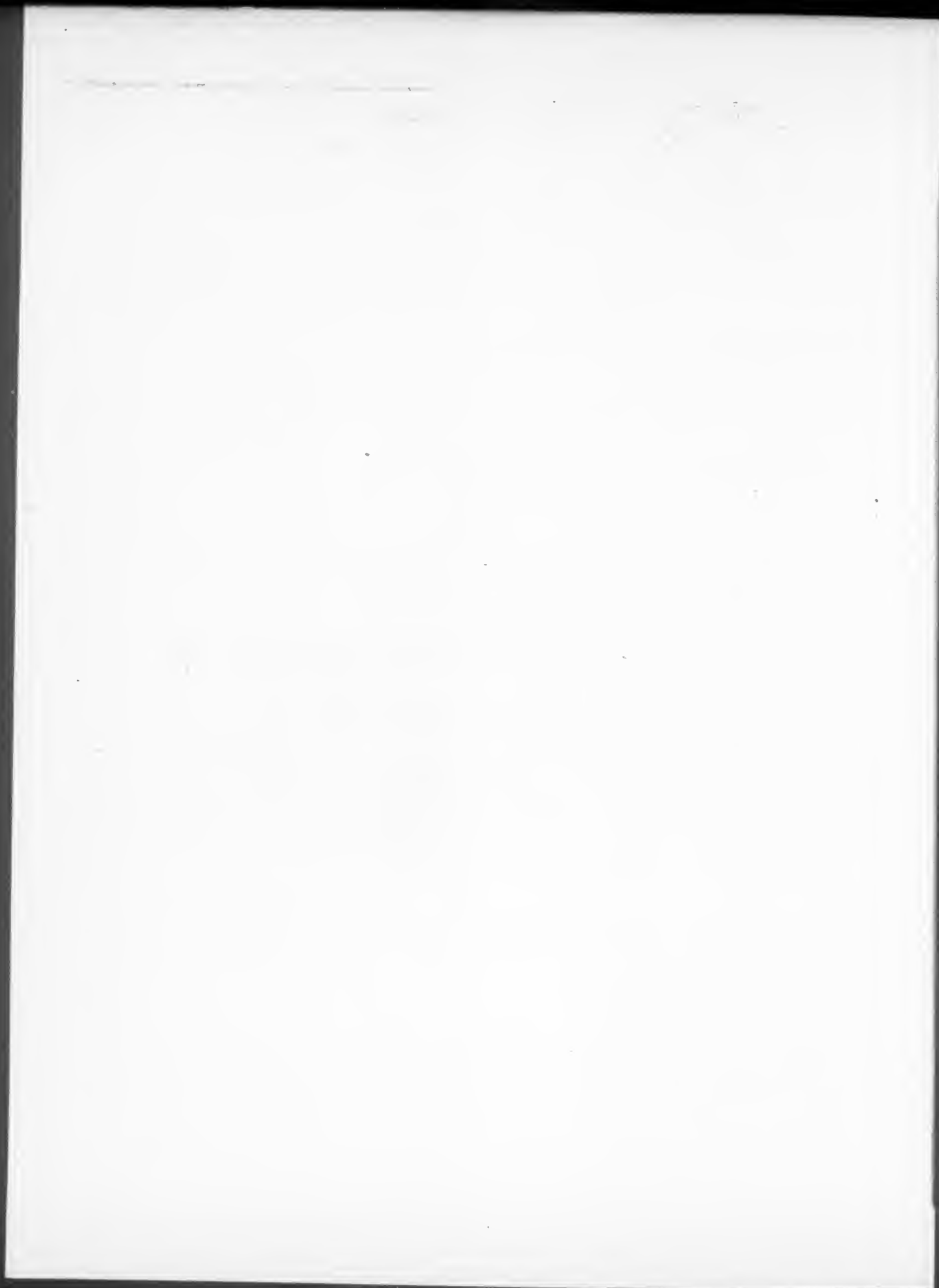
Program Authority: 29 U.S.C. 773(b) and 29 U.S.C. 3051-3056.

Dated: July 31, 2003.

Robert H. Pasternack,
Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 03-19845 Filed 8-4-03; 8:45 am]

BILLING CODE 4000-01-P





Federal Register

Tuesday,
August 5, 2003

Part V

Department of Education

**Special Demonstration Programs—Model
Demonstration Projects—Mentoring for
Transition-Age Youth and Young Adults
With Disabilities; Inviting Applications for
New Awards for Fiscal Year (FY) 2003;
Notices**

DEPARTMENT OF EDUCATION

RIN 1820-ZA28

**Special Demonstration Programs—
Model Demonstration Projects—
Mentoring for Transition-Age Youth
and Young Adults With Disabilities**

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed priority, definitions, and application requirements.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority, definitions, and application requirements under the Special Demonstration Programs focusing on mentoring models that provide appropriate supports for transition-age youth and young adults with disabilities. The mentoring models developed under this program must incorporate effective, research-based mentoring methods. The Assistant Secretary may use this priority, definitions, and the requirements for competitions in fiscal year (FY) 2003 and later years. We take this action to increase meaningful postsecondary education and quality employment outcomes through a mentoring system within State vocational rehabilitation (VR) agencies. Grants would be made to State VR agencies.

DATES: We must receive your comments on or before September 4, 2003.

ADDRESSES: Address all comments about this proposed priority, definitions, and application requirements to Alfreda Reeves, U.S. Department of Education, 400 Maryland Avenue, SW., room 3314, Switzer Building, Washington, DC 20202-2645. If you prefer to send your comments through the Internet, use one of the following addresses: Alfreda.Reeves@ed.gov or Pamela.Martin@ed.gov.

You must include the term "Mentoring Model Demonstration" in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Alfreda Reeves. Telephone: (202) 205-9361 or via Internet: Alfreda.Reeves@ed.gov. Or Pamela Martin, U.S. Department of Education, 400 Maryland Avenue, SW., room 3314, Switzer Building, Washington, DC 20202-2645. Telephone: (202) 205-8494 or via Internet: Pamela.Martin@ed.gov.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205-4475.

Individuals with disabilities may obtain this document in an alternative

format (e.g., Braille, large print, audiotape, or computer diskette) on request to one of the contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:**Invitation to Comment**

We invite you to submit comments regarding this proposed priority, definitions, and application requirements. To ensure that your comments have maximum effect in developing the notice of final priority, definitions, and application requirements, we urge you to be specific about any recommended changes. We are particularly interested in receiving comments on the following topics:

1. The definitions of "mentor" and "mentoring" as they appear in this notice.

2. The requirement to collaborate with a consumer-controlled organization.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from this notice. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed priority, definitions, and application requirements in room 3038, Switzer Building, 330 C Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed priority, definitions, and application requirements. If you want to schedule an appointment for this type of aid, please contact one of the individuals listed under **FOR FURTHER INFORMATION CONTACT**.

We will announce the final priority, definitions, and application requirements in a notice in the **Federal Register**. We will determine the final priority, definitions, and application requirements after considering

responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this proposed priority, definitions, and application requirements, we invite applications through a notice in the **Federal Register**. When inviting applications we designate the priority as absolute, competitive preference, or invitational. The effect of each type of priority follows:

Absolute priority: Under an absolute priority we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority we give competitive preference to an application by either (1) awarding additional points, depending on how well or the extent to which the application meets the competitive priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the competitive priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the invitational priority a competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Priority

Proposed Priority—Model Demonstration Projects—Mentoring for Transition-Age Youth and Young Adults With Disabilities

These model demonstration projects would test whether increases in meaningful postsecondary education and quality employment outcomes can be achieved through the use of mentors by State VR agencies.

The program will be conducted under section 303(b) of the Rehabilitation Act of 1973, as amended (Act). The proposed priority supports section 303(b) by furthering the purposes of the Act, specifically by empowering individuals with disabilities to maximize employment, economic self-sufficiency, independence, and inclusion and integration into society.

Background

The educational and employment achievements of youth and young adults with disabilities lag significantly behind those of their peers without disabilities. The Office of Special Education

Programs reports that only 57.4 percent of youth with disabilities graduate from high school with a standard diploma. In addition, the Final Report of the Presidential Task Force on Employment of Adults with Disabilities, July 2002, estimates that only one-third of youth and young adults with disabilities receive appropriate job training and assistance. Some of the barriers to autonomy and achievement encountered by youth and young adults with disabilities include uncoordinated approaches to transition across service systems, discontinuity between schools and adult disability services, poor preparation of teens for adult life, lack of incentives or supports for early transition planning, and lack of school and community supports.

For transitioning youth and young adults with disabilities, developing positive self-confidence, resilience, and an expectation for achievement in a competitive, high-quality career must take place early in their academic career. Mentors or role models with whom students can identify, and who have shared interests, can have a positive impact that will last a lifetime. These individuals can play a vital role in eliminating barriers to autonomy, community integration, and achievement by motivating youth and young adults with disabilities to develop social competence, academic motivation, career awareness, and other appropriate skills needed for employment and independent living. Successful mentoring programs under this model demonstration program will provide appropriate supports, based on the individual's unique strengths, priorities, concerns, abilities, capabilities, interests, and informed choice. An overall objective of the mentoring program is to encourage youth and young adults with disabilities in meeting and achieving a desired optimal career goal or postsecondary education.

Priority

Under 34 CFR 75.105(b)(2)(v) and 34 CFR 373.6(b)(2) and (c)(8), this priority supports projects that demonstrate mentoring models focusing on transitioning youth and young adults with disabilities that will be effective in increasing meaningful community integration, postsecondary education, and employment outcomes. The mentoring models developed under this program must incorporate effective, research-based mentoring methods. An external evaluation of these projects will be initiated in FY 2004. The projects must cooperate with the external

evaluator including establishing a common data system.

A. Definitions

Mentor means a more successful, experienced person with a disability, who can be most appropriately matched with the youth with a disability and who can impart advice, support, insight, and knowledge on employment and other life activities to a less experienced person. State VR agencies should match mentors and mentees using the best individualized information possible.

Mentoring means the act of a more successful, experienced person or persons with a disability, working with a less experienced youth or young adult, or a group of individuals, by providing guidance in the form of teaching and support, encouraging and motivating, assisting with career and professional development, assisting with goal achievement, and linking the less experienced youth to others who can help enhance growth and development.

Youth and young adults with disabilities, as defined in 34 CFR 373.4, means individuals with disabilities who are between the ages of 16 and 26 inclusive when entering the program.

Consumer-controlled organization is an organization that vests power and authority in individuals with disabilities and a majority of the officers and members of the board of directors are individuals with disabilities.

B: General Requirements for Applicants

These model demonstration projects must focus on research-based mentoring methods that provide appropriate supports for transition-age youth and young adults with disabilities. The projects must demonstrate research-based mentoring models that will be effective in increasing meaningful community integration, postsecondary education, and employment outcomes through collaboration between State VR agencies and consumer-controlled organizations. To meet the requirements an applicant must—

(1) Describe the manner in which mentoring will increase academic achievement, participation in postsecondary education, and high-quality employment outcomes for transitioning youth and young adults with disabilities by including information on the expected impact and outcomes of the project. More specifically, an applicant must project a goal of how many youth and young adults with disabilities will transition into postsecondary education or will achieve high-quality employment outcomes. An applicant also must be specific about what data it will collect

in order to measure project outcomes against the goal;

(2) Describe the research-based mentoring models that will be demonstrated through its project;

(3) Describe clear program goals and intended program outcomes and well-defined operational guidelines that will support these goals;

(4) Describe how the project will collaborate with consumer-controlled organizations that have in-depth knowledge of the rehabilitation process, the outreach methods used to select project participants, and the criteria by which individuals with disabilities will be recruited as mentors by the consumer-controlled organizations;

(5) Describe how the proposed project will increase self-advocacy, high-level personal and career expectations, decisionmaking, and adjustment to disability of the mentored individuals. At a minimum, the project must describe how mentors will help consumers—

(a) Navigate through service delivery systems; and

(b) develop and improve self-confidence, community integration skills, work skills, self-determination skills, advocacy, and decisionmaking;

(6) Describe the design and implementation of an internal evaluation plan for which—

(a) The methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the project;

(b) The methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible;

(c) The methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes; and

(d) The methods of evaluation will be consistent with and can support the program assessment that will be implemented by the Rehabilitation Services Administration; and

(7) Include a plan to widely disseminate the results of the project, including any mentoring methods that demonstrated positive results, so the mentoring model may be adapted, replicated, or integrated into other State VR agencies and disability organizations.

Executive Order 12866

This notice of proposed priority, definitions, and application requirements has been reviewed in accordance with Executive Order 12866.

Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with this notice are those resulting from requirements we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this notice, we have determined that the benefits of the proposed priority, definitions, and application requirements justify the costs.

We have also determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Summary of Potential Costs and Benefits

The Assistant Secretary has determined that the cost to the Federal Government associated with this program will not exceed \$1,200,000 in FY 2003. No other costs will result from the announcement of this proposed priority, definitions, and application requirements.

The benefit of this proposed priority, definitions, and application requirements will be the establishment of model demonstration projects that will lead to increases in meaningful postsecondary education and quality employment outcomes through a mentoring system within State VR agencies.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Applicable Program Regulations

34 CFR part 373.

Electronic Access to This Document

You may review this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/legislation/FedRegister>.

To use PDF you must have Adobe Acrobat Reader, which is available free

at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC, area at (202) 512-1530.

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(Catalog of Federal Domestic Assistance Number 84.235Q, Special Demonstration Programs—Model Demonstration Projects—Mentoring for Transition-Age Youth and Young Adults With Disabilities)

Program Authority: 29 U.S.C. 773(b).

Dated: July 31, 2003.

Robert H. Pasternack,
Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 03-19876 Filed 8-4-03; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.235Q]

Special Demonstration Programs— Model Demonstration Projects— Mentoring for Transition-Age Youth and Young Adults With Disabilities; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003

Purpose of Program: To provide financial assistance to projects that expand and improve the provision of rehabilitation and other services for individuals with disabilities. These model demonstration projects will focus on mentoring models that provide appropriate supports for transition-age youth and young adults with disabilities. The mentoring models developed under this program must incorporate effective, research-based mentoring methods. The model demonstration projects will test whether increases in meaningful postsecondary education and quality employment outcomes can be achieved through the use of mentors by State vocational rehabilitation (VR) agencies.

Eligible Applicants: State VR agencies.

Supplementary Information: Funds under this competition will be used to support projects in FY 2003. Along with other authorized activities, funds may be used for the payment of mentors. In FY 2004, the Assistant Secretary may consider funding high-quality applications submitted in FY 2003, but not funded in FY 2003.

Applications Available: August 5, 2003.

Deadline for Transmittal of Applications: September 4, 2003.
Estimated Available Funds: \$750,000.
Estimated Range of Awards: \$150,000–\$200,000.
Estimated Average Size of Awards: \$185,000.

Estimated Number of Awards: 4.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. It is suggested that you limit Part III to 35 pages.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, 97, and 99. (b) The regulations for this program in 34 CFR part 373.

Selection Criteria: In evaluating an application for a new grant under this competition, we use selection criteria developed in accordance with 34 CFR 75.209 or chosen from the general selection criteria in 34 CFR 75.210 or a combination of both. The selection criteria to be used for this competition will be provided in the application package for this competition.

Priorities

**Model Demonstration Projects—
Mentoring for Transition-Age Youth and
Young Adults With Disabilities**

It is the policy of the Department of Education not to solicit applications before the publication of final priorities. However, in this case it is essential to solicit applications on the basis of the notice of proposed priority, definitions, and application requirements published elsewhere in this issue of the **Federal Register**, because the Department's authority to obligate these funds will expire on September 30, 2003. Applicants should base their applications on the proposed priority, definitions, and application requirements. If changes are made in the final notice in response to public comments or other considerations, applicants will be given an opportunity to revise or resubmit their applications.

For FY 2003, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet the priority, definitions, and application requirements.

Invitational Priority

We are particularly interested in applications that meet the following invitational priority.

Projects of Collaboration Between State VR Agencies and Consumer-Controlled, Membership Organizations Focusing on Mentoring for Transition-Age Youth and Young Adults With Disabilities

We are interested in projects that foster collaborative working relationships between State VR agencies and consumer-controlled, membership organizations in order to demonstrate whether research-based mentoring methods can be effective in increasing meaningful community integration, postsecondary education, and employment outcomes.

A consumer-controlled, membership organization is an entity—(a) With a constitution or bylaws, or both, that detail the operational structure of the organization, including membership classes and dues to be paid by members of each class; (b) that may not be merely a social organization but must actively promote the integration and full inclusion of individuals with disabilities into the mainstream of American society; and (c) of which the majority of the officers and a majority of the membership are individuals with disabilities.

Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority competitive or absolute preference over other applications.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794-1398. Telephone (toll free): 1-877-433-7827.

FAX: (301) 470-1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1-877-576-7734. You may also contact ED Pubs via its Web site: <http://www.ed.gov/pubs/edpubs.html>. Or you may contact ED Pubs at its e-mail address: edpubs@inet.ed.gov.

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.235Q.

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 3317, Switzer Building, Washington, DC 20202-2550. Telephone: (202) 205-8207. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

FOR FURTHER INFORMATION CONTACT:

Alfreda Reeves, U.S. Department of Education, 400 Maryland Avenue, SW., room 3314, Switzer Building, Washington, DC. 20202-2650. Telephone: (202) 205-9361. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this notice in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in the preceding paragraph.

Electronic Access to This Document

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Program Authority: 29 U.S.C. 773(b).

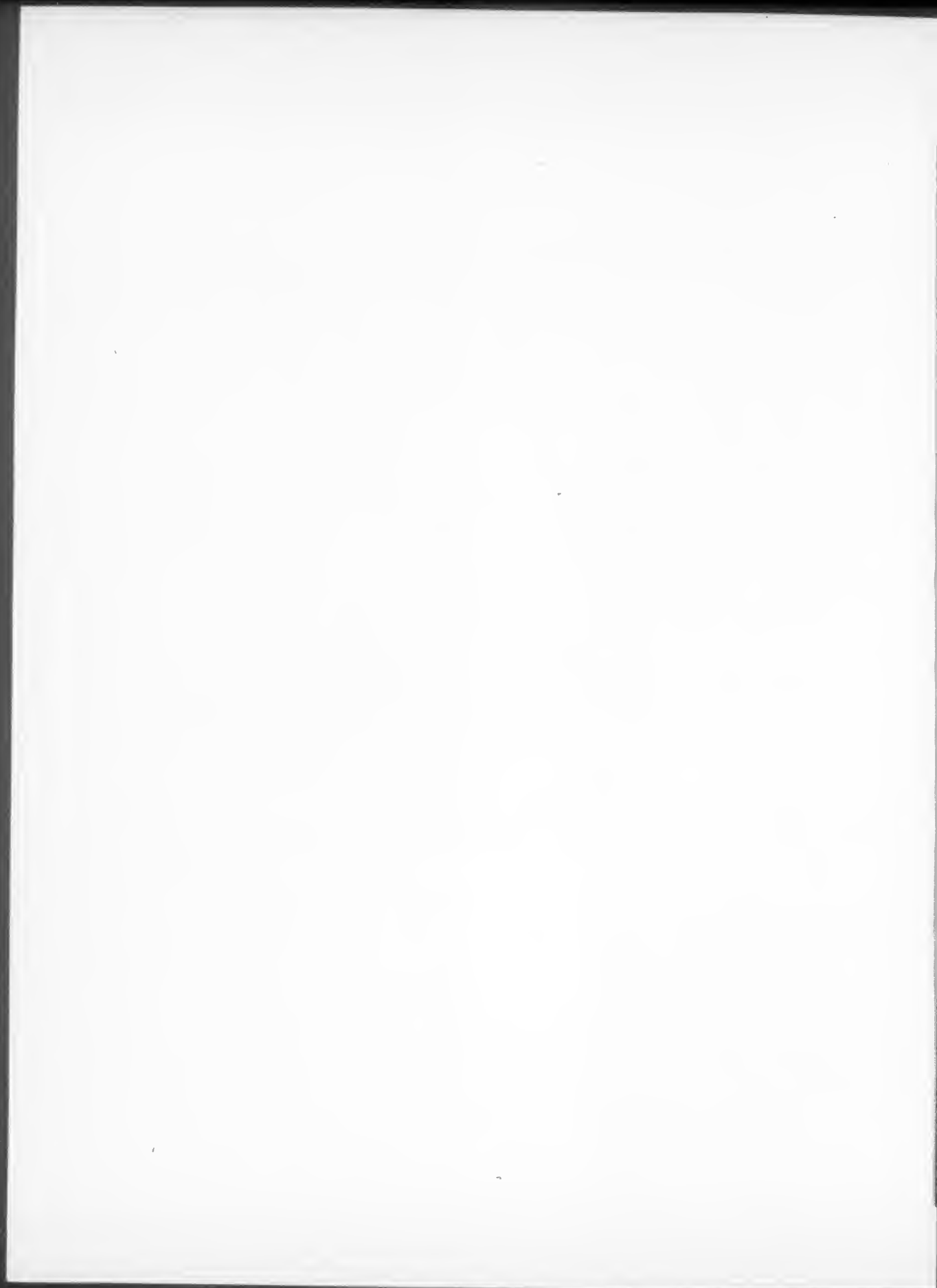
Dated: July 31, 2003.

Robert H. Pasternack,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 03-19875 Filed 8-4-03; 8:45 am]

BILLING CODE 4000-01-P





Federal Register

Tuesday,
August 5, 2003

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 25

Revised Requirement for Material
Strength Properties and Design Values for
Transport Airplanes; Final Rule

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 25**

[Docket No. FAA-2002-11345; Amdt. No. 25-112]

RIN 2120-AH36

Revised Requirement for Material Strength Properties and Design Values for Transport Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends the airworthiness standards for transport category airplanes concerning material strength properties and material design values. It incorporates changes developed in cooperation with the Joint Aviation Authorities of Europe and the U.S. and European aviation industry through the Aviation Rulemaking Advisory Committee (ARAC). This action is necessary because differences between the current U.S. and European requirements impose unnecessary costs on airplane manufacturers. Issuing this amendment eliminates regulatory differences between the airworthiness standards of the U.S. and the Joint Aviation Requirements of Europe, without affecting current industry design practices.

DATES: Effective September 4, 2003.

FOR FURTHER INFORMATION CONTACT: Rich Yarges, Airframe/Cabin Safety Branch, ANM-115, FAA Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, WA 98055-4056; telephone (425) 227-2143, facsimile (425) 227-1320, e-mail rich.yarges@faa.gov.

SUPPLEMENTARY INFORMATION:

How Can I Obtain a Copy of This Final Rule?

You can get an electronic copy using the Internet by:

- (1) Searching the Department of Transportation's electronic Docket Management System (DMS) web page (<http://dms.dot.gov/search>).
- (2) Visiting the Office of Rulemaking's web page at <http://www.faa.gov/avr/arm/nprm.cfm?nav=nprm>; or
- (3) Accessing the Government Printing Office's web page at http://www.access.gpo.gov/su_docs/aces/aces140.html.

You can also get a copy by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by

calling (202) 267-9680. Make sure to identify the amendment number or docket number of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact its local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at <http://www.faa.gov/avr/arm/sbreffa.htm>, or by e-mailing us at 9-AWA-SBREFA@faa.gov.

Background

What Are the Relevant Airworthiness Standards in the United States?

In the United States, Title 14, Code of Federal Regulations (CFR) part 25 contains the airworthiness standards for type certification of transport category airplanes. Manufacturers of transport category airplanes must show that each airplane they produce of a different type design complies with the appropriate part 25 standards. These standards apply to—

- Airplanes manufactured within the U.S. for use by U.S.-registered operators; and
- Airplanes manufactured in other countries and imported to the U.S. under a bilateral airworthiness agreement.

What Are the Relevant Airworthiness Standards in Europe?

In Europe, Joint Aviation Requirements (JAR)-25 contains the airworthiness standards for type certification of transport category airplanes. The Joint Aviation Authorities (JAA) of Europe developed these standards, based on part 25, to provide a common set of airworthiness standards within the European aviation community. Twenty-three European countries accept airplanes type certificated to the JAR-25 standards, including airplanes manufactured in the U.S. that are type certificated to JAR-25 standards for export to Europe.

What Is "Harmonization" and How Did It Start?

Although part 25 and JAR-25 are very similar, they are not identical in every respect. When airplanes are type certificated to both sets of standards, the differences between part 25 and JAR-25 can result in substantial added costs to

manufacturers and operators. These added costs, however, often do not bring about an increase in safety. In many cases, part 25 and JAR-25 may contain different requirements to accomplish the same safety intent. Consequently, manufacturers are usually burdened with meeting the requirements of both sets of standards without a corresponding increase in the level of safety.

Recognizing that a common set of standards would not only benefit the aviation industry economically, but also maintain the necessary high level of safety, the FAA and the JAA began an effort in 1988 to "harmonize" their respective aviation standards. The goal of the harmonization effort is to ensure that—

- Where possible, standards do not require domestic and foreign parties to manufacture or operate to different standards for each country involved; and
- The standards adopted are mutually acceptable to the FAA and the foreign aviation authorities.

The FAA and JAA have identified a number of significant regulatory differences (SRD) between the wording of part 25 and JAR-25. Both the FAA and the JAA consider "harmonization" of the two sets of standards a high priority.

What Is ARAC and What Role Does It Play in Harmonization?

After initiating the first steps towards harmonization, the FAA and JAA soon realized that traditional methods of rulemaking and accommodating different administrative procedures was neither sufficient nor adequate to make noticeable progress towards fulfilling the harmonization goal. The FAA identified the Aviation Rulemaking Advisory Committee (ARAC) as an ideal vehicle for helping to resolve harmonization issues and, in 1992, the FAA tasked ARAC to undertake the entire harmonization effort.

The FAA had formally established ARAC in 1991 (56 FR 2190, January 22, 1991), to provide advice and recommendations on the full range of the FAA's safety-related rulemaking activity. The FAA sought this advice to develop better rules in less overall time and using fewer FAA resources than previously needed. The committee provides the FAA firsthand information and insight from interested parties regarding potential new rules or revisions of existing rules.

There are 74 member organizations on the committee, representing a wide range of interests within the aviation community. Meetings of the committee

are open to the public, except as authorized by section 10(d) of the Federal Advisory Committee Act.

The ARAC sets up working groups to develop recommendations for resolving specific airworthiness issues. Tasks assigned to working groups are published in the *Federal Register*. Although working group meetings are not generally open to the public, the FAA invites participation in working groups from interested members of the public who have knowledge or experience in the task areas. Working groups report directly to the ARAC, and the ARAC must accept a working group proposal before presenting it to the FAA as an advisory committee recommendation.

The activities of the ARAC will not, however, circumvent the public rulemaking procedures; nor is the FAA limited to the rule language "recommended" by ARAC. If the FAA accepts an ARAC recommendation, the agency proceeds with the normal public rulemaking procedures. Any ARAC participation in a rulemaking package is fully disclosed in the public docket.

This rulemaking has been identified as a "fast track" project. Further details on the Fast Track Program can be found in the tasking statement (64 FR 66522, November 26, 1999) and the first NPRM published under this program, Fire Protection Requirements for Powerplant Installations on Transport Category Airplanes (65 FR 36978, June 12, 2000).

What Is the Current Standard?

Section 25.613 of 14 CFR part 25 prescribes requirements for material static strength properties and design values. Metallic material strength properties for aircraft manufactured in the U.S. have traditionally been based on those specified in Military Handbook (MIL-HDBK)-5. For metallic materials not listed in that handbook, the statistical procedures in the handbook were normally used to determine material strength properties. Prior to Amendment 25-72 to part 25 (55 FR 29786, July 20, 1990), the "A" or "B" material strength properties listed in MIL-HDBK-5, or those listed in MIL-HDBK-17, and -23, or Army-Navy-Commerce (ANC)-18, were required to be used unless specific FAA approval was granted to use other properties. With Amendment 25-72, §§ 25.613 and 25.615 were combined into one requirement, § 25.613, and the references to MIL-HDBK-5, -17, -23, and ANC-18 were removed. As part of that amendment, the requirement to use "A" and "B" properties of the military handbook was replaced by a more general requirement specifying

probabilities and confidence levels for material strength properties, with the test procedures and statistical methods unspecified. Those probability and confidence levels apply to metallic as well as non-metallic materials. In Europe, other standards have been used in showing compliance with JAR 25.613, such as the Euronorm, International Standard Organization, and Engineering Sciences Data Unit 00932 Metallic Data Handbook.

Because Amendment 25-72 removed the provision which permitted the Administrator to approve "other design values," such an approval requires an equivalent safety finding, including those where the applicant uses MIL-HDBK-5. This finding results in additional administrative time for both the manufacturer and the FAA. To reduce this administrative burden and to permit applicants to again use MIL-HDBK-5 data, the FAA issued Notice of Proposed Rulemaking No. 02-05 on January 29, 2002 (67 FR 4318).

What Changes to the Current Standard Did the FAA Propose?

In Notice No. 02-05, we proposed to revise § 25.613 of part 25 to reinstate the pre-amendment 25-72 provision that permitted the Administrator to approve "other design values." We also proposed the following changes:

- Revise the heading of § 25.613 to read, "Material Strength Properties and Material Design Values." This change clarifies that the design values are material design values.
- Revise paragraph (b) to clarify that the design values are material design values. The "A" and "B" properties published in MIL-HDBK-5 and -17, or in equivalent handbooks, would be acceptable without further statistical analysis. The statistical methods specified in MIL-HDBK-5 and -17 would be acceptable for use in establishing material design values. Other statistical methods, amounts of data, and material property data might also be acceptable, including those specified in the European Standards previously noted.
- Revise paragraph (c) to require consideration of environmental conditions in general, such as temperature and moisture, on material design values used in an essential component or structure, where those effects are significant in the airplane operating envelope. Paragraph (c) currently requires consideration of the effects of temperature on allowable stresses used for design where thermal effects are significant under normal operating conditions. This change is made because environmental factors

other than temperature may have a significant effect on allowable stresses, not only under normal operating conditions, but also at other conditions within the airplane operating envelope.

- Remove paragraph (d) as fatigue is now adequately addressed in § 25.571.
- Revise the premium selection process of paragraph (e) to clarify that the design values are material design values.
- Add a new paragraph (f), which permits the use of other design values if approved by the Administrator.

Is Existing FAA Advisory Material Adequate?

Draft Advisory Circular (AC) 25.613-1, Material Strength Properties and Material Design Values, which describes acceptable methods of compliance with this rule, was published concurrently with Notice No. 02-05 for public comment. We plan to issue the final AC upon publication of the final rule in the *Federal Register*.

What Comments Were Received in Response to the Proposal?

Only one commenter responded to the request for comments. The commenter thanked the FAA for the opportunity to comment.

What Analyses and Assessments Has the FAA Conducted?

Paperwork Reduction Act

There are no current or new requirements for information collection associated with this final rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. §§ 2531-2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the

United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation).

In conducting these analyses, FAA has determined this rule: (1) Has benefits that justify its costs, is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, and is not "significant" as defined in DOT's Regulatory Policies and Procedures; (2) will not have a significant economic impact on a substantial number of small entities; (3) will reduce barriers to international trade; and (4) does not impose an unfunded mandate on State, local, or tribal governments, or on the private sector. These analyses, available in the docket, are summarized below.

Costs and Benefits

The FAA determines that there will be no additional costs associated with the rule and the current level of safety will be maintained or improved. As discussed in the previous section, in addition to harmonizing § 25.613 and JAA requirements, the amendments will clarify the current rule, codify current practice, and reinstate the provision that permits the Administrator to approve other material design values. Consequently, manufacturers of transport category airplanes will not incur any additional costs. In fact, in certain cases, the manufacturer and the FAA will realize cost savings as a result of the revisions. These cost savings are examined in further detail in the following paragraphs.

Under the current rule, there are three potential options on which to base material strength properties and material design values. First, a manufacturer could conduct a material properties development program for each material, product form, and heat treatment. Second, a manufacturer could test each aircraft structural part (on a sampling basis) to verify strength characteristics. Third, a manufacturer could use another method for establishing material design values and then request FAA approval of an equivalent safety finding. The FAA estimates that the initial cost of the

latter method, which is the least costly, is between \$100,000 and \$150,000.

There will be cost savings to the manufacturer and the FAA associated with the provision in the rule permitting the Administrator to approve other material design values (such as those listed in the draft AC). First, under certain conditions, manufacturers of transport category airplanes will no longer need to employ one of the options, described above. If the material design values can be found in the accepted military or industry handbooks, the manufacturer would avoid the initial or recurring cost of establishing material design values. Based on analysis of the available options described above, the FAA estimates that this cost saving (*i.e.*, benefits) will be at least \$100,000 per initial aircraft certification (the lower estimate of the least costly option).

Second, the (new) provision will eliminate the need for an equivalent safety finding in the third option. The manufacturer will realize minimal cost savings through a reduction in paperwork. For the FAA, the rule will eliminate approximately 30 hours of paperwork per aircraft certificate for an FAA aerospace engineer (GS-14, step 5) to conduct an equivalent safety finding. This converts to a cost savings of approximately \$1,577 in administrative costs per certificate.

Given the findings of no incremental costs, benefits of at least \$100,000 (*i.e.*, cost-savings associated with rule-harmonization), and continuation of the necessary high level of safety, the FAA deems this final rule cost-beneficial.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

If, however, an agency determines that a final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As stated in the initial regulatory flexibility determination, the proposed rule affected only manufacturers of transport category airplanes. And, since all United States transport category airplane manufacturers exceed the Small Business Administration (SBA) small-entity standard of 1,500 employees for aircraft manufacturers, the FAA determined that the proposal "would not have a significant economic impact on a substantial number of small entities." There were no comments to the docket contesting this finding. Consequently, the FAA now certifies that the final rule "will not have a significant economic impact on a substantial number of small entities."

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

In accordance with the above statute, the FAA has assessed the potential effect of this rule and has determined that it complies with the Act since it harmonizes U.S. standards with similar European standards. In addition, the rule will impose no incremental costs on either domestic or international manufacturers.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Pub. L. 104-4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments.

Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments,

in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." This rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule and the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the Administrator, when modifying regulations in Title 14 of the CFR in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish such regulatory distinctions as he or she considers appropriate. Because this final rule applies to the certification of future designs of transport category airplanes and their subsequent operation, it could affect intrastate aviation in Alaska. We received no comments on this final rule as it affects intrastate aviation in Alaska, and we will apply the rule to Alaska in the same way we will apply it nationally.

Plain English

Executive Order 12866 (58 FR 51735, October 4, 1993) requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the regulations clearly stated?
- Do the regulations contain unnecessary technical language or jargon that interferes with their clarity?
- Would the regulations be easier to understand if they were divided into more (but shorter) sections?
- Is the description in the preamble helpful in understanding the regulations?

Please send your comments to the address specified in the ADDRESSES section.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this final rule qualifies for a categorical exclusion.

Energy Impact

The energy impact of the final rule has been assessed in accordance with the Energy, Policy, and Conservation Act (EPCA), Public Law 94-163, as amended (42 U.S.C. 6362), and FAA Order 1053.1. We have determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

- In consideration of the foregoing, the Federal Aviation Administration amends part 25 of Title 14, Code of Federal Regulations, as follows:

PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

- 1. The authority citation for part 25 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701-44702, and 44704.

- 2. Amend § 25.613 as follows:

- a. By revising the section heading and paragraphs (b) introductory text, (c), and (e);
- b. By removing and reserving paragraph (d); and
- c. By adding a new paragraph (f).

The revisions and addition read as follows:

§ 25.613 Material strength properties and material design values.

* * * * *

(b) Material design values must be chosen to minimize the probability of structural failures due to material variability. Except as provided in paragraphs (e) and (f) of this section, compliance must be shown by selecting material design values which assure material strength with the following probability:

* * * * *

(c) The effects of environmental conditions, such as temperature and moisture, on material design values used in an essential component or structure must be considered where these effects are significant within the airplane operating envelope.

(d) [Reserved]

(e) Greater material design values may be used if a "premium selection" of the material is made in which a specimen of each individual item is tested before use to determine that the actual strength properties of that particular item will equal or exceed those used in design.

(f) Other material design values may be used if approved by the Administrator.

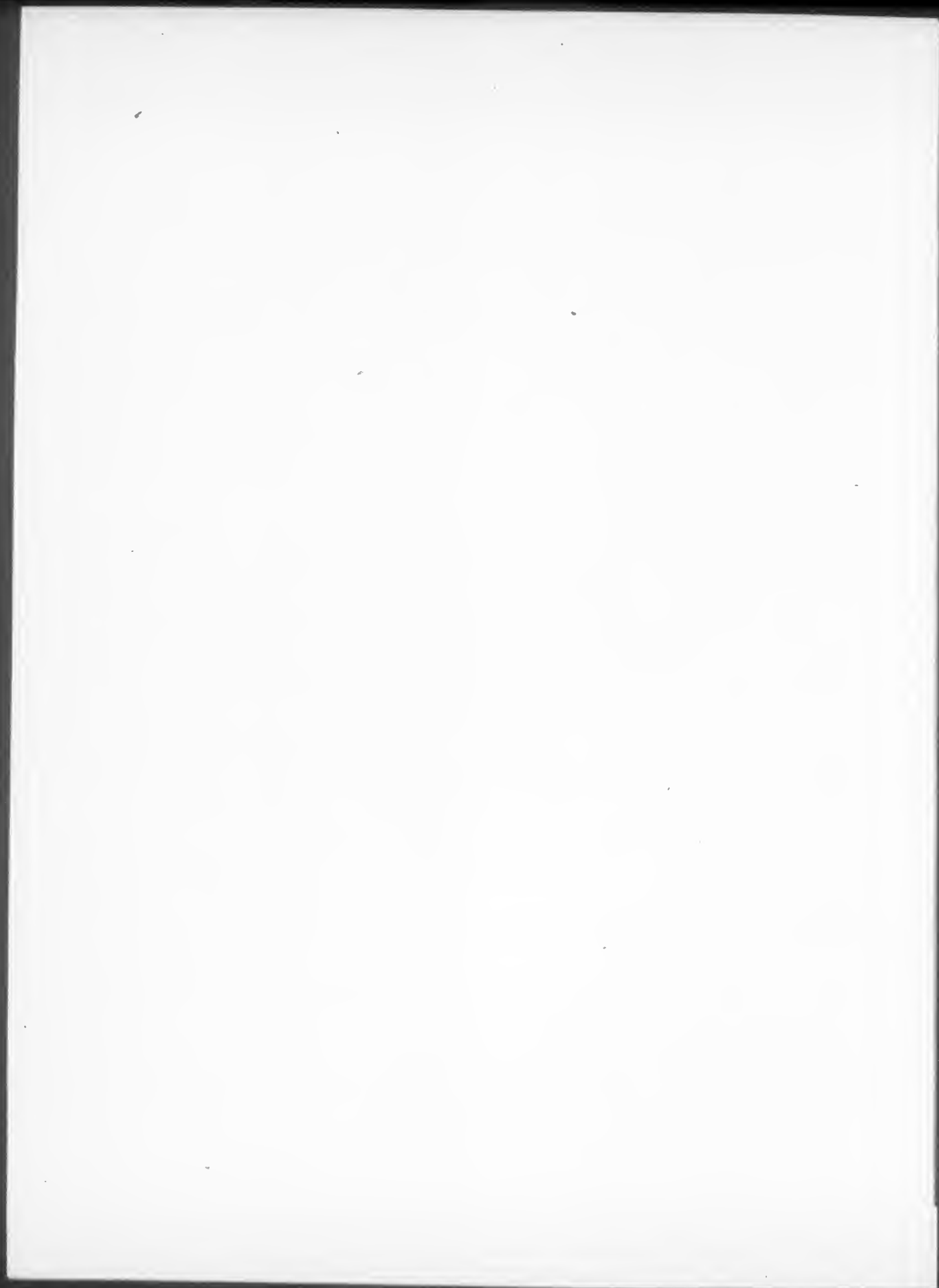
Issued in Renton, Washington, on July 25, 2003.

K.C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03-19748 Filed 8-4-03; 8:45 am]

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The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-1808). The text will also be made available on the Internet from GPO Access at <http://www.access.gpo.gov/nara/nara005.html>. Some laws may not yet be available.

H.R. 74/P.L. 108-67

To direct the Secretary of Agriculture to convey certain land in the Lake Tahoe Basin Management Unit, Nevada, to the Secretary of the Interior, in trust for the Washoe Indian Tribe of Nevada and California. (Aug. 1, 2003; 117 Stat. 880)

S. 1280/P.L. 108-68

To amend the PROTECT Act to clarify certain volunteer liability. (Aug. 1, 2003; 117 Stat. 883)

Last List August 1, 2003

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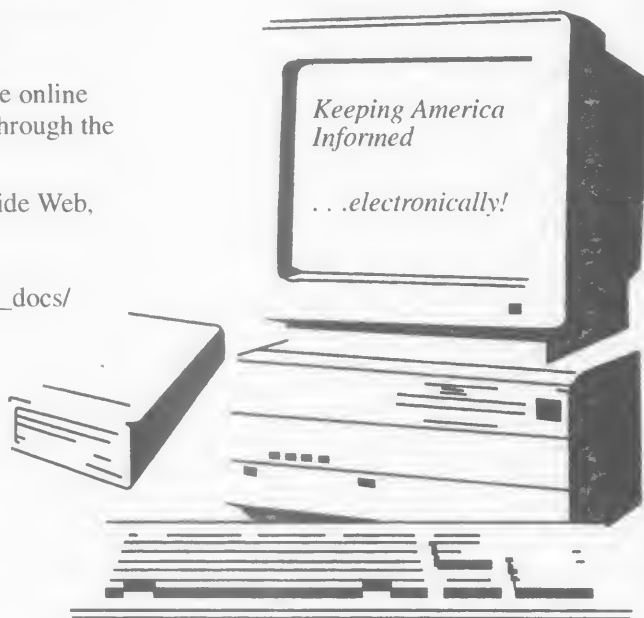
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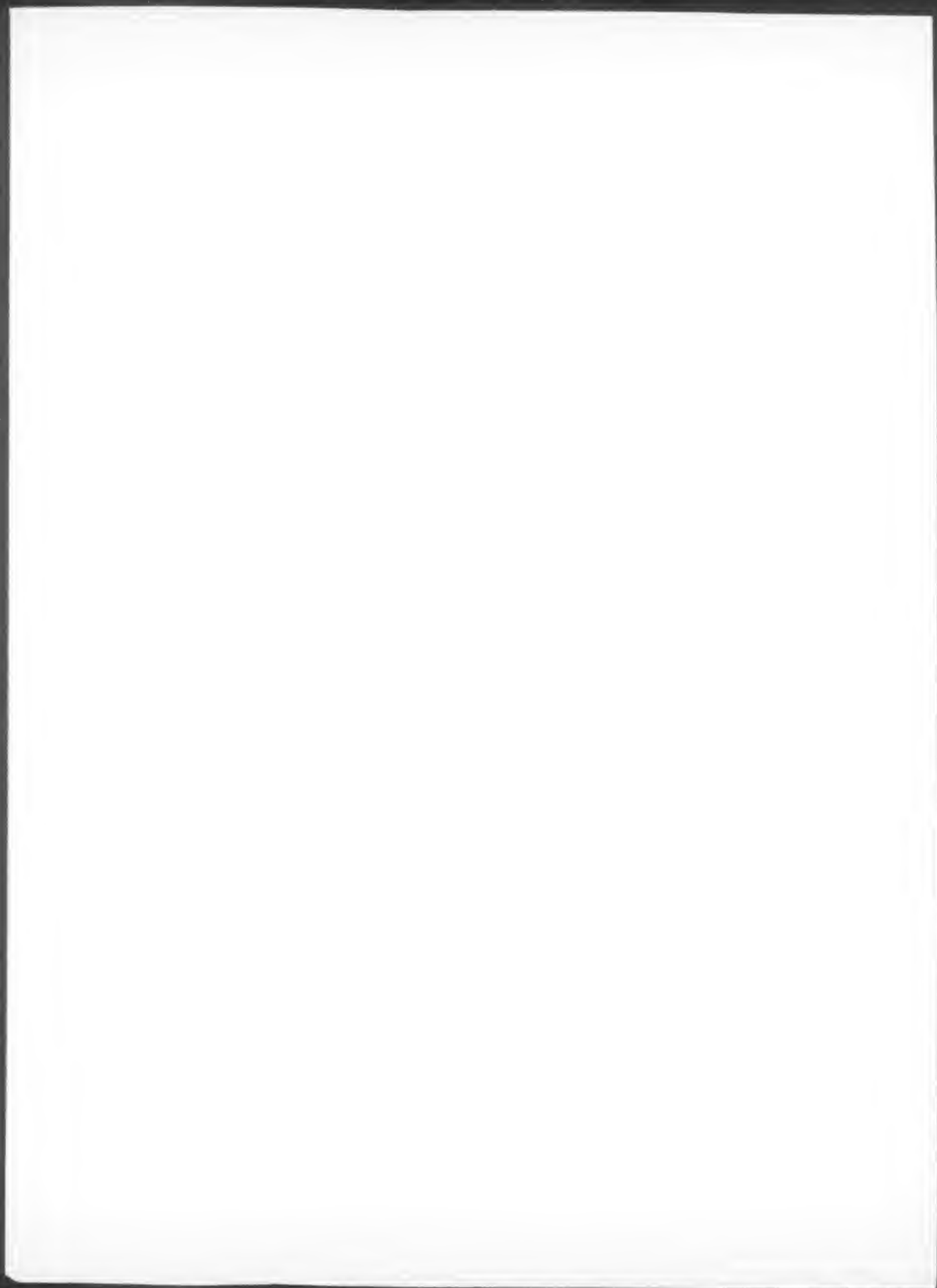


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