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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. 98–059–1]

Specifically Approved States Authorized to Receive Mares and Stallions Imported From Regions Where CEM Exists

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: We are amending the animal importation regulations by adding Georgia to the lists of States approved to receive certain mares and stallions imported into the United States from regions affected with contagious equine metritis (CEM). We are taking this action because Georgia has entered into an agreement with the Administrator of the Animal and Plant Health Inspection Service to enforce its State laws and regulations to control CEM and to require inspection, treatment, and testing of horses, as required by Federal regulations, to further ensure the horses' freedom from CEM. This action relieves unnecessary restrictions on the importation of mares and stallions from regions where CEM exists.

DATES: This rule will be effective on September 25, 1998, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before August 26, 1998.

ADDRESSES: Please send an original and three copies of any adverse comments or notice of intent to submit adverse comments to Docket No. 98–059–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your submission refers to Docket No. 98–059–1. Submissions received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments and notices are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David Vogt, Senior Staff Veterinarian, Animals Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–8423; or e-mail: dvogt@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The animal importation regulations (contained in 9 CFR part 93 and referred to below as the regulations), among other things, prohibit or restrict the importation of certain animals, including horses, into the United States to protect U.S. livestock from communicable diseases. In § 93.301, paragraph (c)(1) prohibits the importation of horses into the United States from certain regions were contagious equine metritis (CEM) exists. Paragraph (c)(2) lists categories of horses that are excepted from this prohibition, including, in § 93.301(c)(2)(vi), horses over 731 days of age imported for permanent entry if the horses meet the requirements of § 93.301(e).

One of the requirements in § 93.301(e) is that mares and stallions over 731 days old imported from regions where CEM exists for permanent entry must be consigned to States listed in § 93.301(h)(6), for stallions, or in § 93.301(h)(7), for mares. These States have been approved by the Administrator of the Animal and Plant Health Inspection Service (APHIS) to receive stallions or mares over 731 days of age from a region where CEM exists because the States have entered into a written agreement with the Administrator, APHIS, to enforce State laws and regulations to control CEM, and the States have agreed to quarantine, test, and treat mares and stallions over 731 days of age from a region where CEM exists in accordance with § 93.301(e) of the regulations.

Georgia has entered into a written agreement with the Administrator of APHIS and has agreed to comply with all the requirements in § 93.301(e) for importing mares and stallions over 731 days old from regions where CEM exists. This direct final rule will, therefore, add Georgia to the lists of States in §§ 93.301 (h)(6) and (h)(7) approved to receive certain stallions and mares imported into the United States from regions where CEM exists.

Dates

We are publishing this rule without a prior proposal because we view this action as noncontroversial and anticipate no adverse public comment. This rule will be effective, as published in this document, 60 days after the date of publication in the **Federal Register** unless we receive written adverse comments or written notice of intent to submit adverse comments within 30 days of the date of publication of this rule in the **Federal Register.**

Adverse comments are comments that suggest the rule should not be adopted or that suggest the rule should be changed.

If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date. We will then publish a proposed rule for public comment. Following the close of that comment period, the comments will be considered, and a final rule addressing the comments will be published.

As discussed above, if we receive no written adverse comments nor written notice of intent to submit adverse comments within 30 days of publication of this direct final rule, this direct final rule will become effective 60 days following its publication. We will publish a notice to this effect in the **Federal Register**, before the effective date of this direct final rule, confirming that it is effective on the date indicated in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

We anticipate that fewer than 20 mares and stallions over 731 days old will be imported into the State of Georgia annually from regions where CEM exists. Approximately 200–300 mares and stallions over 731 days old

from regions where CEM exists were imported into approved States in fiscal year 1996. During this same period, approximately 3,243 horses of all classes were imported into the United States from countries other than Canada and Mexico through air and ocean ports; approximately 18,223 horses were imported from Canada; and, approximately 10,079 horses were imported from Mexico.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 93 is amended as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1305; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

§ 93.301 [Amended]

2. Section 93.301 is amended as follows:

a. In paragraph (h)(6), by adding, in alphabetical order, "The State of Georgia".

b. In paragraph (h)(7), by adding, in alphabetical order, "The State of Georgia".

Done in Washington, DC, this 22 day of July, 1998.

Charles P. Schwable,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–19995 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 145

[Docket No. 97–043–2]

National Poultry Improvement Plan; Special Provisions for Ostrich Breeding Flocks and Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the National Poultry Improvement Plan (the Plan) to provide for the participation of ostrich breeding flocks in the provisions of the Plan. The addition of provisions for ostrich breeding flocks to the Plan was voted on and approved by the voting delegates at the Plan's 1996 National Plan Conference. Adding provisions for ostriches to the Plan will make it possible for the owners of ostrich flocks to voluntarily participate in the Plan's programs for the prevention and control of egg-transmitted, hatchery-disseminated poultry diseases.

EFFECTIVE DATE: August 26, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew R. Rhorer, Senior Coordinator, Poultry Improvement Staff, National Poultry Improvement Plan, Veterinary Services, APHIS, USDA, 1498 Klondike Road, Suite 200, Conyers, GA 30094–5104; (770) 922–3496; E-mail: arhorer@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (referred to below as "the Plan") is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. Participation in all Plan programs is voluntary, but flocks, hatcheries, and dealers must qualify as U.S. Pullorum-Typhoid Clean before participating in any other Plan program. Also, the regulations in 9 CFR part 82, subpart C, which provide for certain testing, restrictions on movement, and other restrictions on certain chickens, eggs, and other articles due to the presence of *Salmonella enteritidis*, require that no hatching eggs or newly hatched chicks from egg-type chicken breeding flocks may be moved interstate unless they are classified U.S. S. Enteritidis Monitored under the Plan, or they meet the requirements of a State classification plan that the Administrator of the Animal and Plant Health Inspection Service (APHIS) has determined to be equivalent to the Plan, in accordance with 9 CFR 145.23(d).

The Plan identifies States, flocks, hatcheries, and dealers that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR part 145 (referred to below as the regulations) contain the general provisions of the Plan (subpart A, §§ 145.1 through 145.14) and special provisions regarding the participation of breeding flocks of egg-type chickens (subpart B, §§ 145.21 through 145.24), meat-type chickens (subpart C, §§ 145.31 through 145.34), turkeys (subpart D, §§ 145.41 through 145.44), and waterfowl, exhibition poultry, and game birds (subpart E, §§ 145.51 through 145.54).

On March 12, 1998, we published in the **Federal Register** (63 FR 12036–12040, Docket No. 97–043–1) a proposal to amend the regulations to add a new subpart F to provide for the participation of ostrich breeding flocks and their products. That proposed amendment had been recommended by the voting delegates to the National Plan Conference that was held from June 30 to July 2, 1996.

We solicited comments concerning our proposal for 60 days ending May 11, 1998. We did not receive any comments. Therefore, for the reasons given in the proposed rule, we are adopting the proposed rule as a final rule without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866

and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amends the Plan to provide for the participation of ostrich breeding flocks in the provisions of the Plan. Adding provisions for ostriches to the Plan will make it possible for the ostrich flocks to voluntarily participate in the Plan's programs for the prevention and control of egg-transmitted, hatchery-disseminated poultry diseases. The changes contained in this document are based on the recommendations of representatives of member States, hatcheries, dealers, flockowners, and breeders who took part in the Plan's 1996 National Plan Conference.

The Plan serves as a "seal of approval" for egg and poultry producers in the sense that tests and procedures recommended by the Plan are considered optimal for the industry. In all cases, the changes have been generated by the industry itself with the goal of reducing disease risk and increasing product marketability.

According to industry estimates, there were approximately 350,000 to 500,000 ostriches of all ages in the United States in 1995. There were approximately 371,000 ostrich chicks hatched during the same period. In comparison, within the chicken industry, about 8,324 million chicks (broiler and meat type) were hatched by commercial hatcheries, with a total value to the poultry industry was about $17.2 billion in 1995. Thus, the ostrich industry, in comparison to the rest of the poultry industry, is very small.

Although participation in the Plan is voluntary, 99 percent of poultry breeders and hatcheries are participants in the Plan and benefit from various aspects of the program. There are several economic and other advantages that will accrue to ostrich breeders and hatcheries if they participate in the Plan as a result of this rule.

If the bulk of ostrich producers participate in the Plan, their implementation of the Plan's management practices can be expected to raise, or at least maintain, the level of health of ostriches in the United States. Wide membership will also provide a voice for the ostrich industry with regard to regulatory control of infectious poultry diseases that affect ostriches.

Allowing ostrich flocks to participate in the Plan may validate the ostrich industry in the eyes of the public and of the agricultural industry as whole, so participating flockowners could anticipate some potential advancement in the marketability of ostriches and ostrich products throughout the country. To those interested in acquiring ostriches or their products, it may be reassuring to know that these are from breeders and hatcheries that are participants in the Plan. Similarly, overseas importers may be more at ease knowing the ostriches and products are derived from flocks that are part of the Plan. We believe that it will be advantageous to those who raise ostriches and to the poultry industry as a whole, as well as to APHIS, that as many producers of poultry and poultry products, including ostriches, participate in the Plan and follow the standards developed and practiced by Plan participants.

Because participation in any Plan program is voluntary, individuals are likely to continue in the program only as long as the benefits they receive from the program outweigh the costs of their participation. Tests and procedures recommended by the Plan are considered optimal for the industry. Any increased cost to ostrich breeders and hatcheries for the detection and prevention programs will be minor compared to the losses that each producer could bear in case of undetected disease spread. Furthermore, the number of birds required to be tested is small compared to the size of flocks within the industry. The costs of conducting tests, as well as the cost of specific antigens used to detect specific diseases, are modest. For example, the cost of performing Pullorum-Typhoid plate test averages between $0.04 and $0.08 per bird. The cost of Mycoplasma gallisepticum plate test antigen is $0.10 per plate test, while the cost of antigen for each pullorum-typhoid plate test is $0.08. In many States, pullorum testing is provided for free. Although the cost for the laboratory testing of blood samples from ostriches will not differ significantly from the cost of testing blood samples from other poultry, the process of obtaining blood samples from ostriches may require more resources than for other birds. Applying these costs to the small sizes of the ostrich flocks, and comparing the total potential losses that individual producers could incur as a result of the loss of some or all of their flock due to disease, the cost of testing a small number of birds would be minor.

Because participation in the Plan is not mandatory, it is not clear how many owners of ostriches will join the program. However, there are about 7,380 flockowners, owning on average between 50 and 70 ostriches each, who may potentially join. The potential entry of the ostrich flocks into the Plan is not be expected to change the supply and demand conditions in the market for poultry of any type, including ostriches; as a result, changes in prices are not anticipated. Finally, since the additional costs will be minor and could be expected to be balanced out by the benefits, we have concluded that this rule is unlikely to have any significant impact on producers or consumers. Including ostrich flocks in the Plan will not likely result in any significant change in program operations.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0007.

List of Subjects in 9 CFR Part 145

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 145 is amended as follows:

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN

1. The authority citation for part 145 continues to read as follows:

Authority: 7 U.S.C. 429; 7 CFR 2.22, 2.80, and 371.2(d).

§ 145.1 [Amended]

2. In § 145.1, the definition of *poultry* is amended by adding the word "ostriches," immediately after the word "turkeys,".

§ 145.3 [Amended]

3. In § 145.3, in the introductory text of paragraph (c), the second sentence is amended by adding the words "or, in the case of ostriches, before the birds reach 20 months of age" immediately after the word "age".

§ 145.5 [Amended]

4. In § 145.5, paragraph (c) is amended by removing the words "or E" and adding the words "E, or F" in their place.

§ 145.10 [Amended]

5. In § 145.10, the introductory text of the section is amended by removing the words "or E" and adding the words "E, or F" in their place, and paragraph (b) is amended by removing the words "and § 145.53(b)" and adding the words "§ 145.53(b), and § 145.63(a)" in their place.

§ 145.14 [Amended]

6. In § 145.14, in the introductory text of the section, the first sentence is amended by adding the words ", and ostriches blood tested under subpart F must be more than 12 months of age" immediately after the word "first".

7. In § 145.14, paragraph (a)(5) is amended by removing the words "and 145.53" and adding the words ", 145.53, and 145.63" in their place.

8. A new subpart F is added to read as follows:

Subpart F—Special Provisions for Ostrich Breeding Flocks and Products

Subpart F—Special Provisions for Ostrich Breeding Flocks and Products

§ 145.61 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Ostrich. Birds of the species *Struthio camelus,* including all subspecies and subspecies hybrids.

§ 145.62 Participation.

Participating flocks of ostriches, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart.

(a) Started poultry shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated or otherwise sanitized (see § 147.22 of this chapter).

§ 145.63 Terminology and classification; flocks and products.

Participating flocks, and the eggs and baby poultry produced from them, that have met the respective requirements specified in this section may be designated by the following terms and their corresponding designs illustrated in § 145.10.

(a) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (a)(1) or (a)(2) of this section. (See § 145.14(a) relating to the official blood test for pullorum-typhoid where applicable.)

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a multiplier or primary breeding flock in which a sample of each bird in flocks of 30 or fewer birds, a minimum of 30 birds from flocks up to 300 birds, or 10 percent of all birds from flocks exceeding 300 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors: *Provided,* That a bacteriological examination monitoring program for ostriches acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing: *And provided further,* That when a flock is a multiplier breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

(b) [Reserved]

Done in Washington, DC, this 22nd day of July 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–19997 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 391 and 381

[Docket No. 98–030N]

Meat, Poultry, and Egg Products Labeling Review Process; Elimination of Appointments With Label Courier/ Expediting Firms

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of procedural change; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing a procedural change for reviewing labeling submitted to the Labeling Review Branch (LRB) of the Labeling and Compounds Review Division (LCRD). The new procedure will eliminate routine, daily, time-set, face-to-face appointments with label courier/ expediting firms. Elimination of the daily, face-to-face appointments will not change the present system of labeling review and will not limit access to all LCRD staff. The labeling review staff will continue to receive and approve labels for meat, poultry, and egg products in a timely and orderly manner. However, the procedural change will lead to a more effective and efficient use of LRB staff time and enable staff to perform labeling reviews and other duties concurrently.

DATES: The change in procedures for labeling review will be effective September 10, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. William J. Hudnall, Assistant Deputy Administrator, Office of Policy, Planning and Evaluation; telephone (202) 205–0495 or FAX (202) 401–1760.

SUPPLEMENTARY INFORMATION: FSIS has stated repeatedly its intent to increase the proportional share of its resources that are devoted to food safety. The Agency reorganization of 1996 reduced the number of administrative support positions, eliminated several management levels, improved supervisor-to-employee ratios, and restructured an expanded front line inspection workforce to perform more effectively. The Agency continues to seek ways to improve the efficiency with which it carries out its consumer protection activities that are not related to food safety. Therefore, FSIS is reviewing all operations in an effort to achieve greater efficiency while improving the level of consumer protection.

The Prior Label Approval System (PLAS) is conducted as part of the

Agency's mandate to ensure that labeling for meat, poultry, and egg products is truthful, not misleading, and in compliance with the misbranding provisions of the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and implementing regulations. FSIS streamlined the system in a final rule issued on December 29, 1995, (60 FR 67444) that became effective July 1, 1996, by expanding the categories of products for which labeling can be approved generically by industry. For example, the rule allows Federal establishments to design and use labeling that conforms to the regulatory requirements for meat, poultry, and egg products that have standards of identity and composition defined in the regulations (9 CFR 319 and 381) or in the Food Standards and Labeling Policy Book. The Agency also maintains a prior label approval system for reviewing and approving sketches and temporary labeling for certain categories of meat and poultry products that are not defined by standards of identity and composition; products that are prepared using novel production methods; products that are formulated with novel additives or ingredients; or products whose labeling bears nutrition, health, quality, or other types of claims.

The final rule on PLAS also indicated that the Agency would implement a Generic Labeling Audit System (GLAS) to determine the extent to which Federal establishments are applying labeling regulations and policies in approving generic labeling, in compliance with the regulations. The Agency is currently developing this audit system. The prospective goals of PLAS include developing and implementing GLAS simultaneously to conducting PLAS, and to devote more time to devising a prior approval system that will be more consistent with Hazard Analysis and Critical Control Point (HACCP) systems and the labeling concepts of the future. The changes to PLAS and the development of a generic labeling system are based on concepts that are consistent with the Agency's effort to proportionally shift resources to food safety and to afford processors flexibility in preparing and modifying their labeling to fit their marketing needs.

Presently, labeling for meat, poultry, or egg products that requires prior approval is submitted daily for review and approval to the LCRD via regular mail; expedited mail and delivery services (such as Federal Express); personal visits to the division by company and trade representatives; and through the services provided by courier firms/expediter services located in the Washington, DC area. Labeling reviews for courier firms/expediter services are conducted during routine, daily, time-set, face-to-face appointments with labeling review staff during a 4-hour core time period each workday.

Representatives of courier firms/expediter services submit labeling for meat, poultry, or egg products for processors who choose to use their services. Each courier firm has a designated time period in a day to have its labeling reviewed by members of the Labeling Review Branch. During these time periods, courier firms could meet with up to four FSIS staff members in 1-hour intervals. FSIS believes that operating in this manner is no longer consistent with the efforts to better use personnel resources. The following factors compel the need to alter the current process:

- An increase in the submission of labeling with complex technical issues has occurred. Greater concentration and more time are needed by the labeling review staff to evaluate labeling that reflects new initiatives within the industry. The current process of reviewing, approving, or rejecting labeling during daily, face-to-face labeling reviews does not allow this time.
- Greater time is needed to research labeling policy issues, such as use of the novel additives not currently approved for use in meat, poultry, or egg products; chemical analysis reviews; variations in nutrition labeling claims; and labeling with animal production claims. Such comprehensive reviews require interaction among the division staff, and with other parts of the Agency, other Federal Agencies, and experts outside FSIS. However, daily appointments with courier firms have taken precedence over the other duties of the staff. Therefore, the effective use of labeling review staff time is restricted because half of the workday of the labeling review staff is devoted to the structured allotment of time for courier service.
- Maintaining a fixed, daily schedule of face-to-face labeling reviews is no longer critical because the immediacy of the need for an on-the-spot labeling approval provided by someone on the labeling review staff has diminished. Before the December 1995 final rule on PLAS took effect, the division was responsible for approving essentially all labeling in both sketch and final form. However, effective July 1, 1996, this requirement changed. Of the labeling that must be submitted for prior approval now, only sketch labeling needs to be submitted. The industry need not submit such labeling in final form. This has shifted the issue of the timeliness of the approvals of final labeling to meet industry's marketing needs to one controlled by industry.
- Given the diminished need for immediate, on-the-spot approval of labeling by labeling review staff, continuing the existing procedure is unfair to companies choosing to mail their labeling to the division or have company employees deliver it for them for review in person. Currently, labeling submitted by mail or submitted personally by processors is not given time for review that is equal to that given to labeling submitted by labeling courier firms/expediter services during face-to-face reviews. It is necessary that staff time be more equitably arranged to review labeling that is mailed to the branch or division or delivered by processors themselves by individuals representing meat, poultry, or egg processors. This can only be done by eliminating face-to-face reviews.

The division will continue to review and approve labeling in a timely and efficient manner and accommodate representatives of industry and other representatives who wish to meet with staff members for consultation on any issues relating to labeling, standards, or ingredients. Labeling approvals will be handled on a first-come, first-served basis, as they are delivered to the LCRD, including expedited labeling, labeling mailed directly to the division, and labeling delivered in person by representatives of the industry. As needed, representatives of industry and other representatives will have the opportunity to arrange appointments with division staff on a time-available basis to discuss novel product and ingredient issues and appeals, and to receive regulatory guidance. The LRB will continue, to the extent possible, to accommodate emergency situations regarding labeling approvals on a case-by-case basis. The Agency believes this procedural change will result in a more productive use of LCRD staffing resources, and most importantly, improve the quality of meat, poultry, and egg products labeling.

It is the Agency's intent to implement the policy described in this notice 45 days from the date it is published. However, the Agency is interested in receiving substantive comments within 30 days of publication on how it can better implement the procedural changes contained in the notice.

Done at Washington DC, on: July 14, 1998.
Thomas J. Billy,
Administrator.
[FR Doc. 98–20002 Filed 7–24–98; 8:45 am]
BILLING CODE 3410–DM–P

FEDERAL RESERVE SYSTEM

12 CFR Parts 220 and 224

Regulations T and X

Securities Credit Transactions; List of Marginable OTC Stocks; List of Foreign Margin Stocks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; determination of applicability of regulations.

SUMMARY: The List of Marginable OTC Stocks (OTC List) is composed of stocks traded over-the-counter (OTC) in the United States that qualify as *margin securities* under Regulation T, Credit by Brokers and Dealers. The List of Foreign Margin Stocks (Foreign List) is composed of foreign equity securities that qualify as *margin securities* under Regulation T. The OTC List and the Foreign List are published four times a year by the Board. This document sets forth additions to and deletions from the previous OTC List and a complete edition of the Foreign List.

EFFECTIVE DATE: August 10, 1998.

FOR FURTHER INFORMATION CONTACT: Peggy Wolffrum, Securities Regulation Analyst, Division of Banking Supervision and Regulation, (202) 452–2837, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. For the hearing impaired only, contact Diane Jenkins, Telecommunications Device for the Deaf (TDD) at (202) 452–3544.

SUPPLEMENTARY INFORMATION: Listed below are the deletions from and additions to the Board's OTC List, which was last published on April 28, 1998 (63 FR 23195), and became effective May 11, 1998. A copy of the complete OTC List is available from the Federal Reserve Banks.

The OTC List includes those stocks traded over-the-counter in the United States that qualify as *OTC margin stock* under Regulation T (12 CFR Part 220) by meeting the requirements of section 220.11. This determination also affects the applicability of Regulation X (12 CFR Part 224). These stocks have the degree of national investor interest, the depth and breadth of market, and the availability of information respecting the stock and its issuer to warrant regulation in the same fashion as exchange-traded securities. The OTC List also includes any OTC stock designated for trading in the national market system (NMS security) under rules approved by the Securities and Exchange Commission (SEC). Additional OTC stocks may be designated as NMS securities in the interim between the Board's quarterly publications. They will become automatically marginable upon the effective date of their NMS designation. The names of these stocks are available at the SEC and at the National Association of Securities Dealers, Inc.

Pursuant to amendments recently adopted by the Board (see, 63 FR 2805, January 16, 1998), the definition of *OTC margin stock* in § 220.2 and the eligibility criteria for these stocks in § 220.11(a) and (b) will be removed from Regulation T on January 1, 1999, and broker-dealers will be permitted to extend margin credit against all equity securities listed in the Nasdaq Stock Market. Lenders subject to Regulation T and borrowers subject to Regulation X who are required under § 224.3(a) to conform credit they obtain to Regulation T will use the OTC List until publication of the next OTC List, anticipated for November, 1998. The November 1998 OTC List will expire on January 1, 1999.

Also listed below is a complete edition of the Foreign List. This supercedes the previous Foreign List, which was last published on April 28, 1998, (63 FR 23195), and became effective May 11, 1998. Pursuant to amendments recently adopted by the Board that became effective for all broker-dealers on July 1, 1998 (see, 63 FR 2805, January 16, 1998), the Foreign List is composed of those foreign equity securities that qualify as *margin securities* because they have been found to meet the criteria in section 220.11 of Regulation T. Additional foreign equity securities qualify as *margin securities* if they are deemed by the Securities and Exchange Commission to have a "ready market" for purposes of SEC Rule 15c3–1. This includes all foreign stocks listed on the Financial Times/Standard & Poor's Actuaries World Indices. Although the Board has included these stocks on its Foreign List since 1996, the recent amendments allow broker-dealers to extend credit on such stocks without regard to the Foreign List.

Public Comment and Deferred Effective Date

The requirements of 5 U.S.C. 553 with respect to notice and public participation were not followed in connection with the issuance of this amendment due to the objective character of the criteria for inclusion and continued inclusion on the Lists specified in 12 CFR 220.17(a), (b), (c) and (d). No additional useful information would be gained by public participation. The full requirements of 5 U.S.C. 553 with respect to deferred effective date have not been followed in connection with the issuance of this amendment because the Board finds that it is in the public interest to facilitate investment and credit decisions based in whole or in part upon the composition of these Lists as soon as possible. The Board has responded to a request by the public and allowed approximately a two-week delay before the Lists are effective.

List of Subjects

12 CFR Part 220

Banks, Banking, Brokers, Credit, Margin, Margin requirements, Investments, National Market System (NMS Security), Reporting and recordkeeping requirements, Securities.

12 CFR Part 224

Banks, Banking, Borrowers, Credit, Margin, Margin requirements, Reporting and recordkeeping requirements, Securities.

Accordingly, pursuant to the authority of sections 7 and 23 of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78g and 78w), and in accordance with 12 CFR 220.2 and 220.11, there is set forth below a listing of deletions from and additions to the OTC List and a complete edition of the Foreign List.

Deletions From the List of Marginable OTC Stocks

Stocks Removed For Failing Continued Listing Requirements

ALTRIS SOFTWARE, INC.
No par common
AMERICAN CINEMASTORES INC.
$.001 par common
AMERICAN INTERNATIONAL PETROLEUM CORP.
Class A, warrants (expire 04–09–1998)
AQUAGENIX INC.
$.01 par common
Warrants (expire 09–13–1999)
ARIELY ADVERTISING, LIMITED
Ordinary Shares
ATKINSON, GUY F., COMPANY OF CALIFORNIA
No par common
AUTOINFO, INC.
$.01 par common
BIOCIRCUITS CORPORATION
$.001 par common
BPI PACKAGING TECHNOLOGIES, INC.
Series A, $.01 par redeemable

convertible preferred
BUILDERS TRANSPORT, INCORPORATED
$.01 par common
8% convertible debentures due 2005
CARE GROUP, INC., THE
$.001 par common
CLEAN DIESEL TECHNOLOGIES, INC.
$.05 par common
CLEVETRUST REALTY INVESTORS
$1.00 par shares of beneficial interest
CONSUMERS FINANCIAL CORPORATION
No par common
CYGNE DESIGNS, INC.
$.01 par common
DAILY JOURNAL CORPORATION
$.01 par common
DATA SYSTEMS NETWORK CORPORATION
$.01 par common
DATA TRANSLATION, INC.
$.01 par common
EAGLE FINANCE CORP.
$.01 par common
ENEX RESOURCES CORPORATION
$.05 par common
EQUIMED, INC.
No par common
FASTCOMM COMMUNICATIONS CORPORATION
$.01 par common
FINE HOST CORPORATION
$.01 par common
FIRST DYNASTY MINES LIMITED
No par common
FIRST FINANCIAL BANCORP, INC. (Illinois)
$.10 par common
FIRSTAR CORPORATION
American Depositary Shares
GEOTEK COMMUNICATIONS INC.
$.01 par common
HELP AT HOME, INC.
Warrants (expire 12–05–2000)
$.02 par common
IMPCO TECHNOLOGIES, INC.
Warrants (expire 03–07–1998)
INSITE VISION INCORPORATED
$.01 par common
INTERNATIONAL PRECIOUS METALS CORPORATION
No par common
LONDON FINANCIAL CORPORATION
No par common
MANATRON, INC.
No par common
NATIONAL MEDICAL FINANCIAL SERVICES CORPORATION
$.01 par common
NEORX CORPORATION
Warrants (expire 04–25–1998)
NITCHES, INC.
No par common
NORTH AMERICAN PALLADIUM LTD.
No par common
NOVAMETRIX MEDICAL SYSTEMS, INC.
Class A, warrants (expire 12–08–1997)
NSA INTERNATIONAL, INC.
$.05 par common
NU–TECH BIO–MED, INC.
$.01 par common
PACIFIC CHEMICAL, INC.
$4.75 par common
PARIS CORPORATION
$.004 par common
PHOTO CONTROL CORPORATION
$.08 par common
PHYSICIAN COMPUTER NETWORK, INC.
$.01 par common
PROVIDENT AMERICAN CORPORATION
$1.00 par common
QUESTRON TECHNOLOGY, INC.
Series B, convertible preferred
RASTER GRAPHICS, INC.
$.001 par common
REPUBLIC SECURITY FINANCIAL CORPORATION (Florida)
Series C, 7% par cumulative convertible preferred
SCIOS INC.
Class D, warrants (expire 06–30–1998)
SEARCH FINANCIAL SERVICES, INC.
$.01 par common
SEMI–TECH CORPORATION
Class A, sub-voting shares
SERENGETI EYEWEAR, INC.
$.001 par common
Warrants (expire 09–29–2000)
SMARTSERV ONLINE, INC.
$.01 par common
SMED INTERNATIONAL, INC.
No par common
SOVEREIGN BANCORP, INC. (Pennsylvania)
Series B, 6¼% cumulative convertible preferred
STAR TECHNOLOGIES, INC.
$5.00 par common
SUBMICRON SYSTEMS CORPORATION
$.0001 par common
SUMITOMO BANK OF CALIFORNIA, THE
Depositary Shares
SWISHER INTERNATIONAL, INC.
$.01 par common
Warrants (expire 06–30–1998)
TAT TECHNOLOGIES LTD.
Ordinary shares (par NIS .15)
TRANSCOR WASTE SERVICES, INC.
$.001 par common
TRANSCRYPT INTERNATIONAL, INC.
$.01 par common
TRANSNET CORPORATION
$.01 par common
ULTRAFEM, INC.
$.001 par common
V BAND CORPORATION
$.01 par common
VALLEY SYSTEMS, INC.
$.01 par common
VERMONT TEDDY BEAR CO., INC.
$.05 par common
VIEW TECH, INC.
Warrants (expire 06–16–1998)
VININGS INVESTMENT PROPERTIES TRUST
No par shares of beneficial interest
WILSONS THE LEATHER EXPERTS
Warrants (expire 05–27–2000)

Stocks Removed for Listing on a National Securities Exchange or Being Involved in an Acquisition

3–D GEOPHYSICAL, INC.
$.01 par common
ACC CORPORATION
$.015 par common
ACCELGRAPHICS, INC.
$.001 par common
ACCUGRAPH CORPORATION
Class A, No par common
ALOETTE COSMETICS, INC.
No par common
AMERIWOOD INDUSTRIES INTERNATIONAL CORPORATION
$1.00 par common
ARTISTIC GREETINGS, INCORPORATED
$.10 par common
AUTHENTIC SPECIALTY FOODS, INC.
$1.00 par common
BCB FINANCIAL SERVICES CORPORATION
$2.50 par common
BEVERLY BANCORPORATION, INC.
$.01 par common
BOARDWALK CASINO, INC.
$.001 par common
CALIFORNIA COMMUNITY BANCSHARES CORPORATION
$.10 par common
CALIFORNIA STATE BANK (California)
No par common
CALLON PETROLEUM COMPANY
$.01 par common
Series A, $.01 par convertible exchangeable preferred
CAMERON ASHLEY BUILDING PRODUCTS, INC.
No par common
CAPITAL SAVINGS BANCORP INC. (Missouri)
$.01 par common
CARRIAGE SERVICES, INC.
Class A, $.01 par common
CBT CORPORATION
No par common
CENFED FINANCIAL CORPORATION
$.01 par common
CENTURY FINANCIAL CORPORATION
$.835 par common
CHARTER BANK, S.B. (Illinois)
$1.00 par common
CHECKMATE ELECTRONICS, INC.
$.01 par common
CHEMI-TROL CHEMICAL CO.
No par common
CHICAGO MINIATURE LAMP, INC.
$.01 par common
CHILDREN'S DISCOVERY CENTERS OF AMERICA, INC.
Class A, $.01 par common

CITFED BANCORP, INC. (Ohio)
$.01 par common
COBANCORP, INC. (Ohio)
No par common
COMPANY DOCTOR, THE
$.01 par common
COMPSCRIPT, INC.
$.0008 par common
CONTOUR MEDICAL, INC.
$.001 par common
CORCOM, INC.
No par common
CORE LABORATORIES, N.V.
Ordinary shares (par NIS .03)
CROSS MEDICAL PRODUCTS, INC.
$.01 par common
DART GROUP CORPORATION
Class A, $1.00 par common
DATAFLEX CORPORATION
No par common
DEVON GROUP, INC.
$.01 par common
DLB OIL & GAS, INC.
$.01 par common
DONNELLEY ENTERPRISE SOLUTIONS, INCORPORATED
$.01 par common
EAGLE FINANCIAL CORPORATION
$.01 par common
ENVIRONMENT/ONE CORPORATION
$.10 par common
ESELCO, INC.
$.01 par common
FIRST AMERICAN CORPORATION
$5.00 par common
FIRST COMMERCE CORPORATION
$5.00 par common
FIRST SHENANGO BANCORP, INC. (Pennsylvania)
$.10 par common
FIRSTBANK OF ILLINOIS CO.
$1.00 par common
FOREFRONT GROUP, INC., THE
$.01 par common
FP BANCORP, INC.
No par common
FRANKLIN BANCORPORATION, INC.
$.10 par common
GRAND PRIX ASSOCIATION OF LONG BEACH, INC.
No par common
GREAT WALL ELECTRONIC INTERNATIONAL LTD.
American Depositary Receipts
GRIST MILL CO.
$.10 par common
HARCOR ENERGY COMPANY
$.10 par common
HERITAGE BANCORP, INC. (Pennsylvania)
$5.00 par common
HERITAGE FINANCIAL SERVICES, INC.
$.625 par common
HOLOPHANE CORPORATION
$.01 par common
HON INDUSTRIES INC.
$1.00 par common
HOUSE OF FABRICS, INCORPORATED
$.01 par common
IBAH, INC.
$.01 par common
INDIANA COMMUNITY BANK, SB
No par common
INTELLIGENT ELECTRONICS, INC.
$.01 par common
INTERNATIONAL MUREX TECHNOLOGIES CORPORATION
No par common
INTERNATIONAL VERIFACT, INC.
No par common
INTIME SYSTEMS INTERNATIONAL, INC.
Class A, $.01 par common
IPC INFORMATION SYSTEMS, INC.
$.01 par common
JABIL CIRCUIT, INC.
$.01 par common
JOACHIM BANCORP, INC. (Missouri)
$.01 par common
LANCIT MEDIA ENTERTAINMENT, LTD.
$.001 par common
LEARMONTH & BURCHETT MANAGEMENT SYSTEMS, INC.
American Depositary Receipts
LOGIC WORKS, INC.
$.01 par common
MASTERING, INC.
$.001 par common
MEDICUS SYSTEMS CORPORATION
$.01 par common
MERITRUST FEDERAL SAVINGS BANK (Louisiana)
$1.00 par common
MICRONICS COMPUTERS, INC.
$.01 par common
MILESTONE SCIENTIFIC, INC.
$.001 par common
MONROC, INC.
$.01 par common
MTL, INC.
$.01 par common
NETWORK LONG DISTANCE, INC.
$.0001 par common
OCWEN ASSET INVESTMENT GROUP
$.01 par common
ORBITAL SCIENCES CORPORATION
$.01 par common
PEOPLES FIRST CORPORATION
No par common
PERPETUAL MIDWEST FINANCIAL, INC.
$.01 par common
PETSEC ENERGY LTD.
American Depositary Receipts
PINNACLE FINANCIAL SERVICES, INC.
$10.00 par common
POUGHKEEPSIE FINANCIAL CORPORATION
$.01 par common
PROSOURCE, INC.
Class A,
$.01 par common
QUIKSILVER, INC.
$.01 par common
REDFED BANCORP INC. (California)
$.01 par common
REGAL CINEMAS, INC.
No par common
REPUBLIC AUTOMOTIVE PARTS, INC.
$.50 par common
REXX ENVIRONMENTAL CORPORATION
$.02 par common
RYAN, BECK & CO., INC.
$.10 par common
SAGE LABORATORIES, INC.
$.10 par common
SCOPUS TECHNOLOGY, INC.
$.001 par common
SEALRIGHT CO., INC.
$.10 par common
SEARCH FINANCIAL SERVICES, INC.
$.01 par convertible preferred
SFX BROADCASTING, INC.
Class A, $.01 par common
Class B, warrants (expire 03–23–1999)
SHOWBIZ PIZZA TIME, INC.
$.10 par common
SIGMA CIRCUITS, INC.
$.001 par common
SIGNATURE RESORTS, INC.
$.01 par common
SIMULATION SCIENCES, INC.
$.001 par common
SOMATOGEN, INC.
$.001 par common
SOURCE SERVICES CORPORATION
$.02 par common
SOUTHWEST BANCSHARES, INC. (Illinois)
$.01 par common
STAR GAS PARTNERS, L.P.
Shares of beneficial interest
STERLING WEST BANCORP (California)
No par common
SUMMIT CARE CORPORATION
No par common
TICKETMASTER GROUP, INC.
No par common
TRACOR, INC.
$.01 par common
Series A, warrants (expire 12–31–2001)
TRESCOM INTERNATIONAL, INC.
$.01 par common
TRUSTED INFORMATION SYSTEMS, INC.
$.01 par common
ULTRA PAC, INC.
No par common
WALSH INTERNATIONAL, INC.
$.01 par common
WAVERLY, INC.
$2.00 par common
WHEELS SPORTS GROUP, INC.
$.01 par common
WHITE RIVER CORPORATION
$.01 par common
WILLIAMS-SONOMA, INC.
No par common
XLCONNECT SOLUTIONS, INC.
$.01 par common
YURIE SYSTEMS, INC.

$.01 par common

Additions to the List of Marginable OTC Stocks

A.C.L.N. LIMITED
$.01 par ordinary shares
ADAMS GOLF, INC.
$.001 par common
ALBION BANC CORPORATION (New York)
$.01 par common
ALLEGIANCE TELECOM, INC.
$.01 par common
ALPHA INDUSTRIES, INC.
$.25 par common
AMERICAN AIRCARRIERS SUPPORT, INC.
$.001 par common
AMERICAN BANCORPORATION (West Virginia)
Trust preferred securities of American Bancorp Capital
AMERICAN BANCSHARES, INC. (Florida)
Cumulative trust preferred ($10.00 liquidation preference)
AMERICAN XTAL TECHNOLOGY, INC.
$.001 par common
AMKOR TECHNOLOGY, INC.
$.001 par common
AMRESCO CAPITAL TRUST
$.01 par common shares of beneficial interest
ANSWERTHINK CONSULTING GROUP, INC.
$.01 par common
ARCHITEL SYSTEMS CORPORATION
No par common
ARIS CORPORATION
Warrants (expire 02–15–2000)
ARM HOLDINGS PLC
American Depositary Shares
ASPEC TECHNOLOGY, INC.
$.001 par common
ASYMETRIX LEARNING SYSTEMS, INC.
$.01 par common
ATG, INC.
No par common
ATLANTIC DATA SERVICES, INC.
$.01 par common
AZTEC TECHNOLOGY PARTNERS, INC.
$.001 par common
BALANCE BAR COMPANY
$.01 par common
BCSB BANKCORP
$.01 par common
BEBE STORES, INC.
$.01 par common
BEL FUSE, INC.
Class B, $.10 par common
BLUE RHINO CORPORATION
$.001 par common
BRIDGESTREET ACCOMMODATIONS, INC.
$.01 par common
BRIGHTSTAR INFORMATION TECHNOLOGY GROUP, INC.
$.001 par common
BRIO TECHNOLOGY, INC.
$.001 par common
BROADCOM CORPORATION
Class A, $.001 par common
CALIBER LEARNING NETWORK, INC.
$.01 par common
CAPITAL BEVERAGE CORPORATION
$.001 par common
CARREKER-ANTINORI, INC.
$.01 par common
CELLNET FUNDING LLC
Preferred securities
CENTRAL COAST BANCORP.
No par common
CENTURY BANCORP, INC. (Massachusetts)
Trust preferred security
CHARLES RIVER ASSOCIATES, INC.
No par common
CHASTAIN CAPITAL CORPORATION
$.01 par common
CITADEL COMMUNICATIONS CORPORATION
$.001 par common
CLEVELAND INDIANS BASEBALL COMPANY, INC.
No par common
CLINICHEM DEVELOPMENT, INC.
Class A, no par common
COLLATERAL THERAPEUTICS, INC.
$.001 par common
COLORADO BUSINESS BANCSHARES, INC.
$.01 par common
COM21, INC.
$.001 par common
COMBICHEM, INC.
$.001 par common
CONRAD INDUSTRIES, INC.
$.01 par common
COVOL TECHNOLOGIES, INC.
$.001 par common
COYOTE SPORTS, INC.
$.001 par common
CTI INDUSTRIES CORPORATION
No par common
CUMULUS MEDIA, INC.
Class A, $.01 par common
CUNNINGHAM GRAPHICS INTERNATIONAL, INC.
No par common
CYBERSHOP INTERNATIONAL, INC.
$.001 par common
DA CONSULTING GROUP, INC.
$.01 par common
DEPOMED, INC.
No par common
DOCUCORP INTERNATIONAL, INC.
$.01 par common
DOREL INDUSTRIES, INC.
No par common
DROVERS BANCSHARES CORPORATION
$5.00 par common
DYNATEC INTERNATIONAL, INC.
$.01 par common
EUROPEAN MICRO HOLDINGS, INC.
$.01 par common
EVOLVING SYSTEMS, INC.
$.001 par common
FFD FINANCIAL CORPORATION
No par common
FIELDS AIRCRAFT SPARES, INC.
$.05 par common
FINE.COM INTERNATIONAL CORPORATION
$6.50 par common
FIRST BANK OF PHILADELPHIA
$2.00 par common
FIRST KANSAS FINANCIAL CORPORATION
$.10 par common
FIRST VIRTUAL CORPORATION
$.001 par common
FLOUR CITY INTERNATIONAL, INC.
$.0001 par common
FNB CORP. (Virginia)
$5.00 par common
GENESIS DIRECT, INC.
$.01 par common
GENTLE DENTAL SERVICE CORPORATION
No par common
GILMAN & CIOCIA, INC.
Warrants (expire 09–09–1998)
GLOBAL IMAGING SYSTEMS, INC.
$.01 par common
GO2NET, INC.
$.01 par common
GOLDEN STATE BANCORP, INC.
Litigation tracking warrants
GRIFFIN LAND & NURSERIES, INC.
$.01 par common
GUARANTY BANCSHARES, INC.
$1.00 par common
HASTINGS ENTERTAINMENT, INC.
$.01 par common
HAUPPAUGE DIGITAL, INC.
$.01 par common
HEADWAY CORPORATE RESOURCES, INC.
No par common
HERBALIFE INTERNATIONAL, INC.
DECS Trust III
HIGH COUNTRY BANCORP, INC.
$.01 par common
HINES HORTICULTURE, INC.
$.01 par common
HORIZON GROUP PROPERTIES, INC.
$.01 par common
HORIZON ORGANIC HOLDING CORPORATION
$.001 par common
HUDSON RIVER BANCORP, INC.
$.01 par common
HYPERION TELECOMMUNICATIONS, INC.
Class A, $.01 par common
ICON PLC
American Depositary Shares
INDUSTRIAL HOLDINGS, INC.
Series D, warrants (expire 01–14–2000)
INDUSTRIAL SERVICES OF AMERICA, INC.
$.01 par common
INKTOMI CORPORATION

$.001 par common
INNOTRAC CORPORATION
$.10 par common
INTERNATIONAL INTEGRATION INCORPORATED
$.01 par common
INTERNATIONAL ISOTOPES, INC.
$.01 par common
INTERPLAY ENTERTAINMENT CORPORATION
$.001 par common
IVI CHECKMATE CORPORATION
$.01 par common
JPS PACKAGING COMPANY
$.01 par common
KING PHARMACEUTICALS, INC.
No par common
KNIGHT/TRIMARK GROUP, INC.
Class A, $.01 par common
KUALA HEALTHCARE, INC.
$.06 par common
LEUKOSITE, INC.
$.01 par common
LEXINGTON B & L FINANCIAL CORPORATION
$.01 par common
LIBERTY BANCORP, INC.
$1.00 par common
LJ INTERNATIONAL, INC.
$.01 par common
Warrants (expire 04–16–2002)
LMI AEROSPACE, INC.
$.02 par common
MAIN STREET BANCORP, INC.
$1.00 par common
MANHATTAN ASSOCIATES, INC.
$.01 par common
MARINE TRANSPORT CORPORATION
$.01 par common
MARINER CAPITAL TRUST PREFERRED
$10.00 par preferred security
MASON–DIXON BANCSHARES, INC. (Maryland)
$20.00 par preferred stock
MASTER GRAPHICS, INC.
$.001 par common
METROPOLITAN FINANCIAL CORPORATION
Trust preferred securities
MGC COMMUNICATIONS, INC.
$.001 par common
MICROSTRATEGY, INCORPORATED
$.001 par common
MID–STATE BANCSHARES
No par common
MIPS TECHNOLOGIES, INC.
$.001 par common
MOBIUS MANAGEMENT SYSTEMS, INC.
$.0001 par common
NATIONAL CITY BANCSHARES, INC. (Indiana)
Cumulative Trust Preferred
NAVIGANT INTERNATIONAL, INC.
$.001 par common
NETGRAVITY, INC.
$.001 par common
NIAGARA BANCORP, INC.
$.01 par common
PACALTA RESOURCES, LTD.
No par common
PACIFICHEALTH LABORATORIES, INC.
$.0025 par common
PALATIN TECHNOLOGIES
$.01 par common
PARADIGM GEOPHYSICAL, LTD.
Ordinary shares (NIS .5 par)
PBOC HOLDINGS, INC.
$.01 par common
PDS FINANCIAL CORPORATION
Warrants (expire 05–04–2003)
PETRO UNION, INC.
Common
PHILADELPHIA CONSOLIDATED HOLDING COMPANY
Growth Prides (expire 04–29–2001)
Income Prides (expire 04–29–2001)
PITTSBURGH HOME FINANCIAL CORPORATION
8.56% cumulative trust preferred
PNB FINANCIAL GROUP
No par common
POINT OF SALE LIMITED
Ordinary shares
POINTE FINANCIAL CORPORATION
$.01 par common
PROFESSIONAL DETAILING, INC.
$.01 par common
PROTRAN CORPORATION
No par common
PROVANT, INC.
$.01 par common
PVC CONTAINER CORPORATION
$.01 par common
RAINBOW RENTALS, INC.
No par common
REALTY INFORMATION GROUP, INC.
$.01 par common
REGENCY BANCORP
No par common
RESTORATION HARDWARE, INC.
$.0001 par common
ROCK FINANCIAL CORPORATION
$.01 par common
SCC COMMUNICATIONS CORPORATION
$.001 par common
SCHOOL SPECIALTY, INC.
$.001 par common
SFX ENTERTAINMENT, INC.
Class A voting, $.01 par common
SILICON VALLEY BANCSHARES, INC. (California)
Cumulative trust preferred securities
SOFTWARE.NET CORPORATION
No par common
SOGNIZANT TECHNOLOGY SOLUTIONS CORPORATION
Class A, $.01 par common
SOMANETICS CORPORATION
$.01 par common
SOURCE INFORMATION MANAGEMENT COMPANY, THE
$.01 par common
SOUTHSIDE BANCSHARES, INC.
$2.50 par common
No par cumulative trust preferred securities
SQL FINANCIALS INTERNATIONAL, INC.
$.0001 par common
STET HELLAS TELECOMMUNICATIONS SA
American Depositary Shares
STOLT COMEX SEAWAY S.A.
American Depositary Shares
SUCCESS BANCSHARES, INC. (Illinois)
8.95% cumulative trust preferred securities
SVB FINANCIAL SERVICES, INC.
$2.08 par common
TCI MUSIC, INC.
Class A, $.01 par common
Series A, convertible preferred
TEARDROP GOLF COMPANY
$.01 par common
TECHNISOURCE, INC.
$.01 par common
TELESYSTEM INTERNATIONAL WIRELESS, INC.
No par common
TRANS GLOBAL SERVICES, INC.
$.01 par common
U.S. HOME & GARDEN, INC.
$.001 par common
U.S. OFFICE PRODUCTS COMPANY
$.001 par common
ULTIMATE SOFTWARE GROUP, INC.
$.01 par common
UNITED COMMUNITY FINANCIAL CORPORATION
No par common
UNITED PANAM FINANCIAL CORPORATION
$.01 par common
UNITED ROAD SERVICES, INC.
$.001 par common
UNITED TENNESSEE BANKSHARES, INC.
No par common
URSUS TELECOM CORPORATION
$.01 par common
US LEC CORPORATION
Class A, $.01 par common
USBANCORP, INC.
Capital Trust 1
V.I. TECHNOLOGIES, INC.
$.01 par common
VERIO, INC.
$.001 par common
WARWICK VALLEY TELEPHONE COMPANY
No par common
WASHINGTON BANKING COMPANY
No par common
WASTE CONNECTIONS, INC.
$.01 par common
WASTE SYSTEMS INTERNATIONAL, INC.
$.01 par common
WORKFLOW MANAGEMENT, INC.
$.001 par common

Complete Foreign Margin List

Germany

GEHE AG

Ordinary shares, par DM 50
HOECHST AG
Ordinary shares, par DM 50

Hong Kong

PEREGRINE INVESTMENT HOLDINGS LTD.
Ordinary, par HK $0.60
SUN HUNG KAI PROPERTIES LIMITED
HK $0.50 par ordinary shares

Japan

AIWA CO., LTD.
¥ 50 par common
AKITA BANK, LTD.
¥ 50 par common
AOMORI BANK, LTD.
¥ 50 par common
ASATSU INC.
¥ 50 par common
BANDAI CO., LTD.
¥ 50 par common
BANK OF KINKI, LTD.
¥ 50 par common
BANK OF NAGOYA, LTD.
¥ 50 par common
CHUDENKO CORP.
¥ 50 par common
CHUGOKU BANK, LTD.
¥ 50 par common
CLARION CO., LTD.
¥ 50 par common
CREDIT SAISON CO., LTD.
¥ 50 par common
DAIHATSU MOTOR CO., LTD.
¥ 50 par common
DAINIPPON SCREEN MFG. CO., LTD.
¥ 50 par common
DAIWA KOSHO LEASE CO., LTD.
¥ 50 par common
DENKI KAGAKU KOGYO
¥ 50 par common
EIGHTEENTH BANK, LTD.
¥ 50 par common
FURUKAWA CO., LTD.
¥ 50 par common
FUTABA CORP.
¥ 50 par common
FUTABA INDUSTRIAL CO., LTD.
¥ 50 par common
HIGO BANK, LTD.
¥ 50 par common
HITACHI CONSTRUCTION MACHINERY CO., LTD.
¥ 50 par common
HITACHI SOFTWARE ENGNEERING CO., LTD.
¥ 50 par common
HITACHI TRANSPORT SYSTEM, LTD.
¥ 50 par common
HOKKOKU BANK, LTD.
¥ 50 par common
HOKUETSU BANK, LTD
¥ 50 par common
HOKUETSU PAPER MILLS, LTD.
¥ 50 par common
IYO BANK, LTD.
¥ 50 par common
JACCS CO., LTD.
¥ 50 par common
JAPAN AIRPORT TERMINAL CO., LTD.
¥ 50 par common
JAPAN SECURITIES FINANCE CO., LTD.
¥ 50 par common
JUROKU BANK, LTD
¥ 50 par common
KAGOSHIMA BANK, LTD.
¥ 50 par common
KAMIGUMI CO., LTD.
¥ 50 par common
KATOKICHI CO., LTD.
¥ 50 par common
KEISEI ELECTRIC RAILWAY CO., LTD.
¥ 50 par common
KEIYO BANK, LTD.
¥ 50 par common
KIYO BANK, LTD.
¥ 50 par common
KOMORI CORP.
¥ 50 par common
KONAMI CO., LTD.
¥ 50 par common
KURIMOTO, LTD.
¥ 50 par common
KYOWA EXEO CORP.
¥ 50 par common
KYUDENKO CORP.
¥ 50 par common
MAEDA ROAD CONSTRUCTION CO., LTD.
¥ 50 par common
MATSUSHITA SEIKO CO., LTD.
¥ 50 par common
MAX CO., LTD.
¥ 50 par common
MEIDENSHA CORP.
¥ 50 par common
MICHINOKU BANK, LTD.
¥ 50 par common
MUSASHINO BANK, LTD.
¥ 500 par common
NAMCO, LTD.
¥ 50 par common
NICHICON CORP.
¥ 50 par common
NICHIMEN CORP.
¥ 50 par common
NIHON UNISYS, LTD.
¥ 50 par common
NIPPON COMSYS CORP.
¥ 50 par common
NIPPON TRUST BANK, LTD.
¥ 50 par common
NISHI-NIPPON BANK, LTD.
¥ 50 par common
NISHI-NIPPON RAILROAD CO., LTD.
¥ 50 par common
NISSAN CHEMICAL INDUSTRIES, LTD.
¥ 50 par common
NISSAN FIRE & MARINE INSURANCE CO., LTD.
¥ 50 par common
NOF CORPORATION
¥ 50 par common
OGAKI KYORITSU BANK, LTD.
¥ 50 par common
Q.P. CORP.
¥ 50 par common
RINNAI CORPORATION
¥ 50 par common
RYOSAN CO., LTD.
¥ 50 par common
SAGAMI RAILWAY CO., LTD.
¥ 50 par common
SAIBU GAS CO., LTD.
¥ 50 par common
SAKATA SEED CORP.
¥ 50 par common
SANKI ENGINEERING CO., LTD.
¥ 50 par common
SANTEN PHARMACEUTICAL CO., LTD.
¥ 50 par common
SANYO SECURITIES CO., LTD.
¥ 50 par common
SHIMADZU CORP.
¥ 50 par common
SHIMAMURA CO., LTD.
¥ 50 par common
SUMITOMO RUBBER INDUSTRIES, LTD.
¥ 50 par common
SURUGA BANK, LTD.
¥ 50 par common
TAIYO YUDEN CO., LTD.
¥ 50 par common
TAKARA STANDARD CO., LTD.
¥ 50 par common
TAKASAGO THERMAL ENGINEERING CO.
¥ 50 par common
TAKUMA CO., LTD.
¥ 50 par common
TOHO BANK, LTD.
¥ 50 par common
TOHO GAS CO., LTD.
¥ 50 par common
TOKYO OHKA KOGYO CO., LTD.
¥ 50 par common
TOKYO SOWA BANK, LTD.
¥ 50 par common
TOKYO TATEMONO CO., LTD.
¥ 50 par common
TOKYO TOMIN BANK, LTD.
¥ 500 par common
TOSHIBA CERAMICS CO., LTD.
¥ 50 par common
UNI-CHARM CORP.
¥ 50 par common
USHIO, INC.
¥ 50 par common
YAMAHA MOTOR CO., LTD.
¥ 50 par common
YAMANASHI CHUO BANK, LTD.
¥ 50 par common
YODOGAWA STEEL WORKS, LTD.
¥ 50 par common

United Kingdom

RACAL ELECTRONICS PLC
Ordinary shares, par value 25 p

By order of the Board of Governors of the Federal Reserve System, acting by its Director of the Division of Banking Supervision and

Regulation pursuant to delegated authority (12 CFR 265.7(f)(10)), July 21, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98–19947 Filed 7–24–98; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL HOUSING FINANCE BOARD

12 CFR Part 933

[No. 98–29]

RIN 3069–AA67

Membership Approval

AGENCY: Federal Housing Finance Board.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Board (Finance Board) is amending its regulation on membership in the Federal Home Loan Banks (Banks) (Membership Regulation) to make certain technical and substantive revisions to the regulation that would improve the operation of the membership application process, as well as further streamline application processing for certain types of applicants for Bank membership.

EFFECTIVE DATE: August 26, 1998.

FOR FURTHER INFORMATION CONTACT: Richard Tucker, Deputy Director, Compliance Assistance Division, Office of Policy, (202) 408–2848, or Sharon B. Like, Senior Attorney-Adviser, Office of General Counsel, (202) 408–2930, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

Under the Federal Home Loan Bank Act (Act), the Finance Board is responsible for the supervision and regulation of the 12 Banks, which provide advances and other financial services to their member institutions. *See* 12 U.S.C. 1422a(a). Institutions may become members of a Bank if they meet certain membership eligibility and minimum stock purchase criteria set forth in the Act and the Finance Board's implementing Membership Regulation. *See id.* sections 1424, 1426, 1430(e)(3); 12 CFR part 933.

On August 16, 1996, the Finance Board published a final rule amending the Membership Regulation to authorize the 12 Banks, rather than the Finance Board, to approve or deny all applications for Bank membership, subject to certain criteria for determining compliance with the statutory eligibility requirements for Bank membership formerly contained in policy guidelines used by the Finance Board in approving membership applications. *See* 61 FR 42531 (Aug. 16, 1996) (codified at 12 CFR part 933); Federal Home Loan Bank System Membership Application Guidelines, Finance Board Res. No. 93–88 (Nov. 17, 1993) (Guidelines). The final rule also provided for streamlined application processing for certain types of membership applications. *See* 12 CFR part 933.

In the course of processing and approving membership applications under the Membership Regulation, the Banks raised a number of technical and substantive issues with the Regulation whose resolution would improve operation of the membership application process and streamline membership application processing for certain types of institutions. To address these concerns, the Finance Board issued a proposed rule revising various provisions of the Membership Regulation, which was published in the **Federal Register** on February 19, 1998, with a 30-day period for public comment. *See* 63 FR 8364 (Feb. 19, 1998). The Finance Board received a total of four letters on the proposed rule. Commenters included three Banks, and one Bank member thrift institution.

II. Analysis of the Final Rule

A. Definitions—Section 933.1

1. Definition of "Primary Regulator"—Section 933.1(y)

Section 933.1(y) of the current Membership Regulation defines the term "primary regulator" as the chartering authority for federally-chartered applicants, the insuring authority for federally-insured applicants that are not federally-chartered, or the appropriate state regulator for all other applicants. *See* 12 CFR § 933.1(y). This definition does not include the Federal Reserve Board (FRB) for state-chartered applicants that are members of the Federal Reserve System (FRS). Under § 933.11(a)(3), a Bank is required to obtain as part of the membership application the applicant's most recent available regulatory examination report prepared by its primary regulator or appropriate state regulator. *See id.* § 933.11(a)(3). Section 933.11(b)(1) provides that an applicant must have received a composite regulatory examination rating from its primary regulator or appropriate state regulator within two years preceding the date the Bank receives the application for membership. *See id.* § 933.11(b)(1).

One Bank identified a potential problem with meeting these financial condition requirements where the FRB and a state financial institution regulator alternate examinations of a state-chartered applicant that is an FRS member. When the state financial institution regulator performs the examination, it provides a copy of the regulatory examination report to the FRB. According to the Bank, certain state financial institution regulators in its district cannot or will not release to the Bank copies of the regulatory examination reports they have prepared, nor will the FRB release to the Bank copies of the state regulatory examination reports. Thus, regulatory examination reports prepared under such circumstances are not available in order for the Bank to obtain a regulatory examination rating for the applicant. Nor may the Bank obtain and rely on a copy of the regulatory examination report and rating of the FRB when the FRB has examined the applicant, because the definition of "primary regulator" in § 933.1(y) does not include the FRB. Thus, in such situations, the Bank may not be able to obtain any examination report and rating for the applicant and, therefore, the applicant cannot be deemed to satisfy the financial condition requirements of §§ 933.11(a)(3) and (b)(1). The presumption of noncompliance with the financial condition requirements would have to be rebutted under § 933.17(d)(1) by preparing a written justification providing substantial evidence acceptable to the Bank that the applicant is in the financial condition required by § 933.6(a)(4), notwithstanding the lack of a regulatory examination rating. *See id.* § 933.17(d)(1).

The exclusion of the FRB from the definition of "primary regulator" in § 933.1(y) was an oversight. The Banks should be able to rely on regulatory examination reports and examination ratings from the FRB to determine an applicant's financial condition under § 933.11. An applicant should not have to go through the additional burden of establishing its satisfactory financial condition through the rebuttal process if an FRB regulatory examination report and rating are available. Two Bank commenters specifically supported allowing the Banks to rely on FRB regulatory examination reports and ratings. One commenter stated that it believes the FRB examination is equivalent in rigor and thoroughness to an examination by the Federal Deposit Insurance Corporation (FDIC) or the Office of the Comptroller of the Currency (OCC).

Accordingly, consistent with the proposed rule, the final rule revises the definition of "primary regulator" in

§ 933.1(y), as further described below, to include the FRB.

Another limitation of the current definition of "primary regulator" in § 933.1(y) is that it requires a Bank to obtain the regulatory examination report and rating only from the "primary" regulator listed, even though a regulatory examination report and rating from an alternate regulator also may be available. For example, many potential members are examined by more than one regulator. However, under the regulation, the Bank is required to obtain the regulatory examination report and rating prepared by the FDIC for a state-chartered, FDIC-insured institution, even though there may be a more recent state regulatory examination report and rating available for such institution. A Bank should not be limited to using only the "primary" regulator's regulatory examination report and rating when more current information is available.

Accordingly, consistent with the proposed rule, the final rule amends § 933.1(y) by changing the term "primary regulator" to the broader term "appropriate regulator," and defining it to mean a regulatory entity listed in § 933.8, as applicable. The regulatory entities listed in § 933.8 are: for depository institution applicants, the FDIC, FRB, National Credit Union Administration, OCC, Office of Thrift Supervision (OTS), or other appropriate state regulator; and for insurance company applicants, an appropriate state regulator accredited by the National Association of Insurance Commissioners. *See id.* § 933.8. The final rule replaces the terms "primary regulator" and "primary regulator or appropriate state regulator" wherever they appear throughout the Membership Regulation with the term "appropriate regulator."

2. Nonperforming Assets Performance Trend Criterion; Definitions of "Nonperforming Loans, Leases and Securities;" "Performing Loans, Leases and Securities"—Sections 933.11(b)(3)(i)(B); 933.1(u), (x)

Section 933.11(b)(3)(i)(B) of the current Membership Regulation provides that if an applicant's most recent composite regulatory examination rating within the past two years was "2" or "3," the applicant's nonperforming loans, leases and securities plus foreclosed and repossessed real estate may not have exceeded 10 percent of its performing loans, leases and securities plus foreclosed and repossessed real estate, in the most recent calendar quarter. *See id.* § 933.11(b)(3)(i)(B). This nonperforming assets performance trend criterion was intended to be the same criterion as that required in the former Finance Board Guidelines, but was described incorrectly in the Membership Regulation. The proposed rule revised the criterion to state it correctly as provided in the Guidelines, and made conforming changes to components of the criterion consistent with the Guidelines. One Bank commenter specifically supported this proposed change.

Accordingly, consistent with the proposed rule, the final rule revises § 933.11(b)(3)(i)(B) to state the criterion correctly, as follows: the applicant's nonperforming loans and leases plus other real estate owned, did not exceed 10 percent of its total loans and leases plus other real estate owned, in the most recent calendar quarter. The final rule makes a conforming change to the definition of "nonperforming loans, leases and securities" in § 933.1(u) by deleting the references to securities. The final rule also makes a conforming change to § 933.1(x) by replacing the definition of "performing loans, leases and securities" with a new definition of "other real estate owned."

3. Definition of "Consolidation"—Section 933.1(ee)

Sections 933.24 and 933.25 of the current Membership Regulation set forth certain requirements and procedures in the event of the "consolidation" of members with other members or members with nonmembers. *See id.* §§ 933.24, 933.25. Questions were raised as to whether the term "consolidation" applies only to transactions falling within the narrow meaning of the term, *i.e.*, combinations where a new company is formed to acquire the net assets of the combining companies. The term "consolidation" was not intended to apply solely to such combinations of entities. The proposed rule clarified this issue by adding a new definition of "consolidation" in § 933.1(ee) to include a consolidation, a merger, or a purchase of all of the assets and assumption of all of the liabilities of an entity by another entity. One Bank commenter specifically supported the proposed definition.

Accordingly, the final rule adopts the proposed definition without change.

B. Action on Applications—Section 933.3(c)

Section 933.3(c) of the current Membership Regulation requires a Bank to notify an applicant when its application is deemed by the Bank to be complete. *See id.* § 933.3(c). Section 933.3(c) also requires a Bank to notify an applicant if the 60-day period for acting on a membership application is stopped, and when the period for acting on the application is resumed. *See id.* The proposed rule required the Bank to provide such notices to the applicant in writing. The intent was to ensure that there is a written record of the Banks' actions during the application processing period, which may be relevant in the event of an appeal of a Bank's denial of an application for membership.

No commenters opposed the proposed requirement that the Banks provide written notice to an applicant when its application is deemed complete, which starts the 60-day processing clock. Accordingly, this requirement is retained in the final rule.

Two Bank commenters specifically opposed requiring the Banks to provide written notice to an applicant when the 60-day processing period is stopped or resumed. They stated that telephone notification to the applicant, with a written log of such notification maintained in the application files at the Bank, should be sufficient. The commenters viewed the notice requirement merely as "bureaucratic paperwork" that would provide no additional information to the applicant, which would already have received verbal notice from the Bank, while increasing the workload for Bank staff. One commenter also noted that the processing clock often is stopped only for short periods of time in order to get additional information from the applicant, and the Bank probably will have received the requested information from the applicant before it has had time to generate the notice letter.

The Finance Board believes there is merit in the commenters' arguments. A written record can be ensured, for purposes of reviewing any appeal of a Bank's denial of a membership application, by requiring the Banks to maintain a written log in their application files of notices provided to applicants when the processing clock is stopped or resumed. Written notice to the applicants in such circumstances does not appear to be necessary. The final rule is revised accordingly.

C. Automatic Membership Approval For Certain Consolidations—Section 933.4(d)

Sections 933.4(a) and (b) of the current Membership Regulation provide for automatic Bank membership approval for institutions required by law to become Bank members, and for institutions that have undergone certain charter conversions, respectively. *See id.* §§ 933.4(a), (b). Several Banks

suggested that the Regulation also should allow for automatic Bank membership approval where a member consolidates with a nonmember, the nonmember is the surviving entity, and a significant percentage of the surviving entity's total assets are derived from the assets of the disappearing member. Where the surviving entity has substantially the same assets as the disappearing member, the surviving entity arguably should not have to go through the membership application process. The proposed rule authorized such automatic membership approval where 90 percent or more of the total assets of the surviving entity are derived from the assets of the disappearing member, and where the surviving entity provides written notice to the Bank that it desires to be a member of the Bank. The Finance Board requested comment on the arguments for or against this proposal, including whether the 90 percent calculation or some other number or approach was an appropriate method for determining the similarity of the disappearing and surviving entities. In response to a Bank suggestion, the Finance Board also requested comment on whether the chief executive officer of the surviving entity should be required to submit a letter or certification stating that the surviving entity continues to meet the membership eligibility requirements.

1. 90 Percent Test

One Bank commenter specifically supported the proposed 90 percent test. Two Bank commenters recommended reducing the percentage requirement to 75 percent or 50 percent, which also was supported by the Bank endorsing the 90 percent test. Two of these commenters recommended that the surviving entity in such consolidations be required to provide a letter or certification stating that it continues to meet the membership eligibility requirements. The other commenter stated that such a letter or certification is not necessary since the preponderance of the assets is derived from the disappearing member, and it is highly unlikely that the surviving entity would not meet the membership eligibility requirements. The commenters stated that lowering the percentage requirement would further streamline the membership process, while posing little financial risk to the Banks. Otherwise, there would be an interruption in membership status while the surviving entity applied for membership, which could result in lost business for the Bank as well as the surviving entity. The thrift member commenter opposed the proposed amendment, stating that any efficiencies that may be gained by allowing automatic membership approval for the small number of institutions that would be eligible for such treatment are outweighed by the risks of not maintaining appropriate vigilance over Bank membership.

After consideration of the comments, the Finance Board has decided to retain in the final rule the proposed 90 percent test, but to make its application discretionary with the Banks. The final rule also clarifies that a consolidated institution that is approved for automatic membership by a Bank may become a member of the Bank only upon the purchase of its minimum stock purchase requirement pursuant to the requirements of § 933.20.

The intent of the 90 percent test is to permit automatic membership approval for consolidated institutions where substantially all of the institution's assets are derived from the assets of the disappearing member, making satisfaction of the membership eligibility requirements essentially automatic. The Finance Board is comfortable that the 90 percent test generally represents a satisfactory proxy for this eligibility determination and that there are not significant risks that would affect the integrity of the membership process. However, the Finance Board recognizes that there may be special circumstances where relying solely on the 90 percent proxy test is not sufficient, and that warrant obtaining additional information about the consolidated institution in order to verify its satisfaction of the membership eligibility requirements. In such cases, a Bank may want to conduct additional due diligence of the consolidated institution's financial condition or other eligibility factors, pursuant to the normal membership application process, in order to verify the institution's compliance with the eligibility requirements. Thus, rather than requiring automatic membership approval for all consolidated institutions meeting the 90 percent test, the final rule authorizes the Banks, in their discretion, to approve automatic membership for consolidated institutions meeting the 90 percent test.

A percentage requirement below 90 percent does not ensure automatic satisfaction of the membership eligibility requirements, as substantially all of the surviving institution's assets cannot be said to be derived from the assets of the disappearing member. An independent determination that the surviving institution continues to meet the eligibility requirements would be necessary. This goes beyond the intent of the proposed rule, which was to streamline the membership process for consolidated institutions that can be deemed to automatically satisfy the membership eligibility requirements. Relying on a self-certification of eligibility from the surviving institution is no longer an automatic membership process, and may not achieve the desired effect of streamlining the process. The surviving institution still would have to work through the data from its regulatory financial report and determine whether it satisfies the eligibility requirements before it could certify its eligibility, and the Bank presumably would need to conduct some sort of informal analysis of the institution's data in order to ensure that it is comfortable with relying on the certification. Moreover, it may not be advisable for a Bank to rely on an institution's self-certification of eligibility, in light of the fact that the Banks often are required to work extensively with membership applicants to get all of the information needed to conduct an adequate eligibility review. In addition, it is not clear how the rebuttable presumption process under the current Regulation should work under a certification process. The Regulation currently allows an applicant to rebut a presumption of noncompliance with eligibility requirements, as determined in the discretion of the Bank. It may not make sense to allow an institution to make its own discretionary certification that it has rebutted a presumption of noncompliance.

In view of all these factors, the final rule does not adopt the commenters' suggestions, which go beyond the intended scope of the proposed rule.

2. Post-Consolidation Notice Requirement

Two Bank commenters recommended that the surviving entity be required to notify the Bank of its desire for membership within 60 days after the effective date of the consolidation, consistent with the 60-day notice requirement for consolidations involving nonmembers that do not satisfy the 90 percent test, which must apply for membership under § 933.25(b) of the current Regulation. *See id.* § 933.25(b). There appears to be no reason why consolidated institutions meeting the 90 percent test should be treated differently, for membership notice purposes, from consolidated institutions that do not meet the 90 percent test and must apply for membership. Sixty days appears to be a reasonable amount of time for consolidated institutions meeting the 90

percent test to make a decision regarding whether they want to be members. Accordingly, the final rule adopts a 60-day post-consolidation notice requirement for automatic consolidations.

3. Treatment of Acquired Advances and Stock During Notice Period

Since the final rule allows for a 60-day post-consolidation notice period, the rule also must clarify how any outstanding Bank advances and Bank stock acquired from the disappearing member will be treated during that period before the consolidated institution has announced its intention whether to accept membership. The final rule treats such advances and stock consistent with the treatment for consolidated institutions not meeting the 90 percent test, under §§ 933.25(d)(1)(i), (e) and (f) of the current regulation, *i.e.*, during the 60-day notice period, the consolidated institution's Bank may permit the institution to continue to hold any outstanding Bank advances and stock, and the institution shall have the limited rights associated with such stock in accordance with §§ 933.25(e) and (f). *See id.* §§ 933.25(d)(1)(i), (e), (f).[1] Of course, if the consolidated institution ultimately decides not to accept membership, then the liquidation of any outstanding indebtedness owed to the disappearing institution's Bank and redemption of stock of such Bank would be carried out in accordance with the requirements of § 933.29 of the current Regulation. *See* 12 CFR 933.29.

4. Multiple Members Merging Into a Nonmember; "Same District" Requirement

A Bank commenter also recommended that automatic membership be allowed for multiple members merging into a single nonmember, but only if the principal places of business of the multiple members are located in the same Bank district as the principal place of business of the surviving nonmember, consistent with the "same district" requirement in § 933.25(b) of the current Regulation. The final rule allows for automatic membership for multiple members merging into a single nonmember, where 90 percent of more of the total assets of the consolidated institution are derived from the total assets of the disappearing members. The final rule also applies to consolidations meeting the 90 percent test the "same district" requirement, which was inadvertently omitted from the proposed rule.

D. Allowance For Loan and Lease Losses Performance Trend Criterion— Section 933.11(b)(3)(i)(C)

Section 933.11(b)(3)(i)(C) of the current Membership Regulation provides that if an applicant's most recent composite regulatory examination rating within the past two years was "2" or "3," the applicant's ratio of its allowance for loan and lease losses to nonperforming loans, leases and securities must have been 60 percent or greater during 4 of the 6 most recent calendar quarters. This allowance for loan and lease losses performance trend criterion was intended to be the same criterion as that required in the former Finance Board Guidelines, but was described incorrectly in the Membership Regulation. The proposed rule revised the criterion to state it correctly as provided in the Guidelines. One Bank commenter specifically supported this proposed change.

Accordingly, consistent with the proposed rule, the final rule revises § 933.11(b)(3)(i)(C) to state the criterion correctly, as follows: the applicant's ratio of its allowance for loan and lease losses plus the allocated transfer risk reserve to nonperforming loans and leases was 60 percent or greater during 4 of the 6 most recent calendar quarters.

One Bank commenter recommended that the minimum 60 percent ratio be reduced to 40 percent, arguing that 60 percent is too high a threshold that too often triggers the need for rebutting a presumption of noncompliance with this criterion for applicants that are in a strong financial condition. The Bank also suggested an alternative measure of compliance through reliance on a determination by the applicant's primary regulator of satisfactory performance of the criterion, based on the primary regulator's own definition of the criterion.

The substantive issue of what amount should be the required ratio for this performance criterion was not specifically raised for comment in the proposed rule, which was intended merely to correct, consistent with the Guidelines, an incorrect statement of the ratio in the current regulation. No other commenter recommended lowering the ratio from 60 percent. This issue, therefore, does not appear to be ripe for review at this time. However, if additional information is brought to the Finance Board's attention at a future time that suggests that the 60 percent figure should be reconsidered, the Finance Board will act accordingly.

E. De Novo Insured Depository Institution Applicants—Section 933.14

Section 933.14 of the current Membership Regulation sets forth the requirements for processing and approving membership applications from de novo insured depository institution applicants. *See id.* § 933.14. Section 933.14(a) provides for streamlined processing for newly-chartered applicants that have not yet commenced operations, which are deemed to meet the duly organized, inspection and regulation, financial condition, and character of management eligibility requirements. *See id.* § 933.14(a)(1). Section 933.14(b) requires newly-chartered applicants that have commenced operations to meet all of the eligibility requirements, subject to certain exceptions provided in paragraph (b). In particular, if such applicants have not yet filed regulatory financial reports for the last six calendar quarters preceding the date the Bank receives the membership application, the applicant need not meet the performance trend criteria in § 933.11(b)(3)(i)(A) through (C) if the applicant has filed regulatory financial reports for at least three calendar quarters of operation. *See id.* § 933.14(b)(2)(iii)(A).

A number of Banks stated that the requirement for having filed three calendar quarters of regulatory financial reports should not be necessary for institutions that have recently commenced operations. The financial condition and character of management of such institutions already will have been recently reviewed and approved by their chartering and insuring regulators (*see, e.g.*, 12 U.S.C. 1816, 12 CFR 303.7(d)(ii) (FDIC); 12 U.S.C. 26, 12 CFR 5.20 (OCC)), will have been based on a forward looking business plan, and should not have changed significantly since the commencement of operations. The Banks should not have to duplicate the review performed by the prospective member's appropriate regulator. Further, de novo insured depository institution applicants should be treated similarly to mandatory de novo thrift institutions, which do not have to satisfy any specific Bank membership

[1] Section 933.25(f) of the current Membership Regulation provides that the consolidated institution may not vote the Bank stock acquired in the consolidation from the disappearing member unless and until the consolidated institution is a Bank member. *See id.* § 933.25(f). Under the Finance Board's proposed amendments to its regulations governing the election of Bank directors, § 933.25(f) would be removed. *See* 63 FR 26532, 26544 (May 13, 1998). The proposed election regulation would provide that the consolidated institution may vote the Bank stock acquired from the disappearing member that was held by such member on the record date (December 31 of the calendar year immediately preceding the election year). *See* proposed §§ 932.1 (definition of "record date"), 932.5(b), 63 FR 26539–40.

eligibility requirements since they are required by law to be Bank members.

Based on these arguments, proposed § 933.14(a)(1) extended the streamlined application processing currently applicable to newly-chartered insured depository institutions that have not yet commenced operations to newly-chartered insured depository institutions that have commenced operations. Such applicants would be deemed to meet the duly organized, inspection and regulation, financial condition, and character of management eligibility requirements. In order to be considered newly-chartered and subject to the streamlined application processing procedures of § 933.14(a)(1), applicants would have to have been chartered within three years prior to the date the Bank receives the application for membership. Three years is consistent with the time period for de novo treatment applied by other financial institution regulators. *See, e.g.*, 12 CFR 543.3(a) (OTS).

The Finance Board requested comment on the arguments for or against this proposal. Three Bank commenters specifically supported the proposal, while the thrift member commenter opposed it. The supporting commenters cited the reasons expressed in the proposed rule for streamlining the process. One commenter also noted that the de novo applicant's other regulators closely scrutinize the financial condition of the institution during its first three years of operations, which should provide additional comfort regarding the safety and soundness of the institution. The commenter also pointed out that after approving a de novo institution for membership, the Bank would closely monitor its financial soundness before providing any advances to the institution. In addition, the commenter noted that streamlining membership approval for such institutions will enable them to more quickly access long-term Bank advances for the purpose of originating long-term housing and community and economic development loans.

The thrift member stated that the efficiencies to be gained by the proposal appeared small compared to the risks being assumed by the Bank System. The commenter indicated that a de novo applicant's first three quarterly reports should be reviewed to compare its actual performance with its business plan, thereby preserving the possibility of early identification and avoidance of financial risks to the Bank System. However, as discussed above, streamlined membership processing for de novos should not increase the financial risks to the Bank System, given the extensive financial scrutiny of the institution already performed by its other regulators, as well as the close monitoring that the Banks will conduct before making advances to such an institution.

Accordingly, the final rule retains the proposed provisions, with a clarification that the charter date to be used in determining the three-year period for de novo status is the date the charter was approved. One commenter suggested that the charter date be the date the letter approving the charter is issued to the applicant by its regulator. This seems unnecessary as the date of charter approval should be easily verifiable.

F. Recent Merger or Acquisition Applicants—Section 933.15

Sections 933.9 and 933.10 of the current Membership Regulation require applicants to show satisfaction of the "makes long-term home mortgage loans" and "10 percent residential mortgage loans" requirements, respectively, based on the applicant's most recent regulatory financial report. *See id.* §§ 933.9, 933.10. An applicant that recently has merged with or acquired another institution prior to applying for Bank membership must show satisfaction of these eligibility requirements based on the most recent regulatory financial report filed by the consolidated entity. *See id.* However, a newly consolidated entity may not be able to show compliance with these requirements as it may be several months before the next quarterly regulatory financial report is due to be filed with the appropriate regulator.

One Bank suggested that in order to allow the applicant to be approved for membership promptly, the applicant should be allowed to demonstrate satisfaction of §§ 933.9 and 933.10 by providing the combined pro forma financial statement that the combined entity filed with the regulator that approved its merger or acquisition. Another suggestion was that the applicant should be allowed to provide the most recent regulatory financial report filed prior to the merger or acquisition by each of the institutions that entered into the merger or acquisition. The Bank then would consolidate the relevant data from both reports for purposes of determining compliance with §§ 933.9 and 933.10. The proposed rule allowed reliance on such regulatory financial reports, provided that in the case of showing satisfaction of the 10 percent residential mortgage loans requirement, the Bank obtained a certification from the applicant that there was no material decrease in the ratio of consolidated residential mortgage loans to consolidated total assets derived from the reports since the reports were filed with the appropriate regulator.

One Bank commenter specifically supported this proposal. However, upon further consideration of the issue, the Finance Board is concerned that simply consolidating the mortgage loan data contained in the regulatory financial reports filed by the entities before the merger or acquisition does not accurately reflect a true valuation of the asset composition of the combined entity. The proposed rule also created a potential difficulty in defining what constitutes a "material" decrease in the ratio of consolidated residential mortgage loans to consolidated total assets. The Finance Board believes that the combined pro forma financial statement filed with the regulator that approved the merger or acquisition represents a more accurate picture of the combined institution's asset composition. Moreover, § 933.15(a)(ii) of the current Regulation already allows such applicants to provide combined pro forma financial statements to show satisfaction of the performance trend criteria in §§ 933.11(b)(3)(i)(A) to (C) where combined regulatory financial reports are not available. *See id.* § 933.15(a)(ii). Accordingly, the final rule provides that, for purposes of determining compliance with §§ 933.9 and 933.10, a Bank may, in its discretion, permit a recent merger or acquisition applicant that has not yet filed the required consolidated regulatory financial report as a combined entity with its appropriate regulator, to provide the combined pro forma financial statement for the combined entity filed with the regulator that approved the merger or acquisition.

III. Regulatory Flexibility Act

The final rule implements statutory requirements binding on all Banks and on all applicants for Bank membership, regardless of their size. The Finance Board is not at liberty to make adjustments to those requirements to accommodate small entities. The final rule does not impose any additional regulatory requirements that will have a disproportionate impact on small entities. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, *see* 5 U.S.C. 605(b), the Finance Board hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act

As part of the proposed rulemaking, the Finance Board published a request

for comments concerning proposed changes to the collection of information in the current Membership Regulation, *see* 63 FR 8364, 8367 (Feb. 19, 1998), which previously was approved by the Office of Management and Budget (OMB) and assigned OMB control number 3069–0004. The Finance Board also submitted to OMB an analysis of the proposed changes to the collection of information contained in § 933.15 of the proposed rule, in accordance with section 3507(d) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d). No comments were received by the Finance Board on the proposed changes to the collection of information. OMB approved the information collection without conditions with an expiration date of April 30, 2001. The final rule does not substantively or materially modify the approved information collection.

The Banks and, where appropriate, the Finance Board, will use the information collection under § 933.15(c) of the final rule to determine whether a recent merger or acquisition applicant meets certain membership eligibility requirements. *See* 12 U.S.C. 1424(a)(1)(C), (a)(2)(A); 12 CFR 933.9, 933.10. Only applicants meeting such requirements may become Bank members. *See id.*; *id.* Responses are required to obtain or retain a benefit. *See* 12 U.S.C. 1424. The Finance Board and the Banks will maintain the confidentiality of information obtained from respondents pursuant to the collection of information as required by applicable statute, regulation, and agency policy. Books or records relating to this collection of information must be retained as provided in the regulation.

Likely respondents and/or recordkeepers will be the Finance Board, Banks, and financial institutions that have recently undergone a merger or acquisition and are eligible to become Bank members under the Act, *see id.* section 1424(a)(1), including any building and loan association, savings and loan association, cooperative bank, homestead association, insurance company, savings bank, or insured depository institution. The title, description of need and use, and a description of the information collection requirements in the final rule are discussed further in part II. of the **SUPPLEMENTARY INFORMATION.** Potential respondents are not required to respond to the collection of information unless the regulation collecting the information displays a currently valid control number assigned by OMB. *See* 44 U.S.C. 3512(a).

The changes to the information collection will not impose any additional costs on the Finance Board or the Banks. The estimated annual reporting and recordkeeping hour burden on respondents is:

a. Number of respondents—15
b. Total annual responses—15
Percentage of these responses collected electronically—0%
c. Total annual hours requested—60
d. Current OMB inventory—59,152
e. Difference—(59,092)

The estimated annual reporting and recordkeeping cost burden on respondents is:

a. Total annualized capital/startup costs—$0
b. Total annual costs (O&M)—$0
c. Total annualized cost requested—$1,800
d. Current OMB inventory—$1,684,000
e. Difference—($1,682,200)

Any comments regarding the collection of information may be submitted in writing to Elaine L. Baker, Executive Secretary, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006, and to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for Federal Housing Finance Board, Washington, D.C. 20503.

List of Subjects in 12 CFR Part 933

Credit, Federal home loan banks, Reporting and recordkeeping requirements.

Accordingly, the Finance Board hereby amends title 12, chapter IX, part 933, Code of Federal Regulations, as follows:

PART 933—MEMBERS OF THE BANKS

1. The authority citation for part 933 continues to read as follows:

Authority: 12 U.S.C. 1422, 1422a, 1422b, 1423, 1424, 1426, 1430, 1442.

PART 933—[AMENDED]

2. Part 933 is amended by removing the term "primary regulator or appropriate state regulator" wherever it appears and adding the term "appropriate regulator" in its place in the following locations:

a. § 933.1(l);
b. § 933.1(z);
c. § 933.2(c)(2);
d. § 933.11(a)(3);
e. § 933.11(a)(4);
f. § 933.11(b)(1);
g. § 933.12(a);
h. § 933.17(e)(1) introductory text;
i. § 933.17(e)(1)(i);
j. § 933.17(e)(2)(i); and
k. § 933.17(e)(3)(i).

§ 933.11 [Amended]

3. Section 933.11(b)(3)(i) introductory text is amended by removing the term "primary regulatory or appropriate state regulator" and adding the term "appropriate regulator" in its place.

§§ 933.11 and 933.17 [Amended]

4. Sections 933.11(a)(4) and 933.17(e)(1)(i) are amended by removing the phrase ", whichever is applicable," wherever it appears.

5. Part 933 is amended by removing the term "primary regulator" wherever it appears and adding the term "appropriate regulator" in its place in the following locations:

a. § 933.1(aa);
b. § 933.9;
c. § 933.10;
d. § 933.11(a)(1);
e. § 933.11(b)(2);
f. § 933.11(b)(3)(i) introductory text;
g. § 933.11(b)(3)(ii);
h. § 933.15(a)(i);
i. § 933.15(a)(ii);
j. § 933.16; and
k. § 933.17(f)(1).

6. Section 933.1 is amended by revising paragraphs (u), (x), and (y), and adding paragraph (ee) to read as follows:

§ 933.1 Definitions.

* * * * *

(u) *Nonperforming loans and leases* means the sum of the following, reported on a regulatory financial report: loans and leases that have been past due for 90 days (60 days in the case of credit union applicants) or longer but are still accruing; loans and leases on a nonaccrual basis; and restructured loans and leases (not already reported as nonperforming).

* * * * *

(x) *Other real estate owned* means all other real estate owned (*i.e.*, foreclosed and repossessed real estate), reported on a regulatory financial report, and does not include direct and indirect investments in real estate ventures.

(y) *Appropriate regulator* means a regulatory entity listed in § 933.8, as applicable.

* * * * *

(ee) *Consolidation* includes a consolidation, a merger, or a purchase of all of the assets and assumption of all of the liabilities of an entity by another entity.

7. Section 933.3 is amended by revising the fourth and fifth sentences of paragraph (c) to read as follows:

§ 933.3 Decision on application.

* * * * *

(c) * * * The Bank shall notify an applicant in writing when its

application is deemed by the Bank to be complete, and shall maintain a copy of such letter in the applicant's membership file. The Bank shall notify an applicant if the 60-day clock is stopped, and when the clock is resumed, and shall maintain a written record of such notifications in the applicant's membership file. * * *

* * * * *

8. Section 933.4 is amended by adding paragraph (d) to read as follows:

§ 933.4 Automatic membership.

* * * * *

(d) *Automatic membership, in the Bank's discretion, for certain consolidations.* (1) If a member institution (or institutions) and a nonmember institution are consolidated and the consolidated institution has its principal place of business in a state in the same Bank district as the disappearing institution (or institutions), and the consolidated institution will operate under the charter of the nonmember institution, on the effective date of the consolidation, the consolidated institution may, in the discretion of the Bank of which the disappearing institution (or institutions) was a member immediately prior to the effective date of the consolidation, automatically become a member of such Bank upon the purchase of stock in that Bank pursuant to § 933.20, provided that:

(i) 90 percent or more of the total assets of the consolidated institution are derived from the total assets of the disappearing member institution (or institutions); and

(ii) The consolidated institution provides written notice to such Bank, within 60 calendar days after the effective date of the consolidation, that it desires to be a member of the Bank.

(2) The provisions of § 933.25(d)(1)(i) shall apply, and upon approval of automatic membership by the Bank, the provisions of §§ 933.25(d)(2)(i), (e) and (f) shall apply.

9. Section 933.11 is amended by revising paragraphs (b)(3)(i)(B) and (b)(3)(i)(C) to read as follows:

§ 933.11 Financial condition requirement for applicants other than insurance companies.

* * * * *

(b) * * *

(3) * * *

(i) * * *

(B) *Nonperforming assets.* The applicant's nonperforming loans and leases plus other real estate owned, did not exceed 10 percent of its total loans and leases plus other real estate owned, in the most recent calendar quarter; and

(C) *Allowance for loan and lease losses.* The applicant's ratio of its allowance for loan and lease losses plus the allocated transfer risk reserve to nonperforming loans and leases was 60 percent or greater during 4 of the 6 most recent calendar quarters.

* * * * *

10. Section 933.14 is amended by removing the heading for paragraph (a), revising paragraph (a)(1), and removing and reserving paragraph (b), as follows:

§ 933.14 De novo insured depository institution applicants.

(a)(1) *Duly organized, subject to inspection and regulation, financial condition and character of management requirements.* An insured depository institution applicant whose date of charter approval is within three years prior to the date the Bank receives the applicant's application for membership in the Bank, is deemed to meet the requirements of §§ 933.7, 933.8, 933.11 and 933.12.

* * * * *

11. Section 933.15 is amended by adding new paragraph (c) to read as follows:

§ 933.15 Recent merger or acquisition applicants.

* * * * *

(c) *Makes long-term home mortgage loans requirement; 10 percent requirement.* For purposes of determining compliance with §§ 933.9 and 933.10, a Bank may, in its discretion, permit an applicant that, as a result of a merger or acquisition preceding the date the Bank receives its application for membership, has not yet filed a consolidated regulatory financial report as a combined entity with its appropriate regulator, to provide the combined pro forma financial statement for the combined entity filed with the regulator that approved the merger or acquisition.

* * * * *

§ 933.20 [Amended]

12. Section 933.20 is amended by removing the citation "§ 933.4(a)" in paragraphs (b)(1) and (b)(2) and adding the citation "§ 933.4(a) or (d)" in its place.

Dated: June 24, 1998.

By the Board of Directors of the Federal Housing Finance Board.

Bruce A. Morrison,

Chairman.

[FR Doc. 98–19912 Filed 7–24–98; 8:45 am]

BILLING CODE 6725–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0274]

Food Labeling; Petitions for Nutrient Content and Health Claims, General Provisions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of May 14, 1998 (63 FR 26717). The document amended FDA's regulations to define the conditions under which certain petitions for nutrient content and health claims shall be deemed to be denied and to codify the statutory timeframe within which the agency will complete rulemakings on such petitions. The document was published with some errors. This document corrects those errors.

DATES: Effective July 27, 1998.

FOR FURTHER INFORMATION CONTACT: Hilario R. Duncan, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8281.

In FR Doc. 98–12832, appearing on page 26717 in the **Federal Register** of Thursday, May 14, 1998, the following corrections are made:

1. On page 26718, in the first column, in the first paragraph under **Supplementary Information**, beginning in the thirtieth line, the phrase "to include the statutory language, i.e., 'Secretary' is replaced with 'FDA'" is corrected to read "by inserting the statutory language (with 'Secretary' replaced by 'FDA')".

§ 101.69 [Corrected]

3. On page 26719, in the first column, in paragraph (m)(3), in the fifteenth line, the phrase "denied without filing," is corrected to read "denied, without filing".

4. On page 26719, in the first column, in paragraph (m)(4)(iii), in the second line, the phrase "of the filing date" is corrected to read "of the date of filing".

§ 101.70 [Corrected]

5. On page 26719, in the second column, in paragraph (j)(3)(iii), in the second line, the phrase "of the filing date" is corrected to read "of the date of filing".

Dated: July 17, 1998.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 98–19895 Filed 7–24–98; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N–0176]

RIN 0910–ZA12

Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying certain previously unclassified preamendments pedicle screw spinal systems into class II (special controls) and reclassifying certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is taking this action because it believes that special controls would provide reasonable assurance of safety and effectiveness. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: August 26, 1998.

FOR FURTHER INFORMATION CONTACT: Aric D. Kaiser, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

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I. Background

The act (21 U.S.C. 331 *et seq.*), as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are: Class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA promulgates a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon "new information." The reclassification can be initiated by FDA or by the petition of an interested person. The term "new information," as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), in light of changes in "medical science." (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the "new information" on which any reclassification is based is required to consist "valid scientific evidence," as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) FDA relies upon "valid scientific evidence" in the classification process to determine the level of

regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

Consistent with the act and the regulation, FDA referred the proposed classification and reclassification of pedicle screw spinal systems to the Orthopedic and Rehabilitation Devices Panel (the Panel), an FDA advisory committee, for its recommendation on the requested classification and change in classification.

The Panel reviewed complication type and rate data present in the literature, a meta-analysis of the literature; a nationwide, retrospective Cohort study of patients treated with the devices;[1] and a review of publicly released investigational device exemptions (IDE) data from patients treated with pedicle screw spinal systems. The Panel recommended that the postamendments pedicle screw spinal systems intended to treat spinal fracture and degenerative spondylolisthesis of the thoracic, lumbar, and sacral spine, be reclassified from class III into class II.

In January, 1995, a manufacturer was able to demonstrate preamendments status for pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to spinal fusion in the treatment of grades 3 or 4 severe spondylolisthesis at the fifth lumbar-first sacral (L_5–S_1) spinal level. In an April 1995, homework assignment, FDA requested that the Panel recommend a classification for this unclassified preamendments device. The Panel recommended that the unclassified preamendments pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to spinal fusion in the treatment of grades 3 or 4 severe spondylolisthesis at the L_5–S_1 spinal level be classified into class II.

In the Federal Register of October 4, 1995 (60 FR 51946), FDA published a proposed rule to classify certain unclassified preamendments pedicle screw spinal systems (for use in certain types of severe spondylolisthesis) into class II, to reclassify certain postamendments pedicle screw spinal systems (for use in fracture and other conditions) from class III to class II, and to retain in class III other postamendments pedicle screw spinal systems. The proposed rule reflected FDA's belief that the clinical outcomes and complications described in the literature, clinical data, and MDR and MedWatch surveillance data bases,[2] described patient risks and benefits of pedicle screw spinal systems comparable to other class II spinal fixation devices and that special controls have been identified which would provide a reasonable assurance of safety and effectiveness, i.e., compliance with material standards, mechanical testing standards, biocompatibility standards, and special labeling requirements. Initially, FDA provided for interested persons to submit comments on the proposal by January 2, 1996. Subsequently, in the Federal Register of December 29, 1995 (60 FR 67345), FDA extended the comment period until March 4, 1996, in response to several requests for extension of the comment period.

FDA received 4,060 comments in response to the proposed rule. These comments were submitted by physicians, patients, lawyers, device manufacturers, trade associations, and other interested parties. The overwhelming majority of these comments were in favor of the proposed rule, although some comments were opposed to the proposed rule, and a few were both in favor of some aspects of the proposed rule and opposed to others.

In response to comments received on the proposed rule, FDA reanalyzed the meta-analysis of the literature, the Cohort study, and the publicly released IDE data for the indications of spinal fractures and degenerative spondylolisthesis. The reanalysis of the meta-analysis of the literature consisted of a review of the summary data and conclusions from the original, published analysis. The review of the Cohort study consisted of an audit (Ref. 1) of a structured sample of all 377 patients enrolled by 21 of the 314 participating surgeons, a reanalysis (Ref. 2) of all of the data from the audit, and a comparison to the data from unaudited surgeons. The Division of Bioresearch Monitoring (BIMO) in the Office of Compliance performed the data audit, while the Office of Device Evaluation and the Office of Surveillance and Biometrics performed the reanalyses. This audit found records were incomplete and investigators had not followed the protocol. In review of the audit, the agency concluded that the disparities and irregularities were consistent, with respect to both type and scope, with other audits of similar studies. After careful reanalysis of the potential impact of the "problem" records, the agency concluded that they could not account for the favorable results reported in this study.

The review of the Cohort study in the context of the audit findings yielded results that supported the safety and effectiveness of these devices. For spinal fracture, pedicle screw spinal systems presented risks and benefits that were comparable to those presented by nonpedicle screw instrumented spinal fusion. The devices used in the comparison group are class II medical devices. For spondylolisthesis, the review in the context of the audit findings described an advantage for pedicle screw spinal systems with regard to the clinical outcome parameters of fusion and improvement in neurological status when compared to noninstrumented spinal fusions. For the other parameters that were analyzed, e.g., pain, function, and reoperation rate, pedicle screw spinal systems did not always demonstrate an advantage compared to noninstrumented spinal fusion. When compared to instrumented spinal fusions, however, results among pedicle screw spinal system patients for these parameters were not statistically equivalent and not worse. Thus, FDA has concluded that the results from the review of the Cohort study are consistent with those reported in the literature and the publicly released IDE data.

The reanalysis of the meta-analysis of the literature describing experience with pedicle screw spinal systems in treating spinal fracture and degenerative spondylolisthesis found that pedicle screw spinal systems present risks and benefits that are comparable to those presented by nonpedicle screw spinal systems and noninstrumented spinal fusions. For degenerative spondylolisthesis, the reanalysis found

[1] The Cohort study was an open, nonblinded, historical Cohort study designed to recruit the maximum number of surgeons to provide clinical data on patients who had undergone spinal fusion surgery. Three hundred fourteen surgeons were recruited through announcements at professional society meetings and direct mailings to professional society memberships. Only clinical data from spinal fusion surgeries intended to treat degenerative spondylolisthesis or spinal trauma (fracture) that were performed between January 1, 1990, and December 31, 1991, were used in the analysis. This was done in an effort to maximize the number of patients with a minimum of 24 months followup. Data from 3,498 patients were collected.

[2] MDR and MedWatch data bases are two reporting systems that FDA uses to track adverse events, e.g., injuries, deaths, and device malfunctions, related to medical devices. The information consists of a combination of mandatory and/or voluntary adverse event reports from manufacturers, distributors, user facilities, healthcare professionals, as well as consumers.

that patient results with pedicle screw spinal systems were comparable to those with noninstrumented spinal fusions; it did not find a clinically significant improvement in results at followup obtained with instrumented spinal fusions over noninstrumented spinal fusions.

The reanalysis of the publicly available IDE data supports the Panel's recommendation for the classification and reclassification of pedicle screw spinal systems intended to treat spinal fractures and severe spondylolisthesis. It also supports the use of pedicle screw spinal systems when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion (pseudarthrosis).

When all of these data are viewed in conjunction with the medical literature and the MDR and MedWatch surveillance data, no new issues relating to the safety or effectiveness of pedicle screw spinal systems are raised. Therefore, the agency has concluded that these data provide valid scientific evidence that certain special controls in conjunction with the general controls applicable to all devices, will provide a reasonable assurance of the safety and effectiveness of pedicle screw spinal systems for L_5–S_1 use and for use at other levels for the treatment of degenerative spondylolisthesis with objective evidence of neurologic impairment.

The agency also reviewed whether the Panel was properly constituted. Investigation of alleged undisclosed and unwaived conflicts of interest held by Panel members found either no omissions of current interests or omissions of minor interests for all but one of the Panel members. The agency has concluded that the minor omissions are insignificant and do not constitute a financial conflict of interest that would credibly influence the members' actions in forming the Panel's recommendations.

The agency has found that one voting Panel member did have significant undisclosed financial conflicts. However, because the recommendation of the Panel, both in the July 23, 1994, meeting and on the subsequent homework assignment, was unanimous and this individual was not controlling, or unduly influential, of the votes of the other Panel members and was not necessary to constitute a quorum, after expunging the participation of this Panel member, FDA has concluded that this Panel, both in the meeting and on the subsequent homework assignment, was a valid scientific Panel to make recommendations to the agency.

The agency's reanalysis of these data has confirmed its original conclusion, reflected in the proposed rule, that the risks and benefits of pedicle screw spinal systems are comparable to those of other class II spinal fixation devices. FDA's decision to classify and reclassify these devices into class II is based upon valid scientific evidence establishing that the special controls described above, along with the general controls applicable to all devices under the act, provide a reasonable assurance of the safety and effectiveness of pedicle screw spinal systems.

III. Summary of the Final Rule

In this final rule, FDA is classifying into class II the unclassified preamendments pedicle screw spinal systems intended for treatment of severe spondylolisthesis (grades 3 and 4) of the L_5–S_1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. In addition, FDA is reclassifying into class II the postamendments class III pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Pedicle screw spinal systems intended for any other uses are considered postamendments class III devices for which premarket approval is required. The following four special controls apply to the devices being classified and reclassified into class II: (1) Compliance with materials standards, (2) compliance with mechanical testing standards of performance, (3) compliance with biocompatibility standards, and (4) adherence to labeling requirements.

IV. Proposed Rule Clarifications

FDA is taking this opportunity to clarify that neither well-controlled investigations nor valid scientific evidence relating to pedicle screw spinal systems intended for use in the cervical spine is available and, therefore, the safety and effectiveness of these devices for this intended use have not been demonstrated. As a result, pedicle screw spinal systems intended for use in the cervical spine are excluded from this classification and reclassification and are considered postamendments class III devices for which premarket approval is required.

In addition, although not specifically stated in the preamble to the proposed rule, all valid scientific evidence reviewed by the Panel and FDA were obtained from skeletally mature populations. To date, the safety and effectiveness of pedicle screw spinal systems in pediatric populations have not been demonstrated. Consequently, pedicle screw spinal systems intended for use in pediatric populations are postamendments class III devices for which premarket approval is required.

V. Analysis of Comments and FDA's Response

A. Issues Relating to the Recommendations of the Panel, FDA's Tentative Findings, and Summary of the Data Upon Which FDA's Findings Were Based

1. Several comments believed that valid scientific evidence was not presented to the Panel or used in formulating the proposed rule. These comments argued that only prospective, randomized, concurrently-controlled clinical trials constitute valid scientific evidence and that anything else is insufficient to support device reclassification.

FDA disagrees that only data from prospective, randomized, concurrently-controlled clinical trials can constitute valid scientific evidence. Although prospective, randomized, concurrently controlled clinical trials have the potential to produce the most convincing and reliable data, e.g., all sources of bias have been reduced to a minimum, such clinical trials are not the only type of study that can produce data adequate to support a determination that there is reasonable assurance that a device is safe and effective for its conditions for use. In fact, § 860.7(c)(2) defines valid scientific evidence as

> * * * evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under

its conditions of use. The evidence may vary according to the characteristics of the device, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use * * *.

From this definition, it is clear that there is a hierarchy of data that fits the definition of valid scientific and that, while well-controlled, prospective clinical trials are at the top of the hierarchy, they are not the only source of data that may support a determination regarding reasonable assurance of safety and effectiveness for purposes of classifying and/or reclassifying a device.

FDA also disagrees that valid scientific evidence was not presented to the Panel or used in support of the proposed rule. The three sources of data presented to the Panel and used in support of the proposed rule were: (1) Reformatted IDE data, (2) a meta-analysis of the literature, and (3) the Cohort study. The reformatted IDE data represent data from well-controlled investigations, while the meta-analysis of the literature and the Cohort study represent studies and objective trials without matched controls or well-documented case histories or reports of significant human experience. All three sources of data used in support of the classification and reclassification of pedicle screw spinal systems clearly fall within the definition of valid scientific evidence in § 860.7(c)(2).

2. One comment objected that, in addition to not being valid scientific evidence, the three sources of data, i.e., the meta-analysis of the literature, the reformatted IDE data and the Cohort study, were flawed.

The comment noted the following deficiencies with the meta-analysis:

- FDA previously determined that the available literature on pedicle screw spinal systems could not be used to support device reclassification.

FDA disagrees. FDA made that statement prior to January, 1993, when no adequate analysis of pedicle screw literature had been provided to the agency. FDA believes that, while individual literature articles describing the use of pedicle screw spinal systems would be insufficient to support reclassification of a device, group analysis of relevant articles may be adequate, especially where, as here, the group analysis is considered in conjunction with other supporting data. Furthermore, after noting the limitations of the individual studies reported in the literature, FDA concluded that the literature, taken as a whole and used in conjunction with the other sources of data, provided adequate information to support the reclassification of pedicle screw spinal systems intended to treat degenerative spondylolisthesis with objective evidence of neurologic impairment or spinal trauma.

- The meta-analysis is not an appropriate scientific technique, as applied to retrospective studies, because different studies have different parameters, biases, and strengths and weaknesses, all of which invalidate the pooling of data.

FDA disagrees. Although meta-analysis of literature may be less rigorous than other forms of scientific research, it still provides useful information. As discussed in section V.A.1 of this document, § 860.7(c)(2) defines "valid scientific evidence" to include many types of evidence of varying degrees of scientific rigor, including meta-analysis of literature. FDA participated in the development of the meta-analysis because the agency believed that this analysis could produce data meeting the definition of valid scientific evidence. Finally, the inherent limitations of a literature meta-analysis were discussed during the presentation of this analysis at the July 23, 1994, Panel meeting and in the preamble to the proposed rule (60 FR 51946).

- The meta-analysis actually lent support to the conclusion that pedicle screw fixation is less effective than other methods of treating degenerative spondylolisthesis and spinal fracture and that it may present the patient with more risks.

FDA disagrees. With respect to degenerative spondylolisthesis, there was no statistically significant difference in fusion rates between the control and the pedicle screw spinal system treatment groups. This is supportive data that clarifies the relative safety and effectiveness of pedicle screw spinal systems for this use. With respect to spinal fracture, significantly higher fusion rates were achieved in the pedicle screw spinal system treatment group than in the nonpedicle screw treatment groups. Thus, the meta-analysis confirmed the comparability of pedicle screw spinal systems to other class II devices used to treat spinal fracture in terms of safety and effectiveness.

- Fifty-five of the 58 studies in the meta-analysis were nonexperimental case-series having no validity as scientific evidence.

FDA disagrees. As discussed in section V.A.1 of this document, § 860.7(c)(2) states that valid scientific evidence may include "* * * well-documented case histories conducted by qualified experts * * *". Moreover, these well-documented case studies, which were conducted by qualified experts, were not the sole basis for the proposed classification/reclassification, but rather were considered in conjunction with data from various other sources.

The comment also noted the following deficiencies with the reformatted IDE data:

- The reformatted IDE data are not appropriate for classifying and reclassifying pedicle screw spinal systems because FDA previously had determined that these data could not support PMA's for these devices.

FDA disagrees in part. Prior to the August 20, 1993, Panel meeting, FDA had determined that data from individual IDE's were insufficient to support PMA's for those devices. Nevertheless, FDA recognized that the IDE data could still be valuable. In 1993, after receiving permission from nine IDE sponsors to publicly release and use their combined data, FDA determined that the data, reviewed as a whole, corroborated the results of other available data sets demonstrating the safety and effectiveness of pedicle screw spinal systems.

- The reformatted IDE data are inherently suspect because they (1) were reformatted by the sponsors and not by FDA, (2) were not provided for public scrutiny during the Panel meeting or at any other time, and (3) may have omitted poor results.

FDA disagrees that the reformatted data were suspect because they were reformatted by the sponsors and not by FDA. If IDE data are not properly formatted, FDA requests the sponsor to reformat its data for proper presentation to the agency. Furthermore, data in all marketing applications are formatted by the sponsor. Therefore, the simple fact that the IDE data were reformatted by the sponsor, not by FDA, does not make these data inherently suspect.

FDA also disagrees that the data were suspect because they were not presented for public scrutiny. For reclassification purposes, the valid scientific evidence upon which the agency relies must be publicly available § 860.5(e) (21 CFR 860.5(e)). Publicly available information excludes trade secret and/or confidential commercial information (21 CFR 20.61). IDE data typically contain trade secret and/or confidential commercial information and, consequently, ordinarily may not be publicly disclosed by the agency to support reclassification of a device (49 FR 17523 at 17531 and 17532, April 24, 1984). In fact, under § 812.38(a) and (b)(3) (21 CFR 812.38 (a) and (b)(3)), FDA generally does not acknowledge the existence of an IDE or disclose any

of the collected data. However, on August 13, 1993, after receiving permission from nine IDE sponsors to publicly release and use their combined data, the Commissioner of Food and Drugs (the Commissioner) exercised his discretionary authority under § 812.38(b)(2) and publicly released the data from nine IDE's, redacted of the identification of the IDE sponsors, institutional review boards, investigators, and patients. Although FDA did not make publicly available the unformatted data from the IDE studies or the identification of the IDE sponsors, institutional review boards, investigators or patients, the agency did provide the public with a detailed report of the combined IDE data (60 FR 51946 at 51961, ref. 173). This information was publicly available for analysis for more than 2 years before the publication of the proposed rule.

Finally, FDA disagrees that the data were suspect because they may have omitted poor results. Nine of fourteen sponsors provided their reformatted IDE data for analysis. There is no evidence that the five sponsors who did not offer their data did so because the data reflected adversely on the performance of their products. They may not have provided their data for any number of reasons. For instance, the sponsors may have believed that they had an inadequate amount of data to contribute to the effort or that the data may not have been in a readily accessible format. Regardless of the reason, the publicly available reformatted IDE data corroborate the results of other studies that demonstrate the safety and effectiveness of pedicle screw spinal systems. Specifically, the fusion rates, complication rates, and reoperation, revision, and removal rates attained under publicly available IDE studies were consistent with what was observed in the literature for such devices.

- The 12-month followup time period was inadequate to support any conclusions. Specifically, the comment stated that the Panel was not supplied with any information on the safety and effectiveness of these devices at more than 1 year following surgery. The comment continued that, without a minimum followup period of 2 years, it is impossible to make appropriate conclusions with regard to the longer-term safety and efficacy of these devices in accordance with accepted scientific convention.

FDA agrees that a 12-month followup time period would be inadequate and, therefore, selected a 24-month followup period for analysis. The 24-month followup period was also supported by the Panel and the literature. Contrary to the comment's statement, the Panel was supplied with information on the safety and effectiveness of pedicle screw spinal systems at more than one year following surgery. Spinal fusion generally occurs within 6 to 18 months after surgery. The majority of post-operative complications occur by the 18th month time point. For these reasons, FDA concluded that a 24-month followup period was adequate. FDA recognizes that not all of the reformatted IDE data were from a 24-month followup examination. However, a sufficient amount of data from a 24 month followup evaluation was examined for the Panel to make a recommendation about the reasonable assurance of safety and effectiveness of pedicle screw spinal systems for their class II intended uses.

- The comment stated that the lost-to-followup rate was too high.

FDA agrees that the lost-to-followup rate was high. FDA believes that patients with poor results tend to either return to their surgeons more frequently or go to other caregivers, attempting to receive the pain relief and return of function that they were originally seeking. It cannot be determined whether the patients who were lost-to-followup had acceptable results or went to other caregivers. However, FDA does not believe that this theoretical weakness in the data is of such a magnitude as to justify rejecting the studies. Thus, both the Panel and FDA believe that the lost-to-followup rate was not unacceptably high.

The comment noted the following deficiencies with the Cohort study:

- The Cohort study did not constitute valid scientific evidence.

FDA disagrees. As described above, valid scientific evidence encompasses a wide variety of data. The Cohort study satisfies the definition of valid scientific evidence because it consisted of data from well-documented case histories conducted by qualified experts and reports of significant human experience.

- The sample size and statistical power used in designing the Cohort study were inadequate and, therefore, no reliable conclusions can be drawn from the study. Another comment attempted to rebut this allegation.

FDA believes that the sample size and statistical power calculations that were performed in the Cohort study were accurate and appropriate and, consequently, that the conclusions drawn from the study had a sound basis.

- The Cohort study was biased and the data were not independently audited.

FDA disagrees. While the potential for bias exists in any study, it was of particular concern in the design of the Cohort study due to its retrospective nature. As described at the July 22, 1994, Panel meeting and in the preamble to the proposed rule (60 FR 51946 at 51954), various steps were taken to minimize the potential effects of bias due to the study design. In addition, contrary to the comment's assertion, there was a review of the data by an independent auditor and a subsequent FDA BIMO audit and review. The review by the independent auditor was not extensive and no definitive conclusions can be drawn from its analysis of the Cohort study data. Although both audits uncovered instances of protocol departures, recordkeeping inconsistencies, or a lack of clear understanding or unfamiliarity with the protocol requirements on the part of a participating surgeon, these inconsistencies and protocol departures did not affect the reliability of the data. For example, one type of reported protocol recordkeeping departure was that some data forms were incomplete. In some instances, the data forms simply omitted the patient's weight, but not the patient's fusion status. The absence of that piece of information, while rendering the form incomplete, clearly did not affect the clinical outcome analysis. A more significant protocol departure related to the inclusion and analysis of data from patients whose diagnosis did not meet patient eligibility criteria. However, no obvious pattern that would improve overall patient outcomes was identified because these departures included indications for surgery both more and less severe than those targeted by the protocol.

The data retrieved from the BIMO audit were analyzed to determine if the major outcomes of the Cohort study were significantly different (statistically or clinically) with or without the presence of protocol departures, with or without the presence of recordkeeping inconsistencies, or at sites where the participating investigator, based on the audit, was or was not familiar with the protocol requirements. While some differences were noted between sites with and without inconsistencies, in most cases, these were not statistically significant and no consistent or clinically relevant patterns were noted. The analysis of the audited data did not find systemic bias in either the conduct of the study or its reported results. None of the analyzed audit data contradicted the published results of the Cohort study. Finally, the data audit analysis concluded that the audited data were consistent with other publicly available

data and that the Cohort study data could be used as part of a larger body of data to support the classification and reclassification of pedicle screw spinal systems.

- Documents relating to the Cohort study were destroyed.

FDA disagrees. All Cohort study data were maintained in a master file. Only extra copies of information were destroyed in an effort to maintain the confidentiality of the identities of the participating surgeons and their patients. In addition, as a matter of course, FDA routinely assists Panel members in destroying copies of documents containing trade secret and/or confidential commercial information that they have received from FDA as preparatory material for a Panel meeting.

- Certain FDA employees had inappropriate relationships with pedicle screw manufacturers and others involved in the Cohort study.

This allegation, which has two parts, is unfounded. FDA performed an internal affairs investigation of the employees about whom allegations were made. This investigation showed that their attendance at a health professional meeting was properly paid for by the agency, not subsidized by the regulated industry. Also in the case of one employee, FDA's investigation showed that negotiations regarding outside employment with the regulated industry had been properly reported to the employee's supervisors and immediate colleagues in all instances.

- The Scientific Committee and the Spinal Implant Manufacturers Group (SIMG) were not independent.

FDA disagrees. The preamble to the proposed rule and the subsequent correction (60 FR 51946 and 60 FR 66227, December 21, 1995) described the makeup of the Scientific Committee and SIMG. SIMG consisted of representatives of manufacturers who provided funding to support a nationwide analysis of clinical data relating to pedicle screw spinal systems. SIMG did not participate in the design of the study. The study was designed and implemented by the Scientific Committee with input from FDA as to the feasibility of various clinical study design parameters. The Scientific Committee was formed by five professional medical societies. Although two SIMG representatives were part of the Scientific Committee, they were nonvoting members. Furthermore, even if there were not independence between the Scientific Committee and SIMG, there is no requirement that clinical studies be performed by parties independent of device manufacturers. In fact, FDA routinely receives and relies upon studies performed by manufacturers.

3. Several comments contended that financial conflicts of interest were present in the three sources of data relied on by FDA to support the classification/reclassification of pedicle screw spinal systems. The comments claimed that, in the meta-analysis of the literature, the authors of the individual articles had financial conflicts of interest due to their relationships with device manufacturers. With respect to the analysis of the reformatted IDE data and the Cohort study, the comment stated that the IDE investigators and Cohort study participants had significant financial interests in the companies whose devices they were using and, therefore, had a strong financial incentive to report only successful results. Similar objections were raised about the authors of the 206 articles cited as constituting the body of medical literature bearing on pedicle screw fixation. The comments stated that almost all of the surgeons who authored these articles failed to disclose their financial connections to manufacturers. The comments stated that such interests raise serious concerns about researchers' motivation to perform the research, the propriety and importance of research questions and research designs, the adequacy of protection of human subjects, lack of bias, and veracity in collecting and analyzing the data and reporting the results.

FDA recognizes that some of the clinical investigators involved in the three sources of data, as well as some of the authors of the 206 literature articles used to support classification and reclassification of pedicle screw spinal systems, had financial interests in the devices they were studying. FDA disagrees, however, that these financial interests resulted in biased or unreliable data. Regardless of the source of the data, the meta-analysis, the reformatted IDE data, the Cohort study, or the collection of cited literature, the conclusions were similar, i.e., that pedicle screw spinal systems are safe and effective for the uses examined. Because of this, even if financial conflicts of interest were present, they did not affect the resulting data and the conclusions. Moreover, the agency has concluded that, despite the failure to disclose the financial interests of clinical investigators, the sponsors of these investigations and/or articles took reasonable steps to minimize potential bias.

Furthermore, the fact that some spine surgeons were compensated by industry for research or consulting services, or were reimbursed for expenses incurred in connection with continuing medical education courses, did not affect the validity of any of the data. Moreover, many of the grants to support research were made directly to university accounts for general research and development, not directly to individual investigators. Consequently, the existence of a financial relationship between some surgeons and manufacturers did not necessarily result in biased case selection or reporting. Finally, FDA notes that research used to support a medical device marketing application has always been supported by the sponsor of the device and there is neither an expectation of nonsupport nor a requirement of disclosure of such support.

4. Several comments stated that pedicle screw spinal systems present different safety and effectiveness issues than do either class II spinal devices using hooks and/or wires or noninstrumented spinal fusions. One comment identified the following areas of concern as having the potential of presenting unreasonable danger for patients:

(1) Difficulty in placing screws completely within the walls of the pedicle;

(2) Inability to determine screw placement postoperatively using radiographic techniques;

(3) Damage to nerve tissue as a result of transient contact with a screw during screw placement;

(4) Nerve root damage (irritation or compression) as a result of screw malposition;

(5) Device failure;

(6) Loss of bone density as a result of stress shielding;

(7) Foreign body tissue response;

(8) Crevice corrosion;

(9) Fretting corrosion;

(10) Fibrosis;

(11) Bone fracture, particularly that of the pedicles;

(12) Nerve root or spinal cord compression as a result of fibrosis or foreign body tissue response;

(13) Chronic irritation;

(14) Spine destabilization possibly leading to nonunion;

(15) Increased venous pressure as a result of blocked venous channels within the bone;

(16) Increased risk of infection;

(17) Loss or decrease of sensory and/or motor function;

(18) Loss of bowel or bladder control; and

(19) Loss of sexual function.

FDA agrees that pedicle screw spinal systems have some potential risks that

are different from those of other class II spinal devices. However, the majority of the potential risks presented by these devices, e.g., bone fracture, foreign body tissue response, loss or decrease in sensory and/or motor function, and device failure or corrosion, are also associated with class II spinal devices which use hooks and/or wires for the same intended uses. Similarly, potential risks such as nonunion and instability are also associated with noninstrumented spinal fusions. Moreover, as described in the proposed rule, the incidence of these adverse outcomes is no greater when a pedicle screw spinal system is used than when other types of spinal fusions, instrumented and noninstrumented, are performed in appropriately selected patients (60 FR 51946 at 51957). Finally, FDA believes that the potential risks that are unique to pedicle screw spinal systems, e.g., difficulty in placing screws completely within the walls of the pedicle, inability to determine screw placement postoperatively using radiographic techniques, damage to nerve tissue as a result of transient contact with a screw during screw placement, and nerve root damage (irritation or compression) as a result of screw malposition, can be adequately addressed by the identified special controls and proper surgeon training and surgical technique.

5. One comment asserted that the supposed advantages of pedicle screw spinal systems are largely theoretical. The comment stated that, while some investigators have shown that instrumented fusions increase the likelihood of obtaining a solid fusion, others have demonstrated that there is no significant increase in fusion rates performed with instrumentation as compared with noninstrumented fusions performed with bone graft alone.

FDA agrees that the data do not always support the theoretical advantages of using pedicle screw spinal systems compared to alternate methods of achieving spinal fusion. However, in forming its recommendations, neither FDA nor the Panel is required to analyze the theoretical behavior of a given device. It is only required to determine whether the data demonstrate that there is a reasonable assurance of safety and effectiveness for its intended uses.

6. The same comment stated that spinal fusion surgery is usually performed because of the belief that spinal instability results in pain. The clinical indicators used to determine which patients have spinal instability and, therefore, are candidates for spinal fusion surgery, are not clearly defined and are often not measurable. Because the results of spinal fusion surgery are also dependent on measurements of instability, a determination of success is difficult, if not impossible.

FDA agrees that the methods used to measure instability are not perfect and that several working definitions of instability exist. Nevertheless, instability is measurable. In addition, the same instability definitions and measurement techniques are used in determining how a patient is to be treated, i.e., with pedicle screw spinal systems, class II spinal devices using hooks and/or wires, or noninstrumented fusions. FDA agrees that the determination of success of spinal fusion surgery is often difficult, but disagrees that it is impossible to determine. In fact, the success rates from using the three treatment methods described above have been determined and found to be reasonably equivalent (60 FR 51946 at 51954).

7. Three comments questioned the most appropriate classification for pedicle screw spinal systems. One comment proposed that pedicle screw spinal systems be classified into class I and two comments suggested placing them in class III.

FDA disagrees. Based on the available information, both the Panel and FDA concluded that general controls alone are not sufficient to provide a reasonable assurance of the safety and effectiveness of pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion attempts (pseudarthrosis). The Panel and FDA also concluded that premarket approval was not necessary to provide such assurance. Both the Panel and FDA identified the potential risks associated with the use of these devices and concluded that sufficient information exists to establish special controls to provide reasonable assurance of their safety and effectiveness. As a result, FDA is classifying and reclassifying these devices in class II.

8. A comment believed that classification and reclassification of pedicle screw spinal systems into class II is inappropriate because FDA was correct in its prior determination that basic principles of physiology, anatomy, biology, and biomechanical engineering demonstrate that pedicle screw spinal systems present a serious risk of injury to the spinal nerves, nerve roots, and surrounding vascular structures, and increase the risk of pseudarthrosis. According to this comment, these risks are not posed by existing spine fusion technology and pedicle screw spinal systems are of questionable efficacy in comparison to existing methodologies of treatment.

FDA disagrees. FDA did not determine that basic principles of physiology, anatomy, biology, and biomechanical engineering demonstrate that pedicle screw spinal systems present a serious risk of injury. Rather, in 1984, FDA determined that a multiple component device system intended for attachment to the spine via the pedicles was not substantially equivalent to any legally marketed predicate device, in accordance with section 513(i)(1) of the act. FDA's decision was based on the fact that: (1) The sponsor did not identify a legally marketed preamendments device incorporating pedicle screw components and (2) the device posed potential risks not exhibited by other legally marketed predicate spinal fixation systems, such as a greater chance of neurological deficit due to imprecise screw placement or the event of a screw failure; pedicle fracture during placement of screws; soft tissue damage or inadequate fusion due to bending or fracture of device components; and greater risk of pseudarthrosis due to instability of the device design (60 FR 51946 at 51947). As stated previously, FDA believes that the risks to health presented by pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion (pseudarthrosis) can be adequately addressed by special controls. Consequently, FDA is classifying and reclassifying these devices into class II.

9. One comment argued that manufacturers of pedicle screw spinal systems are seeking to have FDA down classify the device into class II because the manufacturers are unable to prove that pedicle screws are safe and effective for posterior implantation into the spine.

FDA disagrees. First, contrary to the comment's statement, this classification and reclassification proceeding was

initiated by FDA; it is not in response to a petition for reclassification. Second, under section 513 of the act, devices are classified/reclassified into one of three classes based on reasonable assurance, not "absolute proof," of their safety and effectiveness. Contrary to the comment's statement, it was not pedicle screw spinal system manufacturers, but rather the Panel and FDA, that concluded that pedicle screw spinal systems should be classified and reclassified into class II because they determined that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness, general controls alone are insufficient to provide such assurance, and there is sufficient information to establish special controls to provide such assurance.

10. According to another comment, by classifying and reclassifying pedicle screw spinal systems into class II, FDA is acknowledging that there is no need for the manufacturers of pedicle screw spinal systems to prove that the devices are safe and effective.

FDA agrees. The agency has determined that sufficient information exists to establish special controls to provide reasonable assurance of the safety and effectiveness of pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). FDA has determined that premarket approval is not necessary to provide such assurance.

B. Issues Relating to Information Published in the 1994 Supplementary Issue of the Journal Spine (vol. 20S, 1994)

11. One comment objected that the manner in which the Scientific Committee communicated to the public the results of the Cohort study and related meta-analyses of the literature lacked scientific integrity. According to the comment, the articles were not peer reviewed, but rather they were accepted for publication solely by the Editor-in-Chief of the peer-reviewed journal Spine. The comment contended that publication of the articles without peer review prevented the studies from being submitted to the usual critical scrutiny of any peer review in the future.

While the articles describing the Cohort study and related meta-analysis were not peer-reviewed in the usual manner, they were subjected to a review process and published in an October 19, 1994, Special Supplement of *Spine*. The editorial at the beginning of the supplement states that,

> The members of the Scientific Committee and editors of *Spine* felt it important that presentations from the (July 1994, Panel) meeting be available to the readers of *Spine* in an expedited manner. The articles have been reviewed by the Scientific Committee, but have not gone through the normal review process of the Spine Editorial Board. However, it has been prepared, written, re-written, and critiqued by all members of the Scientific Committee and member of the Spine Editorial Board, as well as presented in an open public forum to the scientists who comprised the Orthopedic and Rehabilitation Devices Advisory Panel to the FDA. Weaknesses and strengths of the studies are readily apparent and have been addressed by each author, as well as in my summation.

12. The comment also stated that the articles should not have been accepted for publication because the editorial policy of the journal requires that the recommended minimum followup period for studies should be 24 months.

FDA disagrees. Under *Spine* policy, a sufficient length of time for followup of articles is necessary for publication. While the recommended time period for surgical procedures is 2 years, the policy does not state that studies with less than 2-year followup will not be published.

C. Issues Relating to the January 1995, 510(k) Substantial Equivalence Determination for a Pedicle Screw Spinal System Intended for Severe Spondylolisthesis

13. A comment stated that the circumstances surrounding the first 510(k) clearance of a pedicle screw spinal system in January 1995, were highly suspect because, until that time, FDA consistently had found bone screws for use in the pedicles to be not substantially equivalent to the identified predicate device, the lag screws used by Dr. Harrington. The comment also stated that the lag screws were manufactured as a custom device and used under a funded research grant and, therefore, were not in commercial distribution prior to 1976.

FDA disagrees. The 510(k) applicant provided new evidence documenting, for the first time, that: (1) A medical device company had manufactured and shipped in interstate commerce bone (lag) screws intended for use in the pedicles of the spine prior to May 28, 1976; (2) the devices were marketed to physicians, including, but not limited to, Dr. Harrington; and (3) the devices were not used solely for research purposes.

14. The same comment also argued that the two devices had different technological characteristics because the lag screws attach to fixation constructs by wires whereas the pedicle screws attach directly to plates or rods. The comment concluded that the applicant could not demonstrate that its device did not raise different questions of safety and effectiveness compared to the predicate device because the lag screws were used on an extremely limited basis and were abandoned because of a lack of effectiveness.

FDA disagrees. The presence of technological differences does not preclude a finding of substantial equivalence under section 513(i) of the act. In accordance with section 513(i)(1)(A)) of the act and § 807.100(b)(2)(ii)(B), for purposes of determining substantial equivalence, manufacturers have to demonstrate that their device (1) Has the same intended use as a predicate device and (2) if it has different technological characteristics than the predicate device, that the device is as safe and as effective as a legally marketed device, and it does not raise different questions of safety and effectiveness. The relative extent of use of one device compared to another is not relevant.

In making its decision, FDA analyzed all of the data provided by the sponsor. This included reports describing the clinical and mechanical behavior of the device, in addition to affidavits. From these data, the Panel and FDA determined that the complications were similar to those of a predicate device and that the technological differences raised no new questions relating to safety or effectiveness.

15. The comment also stated that FDA's reversal of its position with regard to the preamendments status of pedicle fixation devices was insupportable and a clear violation of its own regulations. Specifically, the comment stated that the agency took the unprecedented step of determining the existence of commercial distribution based solely on the affidavit of a former employee of a pedicle screw manufacturer. According to the comment, this was not sufficient evidence to demonstrate that the device was in commercial distribution prior to 1976.

The use of affidavits to document the preamendments status of a predicate device is not unprecedented. In fact, FDA routinely allows affidavits to be used to document the preamendments status of a device. FDA recognizes that obtaining labeling, advertising, and

other records concerning the marketing status of a device dating back more than 20 years is often difficult, if not impossible. Therefore, FDA allows sponsors to rely on alternative methods to demonstrate interstate commerce. Moreover, contrary to the comment's statement, the preamendments status of the device was established by much more than a single affidavit. In fact, the 510(k) submission contained several affidavits from individuals other than the sponsor, correspondence, and other documents, e.g., shipping documentation, that demonstrated the preamendments status of the Harrington lag screws for use in a limited area of the spine, i.e., L_5–S_1, and for a particular indication, i.e., severe spondylolisthesis.

16. Finally, the comment alleged that FDA changed its regulatory position regarding pedicle screw spinal systems after it made a "deal" with the affected industry on or about June 15, 1993. The comment stated that, if manufacturers funded a retrospective study, FDA provided assurances that it would (1) Refrain from taking criminal, regulatory, or other legal actions against them; and (2) reclassify pedicle screw spinal systems without requiring prospective studies and without regard to the quality of any of the retrospective data.

FDA disagrees. Prior to its January 1995 510(k) decision and the publication of this classification and reclassification regulation, FDA consistently maintained that pedicle screw spinal systems, except when intended for a very limited use, were class III devices requiring premarket approval. The purpose of FDA's meeting with the affected industry and the orthopaedic professional societies was to request that these groups submit to the agency all available clinical data on the performance of pedicle screw spinal systems. FDA, at no time, agreed to change the regulatory status of these devices without regard to the quality of the data or to refrain from taking regulatory action if a retrospective study were funded.

D. Issues Relating to Misstatements or False Statements Appearing in the Proposed Rule

17. One comment alleged that the statement in the preamble to the proposed rule regarding the conclusion of the August 20, 1993, Panel meeting, i.e., that pedicle screw spinal systems appear to be safe and effective when used as adjuncts to spinal fusion procedures, was inaccurate.

FDA disagrees. The description of the August 20, 1993, Panel meeting contained in the preamble to the proposed rule states that the Panel concluded that mechanical testing data demonstrated that pedicle screw spinal systems exhibit adequate mechanical strength, rigidity, and fatigue resistance (60 FR 51946 at 51948).

18. The same comment alleged that neither the transcripts from the two Panel meetings, nor the summary in the preamble to the proposed rule accurately reflected the Panel's conclusions regarding potential risks to health associated with the use of the pedicle screw spinal system, special controls, development of performance standards, mechanical performance of the device, and the Panel members' own personal knowledge of, and clinical experience with, the device.

FDA disagrees that the transcripts of the two Panel meetings did not accurately reflect the Panel's conclusions. The proceedings from the two meetings were verbatim stenographic transcripts of oral testimony prepared by an independent transcriptionist. FDA also disagrees that the preamble to the proposed rule did not accurately reflect the Panel's conclusions. The preamble to the proposed rule mirrors the transcripts of the meetings.

19. The same comment alleged that the Panel members (voting members and voting/nonvoting consultants), who met July 23, 1994, had inappropriate relationships, e.g., financial arrangements and *ex parte* communications, with pedicle screw spinal system manufacturers and had participated substantially in the design of the Cohort study, thereby compromising their impartiality.

FDA disagrees in part. While it is expected that Panel members, who are experts in a given field, will often have some financial interests related to that field (e.g., certain arrangements with a manufacturer (designing a device sold by a particular manufacturer; serving as a consultant to a manufacturer; or receiving funding, directly or indirectly, for research), the required FDA conflict-of-interest questionnaire (FDA From 2725a) enables FDA to identify conflicts-of-interest with a device or manufacturer that all substantial and/or material to the subject of a particular Panel meeting, and thereby facilitates the disclosure and possible waived for the Panel member(s) in order to permit their participation in Panel deliberations.

FDA performed an internal affairs investigation of the Panel members regarding conflicts and ex parte communications . The agency reviewed whether the Panel was properly constituted. Investigation of alleged undisclosed and unwaived conflicts of interest held by Panel members found minor disparities and reporting omissions for two voting Panel members and one nonvoting consultant. The agency has concluded these disparities and omissions were insignificant and did not constitute financial conflicts of interest that would credibly influence their recommendations.

The agency has found that one other voting Panel member had significant undisclosed financial conflicts. However, because the recommendation of the Panel, both in the July 23 meeting and on the subsequent homework assignment, was unanimous and this individual was not controlling, of or unduly influential of, the votes of the other Panel members and was not necessary to constitute a quorum, after expunging the participation of this Panel member, FDA has concluded that this Panel, both in the meeting and on the subsequent homework assignment, was a valid scientific Panel for purposes of making recommendations regarding classification and reclassification.

E. Issues Relating to FDA's Issuance of Regulations

20. One comment argued that, in issuing a classification regulation, FDA may not rely on a scientific study unless it makes publicly available all study data, as well as the identities of the persons who furnished the data. The comment cited 21 CFR 10.20(j), 20.63, and 860.5 as authority. In addition, the comment objected that FDA refused to disclose the identities of the physician-investigators who contributed data to the Cohort study, did not disclose the reformatted IDE analysis, the IDE data, or internal information bearing on the reliability of such data.

FDA disagrees. Although the agency did not disclose the raw IDE or the Cohort study data, or the identities of the clinical investigators who furnished such data to the agency, FDA did provide a detailed analysis of the Cohort Study, the clinical data released by the IDE sponsors, and the meta-analysis (60 FR 51946 at 51960–51962; refs. 51, 65, 66, 119, and 201). FDA believes these publicly available data not only satisfy the requirements under the statute, but provide the public with at least the level of detailed information as that usually available from published reports regularly relied upon to support classification and reclassification.

F. Response to Comments Which Contained Clinical Data

21. Several comments provided clinical information to support the comment's position on the proposed

rule. The submitted clinical information consisted of literature articles describing clinical trials and two questionnaires, a surgeon/patient questionnaire and a lawyer/client questionnaire. The surgeon/patient questionnaire provided mixed results, i.e., some patients were satisfied with their clinical results and others were not satisfied, whereas the lawyer/client questionnaire provided only negative results, i.e., all clients were dissatisfied with their results.

The majority of the articles submitted or referenced in these comments were already reviewed by the Panel and used as part of the basis for their recommendation to classify and reclassify pedicle screw spinal systems into class II. The remainder of these articles were not reviewed by the Panel because they were published after the July 1994, Panel meeting. As described in section V.M of this document, these articles did not raise new issues or concerns relating to the safety or effectiveness of pedicle screw spinal systems. Because of the inherent bias present in the questionnaires, e.g., the total number of questionnaires sent to patients/clients in relation to the number returned and the number included as part of the comment are unknown, the data cannot be used in analyzing the success rate of pedicle screw spinal systems. These data can be used, however, as part of an analysis of the complications. As such, the questionnaires did not describe any complications or raise any issues that had not already been reviewed by the Panel and FDA in making their determinations with respect to the classification and reclassification of pedicle screw spinal systems.

G. Requests for Additional Pedicle Screw Clinical Trials and Data Analyses

22. Ten comments requested that FDA require submission of additional data before finalizing the classification and reclassification of pedicle screw spinal systems. The comments recommended that the following types of data be required: Studies to analyze the long-term effects of the device, continuing evaluations, collections of data using a recommended data report form for obtaining data directly from patients rather than from their surgeons, studies similar to the Cohort study but with larger sample sizes, comprehensive reviews of the literature, and comprehensive reviews of all data. In addition, one comment suggested that FDA was reclassifying these devices without reviewing clinical trial data documenting their safety and effectiveness.

FDA disagrees. As previously explained, under section 513 of the act, devices are classified and reclassified into one of three classes based on *reasonable assurance*, not *absolute proof*, of their safety and effectiveness. The Panel recommended, and FDA concurred, that pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of degenerative spondylolisthesis and spinal fractures be classified and reclassified into class II because they determined that premarket approval is not necessary to provide reasonable assurance of safety and effectiveness; general controls alone are insufficient to provide reasonable assurance of the device's safety and effectiveness; and there is sufficient information to establish special controls to provide such assurance. FDA also determined that, when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion attempts (pseudarthrosis), special controls would provide a reasonable assurance of safety and effectiveness. The Panel and FDA reached these conclusions only after considering a substantial amount of valid scientific evidence. As described previously, this valid scientific evidence consisted of clinical data collected from three sources—data from IDE's (the reformatted IDE data), data from the literature (the meta-analysis), and data collected directly from surgeons (the Cohort study). The IDE data was prospective clinical data collected under the protocols of FDA-approved clinical trials. The meta-analysis was retrospective clinical data published in peer-reviewed literature. The Cohort study consisted of retrospective nationwide clinical data collected from surgeons of various experience levels from a patient population that was homogeneous in terms of diagnosis, but mixed in terms of severity of disease. In addition to these sources of clinical data, MDR and MedWatch reports were analyzed for device problems. FDA does not believe that it is necessary to require submission of additional data, to conduct additional studies, or to re-review the literature before classifying and reclassifying these devices. FDA does agree, however, that the longer-term performance of these devices is not fully characterized. For this reason, postmarket surveillance (PMS) studies will be required.

H. Issues Relating to Indications for Use

Over 200 comments addressed the various intended uses of pedicle screw spinal systems.

23. Twenty-three comments questioned FDA's authority to regulate the indications for use of medical devices. They believed that, although restrictions on the use of pedicle screw spinal systems may be appropriate, this aspect of medical device regulation is outside the scope of FDA's authority and should be decided by professional societies, peer review groups, credentialing organizations, and hospitals. One comment stated that FDA should regulate the safety of medical devices only for certain indications. Several other comments stated that there should be no restrictions on the use of pedicle screw spinal systems. All of these comments argued that FDA's actions interfered with the practice of medicine.

FDA disagrees. In determining whether or not a device is safe and effective, FDA first considers the intended uses for the device. Spinal fusion is not a medical indication but a treatment option which can be approached in a variety of ways. It is one of the desired outcomes from using pedicle screw spinal systems. FDA recognizes, however, that fusion in and of itself is not what patients with spinal disease are seeking. They wish to be relieved of their symptoms, have their objective impairment alleviated, and avoid more symptomatic or functional impairment. Devices that share the same outcome for a given condition do not necessarily share the same benefits and risks. One of the aspects in determining if a device may be legally marketed is deciding, based on the available data, what the appropriate indications are. A device may be an appropriate treatment for one indication, but not for another. In addition, to understand the evidence supporting a device's safety and effectiveness, a distinct medical condition requiring treatment must be identified. In reviewing the valid scientific evidence, the Panel recommended and FDA found that the use of pedicle screw spinal systems were safe and effective only for certain indications. The valid scientific evidence did not support unrestricted use of the device.

In determining the safety and effectiveness of a device for the purpose

of classification or reclassification, both the Panel and the agency are to consider the persons for whose use the device is represented or intended, the conditions of use for the device, and the probable benefit to health from the use of the device weighed against any probable injury or illness from such use (§ 860.7(b)). The device is to be considered, not in a vacuum, but rather in the context of the patient population for whose use it is intended. Accordingly, there is reasonable assurance that a device is safe when it can be determined that the probable benefits to health from use of the device for its intended uses and conditions of use outweigh any probable risks (§ 860.7(d)(1)). The benefits and risks to health presented by a device depend, in large part, on the specific use for which the device is intended. There may be reasonable assurance that a device is safe for some, but not other, uses. Similarly, there is reasonable assurance that a device is effective when it can be determined that, "in a significant portion of the target population," the use of the device for its intended uses and conditions of use will provide clinically significant results (§ 860.7(e)(1) (emphasis added)). It is clear, then, that when making determinations regarding the classification or reclassification of a device, it is appropriate for the agency to consider the specific intended uses of a device, including the specific patient populations for which it is intended. Consequently, the agency disagrees that it does not have authority to regulate the indications for use for pedicle screws and that it is interfering with the practice of medicine.

24. One comment objected that FDA's proposed reclassification improperly exceeded the recommendations of the Panel.

The Panel determined that the evidence demonstrated a reasonable assurance of safety and effectiveness of pedicle screw spinal systems intended for two severe and diagnostically distinct indications—fracture and degenerative spondylolisthesis. Accordingly, the Panel recommended that the device be classified and reclassified into class II only when intended for these uses. FDA proposed that the device also be classified and reclassified into class II when intended for the following acute and chronic mechanical instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion (pseudarthrosis). FDA disagrees that it exceeded its authority. 21 CFR 860.3(h) defines a classification panel as an advisory committee established by the Commissioner for the purpose of making "recommendations" (emphasis added) to the Commissioner on the classification/reclassification of devices. These recommendations are designed to assist the Commissioner in the proper classification and/or reclassification of a device. While FDA usually follows a Panel's recommendations, it is not required to do so.

As stated in the preamble to the proposed rule, FDA believes that sufficient clinical data exist to classify and reclassify into class II pedicle screw spinal systems intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion (pseudarthrosis). The medical literature and data from IDE clinical investigations provide adequate evidence that the device can safely and effectively stabilize the spine and maintain spinal alignment while fusion takes place. The risks associated with the use of pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of these acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine are similar to those associated with other class II spinal implant devices, such as those classified in § 888.3050 (21 CFR 888.3050) (60 FR 51946 at 51956).

25. Several comments advocated classifying and reclassifying into class II pedicle screw spinal systems intended for additional uses, including degenerative disc disease, degenerative deformities, stenosis, iatrogenic instability and previous multiple laminectomies, facet joint disease, pseudospondylolisthesis, low back pain, disc herniation, arthritis, and osteomyelitis.

FDA believes that valid scientific evidence does not currently exist to support classifying and reclassifying into class II pedicle screw spinal systems when intended for the indications listed above. Neither the literature nor the clinical data establish the safe and effective use of pedicle screw spinal systems for degenerative disc disease, degenerative deformities, stenosis, iatrogenic instability and previous multiple laminectomies, facet joint disease, pseudospondylolisthesis, low back pain, disc herniation, arthritis, or osteomyelitis. As stated in the preamble to the proposed rule, FDA has determined that, when intended for use in conditions not categorized as acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, premarket approval is necessary to ensure the safety and effectiveness of the device (60 FR 51946 at 51957). FDA-approved clinical trials for some of these indications are ongoing. When data from these or other studies become available for any of the indications described above, they may be submitted in either an application for premarket approval or reclassification petition.

26. Eight comments advocated adding specific pediatric indications and one comment advocated adding general pediatric use to the list of indications. The specific indications included myelodysplasia, spina bifida, cerebral palsy, muscular dystrophy, myelomeningocele, and congenital subluxation.

FDA disagrees. As stated previously, all valid scientific evidence reviewed by the Panel and FDA were obtained from skeletally mature populations. To date, the safety and effectiveness of pedicle screw spinal systems in pediatric populations have not been demonstrated. Therefore, this patient population is excluded from this classification and reclassification. When intended for use in pediatric populations, pedicle screw spinal systems are considered postamendments class III devices for which premarket approval is required.

27. Several comments addressed ways in which FDA should further limit the indications for use of pedicle screw spinal systems, such as by including specific patient evaluation criteria or by specifying the severity of the condition.

FDA disagrees that these actions are necessary. FDA classifies devices based upon, among other things, patient selection, not individual patient management. FDA notes that it is the responsibility of individual surgeons to determine the appropriateness of using a specific medical device for a given patient.

28. Four comments stated that pedicle screw spinal systems should not be allowed on the market for any use. Another comment requested that an additional Panel meeting be convened to discuss further restricting the intended uses of pedicle screw spinal systems.

FDA disagrees. After reviewing all available data and information, FDA believes that there is reasonable assurance that pedicle screw spinal systems are safe and effective for certain intended uses. FDA does not believe that pedicle screw spinal systems present a substantial deception or an

unreasonable and substantial risk of illness or injury. Consequently, FDA does not believe it would be appropriate to ban them under section 516 of the act (21 U.S.C. 360f).

FDA also disagrees that an additional Panel meeting is necessary because the relevant available data have been reviewed.

I. Issues Relating to Special Controls

29. One comment asserted that PMS studies cannot legally be required for pedicle screw spinal systems because the devices are not intended for use in supporting or sustaining life and pose risks no different from those associated with the use of other preamendments class II spinal fixation devices.

FDA disagrees. Under section 522 of the act (21 U.S.C. 360l), postmarket surveillance is required for certain devices and may be required for any device for which FDA determines that it is necessary to protect the public health or to provide safety or effectiveness data for the device. FDA has determined that PMS studies are necessary to provide longer-term data on the safety and effectiveness of pedicle screw spinal systems.

Although originally proposed as a special control, FDA has determined that PMS studies are best imposed by order in the substantial equivalence determination letter for each device. This will preserve the discretionary nature of the PMS studies and will allow the agency to more easily remove the requirement once it determines that these studies are no longer necessary to assure the safety and effectiveness of pedicle screw spinal systems. The final regulation has been modified to reflect that PMS studies are no longer one of the special controls for these devices.

30. One comment stated that PMS studies are appropriate only for devices cleared for marketing with limited clinical performance data. The comment noted that there now exists a vast amount of clinical information gained from use of pedicle screw spinal systems in several thousand patients. The comment also noted that, based on these data, the Panel concluded that, with respect to safety and effectiveness, these devices are comparable to, or better than, currently available spinal systems. The comment concluded that this clinical information and the conclusions drawn from this information provide sufficient clinical data to adequately identify and characterize the performance of pedicle screw spinal systems and the issues pertinent to safety and effectiveness, thereby obviating the need to conduct PMS studies.

FDA disagrees that PMS studies are appropriate only for devices cleared for marketing with limited clinical performance data. Section 522 of the act allows FDA to require PMS studies for any device for which it determines such studies would protect the public health or provide safety or effectiveness data for the device. As stated in the preamble to the proposed rule, FDA will require PMS studies in order to address issues related to device specific design differences, surgical techniques, and device usage (60 FR 51946 at 51955). Although there is ample short-term clinical performance data for these devices, there does not now exist sufficient longer-term, i.e., more than 24-month followup, safety and/or effectiveness data regarding device specific design differences, surgical techniques, and device usage.

31. A second comment noted that components used to construct pedicle screw spinal systems could be identical to those used to construct either spinal interlaminal fixation orthoses (§ 888.3050) or spinal intervertebral body fixation orthoses (21 CFR 888.3060). Because PMS studies are not required for these devices, they should not be required for pedicle screw spinal systems. A third comment believed that PMS studies are inappropriate for well-established, standard of care treatments involving medical devices that were in existence prior to the 1976 amendments, including pedicle screw spinal systems.

FDA disagrees that PMS studies are inappropriate for devices that were in existence prior to the 1976 amendments. Section 522(a)(2) of the act specifically authorizes FDA to require a manufacturer to conduct PMS studies for any device, regardless of when it was first introduced or delivered for introduction into interstate commerce, for which FDA determines that PMS studies are necessary to protect the public health or to provide safety or effectiveness data for the device. Although, as the comment states, certain devices have been used as pedicle screw spinal systems for some time, except for the limited severe spondylolisthesis intended use available since January 1995, pedicle screw spinal systems have not been legally marketed. Collection of the PMS study data will allow FDA to analyze information on the use of devices specifically intended, and legally marketed, for use as pedicle screw spinal systems.

32. Five comments believed that PMS studies are unnecessary and will not further protect the public health because one or more of the following current reporting systems already provides adequate information on the performance of pedicle screw spinal systems: (1) The MDR System, (2) Voluntary Reporting under MedWatch, (3) User Reporting, and (4) Complaint Handling under the current good manufacturing practices. One comment supported a requirement that labeling remind surgeons they are required to report certain events under MDR. Two comments suggested that a statement which encourages health care professionals to submit MDR's under the Voluntary MedWatch System be placed in the required package insert of the device. Two other comments noted that no other class II spinal implant device is subject to PMS studies. Three comments also stated that collecting additional information will increase health care costs.

FDA disagrees in part. The purposes of PMS studies and current reporting systems are different. PMS studies are active investigations of device performance during actual use, whereas other reporting systems, i.e., MedWatch, MDR, User Reporting, and Complaint Reporting, are passive reporting mechanisms. As such, these current reporting systems would not provide the agency with clinical monitoring information on pedicle screw spinal systems other than unexpected problems in the marketplace. The PMS studies, in contrast, will provide longer-term safety and effectiveness data for pedicle screw spinal systems once the devices are distributed in the general population under actual conditions of use. Finally, FDA is aware that PMS studies might have an impact on health care costs. Although this is unfortunate, the agency believes that it is necessary to impose this requirement and collect this information in order to assure the safety and effectiveness of pedicle screw spinal systems.

33. A comment suggested that, due to the litigious climate surrounding these devices, it may be very difficult for manufacturers to recruit surgeons to participate in PMS studies.

FDA recognizes the concern that there may be conditions which would make the collection of the data somewhat difficult. However, FDA believes that it is important that the data be obtained and that it is possible to recruit a sufficient number of surgeons to participate in PMS studies.

34. One comment stated that the proposed identification for pedicle screw spinal systems was inaccurate, or at least misleading. The comment noted that, as proposed, a pedicle screw spinal system assembly must contain all of the components listed as part of the pedicle screw spinal system. The comment stated that, for any given assembly,

some or all of the system components could be used.

FDA agrees in part. As proposed, the identification could be interpreted to require that all of the described components were necessary to construct a pedicle screw spinal system assembly. FDA has amended the identification of the device to clarify that not all of the described components are required to be used in a pedicle screw spinal system assembly.

35. In the preamble to the proposed rule, FDA proposed two labeling special controls. These controls described the intended uses and indications for pedicle screw spinal systems and cautioned the user about potential risks to health if the devices were used under certain conditions. Three comments stated that the two labeling special controls were incorrectly categorized as "warnings" according to FDA's General Program Memorandum No. G91–1, "Device Labeling Guidance." They believed that these labeling requirements are more appropriately described as "precautions" or "important notes" because they describe a particular patient population and not specific risks or hazards associated with the use of a device. Four comments objected that: (1) Use of the phrase "* * * with significant potential risk for serious injury to patients * * *" in the second labeling statement did not accurately reflect the data reviewed by the Panel to make its recommendation,(2) references to training and experience should not be part of the second labeling special control, and (3) the controls containing the language referred to in (1) and (2) should be removed or modified.

FDA agrees with the comments that the two labeling special controls should be rewritten, but disagrees with the specific reasons. General Program Memorandum No. G91–1 states that "A warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk to health * * * Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved." This is the case when pedicle screw spinal systems are used for indications other than significant mechanical instabilities or deformities of the thoracic, lumbar, and sacral spine. Because valid scientific evidence is not available to support a determination that a reasonable assurance exists that pedicle screw spinal systems are safe and effective for other indications, categorizing the first labeling special control as a "warning" is the appropriate mechanism to alert users to the potential for injury to a patient.

The second labeling special control does not warrant being described as a "warning" because it does not meet the definition of this term. It does not describe known serious adverse reactions or known potential safety hazards; it does not provide specific steps to be taken; it does not concern a use for which there is reasonable evidence of association with a serious hazard. It does, however, provide information on special care to be exercised by a practitioner, although the need for special care is implied, not explicitly stated. Accordingly, FDA concludes that it is more appropriately categorized as a "precaution".

After reviewing the proposed special controls regarding labeling, FDA has concluded that the information should be stated more clearly. FDA believes that the labeling special controls reflect the data reviewed by the Panel. FDA also believes that the labeling special controls are necessary to provide reasonable assurance of the safety and effectiveness of the devices. Finally, as described in the next section, the intent of the second control was not to specify the type of training that should be available or to suggest that FDA would provide or approve any training. Rather, it was intended to alert surgeons to the necessity of receiving appropriate training in the use of specific pedicle screw spinal systems. Because of concerns with the proposed wording, the labeling special controls have been modified to read as follows:

"**Warning:** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"**Precaution:** The implantation of pedicle screw spinal systems should be performed only by experienced surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

36. A number of comments stated that appropriate surgeon training should be required prior to use of pedicle screw spinal systems and that classification/reclassification into class II would make access to training and device information easier. In addition, several comments believed that professional societies and hospitals, not FDA or the manufacturers, should determine what constitutes adequate training for surgeons implanting pedicle screw spinal systems.

FDA agrees that it is important that surgeons who use pedicle screw spinal systems have proper training prior to using the device. FDA does not believe, however, that it should identify who is most qualified to provide such training or determine what constitutes adequate training. The precaution statement is intended to inform surgeons (and patients) of the possible effect the device could have on the patient if the surgeon implanting the device is not trained or experienced in the proper use of pedicle screw spinal systems. This includes knowledge of the indications, patient selection criteria, and appropriate surgical techniques.

37. A comment questioned the proposed warning label because, in the past, FDA has prohibited pedicle screw spinal system manufacturers from supporting courses that described surgical techniques of "off label" uses demonstrating such uses or providing hands-on workshops to learn such uses.

FDA disagrees. Previously, the agency issued several warning letters to pedicle screw spinal system manufacturers for participating in or supporting the training of practitioners in the use of long bone screw, pedicle fixation because, at that time, no long bone screw devices had received FDA clearance for use in the pedicles of the spine. As a result, FDA considered such use "off label." Because the association with these training programs was considered the promotion of an "off-label" use, the agency stated that the manufacturers had misbranded and adulterated the long bone screws in accordance with sections 501(f)(1)(B) and 502(o) of the act (21 U.S.C. 351(f)(1)(B) and 352(o)) and promotion of this use was considered a major modification of the intended use, requiring a new premarket notification (510(k)) submission under § 807.81(a)(3)(ii). The regulations and the act are clear that manufacturers must have clearance for the intended use for which their device(s) are promoted, advertised, or held for sale.

With the issuance of this final regulation, the agency now encourages pedicle screw spinal system manufacturers to support training for the class II intended uses. Such training, however, should not be provided before FDA clearance is received. The above referenced warning label will appear

only on devices that have been cleared for pedicle screw spinal fixation.

38. The comment also claimed that the right to free speech guaranteed by the First Amendment to the U.S. Constitution should not be restricted by FDA's suppression of training for "off label" use.

FDA disagrees that its limitations on promotional training conducted or sponsored by manufacturers for "off label" uses for pedicle screw spinal systems violate the First Amendment. As described above, the act requires that FDA regulate devices based on their intended use. The term "intended use" is broadly defined and encompasses the manner in which a company characterizes its product in the marketplace. The intended use of a device refers to the objective intent of the persons legally responsible for its labeling (§ 801.4 (21 CFR 801.4)). "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or *oral or written statements by such persons or their representatives.*" (§ 801.4 (emphasis added)); (see e.g., *Coyne Beahm, Inc. et al.* v. *United States Food and Drug Administration, et al.*, 958 F. Supp. 1060 (M.D.N.C. 1997).) Consequently, oral statements and materials presented at industry-supported training programs may provide evidence of a device's intended use. If these statements or materials promote a use that has not been approved by the agency, the device is misbranded under section 502(f)(1) of the act for failure to bear labeling with adequate directions for all intended uses, and under section 502(o) of the act because premarket notification was not provided as required under section 510(k) of the act. The device is also adulterated under section 501(f) of the act for failure to have FDA approval. Thus, the various means by which manufacturers and their representatives provide information about their products to healthcare professionals and consumers, including statements and materials presented at industry-supported scientific and educational activities, directly bear on whether a device is improperly promoted and, therefore, adulterated or misbranded.

Because the regulation of devices is an area of extensive Federal regulation, the agency may regulate the communications at industry-supported scientific and educational activities without violating the First Amendment. (Cf. *SEC* v. *Wall Street Publishing Institute, Inc.*, 851 F.2d 365 (D.C.Cir. 1988), cert. denied, 109 S.Ct. 1342 (1989).) Moreover, to the extent that such communications constitute protected speech, they are commercial speech and FDA's regulation of such activities does not violate the First Amendment. (See *Bolger* v. *Youngs Drug Products*, 103 S.Ct. 2875 (1983); *S.U.N.Y.* v. *Fox*, 109 S.Ct. 3028 (1989); *Cincinnati* v. *Discovery Network*, 113 S.Ct. 1505 (1993).) Industry-supported scientific educational activities refer to a specific product, are economically motivated, and propose a commercial transaction. These programs are intended to convince the audience to prescribe, purchase, or otherwise use the particular product.

The Supreme Court has afforded commercial speech limited constitutional protection. (See, e.g., *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 96 S.Ct. 1817 (1976); *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 100 S. Ct. 2343 (1990).) In *Central Hudson*, the Supreme Court established a four-prong test to determine whether limitations on commercial speech are constitutional. The four prongs are: (1) Whether the speech concerns lawful activity and is not misleading, (2) whether the asserted government interest is substantial, (3) whether the limitation directly advances the governmental interest asserted, and (4) whether the limitation is not more extensive than is necessary to serve that interest. The Court has clarified that the fourth prong requires that the restriction be "narrowly tailored" to serve the asserted government interest. Narrow tailoring means a fit that is reasonable. (See *S.U.N.Y.* v. *Fox*, 109 S.Ct. 3028. 3035 (1989).)

FDA's regulation of industry-supported scientific and educational activities satisfies all four prongs. First, as previously discussed, industry-supported scientific and educational activities that promote an unapproved device, or promote an approved device for an unapproved use, create an unlawful product—a misbranded or adulterated device. Accordingly, industry-supported activities that promote unlawful products concern illegal activity and may be prohibited. Second, FDA's limitations on promotional activities with respect to off label uses serve the substantial government interest of protecting the public health and safety by helping to ensure the dissemination of truthful and nonmisleading information about devices. The Supreme Court has repeatedly held that the government's "interest in the health, safety, and welfare of its citizens constitutes a substantial interest." (*Posadas de Puerto Rico Associates* v. *Tourism Co.*, 106 S.Ct. 2968, 2977 (1986); *Rubin* v. *Coors*, 115 S.Ct. 1585, 1591 (1995).) The limitations also serve the second substantial government interest of protecting the public health by preserving the integrity of the premarket approval process under which manufacturers are required to establish that their devices are safe and effective for each of their intended uses before they may be marketed and promoted for those uses. Third, FDA's limitations on promotional activities with respect to off-label uses directly advance the government's substantial interests in protecting the public health and safety by helping to ensure the dissemination of truthful and nonmisleading information about devices and by preserving the integrity of the premarket approval process by dissuading manufacturers from using such activities as a means to promote unapproved products and unapproved uses, thereby encouraging scientific research and avoiding unnecessary harm to patients. Finally, FDA's limitations on industry-sponsored training sessions are narrowly tailored and are a reasonable approach to protect the public health and safety by discouraging the dissemination of misleading or biased information, and by maintaining the integrity of the premarket approval process. FDA's limitations apply only to industry-supported activities that relate to the supporting company's device or to competing devices. They are directed to the regulated sponsors of such activities, and do not apply to participating professionals or independent scientists and organizations.

39. Several comments believed that the device should be available for use only by neurosurgeons or orthopaedic surgeons supervised by neurosurgeons.

FDA disagrees. According to section 520(e)(1)(B), FDA may not restrict access to medical devices based on specialty or board certification.

J. Other Issues

40. Several comments objected that publication of the proposed rule in the **Federal Register** was not appropriate because the general public is not aware of the **Federal Register**. The comments noted that another vehicle for disseminating the information would have been more appropriate.

FDA disagrees. The act (sec. 513(d)(1) and 513(e)(1)) requires that a proposed rule be published in the **Federal Register** as the formal mechanism to provide all interested parties an opportunity to submit comments when

an advisory panel recommends an initial classification or change in classification for a medical device. Comments are invited from anyone. FDA recognizes that other mechanisms for distribution of this type of information is also appropriate. One of the alternate mechanisms currently being tested is electronic publication on the World Wide Web.

41. Several comments objected to FDA's consideration of public comments, which may contain only anecdotal information, in determining the appropriate class for these devices.

FDA agrees that comments provided by the public may contain anecdotal information that does not meet the definition of valid scientific evidence. However, FDA considers this information along with the information provided in other comments. These anecdotal comments did not raise any issues or comments that were not already addressed by the information that the Panel reviewed in making its determination that safety and effectiveness of pedicle screw spinal systems could be assured by special controls.

42. Six comments disapproved of the release of the PIN's which identified the surgeons participating in the Cohort study.

FDA regrets any problems that may have been caused by this inadvertent release of information. However, release of this information did not affect the quality, integrity, or value of the data upon which the Panel's recommendation was based.

43. A comment noted that there is no consensus among spine surgeons that pedicle screw fixation has become the standard of care or the gold standard for treatment of spinal instability so as to justify the conclusion that the devices are safe and effective and to justify abandonment of the randomized control trial in making such an assessment.

FDA agrees that there is no consensus among spine surgeons regarding pedicle screw spinal systems. However, a medical device does not need to be viewed as the "gold standard" in order for the agency to determine that there is reasonable assurance of its safety and effectiveness. Nor is it a requirement for the classification and reclassification process that all members of a medical specialty agree that a particular device should be used under all conditions. It is recognized that certain devices provide their best outcome when used for specific indications. This is one of the reasons why degenerative disc disease is not included as one of the intended uses in the classification and reclassification of pedicle screw spinal systems. Finally, as described above, randomized clinical trials are only one of the types of valid scientific evidence upon which FDA may rely in support of a classification/reclassification determination. Many IDE studies from which the reformatted IDE data came are still being actively pursued by their sponsors and the patients are being actively followed.

K. Labeling of Bone Screws

44. A comment requested FDA to formally rescind its April 8, 1994, and June 15, 1994, letters to manufacturers of bone screws and devices classified under §§ 888.3030 and 888.3040 (21 CFR 888.3030 and 888.3040), directing them to amend their labeling by including the following: "Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." According to the comment, this labeling requirement will become unnecessary when pedicle screw spinal systems are classified into class II.

FDA disagrees. In this final rule, FDA is classifying and reclassifying only pedicle screw spinal systems intended for screw attachment or fixation to the pedicles of the thoracic, lumbar, or sacral spine for immobilization and stabilization of spinal segments for the treatment of significant medical instability or deformity requiring fusion with instrumentation. This classification and reclassification in no way affects devices classified as single/multiple component metallic bone fixation appliances and accessories (§ 888.3030) or smooth or threaded metallic bone fixation fasteners (§ 888.3040). Those devices are still not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Hence, the 1994 amended labeling remains appropriate for these devices.

45. One comment noted that in January 1995, FDA began clearing 510(k)'s intended to treat grades 3 and 4 spondylolisthesis at the L_5–S_1 junction. The comment concluded that, by default, grades 1 and 2 spondylolisthesis, less severe conditions, are considered to be postamendments intended uses resulting in the device being automatically classified into class III. According to this comment; this means that FDA, through required manufacturer labeling, is instructing physicians to wait until grades 1 and 2 spondylolisthesis develop into grades 3 and 4 spondylolisthesis before employing treatments utilizing pedicle screw spinal systems, which is not in the patient's best interests.

FDA disagrees. FDA is not limiting physicians, through required manufacturer labeling, to wait until grades 1 or 2 spondylolisthesis develop into grades 3 or 4 spondylolisthesis. FDA is stating that the preamendments documentation in the 510(k) described marketing of the device only for the treatment of grades 3 and 4 spondylolisthesis at L_5–S_1. Treatment of grades 1 or 2 spondylolisthesis does not have to wait until it progresses to grades 3 or 4. Legally marketed devices which do not utilize pedicle screws are available for this purpose.

L. Review of New Pedicle Screw Spinal System 510(k)'s

46. A comment pointed out that since FDA's January 1995, determination regarding the preamendments status of pedicle screw spinal systems in the treatment of severe spondylolisthesis, many 510(k) submissions have been cleared for this use. FDA's proposed rule for pedicle screw spinal systems, once final, will essentially represent a labeling change for these devices, requiring new 501(k) submissions. The comment suggested that the new 510(k)'s should provide a draft copy of the revised labeling and a statement that the previously-cleared device has not been modified in any way that may affect its safety or effectiveness. According to the comment, this limited type of review would facilitate and expedite the review process and would not unnecessarily burden FDA's device evaluation staff.

FDA agrees with this approach and intends to apply it in its review of 510(k)'s for pedicle screw spinal systems that were cleared previously for use in severe spondylolisthesis. Pedicle screw spinal systems which have not been previously reviewed, or that represent significant modifications compared to the previously cleared device(s), will require a complete 510(k) submission, including the device labeling.

M. Review of New Information Published and Submitted After Publication of the Proposed Rule: Pedicle Screw and Related Literature and MedWatch and MDR System Reports

FDA performed a comprehensive search of the English-language medical literature published between 1994 and the present. Thirty-five articles pertained to the clinical performance of pedicle screw spinal systems. The clinical performance results, e.g., fusion rate and complication types and rates,

from these peer-reviewed articles did not differ from those previously reported in the preamble to the proposed rule for either pedicle screw spinal systems or the group of class II spinal devices using hooks and/or wires or noninstrumented fusions.

FDA also performed a review of the MedWatch and MDR databases from 1994 to the present. The complications associated with pedicle screw spinal systems during this period were comparable to those reported in the preamble to the proposed rule for pedicle screw spinal systems and the group of class II spinal devices using hooks and/or wires and noninstrumented fusions.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Rodgers, A. E., "FDA Pedicle Screw Cohort Study: Audit Findings," July 30, 1996.

2. Richter, K. C., "Assessment of the Impact of BIMO Audit Findings for the Pedicle Screw Cohort Study on Study Results," August 29, 1997.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) 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.

VIII. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by Subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule has been determined to be a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification and reclassification of the device from class III to class II when the device is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fractures, dislocations, scoliosis, kyphosis, spinal tumors, and failed previous fusion attempts (pseudarthrosis) will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515(b) of the act.

Because classification and reclassification will reduce regulatory costs with respect to this device, it will not impose significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The Commissioner of Food and Drugs, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in any one year, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3070 is added to subpart D to read as follows:

§ 888.3070 Pedicle screw spinal system.

(a) *Pedicle screw spinal systems*—(1) *Identification.* Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr–13Ni–5Mn stainless steel, Ti–6Al–4V, and unalloyed titanium, that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors. The devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

(2) *Classification.* Class II (special controls). Pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards,

(ii) Compliance with mechanical testing standards,

(iii) Compliance with biocompatibility standards, and

(iv) Labeling which contains these two statements in addition to other appropriate labeling information:

"**Warning:** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"**Precaution:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

(b) *Pedicle screw spinal systems for all other uses*—(1) *Identification.* Pedicle screw spinal systems for all other uses are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr–13Ni–5Mn stainless steel, Ti–6Al–4V, and unalloyed titanium, that allow

the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such an spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* An approved PMA or a declared completed PDP must be in effect before placing the device in commercial distribution. See § 888.3.

Dated: April 22, 1998,

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–19944 Filed 7–23–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN75; FRL–6129–7]

Approval and Promulgation of Implementation Plan; Indiana

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The United States Environmental Protection Agency (USEPA) is approving Indiana's request to grant an exemption for the northwest Indiana (Lake and Porter Counties) severe ozone nonattainment area from the applicable Oxides of Nitrogen (NO_X) transportation conformity requirements. The USEPA proposed approval on January 6, 1998. The proposal was based on information the Indiana Department of Environmental Management (IDEM) submitted to the USEPA as a State Implementation Plan (SIP) revision request for an exemption under section 182(b)(1) of the Clean Air Act (Act). The technical basis for IDEM's request was the urban airshed modeling (UAM) conducted for an attainment demonstration for the Lake Michigan Ozone Study (LMOS) modeling domain.

DATES: This rule is effective August 26, 1998.

ADDRESSES: Copies of the SIP revision, public comments and USEPA's responses are available for inspection at the following address: United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Patricia Morris at (312) 353–8656 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Patricia A. Morris, Regulation Development Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone Number (312) 353–8656.

SUPPLEMENTARY INFORMATION:

I. Background

Clean Air Act section 176(c)(3)(A)(iii) requires, in order to demonstrate conformity with the applicable SIP, that transportation plans and Transportation Improvement Programs (TIPs) contribute to emissions reductions in ozone and carbon monoxide nonattainment areas during the period before control strategy SIPs are approved by USEPA. This requirement is implemented in 40 CFR 93.119, which establishes what is known as the "build/no-build test." The conformity requirements of 176(c)(3)(A) are more fully explained in the notice of proposed rulemaking (63 FR 456, January 6, 1998).

On July 13, 1994, the States of Illinois, Indiana, Michigan, and Wisconsin (the States) submitted to the USEPA a petition for an exemption from the requirements of section 182(f) of the Clean Air Act (Act). The States, acting through the Lake Michigan Air Directors Consortium (LADCo), petitioned for an exemption from the Reasonably Available Control Technology (RACT) and New Source Review (NSR) requirements for major stationary sources of NO_X. The petition also asked for an exemption from the transportation and general conformity requirements for NO_X in all ozone nonattainment areas in the Lake Michigan Modeling domain.

On March 6, 1995, the USEPA published a rulemaking proposing approval of the NO_X exemption petition for the RACT, NSR and transportation and general conformity requirements. A number of comments were received on the proposal. Several commenters argued that NO_X exemptions are provided for in two separate parts of the Act, in sections 182(b)(1) and 182(f), but that the Act's transportation conformity provisions in section 176(c)(3) explicitly reference section 182(b)(1). In April 1995, the USEPA entered into an agreement to change the procedural mechanism through which a NO_X exemption from transportation conformity would be granted (*EDF et al. v. USEPA*, No. 94–1044, U.S. Court of Appeals, D.C. Circuit). Instead of a petition under 182(f), transportation conformity NO_X exemptions for ozone nonattainment areas that are subject to section 182(b)(1) now need to be submitted as a SIP revision request. The northwest Indiana ozone nonattainment area is classified as severe and, thus, is subject to section 182(b)(1). Thus, the NO_X waiver for transportation conformity would have been granted in January 26, 1996, at the same time as the waiver for RACT, NSR and general conformity except for the technical correction to require a SIP revision request under 182(b)(1).

The transportation conformity requirements are found at sections 176(c)(2), (3), and (4) of the Act. The conformity requirements apply on an areawide basis in all nonattainment and maintenance areas. The USEPA's transportation conformity rule was amended on August 29, 1995 (60 FR 44762) to reference section 182(b)(1) rather than 182(f) as the means for exempting areas subject to section 182(b)(1) from the transportation conformity NO_X requirements.

The May 24, 1996, SIP revision request from Indiana was submitted to meet the requirements in accordance with 182(b)(1). Public hearings on this SIP revision request were held on June 11, 1996.

In evaluating the 182(b) SIP revision request, the USEPA considered whether additional NO_X reductions would contribute to attainment of the standard in the northwest Indiana severe ozone nonattainment area and also in the downwind areas of the LMOS modeling domain. The USEPA granted a NO_X waiver for RACT, NSR, and general conformity based on the submitted modeling on January 26, 1996, (61 FR 2428). At the same time and using the same technical support evaluation, the USEPA would have granted the transportation conformity waiver but for the technical correction to grant the waiver under 182(b)(1) instead of 182(f). This rulemaking completes the efforts under this technical correction.

On January 6, 1998, (63 FR 456), the USEPA proposed approval of Indiana's request to grant an exemption for the northwest Indiana severe ozone nonattainment area from the applicable NO_X transportation conformity requirements.

II. Public Comments

The USEPA received two sets of comments during the public comment

period, which ended on February 5, 1998. One set was in favor of the USEPA proposal, and one set was critical. The following are the critical comments on the proposal and USEPA's responses to the comments:

Comment: Indiana has failed to establish a NO_X budget for the ozone nonattainment area. Indiana has yet to develop and submit such a budget as required by November 1994. Until the attainment demonstrations, encompassing verifiable and allocated (biogenic, point, mobile, and area) NO_X emission budgets, are submitted and complete, any determination that required control strategies are not necessary is premature and unfounded.

Response: Approval of the transportation conformity NO_X waiver does not eliminate the need for a NO_X budget determination. As described in the background section, the waiver merely removes the requirement for the build/no-build test. It is anticipated that in the future, Indiana will submit a NO_X transportation budget in its state implementation plan.

Comment: The NO_X waiver technical documentation is outdated, incomplete and inconsistent with USEPA's NO_X SIP call.

Response: USEPA's NO_X SIP call proposal published November 7, 1997, (62 FR 60317) is based on modeling conducted by the Ozone Transport Assessment Group (OTAG). OTAG used information and ozone episodes contributed by LADCo and the State of Indiana. USEPA's NO_X SIP call acknowledges the NO_X "disbenefit" issue and specifically mentions the Lake Michigan states as an area where the modeling shows a disbenefit. A "disbenefit" from NO_X is when reductions in NO_X emissions create an increase in the concentrations of ozone. USEPA's NO_X SIP call encourages local and regional modeling to determine the extent of the NO_X disbenefit; and the appropriate control strategies to deal with the disbenefit. LADCo is currently conducting modeling to refine the NO_X disbenefit and the State of Indiana, in cooperation with the other Lake Michigan states, intends to submit the modeling and analysis in response to the SIP call. Thus, there is nothing in the most recent modeling which contradicts the phenomenon of the NO_X disbenefit in the Lake Michigan area.

Comment: The Indiana submittal failed to demonstrate that low-level NO_X reductions in the northwest Indiana area would not improve air quality. While the submittal did analyze domain-wide low-level NO_X reductions, no such analysis was performed for the specific Indiana counties. The State of Indiana, in coordination with LADCo, has the capabilities to model NO_X emissions from mobile sources in these counties. Therefore, USEPA should require such a demonstration before taking final action on this rulemaking.

Response: The LADCo analysis demonstrated that across-the-board reductions in NO_X from point, area, and mobile sources generally showed a "disbenefit" in many areas of the modeling domain. Further, LADCo performed an analysis which focused on NO_X reductions from point sources. This analysis showed a small increase in ozone formation. From this result, LADCo concluded that low level NO_X controls, i.e. mobile and area sources, would be detrimental to air quality in the modeling domain. The LADCo analysis is consistent with the USEPA NO_X waiver policy which requires consideration of modeling domain wide peak ozone concentrations.

Comment: Indiana and Michigan counties now in violation of the ozone NAAQS will benefit from low-level NO_X emissions reductions.

Response: Regional modeling is currently being conducted to determine more precisely where NO_X reductions give a disbenefit. The OTAG modeling demonstrated that elevated and low-level NO_X reductions across many states will generally reduce transported ozone. The USEPA NO_X SIP call proposed on November 7, 1997, proposed statewide budgets for NO_X. The State has the ability to decide what NO_X reductions would be most beneficial, after consideration of downwind benefits and local disbenefits. The States are currently conducting additional modeling in the Lake Michigan area to determine where NO_X reductions are most beneficial. It is premature to subject transportation sources in Lake and Porter Counties to NO_X reductions until this additional modeling is completed and USEPA finalizes the SIP call notice and Indiana submits its plan for NO_X reductions.

Comment: USEPA's $PM_{2.5}$ NAAQS requires an additional net air quality benefit analysis.

Response: The USEPA timeline for implementation of the $PM_{2.5}$ NAAQS begins with setting up a monitoring network and collecting data for several years before designating areas under the new NAAQS. At this time, the USEPA does not know which areas will be designated nonattainment for $PM_{2.5}$, nor are there any control strategies currently proposed for $PM_{2.5}$. The transportation conformity requirement is to enable attainment of the one hour ozone standard. In this notice, USEPA is only waiving the transportation conformity build/no-build test, which requires reductions in NO_X in ozone nonattainment areas.

Comment: The USEPA has failed to adequately consider the net environmental benefits (such as acid rain reduction) of NO_X emissions reductions in Lake and Porter Counties.

Response: As stated above, the LADCo analysis demonstrated that across the board reductions in NO_X from point, area, and mobile sources showed both benefits and disbenefits in the modeling domain. Further, the transportation conformity rule does not require the build/no-build test for NO_X as an ozone precursor in ozone nonattainment areas where the Administrator determines that additional reductions of NO_X would not contribute to attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. A net benefit analysis for all environmental benefits is not required since this requirement is specific to ozone nonattainment.

Comment: The USEPA and Indiana failed to perform the appropriate environmental justice analysis. The USEPA has failed to consider the spatial impact of where reductions could be anticipated and where increases might occur with and without NO_X conformity compliance in northwest Indiana and southeast Chicago. The USEPA is expected to address the full range of environmental implications including: (1) Will the rulemaking increase already unacceptable levels of air toxics in these communities? (2) Will this rulemaking increase already unacceptable levels of fine particulate matter in these communities? (3) Will the sprawl included by the proposal—or the elevated speed limits allowed—disproportionately impact at-risk populations? (4) Will this proposal further exacerbate the difficulty of low income and unemployed citizens in the region commuting to employment opportunities?

Response: As discussed in the January 6, 1998, proposed approval, the role that NO_X emissions play in producing ozone at any given place and time is complex. Modeling shows that controlling low level NO_X in northwest Indiana could in fact increase ozone concentrations in local urban areas particularly the minority areas in Lake County, Indiana and southeast Chicago. This disbenefit is caused by the reaction of nitrogen oxide with ozone, which locally reduces ozone concentrations, and is referred to as ozone scavenging. Since emissions of NO_X from fuel combustion sources, whether internal combustion engines or stationary combustion sources, such as industrial boilers, contain significant

amounts of NO, it is expected that ozone concentrations immediately downwind of such NO_X sources will be reduced through ozone scavenging. Therefore, reducing NO_X emissions can lead to increased ozone concentrations in the vicinity of the controlled NO_X emission sources, while causing a reduction in ozone concentrations further downwind. Reducing NO_X emissions in VOC-limited areas (areas with low VOC emissions relative to NO_X emissions) may produce minimal ozone reductions or even ozone increases. This pattern of NO_X scavenging is demonstrated in the LADCo modeling. Therefore, controlling low level NO_X in northwest Indiana could in fact increase ozone concentrations in local urban areas particularly the minority areas in Lake County, Indiana and southeast Chicago. This, in fact, is what the LADCo modeling demonstrated.

As for the other environmental and social implications, this rulemaking addresses NO_X reduction for meeting the ozone standard and merely waives the build/no-build reduction requirement for transportation sources. NO_X from the transportation plan is not expected to increase significantly and thus will not increase air toxics or fine particulates. It is through the transportation planning process that transportation decisions are made.

This transportation conformity waiver is not expected to adversely affect the transportation options of minority populations in northwest Indiana. In fact, letters from IDEM and Indiana Department of Transportation and the Northwestern Indiana Regional Planning Commission indicate that the NO_X transportation waiver, will allow transportation planning to be simplified and allow federal funding of transportation improvements to proceed.

Comment: The Indiana request utilizes the BEIS–I inventory for biogenic emissions. OTAG concluded that the BEIS–II inventory is the preferred inventory for UAM analyses.

Response: The BEIS–I was the approved and most appropriate biogenic emissions inventory available to LADCo when the NO_X modeling analysis was performed. Any subsequent modeling performed by LADCo will utilize the BEIS–II biogenic emissions inventory.

Comment: OTAG concluded that both elevated and low level NO_X reductions are effective in reducing ozone levels. These conclusions were based extensively on OTAG modeling, and are significant and relevant to USEPA's action on this rule. The modeling clearly demonstrated the efficacy of reducing low-level (mobile source) NO_X in controlling ozone. The conclusions of the policy group were that such reductions were cost effective, and beneficial to reduce transport to downwind areas.

Response: It should be noted that OTAG concluded that States must have the opportunity to conduct additional local and subregional modeling to assess appropriate, type, and timing of controls. OTAG further concluded that States can work together, in coordination with USEPA, toward developing local SIPs including an evaluation of possible local NO_X disbenefits. In addition, OTAG modeling results demonstrated a significant potential for NO_X control disbenefits in the Lake Michigan area.

Comment: OTAG concluded that disbenefit analyses found ozone increases to be less frequent and severe than USEPA concluded based on the July 13, 1994 LADCo 182(f) NO_X waiver submittal.

Response: The OTAG fine grid analysis utilized a 12 km grid as compared to the LADCo fine grid of 4 km. This disparity in fine grid size can de-emphasize the NO_X disbenefit at the local urbanized area. OTAG concluded that some areas will experience local NO_X disbenefits at more frequent pronounced levels when finer grids are considered.

Comment: In previous rulemakings on similar NO_X waiver requests, USEPA committed to incorporate the OTAG findings in future USEPA rulemakings. OTAG recommendations are now complete, OTAG findings are clear, and USEPA has validated these OTAG findings in proposing its NO_X SIP call. This proposal is inconsistent with and even undermines the USEPA NO_X SIP call.

Response: The summary of OTAG findings states that NO_X reductions decrease and increase ozone: decreases occur domain wide; increases are confined to a few days in a few urban areas.

The USEPA's recently proposed regional NO_X rulemaking uses the OTAG findings to identify States which contribute significantly to ozone problem areas in other states. In addition, the proposed rulemaking establishes State wide NO_X budgets for the year 2007.

A section of the rulemaking also solicits comments on approaches that can be used to address the disbenefit issue in areas such as Lake Michigan. Subsequent modeling by the LADCo States will need to address the disbenefit issue as it pertains to the NO_X budget, ozone transport, and attainment. It is premature at this time to require NO_X reductions from transportation sources in northwest Indiana before completion of modeling, finalization of the NO_X SIP call and preparation of the State implementation plan to address state NO_X reductions.

IV. USEPA Action

In this final action, USEPA is approving the transportation conformity NO_X waiver SIP revision for the State of Indiana. In light of the modeling completed thus far and considering the importance of the Ozone Transport Assessment Group process and attainment plan modeling efforts the USEPA notes that it may reexamine the impact of this NO_X waiver as future modeling becomes available. In the near future, USEPA intends to require appropriate States to submit SIP measures to achieve emissions reductions of ozone precursors needed to prevent significant transport of ozone. The USEPA will evaluate the States' submitted SIP measures and available refined modeling to determine whether the NO_X waiver should remain in place, or whether USEPA will require a new plan revision.

The USEPA also reserves the right to require NO_X emission controls for transportation sources under section 110(a)(2)(D) of the Act if future ozone modeling demonstrates that such controls are needed to achieve the ozone standard in downwind areas.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks," because it is not an "economically significant" action under Executive Order 12866.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and 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.

This final rule will not have a significant impactr on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. This federal action does not impose any new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

E. 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 action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective.

F. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 25, 1998. 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, Intergovernmental relations, Oxides of Nitrogen, Ozone, Transportation-air quality planning, Transportation conformity.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 15, 1998.

David A. Ullrich,

Acting Regional Administrator.

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. 7401–7671q.

Subpart P—Indiana

2. Section 52.777 is amended by adding paragraph (t) to read as follows:

§ 52.777 Control strategy: Photochemical Oxidants (hydrocarbons).

* * * * *

(t) Approval—On May 24, 1996, the Indiana Department of Environmental Management submitted a revision to the ozone State Implementation Plan for Lake and Porter Counties. The submittal pertained to a plan for the implementation of the Federal transportation conformity requirements in accordance with 40 CFR part 51 subpart T—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Act.

* * * * *

[FR Doc. 98–19931 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[KY–90–1–9735a: FRL–6130–3]

Approval and Promulgation of Implementation Plans Kentucky: Adoption of General Conformity Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On November 10, 1995, the Commonwealth of Kentucky, through the Kentucky Natural Resources and Environmental Protection Cabinet (KNREPC), submitted revisions to EPA concerning the adoption of general conformity rules into the Kentucky State Implementation Plan (SIP). Since general conformity rules are required by Section 176 of the Clean Air Act (CAA) in all nonattainment and maintenance areas and the Kentucky submittal is consistent with EPA requirements, these revisions are being incorporated into the Federally approved Kentucky SIP.

DATES: This direct final rule is effective on September 25, 1998 without further notice, unless EPA receives adverse comment by August 26, 1998. If adverse comment is received, EPA 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: Written comments on this action should be addressed to Gregory O. Crawford at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the locations below. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file KY–90–9735. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303, Gregory O. Crawford, 404/562–9046.

Commonwealth of Kentucky, Natural Resources and Environmental

Protection Cabinet, 803 Schenkel Lane, Frankfort, Kentucky 40601, 502/564–3350.

FOR FURTHER INFORMATION CONTACT: Gregory O. Crawford, 404/562–9046, Regulatory Planning Section, Air Planning Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 61 Forsyth Street, SW, Atlanta, Georgia, 30303.

SUPPLEMENTARY INFORMATION: After the 1990 Clean Air Act Amendments, EPA designated Boone County, Boyd County, Campbell County, Daviess County, Edmonson County, Fayette County, Greenup County, Hancock County, Jefferson County, Kenton County, Livingston County, Marshall County, Scott County, and portions of Bullitt and Oldham Counties, Kentucky, as nonattainment areas for the ozone national ambient air quality standards (NAAQS). In the November 30, 1993, **Federal Register** (58 FR 63214), EPA issued a final rule establishing criteria and procedures for determining conformity of general Federal actions to state or Federal implementation plans.

Because the counties mentioned above are either maintenance or nonattainment areas, the general conformity rule is applicable in those counties. Before any industrial development requiring approval from a Federal agency can occur, a determination must be reached that such action, when taken, will conform to the Kentucky SIP to maintain the NAAQS for ozone. The Commonwealth was therefore required to revise their SIP, to include general conformity criteria and procedures that are consistent with the Federal rule. On October 11, 1995, KNREPC formally adopted criteria and procedures for demonstrating and assuring the "Conformity of General Federal Actions to the Kentucky Air Quality Implementation Plan." These regulations were submitted to EPA on November 10, 1995, for adoption into the Federally enforceable SIP.

EPA has evaluated this SIP revision and has determined that the Commonwealth of Kentucky has fully adopted by reference, the provisions of the Federal general conformity rules specified in 40 CFR part 51, subpart W. Therefore, EPA believes that the Commonwealth has met all applicable requirements, and is approving the SIP revision concerning the adoption of the general conformity regulations.

Final Action

EPA is approving the aforementioned changes to the SIP. The Agency has reviewed this request for revision of the Federally-approved State implementation plan for conformance with the provisions of the 1990 amendments enacted on November 15, 1990. The Agency has determined that this action conforms with those requirements.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective September 25, 1998 without further notice unless the Agency receives relevant adverse comments by August 26, 1998.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Only parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 25, 1998 and no further action will be taken on the proposed rule.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Nothing in this action should be construed as making any determination or expressing any position regarding Kentucky's audit privilege and penalty immunity law KRS 224.01-040 or its impact upon any approved provision in the SIP, including the revision at issue here. The action taken herein does not express or imply any viewpoint on the question of whether there are legal deficiencies in this or any other Clean Air Act program resulting from the effect of Kentucky's audit privilege and immunity law. A state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities. EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by a state audit privilege or immunity law.

I. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under Executive Order 12866, entitled Regulatory Planning and Review.

B. Executive Order 13045

The final rule is not subject to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks, because it is not an "economically significant" action under Executive Order 12866.

C. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and 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. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule

that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. 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).

F. 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 September 25, 1998. 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, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: June 25, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Part 52 of chapter I, title 40, 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 S—Kentucky

2. Section 52.938 is added to read as follows:

§ 52.938 General conformity.

The General Conformity regulations were submitted on November 10, 1995, and adopted into the Kentucky State Implementation Plan (SIP). The Commonwealth of Kentucky incorporated by reference regulations 40 CFR part 51, subpart W—determining conformity of General Federal Actions to State or Federal Implementation Plans.

[FR Doc. 98–20007 Filed 7–24–98; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[SC–34–1–9816a: FRL–6129–9]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants: South Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the Sections 111(d)/129 State Plan submitted by the State of South Carolina through the South Carolina Department of Health and Environmental Control (DHEC) on January 14, 1998. The plan provides for implementation and enforcement of the Emissions Guidelines (EG) applicable to existing Municipal Waste Combustors (MWCs) with capacity to combust more than 250 tons per day of municipal solid waste (MSW). (*See* 40 CFR Part 60, Subpart Cb.)

DATES: This direct final rule is effective on September 25, 1998 without further notice, unless EPA receives adverse comment by August 26, 1998. If adverse comment is received, EPA 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: Written comments should be addressed to: Gregory Crawford, EPA Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file SC–34–9816. The Region 4 office may have additional background documents not available at the other locations.

Air Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303, Gregory O. Crawford, 404/562–9046.

South Carolina Department of Health and Environmental Control, Bureau of Air Quality Control, 2600 Bull Street, Columbia, South Carolina 29201, 803/734–4750.

FOR FURTHER INFORMATION CONTACT: Gregory O. Crawford, Regulatory Planning Section, Air Planning Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 61 Forsyth Street, Atlanta, Georgia, 30303.

SUPPLEMENTARY INFORMATION:

I. Background

On December 19, 1995, pursuant to sections 111 and 129 of the Clean Air Act (the Act), EPA promulgated new source performance standards (NSPS) applicable to new MWCs and EG applicable to existing MWCs. The NSPS and EG are codified at 40 CFR Part 60, Subparts Eb and Cb, respectively. (*See* 60 FR 65387.) Subparts Cb and Eb regulate the following: particulate matter, opacity, sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans.

On April 8, 1997, the United States Court of Appeals for the District of Columbia Circuit vacated subparts Cb

and Eb as they apply to MWC units with capacity to combust less than or equal to 250 tons per day of MSW (small MWCs), consistent with their opinion in *Davis County Solid Waste Management and Recovery District* v. *EPA*, 101 F.3d 1395 (D.C. Cir. 1996), *as amended*, 108 F.3d 1454 (D.C. Cir. 1997). As a result, subparts Eb and Cb apply only to MWC units with individual capacity to combust more than 250 tons per day of MSW (large MWC units).

Under section 129 of the Act, EG are not Federally enforceable. Section 129(b)(2) of the Act requires states to submit to EPA for approval, plans that implement and enforce the EG. State plans must be at least as protective as the EG, and become Federally enforceable upon approval by EPA. The procedures for adoption and submittal of state plans are codified in 40 CFR Part 60, Subpart B. EPA originally promulgated the Subpart B provisions on November 17, 1975. EPA amended Subpart B on December 19, 1995, to allow the subparts developed under section 129 to include specifications that supersede the general provisions in Subpart B regarding the schedule for submittal of state plans, the stringency of the emission limitations, and the compliance schedules. (*See* 60 FR 65414.)

This action approves the plan submitted by South Carolina to implement and enforce Subpart Cb, as it applies to large MWC units.

II. Discussion

South Carolina submitted to EPA on January 14, 1998, February 5, 1998, and March 6, 1998, the following in their 111(d)/129 plan for implementation and enforcement of the EG for existing MWCs under their direct jurisdiction in the State of South Carolina: Legal Authority; Enforceable Mechanism; Inventory of MWC Plants/Units; MWC Emissions Inventory; Emission Limits; Compliance Schedule; Testing, Monitoring, Recordkeeping and Reporting Requirements; Demonstration that the Public had Adequate Notice and Opportunity to Submit Written Comments; Submittal of Progress Reports to EPA; and applicable State of South Carolina statutes and rules of the South Carolina DHEC. South Carolina submitted its plan after the Court of Appeals vacated Subpart Cb as it applies to small MWC units. Thus, the South Carolina plan covers only large MWC units. As a result of the *Davis* decision and subsequent vacatur order, there are no EG promulgated under sections 111 and 129 that apply to small MWC units. Accordingly, EPA's review and approval of the South Carolina State plan for MWCs addresses only those parts of the plan which affect large MWC units. Until EPA again promulgates EG for small MWC units, EPA has no authority under section 129(b)(2) of the Act to review and approve state plans applying state rules to small MWC units.

The approval of the South Carolina State plan is based on finding that: (1) the South Carolina DHEC provided adequate public notice of public hearings for the proposed rulemaking and plan which allow the South Carolina DHEC to implement and enforce the EG for large MWCs, and (2) the South Carolina DHEC also demonstrated legal authority to adopt emission standards and compliance schedules applicable to the designated facility; enforce applicable laws, regulations, standards and compliance schedules; seek injunctive relief; obtain information necessary to determine compliance; require recordkeeping; conduct inspections and tests; require the use of monitors; require emission reports of owners and operators; and make emission data publicly available.

In the plan submittal, and as enclosed in supplemental information, the South Carolina DHEC cites the following references for the legal authority: State of South Carolina Attorney General's Opinion Regarding State Authority to Operate the Title V Operating Permit Program; the South Carolina Pollution Control Act (South Carolina Code Sections 48–1–10 through 48–1–350); and Regulation 61–62.5, Standard 3 (Waste Combustion and Reduction), of the South Carolina DHEC Air Pollution Control Regulations and Standards. On the basis of the Attorney General's Opinion, the statutes, and rules of the State of South Carolina, the State plan is approved as being at least as protective as the Federal requirements for existing large MWC units.

In the State plan, the South Carolina DHEC cites all emission standards and limitations for the major pollutant categories related to the only designated facility in the State of South Carolina subject to these standards and limitations, the Foster Wheeler Charleston Resource Recovery Facility (RRF). These standards and limitations in the State plan are approved as being at least as protective as the Federal requirements contained in Subpart Cb for existing large MWC units.

The South Carolina DHEC submitted the compliance schedule and legally enforceable increments of progress for Foster Wheeler Charleston RRF. (This portion of the plan has been reviewed and approved as being at least as protective as Federal requirements for existing large MWC units.)

In the plan, South Carolina submitted an emissions inventory of all designated pollutants for Foster Wheeler Charleston RRF. (This portion of the plan has been reviewed and approved as meeting the Federal requirements for existing large MWC units.)

The South Carolina State plan includes its legal authority to require owners and operators of designated facilities to maintain records and report to their agency the nature and amount of emissions and any other information that may be necessary to enable their agency to judge the compliance status of the facility in the State plan. The South Carolina DHEC also cites its legal authority to provide for periodic inspection and testing and provisions for making reports of MWC emissions data, correlated with emission standards that apply, available to the general public. The South Carolina DHEC submitted the regulations to support the requirements of monitoring, recordkeeping, reporting, and compliance assurance in the plan submittal. (This portion of the plan has been reviewed and approved as being at least as protective as the Federal requirements for existing large MWC units.)

As stated in the plan, South Carolina will provide progress reports of plan implementation updates to the EPA on an annual basis in conjunction with reports required under § 51.321. These progress reports will include the required items pursuant to 40 CFR part 60, subpart B. (This portion of the plan has been reviewed and approved as meeting the Federal requirement for State Plan reporting.)

Final Action

EPA is approving the above referenced state plan because it meets the Agency requirements. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the revision should significant, material, and adverse comments be filed. This action will be effective September 25, 1998 without further notice unless the Agency receives adverse comments by August 26, 1998.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments

received will be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Only parties interested in commenting on the direct final rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 25, 1998 and no further action will be taken.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any State Implementation Plan (SIP). Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Nothing in this action should be construed as making any determination or expressing any position regarding South Carolina's audit privilege and penalty immunity law S.C. Code Ann. Sections 4857–57–10 et. seq. (Supp. 1996) or its impact upon any approved provision in the SIP, including the revision at issue here. The action taken herein does not express or imply any viewpoint on the question of whether there are legal deficiencies in this or any other Clean Air Act program resulting from the effect of South Carolina's audit privilege and immunity law. A state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities. EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by a state audit privilege or immunity law.

I. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled Regulatory Planning and Review.

B. Executive Order 13045

The final rule is not subject to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks, because it is not an "economically significant" action under Executive Order 12866.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and 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.

Pursuant to section 605(b) of the Regulatory Flexibility Act, I certify that this rule will not have a significant economic impact on a substantial number of small entities. This Federal action approves pre-existing requirements under Federal, State or local law, and imposes no new requirements on any entity affected by this rule, including small entities. Therefore, these amendments will not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. 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).

F. 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 September 25, 1998. 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 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Municipal waste combustors, Reporting and recordkeeping requirements.

Dated: July 7, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR Part 62 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart PP—South Carolina

2. Section 62.10100 is amended by adding paragraphs (b)(3) and (c)(3) as follows:

§ 62.10100 Identification of plan.

* * * * *

(b) * * *

(3) South Carolina Implementation Plan for Existing Large Municipal Waste Combustors, submitted on January 14, 1998, by the South Carolina Department of Health and Environmental Control.

(c) * * *

(3) Existing municipal waste combustors.

3. Subpart PP is amended by adding a new § 62.10150 and a new undesignated center heading to read as follows: Metals, acid gases, organic compounds and nitrogen oxide emissions from existing municipal waste combustors with the capacity to combust greater than 250 tons per day of municipal solid waste.

§ 62.10150 Identification of sources.

The plan applies to existing facilities with a municipal waste combustor (MWC) unit capacity greater than 250 tons per day of municipal solid waste (MSW) at the following MWC sites:

(a) Foster Wheeler Charleston Resource Recovery Facility, Charleston, South Carolina.

(b) [Reserved]

[FR Doc. 98–19934 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MN51–01–7276a; FRL–6128–8]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Minnesota; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The United States Environmental Protection Agency (EPA) is approving the Minnesota State Plan submittal for implementing the Municipal Solid Waste (MSW) Landfill Emission Guidelines. The State's plan submittal was made pursuant to requirements found in the Clean Air Act (Act). The State's plan was submitted to EPA on March 4, 1997, in accordance with the requirements for adoption and submittal of State plans for designated facilities in 40 CFR part 60, subpart B. It establishes performance standards for existing MSW landfills and provides for the implementation and enforcement of those standards. The EPA finds that Minnesota's Plan for existing MSW landfills adequately addresses all of the Federal requirements applicable to such plans. If adverse comments are received on this action, the EPA will withdraw this final rule and address the comments received in response to this action in a final rule on the related proposed rule, which is being published in the proposed rules section of this **Federal Register**. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time. This approval makes federally enforceable the State's rule that has been incorporated by reference.

DATES: The "direct final" is effective on September 25, 1998, unless EPA receives adverse or critical comments by August 26, 1998. Should EPA receive adverse comments, a timely withdrawal of the Direct Final Rule will be published in the **Federal Register** to inform the public that the rule will not take effect.

ADDRESSES: Written comments should be sent to: Carlton T. Nash, Chief, Regulation Development Section , Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the proposed State Plan submittal and EPA's analysis are available for inspection at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Douglas Aburano at (312) 353–6960 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Douglas Aburano, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR–18J), U.S. EPA, Region 5, Chicago, Illinois 60604, (312) 353–6960.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 111(d) of the Act, EPA established procedures whereby States submit plans to control certain existing sources of "designated pollutants." Designated pollutants are defined as pollutants for which a standard of performance for new sources applies under section 111, but which are not "criteria pollutants" (i.e., pollutants for which National Ambient Air Quality Standards (NAAQS) are set pursuant to sections 108 and 109 of the Act) or hazardous air pollutants (HAPs) regulated under section 112 of the Act (see 40 CFR 60.21(a)). As required by section 111(d) of the Act, EPA established a process at 40 CFR part 60, subpart B, similar to the process required by section 110 of the Act (regarding State Implementation Plan (SIP) approval) which States must follow in adopting and submitting a section 111(d) plan. Whenever EPA promulgates a new source performance standard (NSPS) that controls a designated pollutant, EPA establishes Emissions Guidelines (EG) in accordance with 40 CFR 60.22 which contain information pertinent to the control of the designated pollutant from those existing facilities that, but for their construction prior to the proposal of the NSPS, would be affected by the standard (i.e., the "designated facility" as defined at 40 CFR 60.21(b)). Thus, a State's section 111(d) plan for a designated facility must comply with the EG for that source category as well as 40 CFR part 60, subpart B.

On March 12, 1996, EPA published Emissions Guidelines for existing MSW landfills (EG) at 40 CFR part 60, subpart Cc (40 CFR 60.30c through 60.36c) and NSPS for new MSW Landfills at 40 CFR part 60, subpart WWW (40 CFR 60.750 through 60.759) (see 61 FR 9905–9929). The pollutant regulated by the NSPS and EG is MSW landfill emissions, which contain a mixture of volatile organic compounds (VOCs), other organic compounds, methane, and HAPs. VOC emissions can contribute to ozone formation which can result in adverse effects to human health and vegetation. The health effects of HAPs include cancer, respiratory irritation, and damage to the nervous system. Methane emissions contribute to global climate change and can result in fires or explosions when they accumulate in structures on or off the landfill site. To determine if control is required, nonmethane organic compounds (NMOCs) are measured as a surrogate for MSW landfill emissions. Thus, NMOC is considered the designated pollutant. The designated facility which is subject to the EG is each existing MSW landfill (as defined in 40 CFR 60.31c) for which construction, reconstruction or modification was commenced before May 30, 1991.

Pursuant to 40 CFR 60.23(a), States were required to submit a plan for the control of the designated pollutant to which the EG applies within nine months after publication of the EG (i.e., by December 12, 1996). If there were no designated facilities in the State, then the State was required to submit a negative declaration by December 12, 1996.

On March 4, 1997, the State of Minnesota submitted its "Section 111(d) Plan for MSW Landfills" for implementing EPA's MSW landfill EG. The following provides a brief discussion of the requirements for an approvable State plan for existing MSW landfills and EPA's review of Minnesota's submittal in regard to those requirements. More detailed information on the requirements for an approvable plan and Minnesota's submittal can be found in the Technical Support Document (TSD) accompanying this document, which is available upon request.

II. Review of Minnesota's MSW Landfill Plan

EPA has reviewed Minnesota's section 111(d) plan for existing MSW landfills against the requirements of 40 CFR part 60, subpart B and subpart Cc, as follows:

A. Identification of Enforceable State Mechanism for Implementing the EG

40 CFR 60.24(a) requires that the section 111(d) plan include emissions standards, defined in 40 CFR 60.21(f) as "a legally enforceable regulation setting forth an allowable rate of emissions into the atmosphere, or prescribing equipment specifications for control of air pollution emissions."

The State of Minnesota, through the Minnesota Pollution Control Agency (MPCA), has adopted State rules to control air emissions from existing landfills in the State. The rules are found at Minn. R. 7011.3500 through 7011.3510. They were proposed in the *State Register* (21 SR 271) on August 26, 1996, and the notice of adoption appeared in the *State Register* (21 SR 993) on January 21, 1997. The rules became effective five working days after publication, January 28, 1997. Also submitted as part of the 111(d) plan were definitions already adopted at the State level as part of Solid Waste regulations. Thus, the State has met the requirement of 40 CFR 60.24(a) to have legally enforceable emission standards.

B. Demonstration of the State's Legal Authority to Carry out the Section 111(d) State Plan as Submitted

40 CFR 60.26 requires the section 111(d) plan to demonstrate that the State has legal authority to adopt and implement the emission standards and compliance schedules.

MPCA has the legal authority to adopt and implement the rules governing landfill gas emissions from existing MSW landfills. The MPCA enclosed a letter dated February 3, 1997, from the Minnesota Assistant Attorney General, Kathleen Winters, that identifies the statutory sources of the MPCA's legal authority.

EPA has reviewed the Assistant Attorney General's opinion and the State laws and has determined that the MPCA has adequate legal authority to adopt and implement the section 111(d) plan in accordance with 40 CFR 60.26.

C. Inventory of Existing MSW Landfills in the State Affected by the State Plan

40 CFR 60.25(a) requires the section 111(d) plan to include a complete source inventory of all existing MSW landfills (i.e., those MSW landfills that were constructed, reconstructed, or modified prior to May 30, 1991) in the State that are subject to the plan. This includes all existing landfills that have accepted waste since November 8, 1987 or that have additional capacity for future waste deposition.

A list of the existing MSW landfills in Minnesota and an estimate of NMOC emissions from each landfill have been submitted as part of the State's landfill 111(d) plan.

D. Inventory of Emissions From Existing MSW Landfills in the State

40 CFR 60.25(a) requires that the plan include an emissions inventory that estimates emissions of the pollutant regulated by the EG, which, in the case of MSW landfills, is NMOC. Minnesota included in Attachment V of its section 111(d) plan an estimation of NMOC emissions for all of the landfills in the State using the Landfill Air Emissions Estimation Model and AP–42 default emission factors.

E. Emission Limitations for MSW Landfills

40 CFR 60.24(c) specifies that the State plan must include emission standards that are no less stringent than the EG (except as specified in 40 CFR 60.24(f) which allows for less stringent emission limitations on a case-by-case basis if certain conditions are met). 40 CFR 60.33c contains the emissions standards applicable to existing MSW landfills.

The MPCA rules require existing MSW landfills to comply with the same equipment design criteria and level of control as prescribed in the NSPS. The controls required by the NSPS are the same as those required by the EG. Thus, the emission limitations/standards are "no less stringent than" subpart Cc, which meets the requirements of 40 CFR 60.24(c).

Section 60.24(f) allows States, in certain case-by-case situations, to provide for a less stringent standard or longer compliance schedule. Minn. R. 7011.3505, subp. 6, requires an owner/operator seeking to apply a less stringent standard, or longer compliance schedule, to submit a written request to the MPCA and the EPA which demonstrates compliance with the criteria set forth in to 40 CFR 60.24(f).

Thus, MPCA's plan meets the emission limitation requirements by requiring emission limitations that are no less stringent than the EG.

F. A Process for State Review and Approval of Site-Specific Gas Collection and Control System Design Plans

40 CFR 60.33c(b) in the EG requires State plans to include a process for State review and approval of site-specific design plans for required gas collection and control systems.

The MPCA's rules regulating landfill gas emissions from MSW landfills essentially make the federal NSPS applicable to existing MSW landfills. The design criteria and the design specifications for active collection systems specified in the NSPS also apply to existing landfills, unless a request pursuant to 40 CFR 60.24(f) has been approved by the MPCA and by EPA. Once a design plan is received, MPCA will record the date the plan is received. MPCA will then review the submittal for completeness and will request additional information if necessary. A review of the design plan will be completed within 180 days of its receipt.

Thus, Minnesota's section 111(d) plan adequately addresses this requirement.

G. Compliance Schedules

The State's section 111(d) plan must include a compliance schedule that owners and operators of affected MSW landfills must meet in complying with the requirements of the plan. 40 CFR 60.36c provides that planning, awarding of contracts, and installation of air emission collection and control equipment capable of meeting the EG must be accomplished within 30 months of the effective date of a State emission standard for MSW landfills. 40 CFR 60.24(e)(1) provides that any compliance schedule extending more than 12 months from the date required for plan submittal shall include legally enforceable increments of progress as specified in 40 CFR 60.21(h), including deadlines for submittal of a final control plan, awarding of contracts for emission control systems, initiation of on-site construction or installation of emission control equipment, completion of on-site construction/installation of emission control equipment, and final compliance.

MPCA has adopted enforceable compliance schedules in Minn. R. 7011.3505 Subpart 5. The State's rules require landfills that are required to install collection and control systems be in final compliance with the requirements of the State plan no later than 30 months from the effective date of State adoption of the State rule or, for those MSW landfills which are not currently subject to the collection and control system requirements, within 30 months of first becoming subject to such requirements (i.e., within 30 months of reporting a NMOC emission rate of 50 Mg/yr or greater). Thus, the State's rule satisfies the requirement of 40 CFR 60.36c.

H. Testing, Monitoring, Recordkeeping and Reporting Requirements

40 CFR 60.34c specifies the testing and monitoring provisions that State plans must include (60.34c references the requirements found in 40 CFR 60.753 to 60.756), and 40 CFR 60.35c specifies the reporting and recordkeeping requirements (60.35c references to the requirements found in 40 CFR 60.757 and 60.758). The MPCA has adopted by reference 40 CFR 60.750 through 60.759 with certain specific exceptions that apply only to those sources subject to the EG standards.

Minn. R. 7011.3505 Subpart 2 allows an exception to the quarterly monitoring requirements for surface methane concentrations in 40 CFR 60.756(f). The State rule only requires surface methane concentration monitoring during the second, third, and fourth quarters of the calendar year. In a November 14, 1997 letter to EPA, the State submitted extensive climatological data and explained why it believes this data shows that exceedingly cold temperatures and snow cover during the winter quarter (essentially the months of December, January and February) would make monitoring of surface methane concentrations nearly impossible. In examining the data for the MSW landfills that currently appear to be subject to the collection and control system requirements of the State plan, the State found the following information:

1. The daily mean temperatures in range from 8.1 to 17.9 degrees Fahrenheit during December, January and February;

2. Average wind chill factors range from −9.0 degrees to 3.0 degrees Fahrenheit;

3. An average total snowfall receive each year is between 45 and 50 inches, of which 27 to 28 inches are received in December, January and February;

4. At least one inch of snow covers the area from November 24 to April 1; and

5. The mean duration of snow on the ground is:

a. Greater than or equal to 1 inch, 95–100 days;

b. Greater than or equal to 3 inches, 75–90 days;

c. Greater than or equal to 6 inches, 50–65 days;

d. Greater than or equal to 12 inches, 20–30 days; and

e. Greater than or equal to 24 inches, 5–10 days.

Thus, MPCA contends that, with mean temperatures during the winter quarter below freezing and with snow covering the landfill at depths sometimes greater than two feet, surface monitoring for methane during the winter quarter is not practical and, at best, extremely difficult.

EPA believes that the State has provided substantial documentation showing that the extremely cold temperatures and wind chill factors, as well as the snow cover, justify the exemption from first quarter monitoring for surface methane concentrations. If any other existing MSW landfills become subject to the State's section 111(d) plan in the future, EPA will need to re-evaluate the State's exemption from first quarter monitoring based on the location and meteorological data for that location.

40 CFR 60.756(b)(2) and 60.756(c)(2) require the installation of a gas flow rate measuring device (which will record the flow to the control device) or that the bypass line valve shall be secured in the closed position with a car-seal or a lock-and-key type configuration. These requirements assume that there is some way to bypass the control device. If there is no bypass, then this requirement for equipment to monitor bypasses is obviated. Minn. R 7011.3505 Subp. 3 allows landfill owners or operators seeking to comply with 40 CFR 60.756(b)(2) and 60.756(c)(2), to alternatively confirm that there is no means to bypass the control device in the design plan. Therefore, MPCA's alternative compliance method is acceptable.

Consequently, EPA finds that the State's section 111(d) plan for MSW landfills adequately addresses the testing, monitoring, reporting, and recordkeeping requirements of the EG.

I. A Record of Public Hearings on the State Plan

40 CFR 60.23 contains the requirements for public hearings that must be met by the State in adopting a section 111(d) plan. Additional guidance is found in EPA's "Summary of the Requirements for Section 111(d) State Plans for Implementing the Municipal Solid Waste Landfill Emission Guidelines (EPA–456R/96–005, October 1996)." Minnesota included documents in its plan submittal demonstrating that these procedures, as well as the State's administrative procedures, were complied with in adopting the State's plan. Therefore, EPA finds that Minnesota has adequately met this requirement.

J. Submittal of Annual State Progress Reports to EPA

40 CFR 60.25(e) and (f) require States to submit to EPA annual reports on the progress of plan enforcement. Minnesota committed in the submittal letter for its section 111(d) plan to submit annual progress reports to EPA. The first progress report will be submitted by the State one year after EPA approval of the State plan.

III. Final Action

Based on the rationale discussed above and in further detail in the TSD associated with this action, EPA is approving Minnesota's March 4, 1997 submittal of its section 111(d) plan for the control of landfill gas from existing MSW landfills. As provided by 40 CFR 60.28(c), any revisions to Minnesota's section 111(d) plan or associated regulations will not be considered part of the applicable plan until submitted by the State in accordance with 40 CFR 60.28(a) or (b), as applicable, and until approved by EPA in accordance with 40 CFR part 60, subpart B.

EPA has been involved in litigation over the requirements of the MSW landfill EG and NSPS since the summer of 1996. On November 13, 1997, EPA issued a notice of proposed settlement in *National Solid Wastes Management Association* v. *Browner, et. al.*, No. 96–1152 (D.C. Cir), in accordance with section 113(g) of the Act. (See 62 FR 60898.) It is important to note that the proposed settlement does not vacate or void the existing MSW landfill EG or NSPS. Pursuant to the proposed settlement agreement, EPA published a direct final rulemaking on June 16, 1998, in which EPA is amending 40 CFR part 60, subparts Cc and WWW, to add clarifying language, make editorial amendments, and to correct typographical errors. See 63 FR 32783–4, 32743–53. EPA regulations at 40 CFR 60.23(a)(2) provide that a State has nine months to adopt and submit any necessary State Plan revisions after publication of a final revised emission guideline document. Thus, States are not yet required to submit State Plan revisions to address the June 16, 1998 direct final amendments to the EG. In addition, as stated in the June 16, 1998 preamble, the changes to 40 CFR part 60, subparts Cc and WWW, do not significantly modify the requirements of those subparts (see 63 FR 32744). Accordingly, the MSW landfill EG published on March 12, 1996 was used as a basis for EPA's review of Minnesota's submittal. Minnesota is not required to make a subsequent submittal since its original submittal was reviewed against the March 12, 1996 EG and these latest amendments to the EG do not increase the stringency of the rule or add additional control requirements, nor do the amendments

alter control, monitoring, recordkeeping, or reporting requirements of the March 12, 1996 EG (see 63 FR 32750).

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the State Plan should adverse or critical comments be filed. This action will be effective September 25, 1998, unless, by August 26, 1998, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the companion proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on September 25, 1998.

IV. Administrative

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks," because it is not an "economically significant" action under Executive Order 12866.

C. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and 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. This direct final rule will not have a significant impact on a substantial number of small entities because State Plan approvals under section 111(d) of the CAA do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal State Plan approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the CAA preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of a State action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. This Federal action approves pre-existing requirements under State law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

E. Audit Privilege and Immunity Law

Nothing in this action should be construed as making any determination or expressing any position regarding Minnesota's audit privilege and penalty immunity law sections 114C.20 to 114C.31 of the Minnesota Statute or its impact upon any approved provision in the State Plan. The action taken herein does not express or imply any viewpoint on the question of whether there are legal deficiencies in this or any other Act program resulting from the effect of Minnesota's audit privilege and immunity law. A State audit privilege and immunity law can affect only State enforcement and cannot have any impact on Federal enforcement authorities. EPA may at any time invoke its authority under the Act including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the State plan, independently of any State enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by a State audit privilege or immunity law.

F. 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. The 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 the publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

G. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 25, 1998. 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 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Methane, Municipal solid waste landfills, Nonmethane organic compounds, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 10, 1998.

David A. Ullrich,

Acting Regional Administrator.

Part 62, Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Subpart Y is amended by adding an undesignated center heading and sections 62.5860, 62.5861 and 62.5862 to read as follows:

Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

§ 62.5860 Identification of plan.

"Section 111(d) Plan for Municipal Solid Waste Landfills," submitted by the State on March 4, 1997.

§ 62.5861 Identification of sources.

The plan applies to all existing municipal solid waste landfills for which construction, reconstruction, or

modification was commenced before May 30, 1991 that accepted waste at any time since November 8, 1987 or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

§ 62.5862 Effective date.

The effective date of the plan for municipal solid waste landfills is September 25, 1998.

[FR Doc. 98–19937 Filed 7–24–98; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[FRL–6129–1]

RIN 2060–AF70

Extension of Operating Permits Program Interim Approval Expiration Dates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes to amend Appendix A of the operating permits regulations codified in part 70 of chapter I of title 40 of the Code of Federal Regulations. Those regulations were originally promulgated on July 21, 1992. These amendments to Appendix A would extend up to June 1, 2000 all operating permits program interim approvals. This action would allow the program revisions necessary to correct interim approval deficiencies to be combined with program revisions necessary to implement the revisions to part 70 that are anticipated to be promulgated in December 1999.

DATES: Comments. Comments must be received on or before August 26, 1998. For those programs whose interim approval dates would be amended by this action, interim approval would expire on June 1, 2000.

ADDRESSES: Comments. Comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–93–50 (see docket section below), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The EPA requests that a separate copy also be sent to the contact person listed below.

Docket. Supporting material used in developing the proposal and final regulatory revisions is contained in Docket Number A–93–50. This docket is available for public inspection and copying between 8:30 a.m. and 5:30 p.m., Monday through Friday, at the address listed above, or by calling (202) 260–7548. The Docket is located at the above address in Room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Roger Powell, Mail Drop 12, United States Environmental Protection Agency, Office of Air Quality Planning and Standards, Information Transfer and Program Integration Division, Research Triangle Park, North Carolina 27711 (telephone 919–541–5331, e-mail: powell.roger@epa.gov).

SUPPLEMENTARY INFORMATION: If no relevant, adverse comments are timely received, no further activity is contemplated in relation to this proposal, and the direct final rule in the final rules section of this **Federal Register** will automatically go into effect on the date specified in that final rulemaking. Public comment received will be addressed in a subsequent final rule based on this proposal. Because EPA will not institute a second comment period on this proposal, any parties interested in commenting should do so during this comment period.

For further supplemental information, the detailed rationale, and the rule provisions, see the information provided in the direct final rule in the final rules section of this **Federal Register**.

Administrative Requirements

A. Docket

The docket for this proposed action is A–93–50. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed rulemaking. The principal purposes of the docket are: (1) to allow interested parties a means to identify and locate documents so that the parties can effectively participate in the rulemaking process, and (2) to serve as the record in case of judicial review (except for interagency review materials). The docket is available for public inspection at EPA's Air Docket, which is listed under the **ADDRESSES** section of this notice.

B. Executive Order (E.O.) 12866

Under E.O. 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether each regulatory action is "significant," and therefore subject to the Office of Management and Budget (OMB) review and the requirements of the Order. The Order defines "significant" regulatory action as one that is likely to lead to a rule that may:

1. Have an annual effect on the economy of $100 million or more, adversely and materially affecting 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 obligation of recipients thereof.
4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Pursuant to the terms of E.O. 12866, it has been determined that this proposed action is not a "significant" regulatory action because it would not substantially change the existing part 70 requirements for States or sources; requirements which have already undergone OMB review. Rather than impose any new requirements, this action would only extend an existing mechanism. As such, this action is exempted from OMB review.

C. Regulatory Flexibility Act Compliance

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this proposed action would not have a significant economic impact on a substantial number of small entities. In developing the original part 70 regulations, the Agency determined that they would not have a significant economic impact on a substantial number of small entities. Similarly, the same conclusion was reached in an initial regulatory flexibility analysis performed in support of the proposed part 70 revisions. This action would not substantially alter the part 70 regulations as they pertain to small entities and accordingly would not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in part 70 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.* and has assigned OMB control number 2060–0243. The Information Collection Request (ICR) prepared for part 70 would not be affected by the action in this proposed rulemaking action because the part 70 ICR determined burden on a nationwide basis, assuming

all part 70 sources were included without regard to the approval status of individual programs. The action in this proposed rulemaking action, which would simply provide for an extension of the interim approval of certain programs, would not alter the assumptions of the approved part 70 ICR used in determining the burden estimate. Furthermore, this proposed action would not impose any additional requirements which would add to the information collection requirements for sources or permitting authorities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 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 a 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 1 year.

The EPA has determined that the action in this proposed rulemaking notice would not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector, in any 1 year. Although the part 70 regulations governing State operating permit programs impose significant Federal mandates, this proposed action would not amend the part 70 regulations in a way that would significantly alter the expenditures resulting from these mandates. Therefore, the Agency concludes that it is not required by section 202 of the UMRA of 1995 to provide a written statement to accompany this proposed regulatory action.

F. Applicability of Executive Order 13045

Executive Order 13045 applies to any rule that EPA determines (1) "economically significant" as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has 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 other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to E.O. 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not an economically significant regulatory action as defined by Executive Order 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

Dated: July 17, 1998.

Carol M. Browner,

Administrator.

[FR Doc. 98–19933 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[FRL–6128–9]

RIN 2060–AF70

Extension of Operating Permits Program Interim Approval Expiration Dates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action amends Appendix A of the operating permits regulations codified in part 70 of chapter I of title 40 of the Code of Federal Regulations. Those regulations were originally promulgated on July 21, 1992. These amendments to Appendix A extend up to June 1, 2000 all operating permits program interim approvals. This action will allow the program revisions necessary to correct interim approval deficiencies to be combined with program revisions necessary to implement the revisions to part 70 that are anticipated to be promulgated in December 1999.

DATES: The direct final revisions to Appendix A will become effective on September 10, 1998. The direct final revisions will become effective without further notice unless EPA receives relevant adverse comments on or before August 26, 1998. Should the Agency receive such comments, it will publish a timely withdrawal and will inform the public that this rule will not take effect. For those programs whose interim approval dates are amended by this action, interim approval will expire on June 1, 2000.

ADDRESSES: Comments. Comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–93–50 (see docket section below), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The EPA requests that a separate copy also be sent to the contact person listed below.

Docket. Supporting material used in developing the proposal and final regulatory revisions is contained in Docket Number A–93–50. This docket is available for public inspection and copying between 8:30 a.m. and 5:30 p.m., Monday through Friday, at the address listed above, or by calling (202) 260–7548. The Docket is located at the above address in Room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Roger Powell, Mail Drop 12, United States Environmental Protection Agency, Office of Air Quality Planning and Standards, Information Transfer and Program Integration Division, Research Triangle Park, North Carolina 27711 (telephone 919–541–5331, e-mail: powell.roger@epa.gov).

SUPPLEMENTARY INFORMATION: A companion proposal to this direct final rule is being published in today's **Federal Register**. If relevant adverse comments are timely received by the date specified in this rule, EPA will publish a document informing the public that this rule will not take effect and the comments will be addressed in a subsequent final rule based on the proposed rule. If no relevant adverse comments on this direct final rule are timely filed, then the direct final rule will become effective on September 10, 1998, and no further action will be taken on the companion proposal published today.

I. Background

On August 29, 1994 (59 FR 44460) and August 31, 1995 (60 FR 45530), EPA proposed revisions to the part 70 operating permits regulations. Primarily, the proposals addressed changes to the system for revising permits. A number of other less detailed proposed changes were also included. Altogether, State and local permitting authorities will have a complex package of program revisions to prepare in response to these changes once promulgated. The part 70 revisions are anticipated to take place in December 1999.

Contemporaneous with permitting authorities revising their programs to meet the revised part 70, many programs have been granted interim approval which will require permitting authorities to prepare program revisions

to correct those deficiencies identified in the interim approval action. The preamble to the August 31, 1995 proposal noted the concern of many permitting authorities over having to revise their programs twice; once to correct interim approval deficiencies, and again to address the revisions to part 70. In the August 1995 preamble, the Agency proposed that States with interim approval "'* * * should be allowed to delay the submittal of any program revisions to address program deficiencies previously listed in their notice of interim approval until the deadline to submit other changes required by the proposed revisions to part 70" (60 FR 45552). The Agency also proposed "* * * to exercise its discretion under proposed § 70.4(i)(1)(iv) to provide States 2 years to submit program revisions in response to the proposed part 70 revisions * * *" (60 FR 45551).

II. Discussion

A. Purpose of Interim Approval Extensions

On October 31, 1996 (61 FR 56368), EPA amended § 70.4(d)(2) to allow the Administrator to grant extensions to interim approvals so permitting authorities could take advantage of the opportunity to combine program revisions as proposed August 31, 1995. The Agency does not believe, however, that the August 31, 1995 blanket proposal to extend all interim approval program revision submittal dates until up to 2 years after part 70 is revised is appropriate. Program deficiencies that caused granting of interim approval of permitting programs vary from a few problems that can be easily corrected to complex problems that will require regulatory changes and, in some cases, legislative action. Where an undue burden will be encountered by developing two program revisions, combining program revisions and thus granting a longer time period for submission of the program revision to correct interim approval deficiencies is warranted. Where no such burden will occur, the Agency encourages permitting authorities to proceed with correcting their interim approval program deficiencies and not wait for the revised part 70.

Due to controversial issues yet to be resolved, the revisions to part 70 have been delayed beyond the date contemplated by the August 31, 1995 proposal. For permitting authorities to be able to combine program revisions, an agency's program interim approval cannot expire. The Agency must therefore extend any interim approval that may expire before the part 70 revisions are promulgated.

B. Original Action

In the original October 31, 1996 action addressing this subject, all interim approvals granted prior to the date of issuance of a memorandum announcing EPA's position on this issue (memorandum from Lydia N. Wegman to Regional Division Directors, "Extension of Interim Approvals of Operating Permits Programs," June 13, 1996) were extended by 10 months. This action was to encourage permitting authorities to proceed with program revisions within their interim approval timeframes, rather than wait for the revised part 70. The June 1996 memorandum is in the docket for this action.

The reason for this automatic extension was that permitting authorities, upon reading the August 1995 proposed action, may have delayed their efforts to develop program revisions to address interim approval deficiencies because they believed the proposed policy to extend interim approvals until revised part 70 program revisions are due would be adopted for all programs. The EPA has been informed that this was the case in many States. Approximately 10 months passed since the August 1995 proposal until the June 1996 memorandum was issued. The additional 10-month extension to all interim approvals offset any time lost in permitting authority efforts to develop program revisions addressing interim approval deficiencies. This 10-month extension was not applicable to application submittal dates for the second group of sources covered by a source-category limited interim approval.[1]

C. Process for Combining Program Revisions

As noted in the June 1996 memorandum, where the permitting authority applies for it after part 70 is revised, EPA may grant a longer extension to an interim approval so that the program revision to correct interim approval program deficiencies may be combined with the program revision to meet the revised part 70. Such a request must be made within 30 days of promulgation of the part 70 revisions. This will make it possible for EPA to take a single rulemaking action to adopt new interim approval deadlines for all programs for which such an application has been made.

As required by § 70.4(f)(2), program revisions addressing interim approval deficiencies must be submitted to EPA no later than 6 months prior to the expiration of the interim approval. The dates for permitting authorities to submit their combined program revisions to address both the revised part 70 and the interim approval deficiencies will be 6 months prior to the interim approval expiration dates which will be set through a future rulemaking.

The longer extension allowing combining of program revisions to meet both the revised part 70 and interim approval deficiencies will be based on the promulgation date of the revisions to part 70. If only regulatory changes to a program are needed to meet the revised part 70, the extension may be for up to 18 months after the part 70 revisions. If legislative changes are needed to a program to meet the revised part 70, the extension may be for up to 2 years. As previously noted, the program revision submittal date will be 6 months prior to expiration of the extended interim approval.

III. Interim Approval Extensions

The June 13, 1996 memorandum and the October 31, 1996 action anticipated promulgation of the part 70 revisions no later than early 1997. As a result of not being able to promulgate the revisions to part 70 by early 1997, on August 29, 1997, EPA extended interim approvals a second time (62 FR 45732). In that action, EPA anticipated the part 70 revisions would be promulgated by mid-summer 1998 and thus extended all interim approvals that would have expired before October 1, 1998 up until that date. This would have provided the necessary time for agencies to apply to combine their program revisions and EPA to take action on those requests.

It now appears that resolution of issues will not take place until late 1998. Promulgation is now anticipated for December 1999.

The EPA believes that the action to extend interim approvals in this rulemaking is necessary because of further delays in promulgation of the part 70 revisions. Due to these delays, all interim approvals will expire before part 70 is revised, thus denying these agencies the opportunity to combine program revisions. The EPA is aware that many States have been expecting to be able to combine the program revision

[1] Several States have been granted source-category limited interim approvals. Under that type approval, a subset of the part 70 source population is to submit permit applications during the first year of the program. The application submittal period for the remaining sources begins upon full approval of the program. The Agency concludes this second group of sources should still submit permit applications during a period beginning on the original expiration date of a State's interim approval as opposed to any extension of that date.

correcting their interim approval deficiencies with the program revision to address the revised part 70. The Agency estimates that it may take until June 1, 2000 to receive all State requests for combining program revisions and to take the necessary rulemaking action to grant the final extension to those interim approvals. This action, therefore, moves all interim approval expiration dates up to June 1, 2000.

IV. Administrative Requirements

A. Docket

The docket for this regulatory action is A–93–50. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this rulemaking. The principal purposes of the docket are: (1) to allow interested parties a means to identify and locate documents so that the parties can effectively participate in the rulemaking process, and (2) to serve as the record in case of judicial review (except for interagency review materials). The docket is available for public inspection at EPA's Air Docket, which is listed under the **ADDRESSES** section of this notice.

B. Executive Order (E.O.) 12866

Under E.O. 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether each regulatory action is "significant," and therefore subject to the Office of Management and Budget (OMB) review and the requirements of the Order. The Order defines "significant" regulatory action as one that is likely to lead to a rule that may:

1. Have an annual effect on the economy of $100 million or more, adversely and materially affecting 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 obligation of recipients thereof.
4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Pursuant to the terms of E.O. 12866, it has been determined that this action is not a "significant" regulatory action because it does not substantially change the existing part 70 requirements for States or sources; requirements which have already undergone OMB review. Rather than impose any new requirements, this action only extends an existing mechanism. As such, this action is exempted from OMB review.

C. Regulatory Flexibility Act Compliance

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities. In developing the original part 70 regulations, the Agency determined that they would not have a significant economic impact on a substantial number of small entities. Similarly, the same conclusion was reached in an initial regulatory flexibility analysis performed in support of the proposed part 70 revisions (a subset of which constitutes the action in this rulemaking notice). This action does not substantially alter the part 70 regulations as they pertain to small entities and accordingly will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in part 70 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0243. The Information Collection Request (ICR) prepared for part 70 is not affected by the action in this rulemaking notice because the part 70 ICR determined burden on a nationwide basis, assuming all part 70 sources were included without regard to the approval status of individual programs. The action in this rulemaking notice, which simply provides for an extension of the interim approval of certain programs, does not alter the assumptions of the approved part 70 ICR used in determining the burden estimate. Furthermore, this action does not impose any additional requirements which would add to the information collection requirements for sources or permitting authorities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 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 a 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 1 year.

The EPA has determined that the action in this rulemaking notice does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector, in any 1 year. Although the part 70 regulations governing State operating permit programs impose significant Federal mandates, this action does not amend the part 70 regulations in a way that significantly alters the expenditures resulting from these mandates. Therefore, the Agency concludes that it is not required by section 202 of the UMRA of 1995 to provide a written statement to accompany this regulatory action.

F. Submission to Congress and the General Accounting Office

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. The 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).

G. Applicability of Executive Order 13045

Executive Order 13045 applies to any rule that EPA determines (1) "economically significant" as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has 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 other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to E.O. 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not an economically significant regulatory action as defined by Executive Order 12866, and it does not address an environmental health or

safety risk that would have a disproportionate effect on children.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Fugitive emissions, Hydrocarbons, Lead, Nitrogen dioxide, Particulate matter, Volatile organic compounds.

Dated: July 17, 1998.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as set forth below.

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

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

2. Appendix A of part 70 is amended by the following:

a. Adding a sentence to the end of paragraph (dd) under California;

b. Replacing the end date of the third sentence with "June 1, 2000" in paragraph (a) under Texas; and

c. Replacing the end date of each paragraph with "June 1, 2000" as follows: Paragraph (a) under Alaska, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oklahoma, Rhode Island, Vermont, Virgin Islands, Virginia, West Virginia, Wisconsin, and Wyoming; Paragraphs (a), (b), and (c) under Alabama and Nevada; Paragraphs (a), (b), (c), (d)(1), and (d)(2) under Arizona, Paragraphs (a) through (cc) and (ee) through (hh) under California; paragraphs (a) and (e) under Tennessee; and paragraphs (a) through (i) under Washington.

Alabama

(a) * * * June 1, 2000.
(b) * * * June 1, 2000.
(c) * * * June 1, 2000.

Alaska

(a) * * * June 1, 2000.
* * * * *

Arizona

(a) * * * June 1, 2000.
(b) * * * June 1, 2000.
(c) * * * June 1, 2000.
(d)(1) * * * June 1, 2000.
(d)(2) * * * June 1, 2000.

Arkansas

(a) * * * June 1, 2000.
* * * * *

California * * *

(a) * * * June 1, 2000.
(b) * * * June 1, 2000.
(c) * * * June 1, 2000.
(d) * * * June 1, 2000.
(e) * * * June 1, 2000.
(f) * * * June 1, 2000.
(g) * * * June 1, 2000.
(h) * * * June 1, 2000.
(i) * * * June 1, 2000.
(j) * * * June 1, 2000.
(k) * * * June 1, 2000.
(l) * * * June 1, 2000.
(m) * * * June 1, 2000.
(n) * * * June 1, 2000.
(o) * * * June 1, 2000.
(p) * * * June 1, 2000.
(q) * * * June 1, 2000.
(r) * * * June 1, 2000.
(s) * * * June 1, 2000.
(t) * * * June 1, 2000.
(u) * * * June 1, 2000.
(v) * * * June 1, 2000.
(w) * * * June 1, 2000.
(x) * * * June 1, 2000.
(y) * * * June 1, 2000.
(z) * * * June 1, 2000.
(aa) * * * June 1, 2000.
(bb) * * * June 1, 2000.
(cc) * * * June 1, 2000.
(dd) * * * Interim approval expires on June 1, 2000.
(ee) * * * June 1, 2000.
(ff) * * * June 1, 2000.
(gg) * * * June 1, 2000.
(hh) * * * June 1, 2000.

Colorado

(a) * * * June 1, 2000.
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Connecticut

(a) * * * June 1, 2000.
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Delaware

(a) * * * June 1, 2000.
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District of Columbia

(a) * * * June 1, 2000.
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Florida

(a) * * * June 1, 2000.
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Georgia

(a) * * * June 1, 2000.
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Hawaii

(a) * * * June 1, 2000.
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Idaho

(a) * * * June 1, 2000.
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Illinois

(a) * * * June 1, 2000.
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Indiana

(a) * * * June 1, 2000.
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Kentucky

(a) * * * June 1, 2000.
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Maine

(a) * * * June 1, 2000.
* * * * *

Maryland

(a) * * * June 1, 2000.
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Massachusetts

(a) * * * June 1, 2000.
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Michigan

(a) * * * June 1, 2000.
* * * * *

Minnesota

(a) * * * June 1, 2000.
* * * * *

Montana

(a) * * * June 1, 2000.
* * * * *

Nevada

(a) * * * June 1, 2000.
(b) * * * June 1, 2000.
(c) * * * June 1, 2000.

New Hampshire

(a) * * * June 1, 2000.
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New Jersey

(a) * * * June 1, 2000.
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New York

(a) * * * June 1, 2000.
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North Carolina

(a) * * * June 1, 2000.
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North Dakota

(a) * * * June 1, 2000.
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Oklahoma

(a) * * * June 1, 2000.
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Rhode Island

(a) * * * June 1, 2000.

* * * * *

Tennessee

(a) * * * June 1, 2000.

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(e) * * * June 1, 2000.

Texas

(a) * * * Interim approval will expire June 1, 2000. * * *

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Vermont

(a) * * * June 1, 2000.

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Virgin Islands

(a) * * * June 1, 2000.

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Virginia

(a) * * * June 1, 2000.

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Washington

(a) * * * June 1, 2000.
(b) * * * June 1, 2000.
(c) * * * June 1, 2000.
(d) * * * June 1, 2000.
(e) * * * June 1, 2000.
(f) * * * June 1, 2000.
(g) * * * June 1, 2000.
(h) * * * June 1, 2000.
(i) * * * June 1, 2000.

West Virginia

(a) * * * June 1, 2000.

* * * * *

Wisconsin

(a) * * * June 1, 2000.

* * * * *

Wyoming

(a) * * * June 1, 2000.

[FR Doc. 98–19932 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101–43

[FPMR Amendment H–198]

RIN 3090–AG64

Excess Personal Property Reporting Requirements

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This regulation streamlines and simplifies the assignment of the disposal condition codes which Federal agencies use to report their excess personal property for utilization and donation. This amendment will reduce the number of codes from 11 to 5 and more accurately define the condition of the excess personal property.

EFFECTIVE DATE: December 1, 1998.

FOR FURTHER INFORMATION CONTACT: Martha Caswell, Director, Personal Property Management Policy Division (MTP) 202–501–3828.

SUPPLEMENTARY INFORMATION:

A. The General Services Administration (GSA) has determined that this rule is not a significant rule for the purposes of Executive Order 12866 of September 30, 1993.

B. Regulatory Flexibility Act

This rule is not required to be published in the **Federal Register** for public comment. Therefore, the Regulatory Flexibility Act does not apply.

C. Paperwork Reduction Act

GSA has determined that the Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain any collection requirements which require the approval of the Office of Management and Budget. This rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Part 101–43

Government property management, Excess government property.

For reasons set forth in the preamble, 41 CFR Part 101–43 is amended as follows:

1. The authority citation for part 101–43 continues to read as follows:

Authority: Sec. 205 (c), 63 Stat. 390: 40 U.S.C. 486(c).

PART 101–43—UTILIZATION OF PERSONAL PROPERTY

Subpart 101–43.48—Exhibits

2. Section 101–43.4801 is amended by revising paragraph (d) and in paragraph (e) by removing the words "paragraph (e)" and adding in their place the words "paragraph (d)" to read as follows:

§ 101–43.4801 Excess personal property reporting requirements.

* * * * *

(d) The appropriate disposal condition code from the table below shall be assigned to each item record, report, or listing of excess personal property:

Disposal condition code	Brief definition	Expanded definition
1	Excellent	Property which is in new condition or unused condition and can be used immediately without modifications or repairs.
4	Usable	Property which shows some wear, but can be used without significant repair.
7	Repairable	Property which is unusable in its current condition but can be economically repaired.
X	Salvage	Property which has value in excess of its basic material content but repair or rehabilitation is impractical and/or uneconomical.
S	Scrap	Property which has no value except for its basic material content.

* * * * *

Dated: July 14, 1998.

David J. Barram,

Administrator of General Services.

[FR Doc. 98–20010 Filed 7–24–98; 8:45 am]

BILLING CODE 6820–23–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 20, 80, and 90

[PR Docket No. 92–257; FCC 98–151]

Maritime Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission has adopted a *Third Report and Order and Memorandum Opinion and Order* in PR Docket No. 92–257 which simplifies the licensing process and introduces additional flexibility for public coast stations. Specifically, the Commission amends the maritime service rules to designate geographic licensing regions for very high frequency (VHF) public coast stations, and assign all currently unassigned VHF public correspondence channels on a geographic basis by competitive bidding. The uniform competitive bidding rules will apply in public coast station auctions. The Commission also adopts small business provisions for qualifying public coast station applicants, and defines the criteria used to determine eligibility for these provisions. The effect will be to promote and facilitate the participation of small businesses in the Commission's auctions and in the provision of spectrum-based services.

EFFECTIVE DATE: September 25, 1998.

FOR FURTHER INFORMATION CONTACT: *Non-auction information:* Scot Stone of the Wireless Telecommunications Bureau, Public Safety and Private Wireless Division, at (202) 418–0680 or via E-mail to "sstone@fcc.gov". *Auction information:* Anne Napoli of the Wireless Telecommunications Bureau, Auctions and Industry Analysis Division, Legal Branch, at (202) 418–0660. *TTY:* (202) 418–7233.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Third Report and Order and Memorandum Opinion and Order*, PR Docket No. 92–257, FCC 98–51, adopted , July 6, 1998, and released, July 9, 1998. The full text of this *Third Report and Order and Memorandum Opinion and Order* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text may be purchased from the Commission's copy contractor, International Transcription Services, 1231 20th Street, NW, Washington, DC 20036, telephone (202) 857–3800, facsimile (202) 857–3805. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260, TTY (202) 418–2555, or at mcontee@fcc.gov. The full text of the *Third Report and Order and Memorandum Opinion and Order* can also be downloaded at: http://www.fcc.gov/Bureaus/Wireless/Orders/1998/fcc98151.txt or http://www.fcc.gov/Bureaus/Wireless/Orders/1998/fcc98151.wp, and the map set out in the paper version may be downloaded at http://www.fcc.gov/Bureaus/Wireless/Orders/1998/fc98151a.pdf.

Summary of the Third Report and Order and Memorandum Opinion and Order

1. The Commission initiated the instant proceeding to update the Maritime Service rules to promote the use of new, spectrally efficient radio communications techniques. In the *Second Further Notice of Proposed Rule Making* (62 FR 37533, July 14, 1997), the Commission proposed rules to simplify the license process for VHF public coast stations.

2. The Commission amends the rules to license VHF public correspondence channel pairs on a geographic basis, in lieu of the site-based approach presently used. The Commission designates forty-two licensing areas: nine maritime VHF Public Coast areas (VPCs), each consisting of one or more Economic Areas (EAs) within one hundred miles of major waterways and grouped together in accordance with Coast Guard Districts; and thirty-three inland VPCs, each consisting of a single EA no part of which is within one hundred miles of a major waterway.

3. The Commission amends the rules to authorize a single geographic area licensee to operate on all currently unassigned VHF public correspondence frequencies within its licensing area for a ten-year license term. Each geographic area licensee may place stations anywhere within its region to serve vessels or units on land, so long as marine-originating traffic is given priority and incumbent operations are protected. Base stations and land units will be blanket licensed under the geographic license, except that individual licensing is required for base stations that require submission of an Environmental Assessment under 47 CFR 1.1307 or international coordination, or will affect the radio frequency quiet zones described in 47 CFR 80.21. The Commission amends the rules to permit partitioning and disaggregation of the geographic licenses, with partitionees and disaggregatees to hold their licenses for the remainder of the original licensee's term and to have a renewal expectancy.

4. Incumbent VHF public coast station licensees, and private land mobile radio (PLMR) licensees sharing marine spectrum in inland regions, may continue operating indefinitely, and incumbents and geographic area licensees must afford interference protection to one another. If an incumbent fails to construct, discontinues operations, or otherwise has its license terminated, its authorization automatically reverts to the geographic licensee. Incumbent licensees may renew, transfer, assign, and modify their license in any manner so long as such modifications do not extend the incumbent's service area; proposed modifications that would extend an incumbent's service area or request additional frequencies are contingent upon an agreement with each affected licensee.

5. Geographic licensees must provide substantial service. Licensees' showings will be reviewed on a case-by-case basis, but the Commission provides the following safe-harbor examples: for maritime VPC licensees, coverage to one-third of the region's major waterways within five years, and continuous to two-thirds of the region's major waterways within ten years; for inland VPC licensees (and partitionees of maritime VPC licensees where the partitioned area is not contiguous with a major waterway), coverage to one-third of the population of the region within five years and two-thirds of the region's population within ten years.

Competitive Bidding Procedures

6. *Background.* In Implementation of Sections 3(n) and 332 of the Communications Act, Regulatory Treatment of Mobile Services, *Second Report and Order*, 59 FR 18493 (March 7, 1994), the Commission classified the public coast station service as a commercial mobile radio service (CMRS). Subsequently, in Implementation of Section 309(j) of the Communications Act—Competitive Bidding, *Second Report and Order*, 59 FR 22980 (May 4, 1994), the Commission determined that as a CMRS service, mutually exclusive applications for public coast station licenses would be resolved through competitive

bidding. The Commission proposed to establish competitive bidding rules for public coast station licenses in the *Second Further Notice*. Following the release of the *Second Further Notice*, Congress passed the Balanced Budget Act of 1997, Pub. L. 105–33, 111 Stat. 251 (Aug. 5, 1997) (Balanced Budget Act), which expanded and extended the Commission's auction authority.

7. *Decision*. The Commission earlier concluded that the public coast station service is subject to competitive bidding. This conclusion is unchanged by the Balanced Budget Act, which provides that all licenses and construction permits for which mutually exclusive applications are accepted, with certain exceptions not applicable here, shall be granted by means of competitive bidding. The Commission therefore believes that it lacks discretion to resolve mutually exclusive public coast license applications by any means other than competitive bidding. Since the Balanced Budget Act expressly provides that competitive bidding shall not be used for public safety radio services, the inland VPC channel pairs set aside for public safety use shall be awarded by other means, to be decided as part of the Commission's pending public safety proceeding, *see* 62 FR 60199 (November 7, 1997).

Competitive Bidding Issues

8. *Proposal*. The Commission proposed in the *Second Further Notice* to adopt service specific rules to govern public coast station auction(s), pending the adoption of final uniform competitive bidding rules, as proposed in Amendment of Part 1 of the Commission's Rules—Competitive Bidding Procedures, *Second Report and Order, Order on Reconsideration, and Fifth Notice of Proposed Rule Making*, 62 FR 13540 (March 21, 1997). In accordance with the Commission's practice of establishing definitions for "small business" on a service-by-service basis, the Commission also sought comment on establishing a "small business" definition for public coast station auction(s). The Commission tentatively concluded that, to determine small business status, public coast station applicants should attribute the gross revenues of their controlling principals and affiliates, and that the definition of affiliate in the public coast context should include an exception for Indian tribes, Alaska Region and Village Corporations. The Commission tentatively decided not to provide special consideration for incumbent licensees in the competitive bidding process.

9. *Decision*. The uniform competitive bidding rules recently adopted in Amendment of Part 1 of the Commission's Rules—Competitive Bidding Procedures, *Third Report and Order*, 63 FR 2315 (January 15, 1998) (*Part 1 Third Report and Order*), and found in Subpart Q of Part 1 of the Commission's rules, will apply in public coast station auction(s). Thus, the Part 1 definition of affiliate, which includes an exemption for Indian Tribes and Alaska Region and Village Corporations, will apply in public coast station auction(s), *see* 47 CFR 1.2110(b)(4). Consistent with this approach, procedural matters such as the general design and timing of the auction(s); license grouping; bid increments; activity and stopping rules; and application and payment requirements, including upfront payments, will be determined by the Wireless Telecommunications Bureau pursuant to its delegated authority. *See* 47 CFR 0.131(c), 0.331, 0.332.

10. For purposes of public coast auction(s), the Commission defines a *small* business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed fifteen million dollars, and a "very small" business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed three million dollars. A two-tiered definition will allow very small incumbents to compete favorably with larger entities, and will provide entities with relatively low gross revenues an opportunity to participate meaningfully in the auction(s).

11. The Commission also adopts its tentative conclusion to attribute the gross revenues of the applicant, its controlling principals and their affiliates in determining small business eligibility. However, the adopted rule refers to "controlling interests" rather than "controlling principals," and provides a definition of this term for further clarification. A "controlling interest" includes individuals or entities with *de jure* and *de facto* control of the applicant. *De jure* control is 50.1% of the voting stock of a corporation or, in the case of a partnership, the general partners. *De facto* control is determined on a case-by-case basis. The *controlling interest* definition also provides for attribution of partnership and other ownership interests, and offers guidance on calculation of various types of ownership interests. When an applicant cannot identify controlling interests under the definition, the revenues of all interest holders in the applicant and their affiliates are counted. This approach is consistent with the Commission's proposal in Amendment of Part 1 of the Commission's Rules—Competitive Bidding Procedures, *Second Further Notice of Proposed Rule Making*, 63 FR 770 (January 7, 1998), and with the attribution rules applied in recent Commission auctions. The effect will be to ensure that only qualifying entities receive small business benefits, and to enable these entities to attract passive financing in a highly competitive and evolving market. The Commission also emphasizes that all bidders are subject to the ownership disclosure requirements set forth in 47 CFR 1.2112.

12. The Commission adopts its tentative decision not to provide special consideration to incumbent public coast service licensees that participate in the auction(s), because the Commission believes that new entrants and incumbents should have an equal opportunity to obtain spectrum. Qualifying incumbents may benefit from the adopted small business provisions.

13. The bidding credit levels for public coast auction(s) will conform to the schedule adopted in the *Part 1 Third Report and Order*. The *Part 1 Third Report and Order* adopted bidding credits of thirty-five percent for entities with annual gross revenues not to exceed three million, and twenty-five percent for entities with annual gross revenues not to exceed fifteen million. *See* 47 CFR 1.21110(e)(2)(i)–(ii). Thus, public coast station applicants meeting the definition of "very small" business will receive a thirty-five percent bidding credit, and applicants meeting the definition of "small" business will receive a twenty-five percent bidding credit.

14. In the *Part 1 Third Report and Order*, the Commission held that installment payments will not be used in the immediate future as a means of financing small business participation in Commission auctions. Since the Commission received no comment on this issue in this proceeding, installment payments will not be available in public coast station auctions for reasons discussed in the *Part 1 Third Report and Order*.

15. The Commission also received no comments or proposals regarding the sufficiency of small business provisions in promoting participation by minority- and women-owned businesses and rural telephone companies. Therefore, the Commission concludes that it lacks a sufficient record to support such provisions at this time.

16. The Commission may seek comment in a future proceeding on

whether the adopted small business provisions should be modified for auctions of high seas and Automated Maritime Telecommunications Service public coast station spectrum.

Regulatory Flexibility Act

17. As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the *Second Further Notice of Proposed Rule Making* in this proceeding (*Second Further Notice*). The Commission sought written public comment on the proposals in the *Second Further Notice*, including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

18. *Need for, and Objectives of, the Third Report and Order and Memorandum Opinion and Order.* Our objective is to simplify our licensing process for VHF public coast stations. Specifically, this action will: (1) convert licensing of VHF public coast station spectrum from site-by-site licensing to geographic area licensing, (2) simplify and streamline the VHF public coast spectrum licensing procedures and rules, (3) increase licensee flexibility to provide communication services that are responsive to dynamic market demands, and (4) introduce market-based forces into the Maritime Services by using competitive bidding procedures (auctions) to resolve mutually exclusive applications for public coast spectrum. We find that these actions will increase the number and types of communications services available to the maritime community and improve the safety of life and property at sea, and that the potential benefits to the maritime community exceed any negative effects that may result form the promulgation of rules for this purpose. Thus, we conclude that the public interest is served by amending our rules as described above.

19. *Summary of Significant Issues Raised by Public Comments in Response to the IRFA.* No comments were submitted in response to the IRFA. In general comments on the *Second Further Notice*, however, some small business commenters raised issues that might affect small business entities. In particular, some small business commenters argued that geographic licensing should be used only in certain areas; or that incumbent licensees be permitted to expand their systems before any auctions are held; or that license areas should be smaller than Coast Guard Districts, to permit smaller licensees to participate in auctions without having to bid for territory far exceeding their operating needs. The Commission carefully considered each of these comments in reaching the decision set forth herein.

20. *Description and Estimate of the Number of Small Entities to Which Rules Will Apply.* The rules adopted herein will apply to licensees using public coast spectrum. The Commission has not developed a definition of the term "small entity" specifically applicable to public coast station licensees. Therefore, the applicable definition of small entity is the definition under the Small Business Administration rules applicable to radiotelephone service providers. This definition provides that a small entity is any entity employing less than 1,500 persons. *See* 13 CFR 121.201, Standard Industrial Classification (SIC) Code 4812. Since the size data provided by the Small Business Administration does not enable us to make a meaningful estimate of the number of current or prospective public coast station licensees which are small businesses, no commenters responded to our request for information regarding the number of small entities that use or are likely to use public coast spectrum, we used the 1992 Census of Transportation, Communications, and Utilities, conducted by the Bureau of Census, which is the most recent information available. This document shows that only 12 radiotelephone firms out of a total of 1,178 such firms which operated during 1992 had 1,000 or more employees. There are over 100 public coast station licensees. Based on the proposals contained herein, it is unlikely that more than 50 licensees will be authorized in the future. Therefore, for purposes of our evaluations and conclusions in this FRFA, we estimate that there are approximately 150 public coast station licensees which are small businesses, as that term is defined by the Small Business Administration.

21. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements.* All small businesses that choose to participate in the competitive bidding for these services will be required to demonstrate that they meet the criteria set forth to qualify as small businesses, as required under part 1, subpart Q of the Commission's Rules, 47 CFR part 1, subpart Q. Any small business applicant wishing to avail itself of small business provisions will need to make the general financial disclosures necessary to establish that the small business is in fact small. Prior to auction each small business applicant will be required to submit an FCC Form 175, OMB Clearance Number 3060–0600. The estimated time for filling out an FCC Form 175 is 45 minutes. In addition to filing an FCC Form 175, each applicant will have to submit information regarding the ownership of the applicant, any joint venture arrangements or bidding consortia that the applicant has entered into, and financial information demonstrating that a business wishing to qualify for bidding credits is a small business. Applicants that do not have audited financial statements available will be permitted to certify to the validity of their financial showings. While many small businesses have chosen to employ attorneys prior to filing an application to participate in an auction, the rules are intended to enable a small business working with the information in a bidder information package to file an application on its own. When an applicant wins a license, it will be required to submit an FCC Form 494 (common carrier), which will require technical information regarding the applicant's proposals for providing service. This application will require information provided by an engineer who will have knowledge of the system's design.

22. *Steps Taken to Minimize Burdens of Small Entities, and Significant Alternatives Considered.* The Commission in this proceeding has considered comments on ways to implement broad changes to the Maritime Service rules. In doing so, the Commission has adopted alternatives which minimize burdens placed on small entities. First, it has decided to establish a presumption that geographic area licensees are telecommunications carriers, avoiding the need for small telecommunications to provide detailed information about their operations. Also, it has exempted by rule from the Channel 16 safety watch requirement public coast stations eligible whose areas are served by government stations, replacing the prior requirement that such coast stations individually request an exemption. In addition, the Commission has eased the construction requirements for VHF public coast stations.

23. The Commission considered and rejected several significant alternatives. It rejected the alternative of licensing all VHF public coast spectrum by Coast Guard District. Instead, it will license such spectrum in areas removed from major waterways by inland VHF Public Coast Station Area (VPCs), identical to Economic Areas (EAs), allowing small entities there to participate in the auction without bidding for territory far exceeding their operating needs. The Commission rejected the alternative of

delaying the auctions for the inland VPCs by holding frequencies open for public safety applications. Instead, the Commission designated public safety channels in advance. The Commission rejected the alternative of requiring each geographic area licensee to provide detailed information about the services it will offer, so the Commission could determine whether the licensee is a telecommunications carrier. Instead, the Commission established a rebuttable presumption that geographic area licensees are telecommunications carriers, so only those seeking to avoid that classification need submit such information.

24. The Commission will send a copy of the *Third Report and Order and Memorandum Opinion and Order*, including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, *see* 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of the *Third Report and Order and Memorandum Opinion and Order*, including this FRFA, to the Chief Counsel for Advocacy of the Small Business.

Paperwork Reduction Act

25. This *Third Report and Order and Memorandum Opinion and Order* contains neither a modified nor a new information collection.

List of Subjects

47 CFR Part 20

Communications common carriers, Radio, Reporting and recordkeeping requirements.

47 CFR Part 80

Communications equipment, Radio, Vessels.

47 CFR Part 90

Communications equipment, Radio.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

Rule Changes

Accordingly, 47 CFR parts 20, 80, and 90 are amended as follows:

PART 20—COMMERCIAL MOBILE RADIO SERVICES

1. The authority citation for part 20 continues to read as follows:

Authority: Secs. 4, 251–2, 303, and 332, 48 Stat. 1066, 1062, as amended; 47 U.S.C. 154, 251–4, 303, and 332 unless otherwise noted.

2. Amend § 20.9 by revising paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 20.9 Commercial mobile radio service.

* * * * *

(b) Licensees of a Personal Communications Service or applicants for a Personal Communications Service license, and Public Coast Station licensees or applicants, proposing to use any Personal Communications Service or Public Coast Station spectrum to offer service on a private mobile radio service basis must overcome the presumption that Personal Communications Service and Public Coast Stations are commercial mobile radio services.

(1) The applicant or licensee (who must file an application to modify its authorization) seeking authority to dedicate a portion of the spectrum for private mobile radio service, must include a certification that it will offer Personal Communications Service or Public Coast Station service on a private mobile radio service basis. The certification must include a description of the proposed service sufficient to demonstrate that it is not within the definition of commercial mobile radio service in § 20.3 of this chapter. Any application requesting to use any Personal Communications Service or Public Coast Station spectrum to offer service on a private mobile radio service basis will be placed on public notice by the Commission.

* * * * *

PART 80—STATIONS IN THE MARITIME SERVICES

3. The authority citation for part 80 is revised to read as follows:

Authority: Secs. 4, 303, 307(e), 309, and 332, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, 307(e), 309, and 332, unless otherwise noted. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–155, 301–609; 3 UST 3450, 3 UST 4726, 12 UST 2377.

4. Amend § 80.3 by revising paragraph (b) to read as follows:

§ 80.3 Other applicable rule parts of this chapter.

* * * * *

(b) *Part 1.* This part includes rules of practice and procedure for license applications, adjudicatory proceedings, procedures for reconsideration and review of Commission actions; provisions concerning violation notices and forfeiture proceedings; and the environmental processing requirements that, if applicable, must be complied with prior to the initiation of construction. Subpart Q of Part 1 contains rules governing competitive bidding procedures for resolving mutually exclusive applications for certain initial licenses.

* * * * *

5. Amend § 80.25 by revising paragraph (b) to read as follows:

§ 80.25 License term.

* * * * *

(b) Licenses other than ship stations in the maritime services will normally be issued for a term of five years from the date of original issuance, major modification, or renewal, except that licenses for VHF public coast stations will normally be issued for a term of ten years from the date of original issuance, major modification, or renewal. Licenses, other than Public Coast and Alaska Public Fixed stations, may be renewed up to ninety (90) days after the date the license expires.

* * * * *

6. Revise § 80.49 to read as follows:

§ 80.49 Construction and regional service requirements.

(a) *Public coast stations.* (1) Each VHF public coast station geographic area licensee must make a showing of substantial service within its region or service area (subpart P) within five years of the initial license grant, and again within ten years of the initial license grant, or the authorization becomes invalid and must be returned to the Commission for cancellation. "Substantial" service is defined as service which is sound, favorable, and substantially above a level of mediocre service which just might minimally warrant renewal. For site-based VHF public coast station licensees, when a new license has been issued or additional operating frequencies have been authorized, if the station or frequencies authorized have not been placed in operation within twelve months from the date of the grant, the authorization becomes invalid and must be returned to the Commission for cancellation.

(2) For LF, MF, HF, and AMTS band public coast station licensees, when a new license has been issued or additional operating frequencies have been authorized, if the station or frequencies authorized have not been placed in operation within eight months from the date of the grant, the authorization becomes invalid and must be returned to the Commission for cancellation.

(b) *Public fixed stations.* When a new license has been issued or additional operating frequencies have been authorized, if the station or frequencies authorized have not been placed in operation within twelve months from the date of the grant, the authorization

becomes invalid and must be returned to the Commission for cancellation.

7. Add § 80.60 to subpart B to read as follows:

§ 80.60 Partitioned licenses and disaggregated spectrum.

(a) *Eligibility.* VHF Public Coast Station Area (VPCSA) licensees, *see* § 80.371(c)(1)(ii) of this part, may partition their geographic service area or disaggregate their spectrum pursuant to the procedures set forth in this section. Parties seeking approval for partitioning and disaggregation shall request an authorization for partial assignment pursuant to § 1.924 of this chapter.

(b) *Technical standards.* (1) *Partitioning.* In the case of partitioning, all requests for authorization for partial assignment of a license must include, as an attachment, a description of the partitioned service area. The partitioned service area shall be defined by coordinate points at every 3 degrees along the partitioned service area unless an FCC-recognized service area is utilized (e.g., Metropolitan Service Area, Rural Service Area, or Economic Area) or county lines are used. The geographic coordinates must be specified in degrees, minutes, and seconds to the nearest second of latitude and longitude, and must be based upon the 1983 North American Datum (NAD83). In a case where an FCC-recognized service area or county lines are utilized, applicants need only list the specific area(s) (through use of FCC designations or county names) that constitute the partitioned area.

(2) *Disaggregation.* Spectrum may be disaggregated in any amount, provided acquired spectrum is disaggregated according to frequency pairs.

(3) *Combined partitioning and disaggregation.* The Commission will consider requests for partial assignment of licenses that propose combinations of partitioning and disaggregation.

(c) *License term.* The license term for a partitioned license area and for disaggregated spectrum shall be the remainder of the original licensee's term as provided for in § 80.25 of this part.

(d) *Construction Requirements.* (1) *Partitioning.* Partial assignors and assignees for license partitioning have two options to meet construction requirements. Under the first option, the partitionor and partitionee would each certify that they will independently satisfy the substantial service requirement for their respective partitioned areas. If either licensee failed to meet its substantial service showing requirement, only the non-performing licensee's renewal application would be subject to dismissal. Under the second option, the partitioner certifies that it has met or will meet the substantial service requirement for the entire market. If the partitioner fails to meet the substantial service standard, however, only its renewal application would be subject to forfeiture at renewal.

(2) *Disaggregation.* Partial assignors and assignees for license disaggregation have two options to meet construction requirements. Under the first option, the disaggregator and disaggregatee would certify that they each will share responsibility for meeting the substantial service requirement for the geographic service area. If parties choose this option and either party fails to do so, both licenses would be subject to forfeiture at renewal. The second option would allow the parties to agree that either the disaggregator or the disaggregatee would be responsible for meeting the substantial service requirement for the geographic service area. If parties choose this option, and the party responsible for meeting the construction requirement fails to do so, only the license of the nonperforming party would be subject to forfeiture at renewal.

8. Amend § 80.70 by adding new paragraph (c) to read as follows:

§ 80.70 Special provisions relative to coast station VHF facilities.

* * * * *

(c) A VHF (156–162 MHz) public coast station licensee initially authorized on any of the channels listed in the table in § 80.371(c)(1)(i) of this part may transfer or assign its channel(s) to another entity. If the proposed transferee or assignee is the geographic area licensee for the geographic area to which the channel is allocated, such transfer or assignment will be deemed to be in the public interest. However, such presumption will be rebuttable.

9. Revise § 80.105 to read as follows:

§ 80.105 General obligations of coast stations.

Each coast station or marine-utility station must acknowledge and receive all calls directed to it by ship or aircraft stations. Such stations are permitted to transmit safety communication to any ship or aircraft station. VHF (156–162 MHz) public coast stations may provide fixed or hybrid services on a co-primary basis with mobile operations.

10. Amend § 80.303 by revising paragraph (b) to read as follows:

§ 80.303 Watch on 156.800 MHz (Channel 16).

* * * * *

(b) A coast station is exempt from compliance with the watch requirement when Federal, State, or Local Government stations maintain a watch on 156.800 MHz over 95% of the coast station's service area. Each licensee exempted by rule must notify the nearest district office of the U.S. Coast Guard at least thirty days prior to discontinuing the watch, or in the case of new stations, at least thirty days prior to commencing service. The Coast Guard may require any coast station to maintain the watch temporarily or permanently. The Coast Guard may also require any coast station to remain capable of either immediately resuming the watch or providing the Coast Guard direct dial-up access to the necessary 156.800 MHz transceiver at no charge so that the Coast Guard can maintain the watch.

* * * * *

11. Amend § 80.371 by revising paragraph (c) intoductory text, adding paragraph (c)(1)(i) before the table, and adding paragraphs (c)(1)(ii), (c)(1)(iii), (c)(2), (c)(3), and (c)(4) to read as follows:

§ 80.371 Public correspondence frequencies.

* * * * *

(c) *Working frequencies in the marine VHF 156–162 MHz band.* (1)(i) The frequency pairs listed in the table in paragraph (c)(1)(ii) are available for assignment to public coast stations for public correspondence communications with ship stations and units on land.

* * * * *

(ii) Service areas in the marine VHF 156–162 MHz band are VHF Public Coast Station Areas (VPCSAs). As listed in the table in this paragraph, VPCSAs are based on, and composed of one or more of, the U.S Department of Commerce's 172 Economic Areas (EAs). See 60 FR 13114 (March 10, 1995). In addition, the Commission shall treat Guam and the Northern Mariana Islands, Puerto Rico and the United States Virgin Islands, American Samoa, and the Gulf of Mexico as EA-like areas, and has assigned them EA numbers 173–176, respectively. Maps of the EAs and VPCSAs are available for public inspection and copying at the Public Safety and Private Wireless Division, room 8010, 2025 M Street, NW, Washington, DC. Except as shown in the table, the frequency pairs listed in paragraph (c)(1)(i) of this section are available for assignment to a single licensee in each of the VPCSAs listed in the table in this paragraph. In addition to the listed EAs listed in the table in this paragraph, each VPCSA also includes the adjacent waters under the jurisdiction of the United States.

VHF Public coast station areas (VPCSAs)

VPCSAs	EAs	Frequency pairs not available for assignment
1 (Northern Atlantic)	1–5, 10	
2 (Mid-Atlantic)	9, 11–23, 25, 42, 46	
3 (Southern Atlantic)	24, 26–34, 37, 38, 40, 41, 174	
4 (Mississippi River)	34, 36, 39, 43–45, 47–53, 67–107, 113, 116–120, 122–125, 127, 130–134, 176.	
5 (Great Lakes)	6–8, 54–66, 108, 109	
6 (Southern Pacific)	160–165	
7 (Northern Pacific)	147, 166–170	
8 (Hawaii)	172, 173, 175	
9 (Alaska)	171	
10 (Grand Forks)	110	84, 25.
11 (Minot)	111	84, 25.
12 (Bismarck)	112	84, 25.
13 (Aberdeen)	114	84, 25.
14 (Rapid City)	115	84, 25.
15 (North Platte)	121	84, 25.
16 (Western Oklahoma)	126	25, 85.
17 (Abilene)	128	25, 85.
18 (San Angelo)	129	25, 85.
19 (Odessa-Midland)	135	25, 85.
20 (Hobbs)	136	25, 85.
21 (Lubbock)	137	25, 85.
22 (Amarillo)	138	25, 85.
23 (Santa Fe)	139	84, 25.
24 (Pueblo)	140	84, 25.
25 (Denver-Boulder-Greeley)	141	84, 25.
26 (Scottsbluff)	142	84, 25.
27 (Casper)	143	84, 25.
28 (Billings)	144	84, 25.
29 (Great Falls)	145	84, 25.
30 (Missoula)	146	84, 25.
31 (Idaho Falls)	148	25, 85.
32 (Twin Falls)	149	25, 85.
33 (Boise City)	150	84, 25.
34 (Reno)	151	84, 25.
35 (Salt Lake City-Ogden)	152	25, 85.
36 (Las Vegas)	153	84, 25.
37 (Flagstaff)	154	84, 25.
38 (Farmington)	155	84, 25.
39 (Albuquerque)	156	84, 25.
40 (El Paso)	157	25, 85.
41 (Phoenix-Mesa)	158	84, 25.
42 (Tucson)	159	84, 25.

(iii) Subject to paragraph (c)(3) of this section, each licensee may also operate on 12.5 kHz offset frequencies in areas where the licensee is authorized on both frequencies adjacent to the offset frequency, and in areas where the licensee on the other side of the offset frequency consents to the licensee's use of the adjacent offset frequency.

(2) Any recovered channel pairs will revert automatically to the holder of the VPCSA license within which such channels are included, except the channel pairs listed in the table in paragraph (c)(1)(ii) of this section. Those channel pairs, and any channel pairs recovered where there is no VPCSA licensee, will be retained by the Commission for future licensing.

(3) VPCSA licensees may not operate on Channel 228B (162.0125 MHz), which is available for use in the Coast Guard's Ports and Waterways Safety System (PAWSS)). In addition, within six months of the conclusion of the competitive bidding procedures to determine the licensees in each VPCSA, the U.S. Coast Guard shall submit to each licensee of VPCSAs 1–9 a plan specifying up to two narrowband channel pairs offset 12.5 kHz from the channels set forth in the table in paragraph (c)(1)(i) of this section, for use in the PAWSS. The final selection of the PAWSS channel pairs can be negotiated (if the VPCSA licensee objects to the Coast Guard proposal, it shall make a counterproposal within three months) and established by an agreement between the parties. All parties are required to negotiate in good faith. If no agreement is reached within one year of the date the Coast Guard submitted its plan, the Coast Guard may petition the Commission to select the channel pairs.

(4) Subject to the requirements of § 80.21, each VPCSA licensee may place stations anywhere within its region without obtaining prior Commission approval provided:

(i) It provides to co-channel coast station incumbent licensees, and incumbent Private Land Mobile Radio licensees authorized under part 90 of this chapter on a primary basis, protection as defined in subpart P of this part. VPCSA licensees that share a common border may either distribute the available frequencies upon mutual agreement or request that the Commission assign frequencies along the common border.

(ii) The locations and/or technical parameters of the transmitters are such that individual coordination of the channel assignment(s) with a foreign administration, under applicable international agreements and rules in this part, is not required.

(iii) For any construction or alteration that would exceed the requirements of § 17.7 of this chapter, licensees must notify the appropriate Regional Office of the Federal Aviation Administration (FAA Form 7460–1) and file a request for antenna height clearance and obstruction marking and lighting specifications (FCC Form 854) with the FCC, Attn: Information Processing Branch, 1270 Fairfield Rd., Gettysburg, PA 17325–7245.

(iv) The transmitters must not have a significant environmental effect as defined by §§ 1.1301 through 1.1319 of this chapter.

* * * * *

12. Revise § 80.751 to read as follows:

§ 80.751 Scope.

This subpart specifies receiver antenna terminal requirements in terms of power, and relates the power available at the receiver antenna terminals to transmitter power and antenna height and gain. It also sets forth the co-channel interference protection that VHF public coast station geographic area licensees must provide to incumbents.

13. Revise § 80.773 to read as follows:

§ 80.773 Co-channel interference protection.

(a) Where a VHF public coast station geographic area licensee shares a frequency with an incumbent VHF public coast station licensee, the ratio of desired to undesired signal strengths must be at least 12 dB within the service area of the station.

(b) Where a VHF public coast station geographic area licensee shares a frequency with an incumbent private land mobile radio licensee, the VHF public coast station geographic area licensee must provide at least 10 dB protection to the PLMR incumbent's predicted 38 dBu signal level contour. The PLMR incumbent's predicted 38 dBu signal level contour is calculated using the F(50, 50) field strength chart for Channels 7–13 in § 73.699 (Fig. 10a) of this chapter, with a 9 dB correction factor for antenna height differential, and is based on the licensee's authorized effective radiated power and antenna height-above-average-terrain.

14. Add new subpart Y to read as follows:

Subpart Y—Competitive Bidding Procedures

Sec.

§ 80.1251 Maritime communications services subject to competitive bidding.

Mutually exclusive initial applications for VPCSA licenses, high seas public coast station licenses, and AMTS coast station licenses are subject to competitive bidding procedures. The procedures set forth in part 1, subpart Q of this chapter will apply unless otherwise provided in this part.

§ 80.1252 Designated entities.

(a) This section addresses certain issues concerning designated entities in maritime communications services subject to competitive bidding. Issues that are not addressed in this section are governed by the designated entity provisions in part 1, subpart Q of this chapter.

(b) *Eligibility for small business provisions.* (1) A small business is an entity that, together with its affiliates and controlling interests, has average gross revenues not to exceed $15 million for the preceding three years.

(2) A very small business is an entity that, together with its affiliates and controlling interests, has average gross revenues not to exceed $3 million for the preceding three years.

(3) For purposes of determining whether an entity meets either of the definitions set forth in paragraph (b)(1) or (b)(2) of this section, the gross revenues of the entity, its affiliates, and controlling interests shall be considered on a cumulative basis and aggregated.

(4) Where an applicant or licensee cannot identify controlling interests under the standards set forth in this section, the gross revenues of all interest holders in the applicant, and their affiliates, will be attributable.

(5) A consortium of small businesses (or a consortium of very small businesses) is a conglomerate organization formed as a joint venture between or among mutually independent business firms, each of which individually satisfies the definition in paragraph (b)(1) of this section (or each of which individually satisfies the definition in paragraph (b)(2) of this section). Where an applicant or licensee is a consortium of small businesses (or very small businesses), the gross revenues of each small business (or very small business) shall not be aggregated.

(c) Controlling interest. (1) For purposes of this section, controlling interest includes individuals or entities with *de jure* and *de facto* control of the applicant. *De jure* control is greater than 50 percent of the voting stock of a corporation, or in the case of a partnership, the general partner. *De facto* control is determined on a case-by-case basis. An entity must disclose its equity interest and demonstrate at least the following indicia of control to establish that it retains *de facto* control of the applicant:

(i) The entity constitutes or appoints more than 50 percent of the board of directors or management committee;

(ii) The entity has authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the licensee; and

(iii) The entity plays an integral role in management decisions.

(2) *Calculation of certain interests.* (i) Ownership interests shall be calculated on a fully diluted basis; all agreements such as warrants, stock options and convertible debentures will generally be treated as if the rights thereunder already have been fully exercised.

(ii) Partnership and other ownership interests and any stock interest equity, or outstanding stock, or outstanding voting stock shall be attributed as specified in paragraphs (c)(2)(iii) through (c)(2)(ix) of this section.

(iii) 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.

(iv) Non-voting stock shall be attributed as an interest in the issuing entity.

(v) Limited partnership interests shall be attributed to limited partners and shall be calculated according to both the percentage of equity paid in and the percentage of distribution of profits and losses.

(vi) Officers and directors of an entity shall be considered to have an attributable interest in the entity. The officers and directors of an entity that controls a licensee or applicant shall be considered to have an attributable interest in the licensee or applicant.

(vii) Ownership interests 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 if the ownership percentage for an interest in any link in the chain exceeds 50 percent or represents actual control, it shall be treated as if it were a 100 percent interest.

(viii) Any person who manages the operations of an applicant or licensee pursuant to a management agreement shall be considered to have an attributable interest in such applicant or licensee if such person, or its affiliate pursuant to § 1.2110(b)(4) of this chapter, has authority to make decisions or otherwise engage in practices or activities that determine, or significantly influence:

(A) The nature or types of services offered by such an applicant or licensee;

(B) The terms upon which such services are offered; or

(C) The prices charged for such services.

(ix) Any licensee or its affiliate who enters into a joint marketing arrangement with an applicant or licensee, or its affiliate, shall be considered to have an attributable interest, if such applicant or licensee, or its affiliate, has authority to make decisions or otherwise engage in practices or activities that determine, or significantly influence,

(A) The nature or types of services offered by such an applicant or licensee;

(B) The terms upon which such services are offered; or

(C) The prices charged for such services.

(d) A winning bidder that qualifies as a small business or a consortium of small businesses as defined in § 80.1252(b)(1) or § 80.1252(b)(5) of this subpart may use the bidding credit specified in § 1.2110(e)(2)(ii) of this chapter. A winning bidder that qualifies as a very small business or a consortium of very small businesses as defined in § 80.1252(b)(2) or § 80.1252(b)(5) of this subpart may use the bidding credit specified in § 1.2110(e)(2)(i) of this chapter.

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

15. The authority citation for part 90 continues to read as follows:

Authority: Secs. 4, 251–2, 303, 309, and 332, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 251–2, 303, 309 and 332, unless otherwise noted.

§ 90.283 [Removed and Reserved]

16. Removed and reserve § 90.283.

[FR Doc. 98–19943 Filed 7–24–98; 8:45 am]
BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 971015246–7293–02; I.D. 072098D]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for Massachusetts

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

ACTION: Commercial quota harvest.

SUMMARY: NMFS announces that the summer flounder commercial quota available to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 1998, unless additional quota becomes available through a transfer. Regulations governing the summer flounder fishery require publication of this document to advise the Commonwealth of Massachusetts that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no commercial quota is available for landing summer flounder in Massachusetts.

DATES: Effective 0001 hours, July 23, 1998, through December 31, 1998.

FOR FURTHER INFORMATION CONTACT: Tom Warren, Fishery Management Specialist, (978) 281–9347.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The initial total commercial quota for summer flounder for the 1998 calendar year was set equal to 11,105,636 lb (5,037,432 kg) (62 FR 66304, December 18, 1997). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, or 757,841 lb (343,751 kg).

Section 648.100(e)(4) stipulates that any overages of commercial quota landed in any state be deducted from that state's annual quota for the following year. In the calendar year 1997, a total of 745,171 lb (338,004 kg) were landed in Massachusetts, creating a 35,942 lb (16,303 kg) overage that was deducted from the amount allocated for landings in the Commonwealth during 1998 (63 FR 23227, April 28, 1998). The resulting quota for Massachusetts is 721,899 lb (327,488 kg).

Section 648.101(b) requires the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor state commercial quotas and to determine when a state's commercial quota is harvested. The Regional Administrator is further required to publish a document in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. The Regional Administrator has determined, based upon dealer reports and other available information, that the Commonwealth of Massachusetts has attained its quota for 1998.

The regulations at § 648.4(b) provide that Federal permit holders agree as a condition of the permit not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours July 23, 1998, further landings of summer flounder in Massachusetts by vessels holding commercial Federal fisheries permits are prohibited for the remainder of the 1998 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective July 23, 1998, federally permitted dealers are also advised that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the calendar year, or until additional quota becomes available through a transfer.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12866.

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

Dated: July 21, 1998.

Bruce C. Morehead,

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

[FR Doc. 98–19975 Filed 7–22–98; 2:35 pm]
BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 971208294–8154–02; I.D. 103097B]

RIN 0648–AJ20

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Correction

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

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations (I.D. 103097B), which were published in the **Federal Register** of Thursday, June 25, 1998, (63 FR 34606). The regulations implemented management measures that restrict the frequency of limited entry permit transfers to once every 12 months, with transfers taking effect on the first day of a cumulative landings limit period. This rule also required the sorting of groundfish species with trip limits, size limits, quotas, or harvest guidelines at the point of landing, and the retention of landings receipts on board the vessel that has made those landings.

DATES: Effective July 27, 1998.

FOR FURTHER INFORMATION CONTACT: Yvonne de Reynier, NMFS, 206–526–6120.

Correction

In final rule document 98-16789 beginning on page 34606,in the issue of Thursday, June 25, 1998, make the following corrections:

§ 660.302 [Corrected]

1. On page 34608, in the second column, in § 660.302, in the definition, in the second and third lines, "Fisheries Management Division," should read "Sustainable Fisheries Division,".

§ 660.333 [Corrected]

2. On page 34608, in the second and third columns, in§ 660.333, paragraph (c)(1), the first sentence should read, "When the SFD transfers the limited entry permit on behalf of the permit holder, the SFD will reissue the permit in the name of the new permit holder with such gear and, if applicable, species endorsements and tier assignments as are eligible for transfer with the permit."

§ 660.333 [Corrected]

3. On page 34608, in the third column, in § 660.333, paragraph (d) introductory text, the second sentence is corrected to read as follows: "The owner of a permit endorsed for longline or trap (or pot) gear applying for a sablefish endorsement or a tier assignment under § 660.336(c) or (d) has the burden to submit evidence to prove that qualification requirements are met."

Dated: July 22, 1998.

Rolland A. Schmitten,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 98–20011 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 63, No. 143
Monday, July 27, 1998

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

Agricultural Marketing Service

7 CFR Part 1079

[DA–98–07]

Milk in the Iowa Marketing Area; Proposed Temporary Revision of Pool Supply Plant Shipping Percentage

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed temporary revision of rule.

SUMMARY: This document invites written comments on a proposal to reduce the percentage of a supply plant's receipts that must be delivered to fluid milk plants to qualify a supply plant for pooling under the Iowa Federal milk order. The applicable percentage would be decreased by 10 percentage points, from 35 percent of plant receipts to 25 percent of such receipts for the months of September through November 1998. The action is requested by Beatrice Cheese, Inc., a proprietary manufacturer of dairy products in Fredericksburg, Iowa. The proponent contends that the action is needed to prevent uneconomic milk movements.

DATES: Comments must be submitted on or before August 26, 1998.

ADDRESSES: Comments (two copies) should be sent to USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456. Advance, unofficial copies of such comments may be faxed to (202) 690–0552 or e-mailed to OFB—FMMO—Comments@usda.gov. Reference should be made to the title of action and docket number.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456 (202) 720–2357, e-mail address: connie__m__brenner@usda.gov.

SUPPLEMENTARY INFORMATION: The Department is issuing this proposed rule in conformance with Executive Order 12866.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. If adopted, this proposed rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with the rule.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may request modification or exemption from such order by filing with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Small Business Consideration

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service has considered the economic impact of this action on small entities and has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. For the purpose of the Regulatory Flexibility Act, a dairy farm is considered a "small business" if it has an annual gross revenue of less than $500,000, and a dairy products manufacturer is a "small business" if it has fewer than 500 employees. For the purposes of determining which dairy farms are "small businesses," the $500,000 per year criterion was used to establish a production guideline of 326,000 pounds per month. Although this guideline does not factor in additional monies that may be received by dairy producers, it should be an inclusive standard for most "small" dairy farmers. For purposes of determining a handler's size, if the plant is part of a larger company operating multiple plants that collectively exceed the 500-employee limit, the plant will be considered a large business even if the local plant has fewer than 500 employees.

For the month of March 1998, 3,768 dairy farmers were producers under the Iowa Order. Of these, all but 68 would be considered small businesses, having under 326,000 pounds of production for the month. Of the dairy farmers in the small business category, 2,682 produced under 100,000 pounds of milk, 876 produced between 100,000 and 200,000, and 142 produced between 200,000 and 326,000 pounds during March 1998.

Generally, the reports filed on behalf of the slightly more than 20 milk plants pooled, or regulated, under the Iowa Order in March 1998 were filed for establishments that would meet the SBA definition of a small business on an individual basis, having less than 500 employees. However, all but four of the milk handlers represented in the market are part of larger businesses that operate multiple plants at which their collective size exceeds the SBA definition of a small business entity.

Interested parties are invited to submit comments on the probable regulatory and informational impact of this proposed rule on small entities. Also, parties may suggest modifications of this proposal for the purpose of tailoring their applicability to small businesses.

The reduction of the required supply plant shipping percentage for the months of September through November 1998 would allow the milk of producers traditionally associated with the Iowa market to continue to be pooled and priced under the order. The revision would lessen the likelihood that more milk shipments to pool plants might be required under the order than are actually needed to supply the fluid milk needs of the market and would result in savings in hauling costs for handlers and producers.

Notice of Proposed Revision and Opportunity to File Comments

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act and the provisions of § 1079.7(b)(1) of the Iowa Federal milk order, the temporary revision of certain provisions of the

order regulating the handling of milk in the Iowa marketing area is being considered for September 1, 1998, through November 30, 1998.

All persons who desire to submit written data, views or arguments about the proposed revision should send two copies of their views to USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456 by the 30th day after publication of this notice in the Federal Register. The filing period is limited to 30 days because a longer period would not provide the time needed to complete the required procedures and include September in the temporary revision period.

All written submissions made pursuant to this notice will be made available for public inspection in the Dairy Programs offices during regular business hours (7 CFR 1.27(b)).

Statement of Consideration

The provision proposed to be revised is the percentage of a supply plant's receipts required to be shipped to pool distributing plants pursuant to § 1079.7(b) of the Iowa Federal milk marketing order (Order 79). As proposed, the percentage of a supply plant's receipts that must be shipped to pool distributing plants (fluid milk plants) if the supply plant is to be considered a pool plant would be decreased by the maximum allowable 10 percentage points, from 35 percent to 25 percent for the period September 1, 1998, through November 30, 1998.

Section 1079.7(b)(1) of the Iowa milk marketing order allows the Deputy Administrator, Dairy Programs, to reduce or increase a pool supply plant's minimum shipping requirement by up to 10 percentage points to prevent uneconomic milk shipments or to assure an adequate supply of milk for fluid use.

Beatrice Cheese, Inc. (Beatrice), a proprietary manufacturer of dairy products in Fredericksburg, Iowa, is regulated under Order 79 as a pool supply plant. Beatrice requested that the shipping percentage be reduced by 10 percentage points for the months of September through November 1998. The handler's request states that this decrease is warranted due to the fact that current raw milk supplies available for fluid use exceed the needs of the fluid milk plants in Order 79. Beatrice states that if the pool supply shipping percentages remain unchanged, Beatrice will be forced to move milk uneconomically or unfairly depool some milk produced by Iowa dairymen, denying them participation in the Order 79 pool.

In view of the current supply and demand relationship, it may be necessary to decrease the shipping percentage requirements for pool supply plants to provide for the efficient and economic marketing of milk during the period September 1, 1998, through November 30, 1998.

List of Subjects in 7 CFR Part 1079

Milk marketing orders.

The authority citation for 7 CFR part 1079 continues to read as follows:

Authority: 7 U.S.C. 601–674.

Dated: July 21, 1998.

Richard M. McKee,

Deputy Administrator, Dairy Programs.

[FR Doc. 98–19908 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–02–P

NORTHEAST DAIRY COMPACT COMMISSION

7 CFR Part 1301

Notice of Meeting

AGENCY: Northeast Dairy Compact Commission.

ACTION: Notice of Meeting.

SUMMARY: The Compact Commission will hold its monthly meeting to consider whether to adopt as a Final rule the Proposed Rule to amend the current Compact Over-order Price Regulation to exclude milk from the pool which is either diverted or transferred, in bulk, out of the Compact regulated area. The Commission will also consider whether to adopt as a Final Rule the Proposed Rule to establish a reserve fund for reimbursement to school food authorities. Matters relating to administration and the price regulation to include the reports and recommendations of the Commission's standing Committees and action upon the Proposed Amendments to the Bylaws as noticed to the Commission at the July 1, 1998 are also scheduled.

DATES: The meeting is scheduled for Wednesday, August 5, 1998 to commence at 10:00 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, Capitol Room, 172 North Main Street, Concord, NH (exit 14 off I–93).

FOR FURTHER INFORMATION CONTACT: Kenneth Becker, Executive Director, Northeast Dairy Compact Commission, 43 State Street, PO Box 1058, Montpelier, VT 05601. Telephone (802) 229–1941.

SUPPLEMENTARY INFORMATION: The Compact Commission will hold its monthly meeting to consider whether to adopt as a Final rule the Proposed Rule to amend the current Compact Over-order Price Regulation to exclude milk from the pool which is either diverted or transferred, in bulk, out of the Compact regulated area. The proposal will limit the payment of the compact over-order producer price to milk disposed of within the Compact regulated area. The Commission will also consider whether to adopt as a Final Rule the Proposed Rule to establish a reserve fund for reimbursement to school food authorities. The current Compact Over-order Price Regulation is codified at 7 CFR 1300 through 1308. The proposed reserve fund is required to implement the previously issued regulation exempting certain milk sold by school food authorities from the Over-order Price Regulation. Matters relating to administration and the price regulation to include the reports and recommendations of the Commission's standing Committees and action upon the Proposed Amendments to the Bylaws as noticed to the Commission at the July 1, 1998, as required, are also scheduled.

(Authority: (a) Article V, Section 11 of the Northeast Interstate Dairy Compact, and 7 U.S.C. 7256.)

Kenneth Becker,

Executive Director.

[FR Doc. 98–19923 Filed 7–24–98; 8:45 am]

BILLING CODE 1650–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 98N–0518]

Public Information; Communications With State and Foreign Government Officials

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing communications with State and foreign government officials. The proposed rule would permit FDA to disclose confidential commercial information to international organizations having responsibility to facilitate global or regional harmonization of standards and requirements. These disclosures would, in almost all instances, occur only with

the consent of the person providing the confidential commercial information to FDA. The proposed rule would also streamline the process for FDA officials to disclose certain nonpublic, predecisional documents (such as draft rules and guidance documents) to State and foreign government officials. The proposal does not alter current procedures for sharing documents that contain confidential commercial information. These changes are intended to facilitate information exchanges with State and foreign governments and certain international organizations.

DATES: Written comments by October 13, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of December 24, 1974 (39 FR 44602), FDA published a regulation implementing the Freedom of Information Act and other laws that affect public access to government records and information. The rule exempted certain records, such as law enforcement records, from public disclosure, but did not include any provisions for special disclosures to foreign government officials of documents that were not available to the public generally.

In the **Federal Register** of November 19, 1993 (58 FR 61598), FDA published a final rule which, among other things, authorized the agency to disclose confidential commercial information concerning FDA-regulated products to foreign government officials who perform counterpart functions to FDA. The rule, which is now codified at § 20.89 (21 CFR 20.89), permits these disclosures to occur only under various safeguards, such as a written statement from the foreign government agency establishing its authority to protect the confidential commercial information from public disclosure and a written commitment not to disclose such information without the consent of the sponsor for the confidential commercial information or written confirmation from FDA that the information is no longer confidential. Additionally, the rule requires FDA to determine either that the sponsor of the confidential commercial information has authorized the disclosure to the foreign government, or that disclosure would be in the interest of public health, or that disclosure is to a foreign scientist visiting FDA as part of a joint review or long-term cooperative training effort and subject to other restrictions. FDA included these safeguards to protect sensitive commercial information and to lessen industry concerns that foreign governments would further disclose such information without the sponsor's permission.

Later, in the **Federal Register** of December 8, 1995 (60 FR 63372), FDA issued a final rule to permit FDA to disclose nonpublic, predecisional and other documents, such as draft guidance documents and regulations, to State and foreign government officials. (Currently, the term "nonpublic, predecisional document," as used in §§ 20.88(e) (21 CFR 20.88) and 20.89(d), does not include documents containing confidential commercial information such as FDA-prepared documents that analyze confidential commercial information.) Disclosures of nonpublic, predecisional documents were subject to certain safeguards similar to those in the 1993 rule (58 FR 61598), such as a written statement by the State or foreign government agency establishing its authority to protect the nonpublic, predecisional documents from public disclosure and a commitment not to disclose such documents without FDA's written confirmation that the documents no longer have nonpublic status (see §§ 20.88(e)(1)(i) and 20.89(d)(1)(i)).

The 1995 final rule (60 FR 63372) also stated that, for purposes of disclosing nonpublic, predecisional documents, the term "official of a foreign government agency" includes, but is not limited to, "an agent contracted by the foreign government, and an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility" (see 21 CFR 20.89(d)(3)). This enabled FDA to disclose nonpublic, predecisional documents to international organizations such as the World Health Organization and the Food and Agriculture Organization of the United Nations.

The 1995 rule also established similar authority for disclosing both confidential commercial information and nonpublic, predecisional documents to U.S. State government officials.

FDA's experience under § 20.89 has been excellent. Thus far, disclosures of confidential commercial information to foreign governments have occurred with the sponsor's consent in almost every case, and only after the foreign government has provided the necessary documents establishing its authority to protect the shared confidential commercial information from disclosure. These documents are usually written commitments that the foreign government has the authority to protect the documents from public disclosure and will protect such documents provided by FDA, although, on occasion, the document may be an exchange of letters or other agreement between FDA and the foreign country (see, e.g., 62 FR 60901, November 13, 1997) (exchange of letters between FDA and the Australian Therapeutic Goods Administration regarding information about a drug or biologic being considered for orphan status)).

A sponsor's consent is not always necessary under § 20.89. FDA may disclose confidential commercial information without the sponsor's consent where the agency determines that disclosure would be in the interest of public health by reason of the foreign government's possession of information concerning a product's safety, efficacy, or quality or information concerning an investigation.

Generally, the confidential information which FDA has shared has consisted of internal FDA documents discussing data (rather than the data themselves) as the foreign governments usually have the data in an application for marketing authorization.

Disclosures of nonpublic, predecisional information, mostly involving draft guidance documents, have been less frequent, and all have involved disclosures to foreign governments.

As for disclosures to international organizations, current FDA regulations expressly permit the agency to disclose nonpublic, predecisional documents, but do not permit disclosures of confidential commercial information, including FDA-prepared documents that discuss confidential commercial information, to international organizations.

II. Description of the Proposed Rule

FDA is now contemplating possible arrangements with international organizations in which FDA may want to be able to disclose confidential commercial information to international organizations under the same conditions and procedures found in § 20.89 for disclosing confidential commercial information to foreign governments. The agency is not proposing to change those conditions or procedures with respect to sharing confidential commercial

information with foreign governments. The proposal would simply add international organizations to the disclosure provisions of § 20.89 dealing with confidential commercial information.

For example, an international organization may wish to request certain confidential commercial information from FDA so that it may investigate possible adverse events associated with an approved drug product or as part of a cooperative investigation. This occurred recently when the Pan American Health Organization (PAHO) sought certain product and manufacturing information from FDA after an incident in Haiti where over 80 children died and even more were injured by an acetaminophen syrup contaminated with diethylene glycol. FDA was able to share the information with PAHO only after information had been publicly disclosed by non-FDA sources. As stated earlier, current FDA regulations do not explicitly provide a mechanism for providing confidential commercial information to an international organization even under the same circumstances in which FDA can provide confidential commercial information to a foreign government under § 20.89.

The proposal would amend § 20.89 to clarify that disclosures of confidential commercial information and nonpublic, predecisional documents may be made to an international organization having responsibility to facilitate harmonization of standards and requirements in FDA's areas of responsibility. Thus, the proposed rule would move the language regarding an "official of a foreign government agency" from § 20.89(d)(3), where it applies only to disclosures of nonpublic, predecisional documents, to a new § 20.89(e) so that it would apply to all disclosures under § 20.89. The proposal would also revise the reference to international organizations to refer to international organizations that facilitate "global or regional" harmonization of standards and requirements. The reference to "regional" harmonization efforts is intended to reflect the fact that some international organizations operate primarily on a regional, rather than global, scale. (FDA, for purposes of this rule, interprets the term "international organizations" as referring to public or intergovernmental organizations, whether established by treaties or other means, instead of private or nongovernmental organizations.)

The proposal would also clarify that the term "official of a foreign government" includes both temporary and permanent employees and agents. When FDA first proposed § 20.89(d)(3) on January 27, 1995 (60 FR 5530), the term "official of a foreign government" was understood as including foreign government employees. Comments submitted in response to the 1995 proposed rule (60 FR 5530) suggested including "agents" of a foreign government, and so FDA amended the rule to include "agents" on December 8, 1995 (60 FR 63372 at 63377). However, the express mention of agents, and not employees of a foreign government, has caused some confusion, and so FDA is proposing to amend the rule to refer to employees of and agents contracted by a foreign government or by an international organization. This change would be especially appropriate for international organizations because many international organizations rely on government officials who are temporarily assigned to the international organization and on consultants and contractors. It would also be analogous to the existing requirements for FDA's consultants, advisory committee members, and commissioned officials who are subject to the same disclosure restrictions that apply to FDA employees even though such persons are not agency employees themselves (see 21 CFR 20.84).

Additionally, the proposed rule would amend §§ 20.88(e)(1)(i) and 20.89(d)(1)(i) to eliminate the need for the written statement from a U.S. State or a foreign government agency official when FDA provides nonpublic, predecisional documents. The requirement of a written statement was originally included to mirror the existing parallel requirement for such a statement before FDA disclosed any confidential commercial information to a foreign government. However, because information exchanges involving nonpublic, predecisional documents do not contain confidential commercial information, the written statement adds little value because only FDA's deliberative interests would be directly affected by a premature public disclosure. Furthermore, FDA's experience under § 20.89 suggests that the written statement requirement is contrary to customary international practice in which drafts are shared with trusted individuals in counterpart agencies as part of a well-understood, well-established practice that the document will not be disclosed or made public. Moreover, some foreign agencies have been reluctant to execute the written statement due to uncertainties as to who in their government possesses the authority to sign such a statement. Others have even expressed concern that the written statement might, under their government's policies or laws, be considered an international agreement under international treaty law that might require new national legislation or legislative consent.

Thus, the proposed rule would delete the written statement from § 20.89(d) for exchanges involving nonpublic, predecisional information. Furthermore, the proposal would delete the written statement from § 20.88(e) so that State government officials have the same access to nonpublic, predecisional documents as foreign government officials. The agency will require State and foreign governments to execute a written statement establishing their authority to protect documents from public disclosure only where the documents contain confidential commercial information.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

IV. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and the principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined in the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule will have no significant economic impact on small entities under the Regulatory Flexibility Act because it regulates only conduct of FDA, foreign governments, and international organizations, and not small entities under the Regulatory Flexibility Act. In any case, the proposed rule will have no significant economic impact on any small entities.

The proposed rule would authorize FDA to disclose confidential commercial information to international organizations, subject to the same safeguards against public disclosure of that information that apply in the case of disclosures to foreign government agencies and to disclose predecisional information to foreign governments under relaxed procedures. These disclosures would likely facilitate marketing review and approval of various FDA-regulated products in foreign countries, and disclosures would almost always occur only with the consent of the business that generated the confidential commercial information. This beneficial effect of the rule would outweigh any possible adverse impact. Thus, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. FDA requests comment on this conclusion.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Interested persons may, on or before October 13, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

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 part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.88 is amended by revising paragraph (e)(1)(i) to read as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(e)(1) * * *

(i) The State government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

3. Section 20.89 is amended by revising paragraph (d)(1)(i), by removing paragraph (d)(3), and by adding paragraph (e) to read as follows:

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) * * *

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

(e) For purposes of this section, the term "official of a foreign government agency" includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government or by an international organization having responsibility to facilitate global or regional harmonization of standards and requirements in the Food and Drug Administration's areas of responsibility. For such officials, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.

Dated: July 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19898 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket Nos. 97N–0511, 93N–0325, and 97N–0296]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Extension of Comment Period; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; preliminary regulatory impact analysis; extension of comment period; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of July 8, 1998 (63 FR 37057). The document extended the comment period on a proposed rule published in the **Federal Register** of April 24, 1998, to ensure the safe and sanitary processing of fruit and vegetable juices and juice products and on the related preliminary regulatory impact analysis and initial regulatory flexibility analysis published in the **Federal Register** of May 1, 1998. The document was published with an incorrect agency contact. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–18286, appearing on page 37057 in the **Federal Register** of Wednesday, July 8, 1998, the following correction is made:

1. On page 37057, in the second column, the agency contact is corrected to read "**FOR FURTHER INFORMATION CONTACT:** Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681."

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19954 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AC09

Establishing Oil Value for Royalty Due on Federal Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Further supplementary proposed rule; notice of extension of public comment period.

SUMMARY: The Minerals Management Service (MMS) hereby gives notice that it is extending the public comment period on a further supplementary proposed rule, which was published in the **Federal Register** on July 16, 1998 (63 FR 38355). This proposal amends the royalty valuation regulations for crude oil produced from Federal leases. MMS will extend the comment period from July 24, 1998, to July 31, 1998.

DATES: Comments must be submitted on or before July 31, 1998.

ADDRESSES: Mail comments, suggestions, or objections about this further supplementary proposed rule to: Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado, 80225–0165. Courier address is Building 85, Denver Federal Center, Denver, Colorado 80225. E-mail address is RMP.comments@mms.gov.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, telephone number (303) 231–3432, fax number (303) 231–3385, e-mail RMP.comments@mms.gov.

SUPPLEMENTARY INFORMATION: The purpose of this time extension is to allow the public an opportunity to comment on the recent Congressional meetings about the proposed oil royalty valuation rule. Notes from these meetings are posted on the MMS website at: http://www.rmp.mms.gov/library/readroom/readrm.htm.

Dated: July 23, 1998.

R. Dale Fazio,

Acting Associate Director for Royalty Management.

[FR Doc. 98–20149 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[KY 90–1–9735b: FRL6130–2]

Approval and Promulgation of State Implementation Plans: Kentucky: Adoption of General Conformity Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposal rule.

SUMMARY: On November 10, 1995, the Commonwealth of Kentucky Natural Resources and Environmental Protection Cabinet (KNREPC) submitted revisions to the Kentucky State Implementation Plan (SIP) concerning the adoption of criteria and procedures for demonstrating and assuring the "Conformity of General Actions." In the final rules section of this **Federal Register**, the EPA is approving the Commonwealth of Kentucky's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment 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 that direct final rule, no further activity is contemplated in relation to this proposed rule. 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. The EPA will not institute a second comment period. Any parties interested in commenting should do so at this time.

DATES: Comments must be received by August 26, 1998.

ADDRESSES: Written comments should be addressed to Mr. Gregory Crawford at the EPA Regional Office listed below.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch 61 Forsyth Street, SW, Atlanta, Georgia 30303.

The Commonwealth of Kentucky Natural Resources and Environmental Protection Cabinet, 803 Schenkel Lane, Frankfort, Kentucky 40601.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Crawford, Regulatory Planning Section, Air Planning Branch, Air, Pesticides, and Toxics Management Division, Region 4, Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303. The telephone number is 404/562–9046. (E-mail: crawford.gregory@epamail.epa.gov).

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: June 25, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 98–20008 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[SC–34–1–9816b: FRL–6130–1]

Approval and Promulgation of State Plans For Designated Facilities and Pollutants: South Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the Section 111(d)/129 plan submitted by the State of South Carolina through the South Carolina Department of Health and Environmental Control (DHEC) on January 14, 1998, February 5, 1998, and March 6, 1998. The Plan was submitted by the State to satisfy certain **Federal Register**, EPA is approving the South Carolina State Plan submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates that it will not receive any significant, material, and adverse comments. A detailed rationale for the approval is set forth in the direct final rule and incorporated herein. If no significant, material, and adverse comments are received in response to the direct final rule, no further activity is contemplated in relation to this proposed rule. 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.

DATES: Comments must be received in writing by August 26, 1998.

ADDRESSES: Written comments should be addressed to Gregory Crawford at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the day of the visit.

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104.

South Carolina Department of Health and Environmental Control, Bureau of Air Quality Control, 2600 Bull Street, Columbia, South Carolina 29201.

FOR FURTHER INFORMATION CONTACT: Scott Davis at (404) 562–9127 or Gregory Crawford at (404) 562–9046. Air, Pesticides & Toxics Management Division, Region 4, Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: July 7, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 98–19935 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MN51–01–7276b; FRL–6128–7]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Minnesota; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The United States Environmental Protection Agency (EPA) proposes to approve the Minnesota State Plan submittal for implementing the Municipal Solid Waste (MSW) Landfill Emission Guidelines. The State's plan submittal was made pursuant to requirements found in the Clean Air Act (Act). The State's plan was submitted to EPA on March 4, 1997 in accordance with the requirements for adoption and submittal of State plans for designated facilities in 40 CFR part 60, subpart B. It establishes performance standards for existing MSW landfills and provides for the implementation and enforcement of those standards. The EPA finds that Minnesota's Plan for existing MSW landfills adequately addresses all of the Federal requirements applicable to such plans. In the final rules of this **Federal Register**, the EPA is approving this action as a direct final without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse comments. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. 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. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed action must be received by August 26, 1998.

ADDRESSES: Written comments should be sent to: Carlton T. Nash, Chief, Regulation Development Section, Air Programs Branch (AR–18J), EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590.

FOR FURTHER INFORMATION CONTACT: Douglas Aburano, (312) 353–6960.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final document which is located in the Rules section of this **Federal Register**. Copies of the request and the EPA's analysis are available for inspection at the following address: (Please telephone Douglas Aburano at (312) 353–6960 before visiting the Region 5 office.) EPA, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 10, 1998.

David A. Ullrich,

Acting Regional Administrator.

[FR Doc. 98–19938 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AE66

Migratory Bird Hunting; Temporary Approval of Tungsten-Polymer Shot as Nontoxic for the 1998–99 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to amend Section 20.21(j) and provide temporary approval of tungsten-polymer shot as nontoxic for the 1998–99 migratory bird hunting season, except in the Yukon-Kuskokwim (Y–K) Delta, Alaska. A toxicological report includes an extensive literature review, and analysis of tungsten and Nylon 6 (the polymer) suggests that these compounds are nontoxic under assumed use and in the environment. The toxicity study reveals no adverse effects over a 30-day period on mallards (*Anas platyrhynchus*) dosed with 8 BB–size tungsten-polymer shot. However, there is some concern that the absorption of tungsten into the femur, kidney, and liver could potentially affect the spectacled eider (*Somateria fischeri*), a species already subject to adverse weather, predation, and lead poisoning on the Yukon-Kuskokwim (Y–K) Delta, Alaska. Until a reproductive/chronic toxicity test has been completed and the Service has reviewed the results, the Service proposes not to approve the use of tungsten-polymer shot on the Y–K Delta.

DATES: Comments on the proposed rule must be received no later than August 26, 1998.

ADDRESSES: Comments may be sent to the Chief, Office of Migratory Bird Management (MBMO), U.S. Fish and Wildlife Service, 1849 C Street, NW., ms 634–ARLSQ, Washington, DC 20240. The public may inspect comments during normal business hours in room 634, Arlington Square Building, 4401 N. Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Paul R. Schmidt, Chief, Office of Migratory Bird Management, (703) 358–1714.

SUPPLEMENTARY INFORMATION: Since the mid-1970s, the Service has sought to identify shot that does not pose a significant toxic hazard to migratory birds or other wildlife. Currently, only steel and bismuth-tin shot are approved by the Service as nontoxic. The Service previously granted temporary approval

for bismuth-tin on two separate actions for the hunting seasons of 1994–95 and 1995–96. Tungsten-iron shot was given temporary approval for the 1997–98 migratory bird hunting season. The Service believes that approval of other suitable candidate shot materials as nontoxic is feasible. Compliance with the use of nontoxic shot has increased over the last few years. The Service believes that compliance will continue to increase with the approval and availability of other nontoxic shot types.

Federal Cartridge Company's (Anoka, Minnesota) candidate shot is a matrix of Nylon 6 or 11 polymer surrounding particles of elemental tungsten. Shot made from this material has a density of approximately 11.2 g/cm^3 or approximately the density of lead. The shot will contain approximately 95.5 percent tungsten and 4.5 percent Nylon 6 or 11 by weight, plus sufficient iron to attract a magnet.

Federal's application includes a description of the new tungsten-polymer (TP) shot, a toxicological report (Barr, 1996), and the results of a 30-day dosing study of the toxicity of this shot in game-farm mallards (*Anas platyrhynchos*). The toxicological report incorporates toxicity information (a synopsis of acute and chronic toxicity data for mammals and birds, potential for environmental concern, and toxicity to aquatic and terrestrial invertebrates, amphibians and reptiles) and information on environmental fate and transport (shot alteration, environmental half-life, and environmental concentration). The toxicity study is a 30-day dosing test to determine if the candidate shot poses any deleterious effects to game-farm mallards. This will meet the requirements for Tier 2 consideration, as described in 50 CFR 20.134(b)(3).

Toxicity Information

There is considerable difference in the toxicity of soluble and insoluble compounds of tungsten. Elemental tungsten is virtually insoluble and is, therefore, expected to be relatively nontoxic. The potential toxicity of nylon compounds due to degradation is primarily associated with the stabilizers, antioxidants, plasticizers, and unreacted prepolymers. Residual caprolactum has been found in some commercial Nylon 6 products, but little concern regarding this compound has been developed (Patty, 1981). Even though most toxicity tests reviewed were based on soluble tungsten compounds rather than elemental tungsten (while the toxicity of Nylon 6 is negligible due to its insolubility), there appears to be no basis for concern of toxicity to wildlife for the TP shot (metallic tungsten and Nylon 6) via ingestion by fish, birds, or mammals (Bursian et al., 1996; Gigiena, 1983; Patty, 1981; Industrial Medicine, 1946; Karantassis, 1924).

Environmental Fate and Transport

Tungsten is insoluble in water and, therefore, not mobile in hypergenic environments. Tungsten is very stable in acids and does not easily complex. Preferential uptake by plants in acid soil suggests that uptake of tungsten in the anionic form is associated with tungsten minerals rather than elemental tungsten (Kabata-Pendias and Pendias, 1984).

Environmental Concentrations

Calculation of the estimated environmental concentration (EEC) of tungsten in a terrestrial ecosystem is based on 69,000 shot per hectare (Pain, 1990), assuming complete erosion of material in 5 cm of soil. The EECs for tungsten and Nylon 6 in soil are 58.3 mg/kg and 2.7 mg/kg, respectively. Calculation of the EEC in an aquatic ecosystem assumes complete erosion of the shot in one cubic foot of water. The EECs in water for tungsten and Nylon 6 are 18.7 mg/L and 0.9 mg/L, respectively. The Hazard Quotients assume that complete erosion of the shot components would occur; however, the TP shot is considered insoluble and is stable in basic, neutral, and mildly acidic environments. Therefore, erosion is expected to be minimal, and adverse effects on biota are not expected to occur.

Effects on Birds

An extensive literature review provided information on the toxicity of elemental tungsten to waterfowl and other birds. Ringelman et al. (1993) orally dosed 20 8-week-old game-farm mallards with 12–17 (1.03g) tungsten-bismuth-tin (TBT) pellets and monitored them for 32 days for evidence of intoxication. No birds died during the trial, gross lesions were not observed during the postmortem examination, histopathological examinations did not reveal any evidence of toxicity or tissue damage, and tungsten was not detectable in kidney or liver samples. The authors concluded that TBT shot presented virtually no potential for acute intoxication in mallards.

Kraabel et al. (1996) assessed the effects of embedded TBT shot on mallards and concluded that TBT was not acutely toxic when implanted in muscle tissue. Inflammatory reactions to TBT shot were localized and had no detectable systemic effects on mallard health.

Nell (1981) fed laying hens (Gallus domesticus) 0.4 or 1 g/kg tungsten in a commercial mash for five months to assess reproductive performance. Weekly egg production was normal and hatchability of fertile eggs was not affected. Exposure of chickens to large doses of tungsten either through injection or by feeding, resulted in an increased tissue concentration of tungsten and a decreased concentration of molybdenum (Nell, 1981). The loss of tungsten from the liver occurred in an exponential manner with a half-life of 27 hours. The alterations in molybdenum metabolism seemed to be associated with tungsten intake rather than molybdenum deficiency. Death due to tungsten occurred when tissue concentrations increased to 25 mg/g liver. At that concentration, xanthine dehydrogenase activity was zero.

Nylon 6 is the commercially important homopolymer of caprolactum. Most completely polymerized nylon materials are physiologically inert, regardless of the toxicity of the monomer from which they are made (Peterson, 1977). Few data exist on the toxicity of Nylon 6 in animals. Most toxicity studies relate to thermal degradation products and so are not relevant to the exposure of wildlife to shot containing nylon. Montgomery (1982) reported that feeding Nylon 6 to rats at a level of 25 percent of the diet for 2 weeks caused a slower rate of weight gain, presumably due to a decrease in food consumption and feed efficiency. However, the rats suffered no anatomic injuries due to the consumption of nylon.

Federal's 30-day dosing study (Bursian et al., 1996) included four treatment groups of game-farm mallards (16 birds in each group, 8 males and 8 females) exposed to different types of shot: 8 No. 4 steel, 8 No. 4 lead, 8 BBs of tungsten-polymer, and none (control). All TP-dosed birds survived the test with no significant alteration in body weight. There were no changes in hematocrit, hemoglobin concentration, or ALAD activity. The only significant difference between no-shot, steel, and TP males in any of the 25 plasma chemistry parameters at day 15 was an increase in the albumin/globulin ratio in the TP birds when compared to the other two groups, but the authors felt this was not remarkable. Three TP-dosed males developed mild biliary stasis. The authors attributed this to the intubating of mallards with 8 BBs of TP shot inducing a pathological condition, however, slight, that is not found in the control birds. No other histopathological lesions were found. In general, no adverse effects were seen in mallards

given 8 BB-size TP shot and monitored over a 30-day period. Tungsten was detected in the femur of 2 TP-dosed females and the kidneys of 2 TP-dosed birds; in both tissues, concentrations were only slightly above detection limits.

Based on the results of the toxicological report and the toxicity test (Tier 1 and 2), the Service concludes that TP shot (95.5 percent tungsten and 4.5 percent Nylon 6 or 11, by weight with <1 percent residual lead), does not pose a significant danger to migratory birds or other wildlife and their habitats. However, the Service has some concern that the absorption of tungsten into the femur, kidney, and liver could potentially affect the spectacled eider (Somateria fischeri), a species already subject to adverse weather, predation, and lead poisoning on the Yukon-Kuskokwim (Y–K) Delta, Alaska. Until a reproductive/chronic toxicity test has been completed and the Service has reviewed the results, TP shot cannot be approved for the Y–K Delta.

The first condition of approval is toxicity testing. Candidate materials not approved under Tier 1 and/or 2 testing are subjected to standards of Tier 3 testing. The scope of Tier 3 includes chronic exposure under adverse environmental conditions and effects on reproduction in game-farm mallards, as outlined in 50 CFR 20.134 (b)(4)(A and B) (Tier 3) and in consultation with the Service's Office of Migratory Bird Management and the U.S. Geological Survey's Division of Biological Resources. This study includes assessment of long-term toxicity under depressed temperature conditions using a nutritionally-deficient diet, as well as a moderately long-term study that includes reproductive assessment. The tests require the applicant to demonstrate that TP shot is nontoxic to waterfowl and their offspring.

The second condition of approval is testing for residual lead levels. Any TP shot with lead levels equal to or exceeding 1 percent will be considered toxic and, therefore, illegal. In the August 18, 1995, **Federal Register** (60 FR 43314), the Service indicated that it would establish a maximum level for residual lead. The Service has determined that the maximum environmentally acceptable level of lead in any nontoxic shot is trace amounts of <1 percent, and has incorporated this requirement (50 CFR 20.134(b)(5)) in the December 1, 1997, final rule (62 FR 63608).

The third condition of approval involves enforcement. In the August 18, 1995, Federal Register (60 FR 43314), the Service indicated that final unconditional approval of any nontoxic shot would be contingent upon the development and availability of a noninvasive field testing device. Several noninvasive field testing devices are under development to separate TP shot from lead shot. Furthermore, TP shot can be drawn to a magnet as a simple field detection method. This requirement was incorporated into regulations at 50 CFR 20.134(b)(6) in the December 1, 1997, final rule (62 FR 63608).

This proposed rule would amend 50 CFR 20.21(j) by approving temporary approval of TP shot as nontoxic for migratory bird hunting, except in the Yukon-Kuskokwim (Y–K) Delta, Alaska. It is based on the original request made to the Service by Federal Cartridge Company on July 16, 1997, the toxicological report, and acute toxicity study. Results of the toxicological report and 30-day toxicity test undertaken for Federal Cartridge Company document the apparent absence of any deleterious effects of TP shot when ingested by captive-reared mallards or to the ecosystem.

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NEPA Consideration

In compliance with the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR 1500–1508), the Service prepared an Environmental Assessment (EA) in May, 1998. This EA is available to the public at the location indicated under the **ADDRESSES** caption. Based on review and evaluation of the information in the EA, the Service has determined that amending 50 CFR 20.21(j) to provide approval of TP shot as nontoxic for migratory bird hunting would not be a major Federal action that would significantly affect the quality of the human environment.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531 et seq.), provides that Federal agencies shall "insure that any action authorized, funded or carried out . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat . . ." The Service has completed a Section 7 consultation under the ESA for this proposed rule, which stated the "use of tungsten-polymer shot is not likely to adversely affect listed species." The result of the Service's consultation under Section 7 of the ESA is available to the public at the location indicated under the **ADDRESSES** caption.

Regulatory Flexibility Act, Executive Order 12866, and the Paperwork Reduction Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which includes small businesses, organizations, or

governmental jurisdictions. The economic impacts of annual hunting on small business entities were analyzed in detail and a Small Entity Flexibility Analysis (Analysis), under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), was issued by the Service in 1996 (copies available upon request from the Office of Migratory Bird Management). The Analysis documented the significant beneficial economic effect on a substantial number of small entities. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The Analysis utilized the 1991 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns from which it was estimated that migratory bird hunters would spend between $254 and $592 million at small businesses in 1996. The approval of tungsten-polymer as an alternative shot to steel and bismuth-tin will have a minor positive impact on small businesses by allowing them to sell a third nontoxic shot to the hunting public. However, the overall effect to hunting expenditures in general would be minor. Therefore, the Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act. The approved shot will merely supplement nontoxic shot already in commerce and available throughout the retail and wholesale distribution systems, therefore, this rule would have minimal effect on such entities. The Service anticipates no dislocation or other local effects with regard to hunters and others. This document is not a significant rule subject to Office of Management and Budget review under Executive Order 12866.

This rule does not contain collections of information that require approval by the Office of Management and Budget under 44 U.S. C. 3501 et seq. The Service does have OMB approval (1018–0067; expires 06/30/2000) for information collection relating to what manufacturers of shot are required to provide the Service for the nontoxic shot approval process. For further information see 50 CFR 20.134.

Unfunded Mandates Reform

The Service has determined and certifies pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502 et seq., that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities.

Civil Justice Reform—Executive Order 12988

The Department has determined that these proposed regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, the Service proposes to amend part 20, subchapter B, chapter 1 of Title 50 of the Code of Federal Regulations as follows:

PART 20—[AMENDED]

1. The authority citation for part 20 continues to read as follows:

Authority: 16 U.S.C. 703–712 and 16 U.S.C. 742 a–j.

2. Section 20.21 is amended by revising paragraph (j) introductory text and adding paragraph (j)(3) to read as follows:

20.21 Hunting methods.

* * * * *

(j) While possessing shot (either in shotshells or as loose shot for muzzleloading) other than steel shot, or bismuth-tin (97 parts bismuth: 3 parts tin with <1 percent residual lead) shot, or tungsten-iron ([nominally] 40 parts tungsten: 60 parts iron with <1 percent residual lead) shot, or tungsten-polymer (95.5 part tungsten: 4.5 parts Nylon 6 or 11 with <1 percent residual lead) shot, or such shot approved as nontoxic by the Director pursuant to procedures set forth in 20.134, provided that:

* * * * *

(3) Tungsten-polymer shot (95.5 parts tungsten: 4.5 parts Nylon 6 or 11 with <1 percent residual lead) is legal as nontoxic shot for the 1998–99 migratory bird hunting season, except for the Yukon-Kuskokwim Delta habitat in Alaska.

Dated: July 14, 1998.

Donald J. Barry,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 98–19890 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AE35

Migratory Bird Hunting; Extension of Temporary Approval of Tungsten-Iron Shot as Nontoxic for the 1998–99 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) is proposing to amend Section 20.21(j) to grant temporary approval of tungsten-iron shot as nontoxic for the 1998–99 migratory bird hunting season, except in the Yukon-Kuskokwim (Y–K) Delta, Alaska. The Service had previously granted temporary approval of tungsten-iron shot as nontoxic for the 1997–98 season. The toxicological report, which is an extensive literature search and analysis of tungsten and tungsten-iron, suggests that these compounds are nontoxic under assumed use and in the environment. Analysis of the toxicity study reveal no adverse effects over a 30-day period when dosing mallards (Anas platyrhynchos) with 8 BB size tungsten-iron shot. However, there is some concern that the absorption of tungsten into the femur, kidney, and liver could potentially affect the spectacled eider (Somateria fischeri), a species already subject to adverse weather, predation, and lead poisoning on the Y–K Delta. Until a reproductive/chronic toxicity test has been completed and the Service has reviewed the results, tungsten, iron shot will not be approved for the Y–K Delta.

DATES: Comments on the proposed rule must be received no later than August 26, 1998.

ADDRESSES: Copies of the EA are available by writing to the Chief, Office of Migratory Bird Management (MBMO), U.S. Fish and Wildlife Service, 1849 C Street, NW., room 634-ARLSQ, Washington, DC 20240. The public may inspect comments during normal business hours in room 634, Arlington Square Building, 4401 N. Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Paul R. Schmidt, Chief, Office of Migratory Bird Management, (703) 358–1714.

SUPPLEMENTARY INFORMATION: Since the mid-1970s, the Service has sought to identify shot that, when spent, does not pose a significant toxic hazard to migratory birds and other wildlife. The

Service established procedures and requirements for approval of shot and shot coatings as nontoxic in 1986 and published them in 50 CFR 20.134. The Service adopted new procedures in December 1997. These are published at 50 CFR 20.134. Currently, only steel shot and bismuth-tin shot are approved by the Service as nontoxic shot. The Service granted temporary approval of bismuth-tin as nontoxic on two separate actions for the hunting seasons of 1994–95 and 1995–96. Tungsten-iron shot was given temporary approval for the 1997–98 migratory bird hunting season (62 FR 43444 published August 18, 1997). The Service believes approval for other suitable candidate shot materials as nontoxic is feasible. Compliance with the use of nontoxic shot is increasing over the last few years. The Service believes that this level of compliance will continue to increase with the availability and approval of other nontoxic shot types.

Federal Cartridge Company's (Anoka, Minnesota) candidate shot is made from sintering tungsten and iron, which together forms a two-phase alloy. Shot made from this material has a density of approximately 10.3 g/cc or 94 percent of the density of lead. The shot will contain nominally 55 percent tungsten and 45 percent iron, by weight. The pellet will have sufficient iron to attract a magnet.

Federal's application includes a description of the new tungsten-iron shot, a toxicological report, and results of a 30-day dosing study to assess the toxicity of this shot in game-farm mallards (Anas platyrhynchos). The toxicological report incorporates toxicity information (a synopsis of acute and chronic toxicity data for birds, acute effects on mammals, potential for environmental concern, toxicity to aquatic and terrestrial invertebrates, amphibians and reptiles), and information on environmental fate and transport (shot alteration, environmental half-life, and environmental concentration). The toxicity study is a 30-day dosing test to determine if the candidate shot poses any deleterious effects to game farm mallards. This meets the requirements of Tier 1 and Tier 2, 50 CFR § 20.134(b)(2) and (b)(3)(B).

Toxicity Information

There is considerable difference in the toxicity of soluble and insoluble compounds of tungsten and iron. Elemental tungsten and iron are virtually insoluble and, therefore, are expected to be nontoxic. After completion of the literature review, there appears to be no known basis for concern of toxicity to wildlife for the candidate shot material (metallic tungsten and iron) via ingestion by fish, birds, or mammals (Bursian et al., 1996; Gigiena, 1983; Patty, 1981; Industrial Medicine, 1946; Karantassis, 1924). However, there is some concern that the absorption of tungsten into the femur, kidney, and liver could potentially affect certain endangered or threatened species such as the spectacled eider (Somateria fischeri) on the Y–K Delta, Alaska. Until a reproductive/chronic toxicity test has been completed and the Service has reviewed the results, tungsten-iron shot will not be approved for the Y–K Delta.

Environmental Fate and Transport

Tungsten is insoluble in water and, therefore, not mobile in hypergenic environments. Tungsten is very stable with acids and does not easily complex. Preferential uptake by plants in acid soil suggests uptake of tungsten in the anionic form associated with tungsten minerals rather than elemental tungsten (Kabata-Peddias, 1984).

Environmental Concentration

Calculation of the environmental concentration (EEC) for a terrestrial ecosystem is on 69,000 shot per hectare (Pain 1990), assuming complete erosion of material in 5 cm of soil. The EEC for tungsten in soil is 32.9 mg/kg for a shot composition of 62.9 percent tungsten-iron alloy, 11.87 percent tungsten, and 25.31 percent iron. Adverse effects on biota are not expected to occur for shot components, given the Hazard Quotients (HQs).

Environmental Concentration

Calculation of the environmental concentration (EEC) for an aquatic ecosystem assumes complete erosion of the shot in one cubic foot of water. The EEC in water for tungsten was 10.5 mg/L for a shot composition of 62.9 percent tungsten-iron alloy, 11.87 percent tungsten, and 25.31 percent iron. Given these HQs, adverse effects on biota are not expected to occur for shot components.

An extensive literature search and review provides information on the toxicity of elemental tungsten to waterfowl and other birds. In Ringelman et al. (1993) effects of ingested tungsten-bismuth-tin shot (TBT) on captive mallards saw no acute toxicity. Orally dosing 20 8-week-old game farm mallards with 12 to 17 pellets (1.03g) TBT and monitoring for 32 days for evidence of intoxication saw no effect. No birds died during the trial. Gross lesions were not observed during the postmortem examination. Histopathological examination did not reveal any evidence of toxicity or tissue damage. Tungsten was not detectable in kidney or liver samples. The author's conclusion is that TBT shot presents virtually no potential for acute intoxication in mallards.

A study by Kraabel et al. (1996) assesses the effects of embedded tungsten-bismuth-tin shot on mallards. The authors' conclusion was that TBT is not acutely toxic when implanted in mallard muscle tissue. Inflammatory reactions to TBT shot were localized, and had no detectable systemic effects on mallard health.

Nell (1981) fed laying hens 0.4 or 1 g/kg tungsten in a commercial mash for five months to assess the reproductive performance. Weekly egg production was normal and hatchability of fertile eggs was not affected.

Large doses of tungsten given to chickens (*Gallus domesticus*) either through injection or by feeding saw an increase in tissue concentration of tungsten and a decreased tissue concentration of molybdenum (Nell, 1981). The loss rate of tungsten from the liver occurred in an exponential manner with a half-life of 27 hours. The alterations in molybdenum metabolism seem to identify with tungsten and not of molybdenum deficiency. Death due to tungsten occurred when tissue concentrations were increased to 25 mg/g liver. At this concentration, the activity of xanthine dehydrogenase was zero.

In Federal's 30-day dosing study 8 male and 8 female adult mallards given 8 No. 4 steel shot, 8 No. 4 lead shot or 8 BB's of tungsten-iron were observed over a 30-day period. An additional 8 males and 8 females were given no shot. All tungsten-iron birds survived the test with a slight increase in body weight. There were no changes in hematocrit, hemoglobin concentration, and ALAD activity, as well as 25 plasma chemistry parameters. Five of the 16 tungsten-iron birds had a mild hepatocellular biliary stasis, but the authors felt this was not remarkable. No other histopathological lesions were found. In general, no adverse effects were seen when mallards were given 8 BB size tungsten-iron shot and monitored over a 30-day period. Fifty percent of the lead-dosed birds (5 males and 3 females) died during the 30-day test while there were no mortalities in the other groups. Lead-dosed birds were the only ones to display green excreta, lethargy, and ataxia. Alteration of body weights is not significant in any of the treatments, although lead-dosed birds which died during the trial lost an average of 30 percent of their body weight.

Hematocrit, hemoglobin concentrations, and ALAD activity were significantly depressed at day 15 in the lead-dosed females, while lead-dosed males had significantly depressed hematocrit and hemoglobin concentration in comparison to the other three groups. There were no significant differences in these whole-blood parameters at day 30.

As a result of the toxicological report and toxicity test, the Service concludes at this time that the available information indicates that tungsten-iron shot, nominally 40–55 percent tungsten and 60–45 percent iron, by weight with <1 percent residual lead, does not impose significant danger to migratory birds and other wildlife and their habitats, but that reproductive/chronic toxicity data is lacking.

Lacking sufficient reproductive/chronic toxicity data on the candidate shot, the applicant was advised to conduct additional testing as described in Tier 2 and Tier 3 as outlined in 50 CFR 20.134 (b)(3) and (4), and in consultation with the Service's Office of Migratory Bird Management and the U.S. Geological Survey's Division of Biological Resources (BRD). One test includes assessment of reproduction, fertility rates, and egg hatchability (egg weight, shell thickness, and content analysis). The test requires the applicant to demonstrate that tungsten-iron shot is nontoxic to waterfowl and their offspring.

The Service's maximum environmentally acceptable level of residual lead in shot is trace amounts of <1 percent (50 CFR 20.134 (b) (5)). The Service will consider any tungsten-iron shot manufactured with lead levels equal to or exceeding 1 percent as toxic and, therefore, illegal. At this time, the tungsten-iron shot meets the acceptable specifications.

Before approval of any shot for use in migratory game bird hunting, a noninvasive field testing device must be available for enforcement officers to determine the shot material in a given shell in the field (50 CFR 20.134 (b)(6)). Several noninvasive field testing devices are under development to separate tungsten-iron shot from lead shot. Tungsten-iron shot can be drawn to a magnet as a simple field detection method.

In summary, this proposed rule would amend 50 CFR 20.21(j) by extending temporary approval of tungsten-iron shot as nontoxic for the 1998–99 migratory bird hunting season, except in the Y–K Delta, Alaska. It is based on the original request made to the Service by Federal Cartridge Company on August 20, 1996, the toxicological report, and acute toxicity study reviewed by the Service in its initial decision to grant temporary approval for the 1997–98 season (62 FR 43444). Results of the toxicological report and 30-day toxicity test undertaken for Federal Cartridge Company document the apparent absence of any deleterious effects of tungsten-iron shot when ingested by captive-reared mallards or to the ecosystem. Information since the Service's initial decision has not changed or been supplemented to date. A reproductive/chronic toxicity test will be completed and the Service will review the results, prior to any final unconditional approval of tungsten-iron shot for migratory bird hunting.

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Ringelman, J. K., M. W. Miller, and W. F. Andelt. 1992. Effects of ingested tungsten-bismuth-tin shot on mallards. CO Div. Wildl., Fort Collins, 24 pp.

NEPA Consideration

In compliance with the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR 1500–1508), the Service prepared an Environmental Assessment (EA) in May, 1998. This EA is available to the public at the location indicated under the **ADDRESSES** caption. Based on review and evaluation of the information in the EA, the Service has determined that amending 50 CFR 20.21(j) to extend temporary approval of tungsten-iron shot as nontoxic for the 1998–99 migratory bird hunting season would not be a major Federal action that would significantly affect the quality of the human environment.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531, *et seq.*), provides that Federal agencies shall "insure that any action authorized, funded or carried out . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat . . ." The Service has completed a Section 7 consultation under the ESA for this rule and determined that granting temporary approval of tungsten-iron shot for the 1998–99 hunting season, except on the Yukon-Kuskokwin (Y–K) Delta, is not likely to affect any threatened, endangered, proposed or candidate species. The result of the Service's consultation under Section 7 of the ESA is available to the public at the location indicated under the ADDRESSES caption.

Regulatory Flexibility Act, Executive Order 12866, and the Paperwork Reduction Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*) requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which includes small businesses, organizations or governmental jurisdictions. The economic impacts of annual hunting on small business entities were analyzed in detail and a Small Entity Flexibility Analysis (Analysis), under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), was issued by the Service in 1996 (copies available upon request from the Office of Migratory Bird Management). The Analysis documented the significant beneficial economic effect on a substantial number of small entities. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The Analysis utilized the 1991 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns from which it was

estimated that migratory bird hunters would spend between $254 and $592 million at small businesses in 1996. The approval of tungsten-iron as an alternative shot to steel and bismuth-tin will have a minor positive impact on small businesses by allowing them to sell a third nontoxic shot to the hunting public. However, the overall effect to hunting expenditures in general would be minor. Therefore, the Service determined this rule will have no effect on small entities since the approved shot merely will supplement nontoxic shot already in commerce and available throughout the retail and wholesale distribution systems. The Service anticipates no dislocation or other local effects, with regard to hunters and others. This rule was not subject to Office of Management and Budget (OMB) review under Executive Order 12866. The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements. However, the Service does have OMB approval (1018–0067; expires 06/30/2000) for information collection relating to what manufacturers of shot are required to provide the Service for the nontoxic shot approval process. For further information see 50 CFR 20.134.

Unfunded Mandates Reform

The Service has determined and certifies pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502, *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities.

Civil Justice Reform—Executive Order 12988

The Service, in promulgating this rule, determines that these regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, the Service proposes to amend Part 20, Subchapter B, Chapter 1 of Title 50 of the Code of Federal Regulations as follows:

PART 20—[AMENDED]

1. The authority citation for Part 20 continues to read as follows:

Authority: 16 U.S.C. 703–712; and 16 U.S.C. 742 a–j.

2. Amend Section 20.21 by revising paragraph (j)(2) to read as follows:

§ 20.21 Hunting methods.

* * * * *

(j) * * *

(2) Tungsten-iron shot (nominally 40 parts tungsten: 60 parts iron with <1 percent residual lead) is legal as nontoxic shot for the 1998–99 migratory bird hunting season, except in the Yukon-Kuskokwim (Y–K) Delta, Alaska.

Dated: July 14, 1998.

Donald J. Barry,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 98–19891 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

RIN 1018–AE68

1998–99 Refuge-Specific Hunting and Fishing Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Fish and Wildlife Service (Service) proposes to add additional national wildlife refuges (refuges) to the list of areas open for hunting and/or sport fishing, along with pertinent refuge-specific regulations for such activities; and amend certain regulations on other refuges that pertain to migratory game bird hunting, upland game hunting, big game hunting and sport fishing for the 1998–99 seasons.

DATES: Comments may be submitted on or before August 26, 1998.

ADDRESSES: Assistant Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1849 C Street, NW, MS 670 ARLSQ, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Stephen R. Vehrs, at the above address; Telephone (703) 358–2397; Fax (703) 358–1826.

SUPPLEMENTARY INFORMATION: National wildlife refuges generally are closed to hunting and sport fishing until opened by rulemaking. The Secretary of the Interior (Secretary) may open refuge areas to hunting and/or fishing upon a determination that such uses are compatible with the mission of the System or purpose(s) for which individual refuges were established. The action also must be in accordance with provisions of all laws applicable to the areas, must be consistent with the principles of sound fish and wildlife management and administration. Management is intended to ensure that the biological integrity, diversity, and environmental health of the System are maintained for the benefit of present and future generations of Americans, and otherwise must be in the public interest.

The Service reviews refuge hunting and fishing programs annually to determine whether to add additional refuges or whether individual refuge regulations governing existing programs need modification, deletion or additions made to them. Changing environmental conditions, State and Federal regulations, and other factors affecting wildlife populations and habitat may warrant modifications ensuring continued compatibility of hunting and fishing programs and that these programs will not materially interfere with or detract from the fulfillment of the mission of the System or the purposes of the refuge.

50 CFR part 32 contains provisions governing hunting and fishing on national wildlife refuges. Hunting and fishing are regulated on refuges to:

- Ensure compatibility;
- Properly manage the fish and wildlife resource;
- Protect other refuge values; and
- Ensure refuge user safety.

On many refuges, the Service policy of adopting regulations identical to State hunting and fishing regulations is adequate in meeting these objectives. On other refuges, it is necessary to supplement State regulations with more restrictive Federal regulations to ensure that the Service meets its management responsibilities, as outlined under the section entitled "Statutory Authority." The Service issues refuge-specific hunting and fishing regulations when a wildlife refuge is opened to either migratory game bird hunting, upland game hunting, big game hunting or sport fishing. These regulations list the wildlife species that may be hunted or are subject to sport fishing, seasons, bag limits, methods of hunting or fishing, descriptions of open areas, and other provisions as appropriate. 50 CFR part 32 contains previously issued refuge-specific regulations for hunting and fishing. The Service promulgates many of the amendments to these sections to standardize and clarify the existing language of these regulations.

The Service proposes to revise nontoxic shot provisions for hunting upland game on Waterfowl Production Areas and other areas of the National Wildlife Refuge System (System).

Specifically part 32 would prohibit the use or possession of toxic shotgun pellets by upland game hunters onto Waterfowl Production Areas and other areas of the System. The only shot

allowed in areas of the System would be specifically identified in 50 CFR 20.21 (j). The currently approved shot listed in that regulation are: steel, bizmuth-tin and tungsten-iron. Refuge wildlife ingest toxic lead by-products of refuge public hunting programs through their feeding habits and die from lead poisoning. The Service permits hunting programs on many areas of the System in accordance with existing management plans, policy procedures and regulations.

In the August 16, 1995 issue of the **Federal Register** (60 FR 42668), the Service published a proposed regulations that would require hunters to use nontoxic shot while hunting on certain refuges, because of the likelihood of depositing toxic lead shot pellets on the land, with resulting impacts to waterfowl and other migratory birds. In 1992, the Service first required nontoxic shot on all areas of the System while hunting waterfowl.

In the December 4, 1995 **Federal Register** (60 FR 62035), the Service published an evaluation of public comments received in the previously issued proposed rule and announced that it had decided to delay nontoxic shot implementation for hunting upland game until the 1996–97 hunting season on those refuges it had proposed to convert to nontoxic shot during the 1995–96 season. The Service also announced delay of implementation of this regulation in Alaska until the 1997–98 season, to allow coordination with the State and the outlying native villages. The Service also announced it had decided to delay implementation of this regulation with regard to Waterfowl Production Areas principally in the Dakotas, Iowa, Minnesota, Montana, and Wisconsin, until the 1998–99 season.

The Service took these actions to allow adequate time for additional coordination and educational outreach with the affected States, hunting organizations and the general public on the effects of toxic lead shot to waterfowl and other migratory birds. The Service requested voluntary hunter use of nontoxic shotshells until implementing specific rules.

Lead shot from hunters' shotguns deposited onto open and ice-covered wetlands, seasonally flooded habitats, and upland habitats in close proximity to these wetlands is toxic to waterfowl that directly ingest lead products during feeding, and secondarily toxic to predators and carrion feeders that consume these toxic wildlife carcasses. The documented scientific evidence is clear in this regard. Information not adequately communicated to some hunters and habitat managers for their consideration is the effect of this deposition of toxic lead shot onto these marginal or fringe wetland areas by hunting activities other than waterfowl and coot hunting. Nationwide, efforts by the Service, State wildlife agencies, and several conservation organizations have been ongoing to educate the public and activate programs to reduce this threat to waterfowl, raptors and other susceptible wildlife species. A scientifically recognized toxic lead problem exists on these adjoining upland areas. Lead pellets ingested by waterfowl and secondarily by raptors, including eagles, results in the death of these animals due to toxic lead poisoning. Waterfowl ingest lead shot pellets deposited during upland or small game hunting on dry areas that are subject to seasonal flooding, while feeding in these areas during high water periods and are vulnerable to lead poisoning. This proposed rule will significantly reduce this threat to wildlife.

Scientific information on the "Toxicity of Lead Shot to Wildlife" may be obtained by calling the U.S. Fish and Wildlife Reference Service at 1–800–582–3421 or by accessing the bibliographic databases information directly on the INTERNET at "http://www.fws.gov/fwrefser.html".

The Service determines that uses in this proposed rule are compatible. The Service further determined that this proposed action is:

- In accordance with the provisions of all applicable laws;
- Consistent with principles of sound fish and wildlife management and administration;
- Consistent with the principles of available science and resources;
- Helps implement Executive Orders 12996 (Management and Public Use of the National Wildlife Refuge System) and 12962 (Recreational Fisheries); and
- Is otherwise in the public interest by providing additional recreational opportunities at national wildlife refuges.

Sufficient funds will be available within the refuge budgets to operate the hunting and sport fishing programs as proposed.

Request for Comments

Department of the Interior policy is, whenever practicable, to afford the public a meaningful opportunity to participate in the rulemaking process. A 30-day comment period is specified in order to facilitate public input. Consideration was given to providing a 60-day comment period, however, the Service determined that an additional 30 day delay in processing these refuge-specific hunting and fishing regulations would hinder the effective planning and administration of hunting and fishing programs. Specifically, a delay of an additional 30 days would jeopardize holding the hunting or fishing programs this year, or shorten their duration and thereby lessen the management effectiveness of this regulation. Many of these rules also relieve restrictions and allow the public to participate in recreational activities on a number of refuges. In addition, good cause exists in that, in order to continue to provide for previously authorized hunting opportunities while at the same time provide for adequate resource protection, the Service must be timely in providing modifications to certain hunting programs on some refuges. Accordingly, good cause exists to limit the comment period to 30 days.

Interested persons may submit written comments concerning this proposed rule to the person listed above under the heading **ADDRESSES**. All substantive comments will be reviewed and considered.

Statutory Authority

The National Wildlife Refuge System Administration Act (NWRSAA) of 1966, (16 U.S.C. Sec. 668dd–668ee), and the Refuge Recreation Act (RRA) of 1962 (16 U.S.C. 460k–460K–4), govern the administration and public use of national wildlife refuges.

The National Wildlife Refuge System Improvement Act (NWRSIA) of 1997 (Pub. L. 105–57) is the latest amendment to the NWRSAA. It amends and builds upon the NWRSAA in a manner that provides an improved "Organic Act" for the Refuge System similar to those which exist for other public lands. It serves to ensure that the System is effectively managed as a national system of lands, waters and interests for the protection and conservation of our nation's wildlife resources. The NWRSAA states first and foremost that the mission of the System be focused on conservation of fish, wildlife, and plant resources and their habitat. This Act prevents the Secretary from initiating or permitting a new use of a refuge or expanding, renewing, or extending an existing use of a refuge, unless the Secretary has determined that the use is a compatible use and that the use is not inconsistent with public safety.

The RRA, authorizes the Secretary to administer areas within the System for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary purpose(s) for which the areas were

established. This Act requires that any recreational use of refuge lands be compatible with the primary purposes for which a refuge was established and not inconsistent with other previously-authorized operations.

The NWRSAA, and RRA, also authorize the Secretary to issue regulations to carry out the purposes of the Acts and regulate uses.

Hunting and sport fishing plans are developed for each existing refuge prior to opening it to hunting or fishing. In many cases, the Service develops refuge-specific regulations to ensure the compatibility of the programs with the purposes for which the refuge was established. Initial compliance with the NWRSAA and the RRA has been ensured for hunting and sport fishing on newly acquired refuges through an interim determination of compatibility made at the time of acquisition. This ensures that the determinations required by these acts are made prior to the addition of refuges to the lists of areas open to hunting and fishing in 50 CFR part 32. The Service ensures continued compliance by the development of long-term hunting and sport fishing plans and by annual review of hunting and sport fishing programs and regulations.

In preparation for new openings, the following documents are included in the refuge's "openings package" for Regional review and approval from the Washington Office: an interim hunting and fishing management plan; a Section 7 determination pursuant to the Endangered Species Act, that these openings will have no effect, or are not likely to have an adverse effect, on listed species or critical habitats; a letter of concurrence from the affected State; interim compatibility determination; and refuge-specific regulations to administer the hunting and/or fishing programs. Upon review of these documents, the Service, acting for the Secretary, has determined that the opening of these National Wildlife Refuges to hunting and fishing is compatible with the principles of sound fish and wildlife management and administration and otherwise will be in the public interest.

The following wildlife-dependent recreational activities are proposed:

Hunting of migratory game birds, upland game and big game is proposed to start at Canaan Valley National Wildlife Refuge, West Virginia.

Hunting of migratory game birds and upland game is proposed to be opened for the first time on Key Cave National Wildlife Refuge, Alabama.

Hunting of Migratory Game Birds and sport fishing is proposed to open at Trustom Pond National Wildlife Refuge, Rhode Island.

Sport fishing is proposed to be opened for the first time at Breton National Wildlife Refuge, Louisiana; Amagansett, Oyster Bay, Seatuck and Target Rock National Wildlife Refuges, New York; Block Island, Ninigret, Pettaquamscutt Cove and Sachuest Point National Wildlife Refuges, Rhode Island; Dungeness and Nisqually National Wildlife Refuges, Washington; Guam, Kilauea Point and Midway Atoll National Wildlife Refuges, Pacific Islands Territory. The remaining regulations represent revisions to existing refuge specific regulations.

In accordance with the NWRSAA and the RRA, the Service has determined that these openings are compatible and consistent with the primary purposes for which the refuge was established.

Need for This Regulation

The Service proposes to add additional refuges to the list of areas open for hunting and/or sport fishing, along with pertinent refuge-specific regulations for such activities; and amend certain regulations on other refuges that pertain to migratory game bird hunting, upland game hunting, big game hunting and sport fishing for the 1998–99 seasons. On many refuges, the Service policy of adopting regulations identical to State regulations is adequate in meeting National Wildlife Refuge System objectives. On other refuges, it is necessary to supplement State regulations with more restrictive Federal regulations to ensure that the Service meets its management responsibilities, as outlined under the section entitled "Statutory Authority" in the proposed rule. The Service issues refuge-specific regulations when opening a national wildlife refuge or modifying the various uses of a refuge, and for all hunting or sport fishing. These regulations list the prohibited uses, limited uses and those activities that are available without restriction. They also list those wildlife species that may be hunted or fished for along with the respective, seasons, bag limits, methods of hunting or fishing, descriptions of open areas, and other provisions as appropriate. Many of the amendments to these sections in this proposed regulation are promulgated to provide greater restriction and clarify the existing language of existing regulations and should result in less violations of refuge regulations.

Why Alternative Approaches Are Not Feasible

Refuge officers process violations notices through the Federal District Court's Violation Notice procedures. U.S. Magistrates have required refuge regulations to be printed in the Code of Federal Regulations before they will accept refuge violations into their courts. Federal recreation regulations are not prosecuted in the State courts, and voluntary compliance of regulations has not been successful.

Authority Under Which This Rule Will be Published

The National Wildlife Refuge System Administration Act of 1966, (16 U.S.C. Sec. 668dd (b)(5) and (d)(1)).

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this rule is not a significant regulatory action.

a. This rule will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit and economic analysis is not required. This proposed rule is administrative, legal, technical and procedural in nature and makes only minor modifications to existing refuge public use programs. The proposed regulations do not liberalize refuge regulations, but clarifies what a refuge visitor may or may not do on a refuge.

b. This rule will not create inconsistencies with other agencies' actions. Recreational use on National Wildlife Refuges is coordinated with State governments as well as other Federal agencies having adjoining or over-lapping jurisdiction before the regulations are proposed. The proposed regulation is consistent with, and not less restrictive than, other agencies' rules.

c. This rule will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. The provisions of this proposed rule only applies to persons involved in wildlife-dependent public use including regulated hunting and sport fishing on National Wildlife Refuges, which is a privilege and not a right. User fees will not change as a result of this rule.

d. This rule will not raise novel legal or policy issues. The Solicitor's office has reviewed and approved the contents of this proposed rule.

Regulatory Flexibility Act

I certify that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 USC 601 *et seq.*). A final Regulatory Flexibility Analysis is not

attached. Accordingly, a Small Entity Compliance Guide is not required.

This rulemaking will not have a significant economic impact on a substantial number of small entities. The National Wildlife Refuge System was created to conserve fish, wildlife, and plants and their habitats. This conservation mission has been facilitated by providing Americans opportunities to visit and participate in compatible wildlife-dependent recreation, including fishing, hunting, wildlife observation and photography, and environmental education and interpretation as priority public uses on National Wildlife Refuges and to better appreciate the value of, and need for, fish and wildlife conservation.

This proposed rule is administrative, legal, technical and procedural in nature and provides for minor changes to the methods of hunting and fishing permitted within the National Wildlife Refuge System, but does not stop the overall use permitted. This proposed rule will not change the number of visitors using refuges, nor the amount of revenue spent in the area of refuges during these visits. This rulemaking will have no impact on local economies by increasing or decreasing visitation and expenditures in the surrounding area of national wildlife refuges because this proposed rule does not restrict visitors from utilizing refuges, but rather modifies their behavior while they are on refuges.

Refuge visitors will continue to contribute to the local economies at the same rate for food and lodging, transportation, fishing and hunting licenses, binoculars, spotting scopes, outdoor magazines, sportsman's club membership dues, contributions, land leasing and ownership, hunting and fishing stamps, tags, permits, arms, ammunition and fishing tackle.

Economic impacts of refuge fishing and hunting programs on local communities are calculated from average expenditures in the "1996 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation" and "Banking on Nature: The Economic Benefits to Local Communities of National Wildlife Refuge Visitation."

In 1996, 77 million U.S. residents, about 40 percent of the population 16 years old and older, participated in wildlife-associated recreation activities expending $101 billion in the United States. Of this group, 35.2 million enjoyed a variety of fishing opportunities and 14 million hunted, while 62.9 million enjoyed at least one type of wildlife-watching recreation activity including observing, feeding or photographing fish and other wildlife, in the United States.

Recreational visits to national wildlife refuges generates substantial economic activity. In fiscal year 1995, people visited refuges more than 27.7 million times for recreation and environmental education. Their spending generated $401.1 million of sales in regional economies. As this spending flowed through the economy, it generated more than 10,000 employed people and $162.9 million in employment income. This spending should continue at a proportionate rate into the future.

At these 65 National Wildlife Refuges included in this proposed regulation, 701,000 fishermen are estimated to spend $28.7 million annually in pursuit of their sport, while approximately 343,000 hunters will spend $11.3 million annually hunting on the refuges. While many of these fishermen and hunters already make such expenditures prior to the refuge opening, some of these additional expenditures directly are due to the land now being open to the general public.

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities such as businesses, organizations and governmental jurisdictions in the area under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*).

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million or more. These proposed regulations will affect only visitors at National Wildlife Refuges. It will not cause any changes in the number of visitors using the refuge, but only limit what they can do while they are on a refuge. Refer to response under Regulatory Flexibility Act.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. These proposed regulations will affect only visitors at National Wildlife Refuges. It will not cause any changes in the number of visitors using the refuge, but only limit what they can do while they are on a refuge. Refer to response under Regulatory Flexibility Act.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. These proposed regulations will affect only visitors at National Wildlife Refuges. It will not cause any changes in the number of visitors using the refuge, but only limit what they can do while they are on a refuge. Refer to response under Regulatory Flexibility Act.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

a. This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required.

b. This rule will not produce a Federal mandate of $100 million or greater in any year, i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

Takings

In accordance with Executive Order 12630, the rule does not have significant takings implications. The Service has determined that the rule has no potential takings of private property implications A takings implication assessment is not required. These proposed regulations will affect only visitors at National Wildlife Refuges. It will not cause any changes in the number of visitors using the refuge, but only limit what they can do while they are on a refuge. Refer to response under Regulatory Flexibility Act.

Federalism

In accordance with Executive Order 12612, the rule does not have significant Federalism effects. A Federalism assessment is not required. This rule will not have substantial direct effects on the States, in their 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, the Service has determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The proposed regulation will clarify established regulations, and result in better understanding of the regulations by refuge visitors. They will be enforced through the use of U.S. District Court

Violation Notice procedures. A refuge regulation violator can plead guilty and forfeit a set amount of fine established at the time of the violation by the refuge officer. This is completed through the mail without a court appearance. A violator can also plead not guilty on the notice and the Magistrates Court will set an appearance date and time and notify both the violator and officer to appear in Magistrates Court for a hearing and/or trial,in accordance with U.S. District Court Rules of Procedure.

Paperwork Reduction Act (44 U.S.C. 3501 et seq., 5 CFR 1320, Pub. L. 04–13)

This regulation does not contain any information collection that requires Office of Management and Budget approval under the Paperwork Reduction Act 44 U.S.C. 3501 *et seq.*

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) and 512 DM 2: We have evaluated possible effects on Federally recognized Indian tribes and have determined that there are no effects.

Section 7 Consultation (16 U.S.C. 1531 et seq., 50 CFR 402)

In preparation for new openings, Section 7 consultation documents are included in the refuge's "openings package" for Regional review and approval from the Washington Office. The Service reviewed the changes in hunting and fishing herein proposed with regard to Section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) and finds the proposed action is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species within the System since the rule is primarily administrative, legal, technical or procedural in nature and/or makes minor modifications to existing public use programs. The Service complies with Section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) when developing comprehensive conservation plans, refuge public use management plans, and prior to implementing any new or revised public recreation program on a refuge as identified in 50 CFR 26.32 Determinations required by the Endangered Species Act are also made on a case-by-case basis before the addition of a refuge to the lists of areas open to hunting or fishing as contained in 50 CFR 32.7.

National Environmental Policy Act

The Service analyzed this rule in accordance with the criteria of the National Environmental Policy Act and 318 DM 2.2(g) and 6.3(D). This rule does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental impact statement/assessment is not required. The Service ensures compliance when hunting and sport fishing plans are developed, and the determinations required by NEPA are made prior to the addition of refuges to the lists of areas open to hunting and fishing in 50 CFR part 32. The amendment of refuge-specific hunting and fishing regulations are subject to a categorical exclusion from the NEPA process if they do not significantly alter the existing use of a particular national wildlife refuge. The Service exclusion found at 516 DM 6, App. 1.4 B(5) is employed here as these amendments are considered "[m]inor changes in the amounts or types of public use on FWS or State-managed lands, in accordance with regulations, management plans, and procedures." These refuge-specific hunting and fishing regulations simply qualify or otherwise define a hunting or fishing activity, for purposes of resource management. These documents are on file in the offices of the Service and may be viewed by contacting the primary author noted below.

Available Information for Specific Refuges

Individual refuge headquarters retain information regarding public use programs and the conditions that apply to their specific programs, and maps of their respective areas. You may also obtain information from the regional offices at the addresses listed below:

Region 1—California, Hawaii, Idaho, Nevada, Oregon, and Washington. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Eastside Federal Complex, Suite 1692, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181; Telephone (503) 231–6214.

Region 2—Arizona, New Mexico, Oklahoma and Texas. Assistant Regional Director—Refuges and Wildlife U.S. Fish and Wildlife Service, Box 1306, Albuquerque, New Mexico 87103; Telephone (505) 766–1829.

Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio and Wisconsin. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111; Telephone (612) 725–3507.

Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Tennessee, South Carolina, Puerto Rico and the Virgin Islands. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Room 324, Atlanta, Georgia 30345; Telephone (404) 679–7152.

Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and West Virginia. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035–9589; Telephone (413) 253–8550.

Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Box 25486, Denver Federal Center, Denver, Colorado 80225; Telephone (303) 236–8145.

Region 7—Alaska. Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, Alaska 99503; Telephone (907) 786–3545.

Primary Author: Stephen R. Vehrs, Refuge Program Specialist, Division of Refuges, U.S. Fish and Wildlife Service, Washington, DC 20240, is the primary author of this proposed rulemaking document.

List of Subjects in 50 CFR Part 32

Fishing, Hunting, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

For the reasons set forth in the preamble, the Service proposes to amend Title 50, Chapter I, subchapter C of the Code of Federal Regulations as follows:

PART 32—[AMENDED]

1. The authority citation for part 32 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd–ee, and 715i.

2. Section 32.2 is amended by revising the heading, the introductory text, and by adding paragraph (k) to read as follows:

§ 32.2 General provisions regarding hunting on areas of the National Wildlife Refuge System.

The following provisions shall apply to each person while engaged in public

hunting on areas of the National Wildlife Refuge System:

* * * * *

(k) Persons may only use or possess nontoxic shot identified in 50 CFR 20.21(j) while hunting with shotguns or muzzleloaders on Waterfowl Production Areas, or on certain other areas of the National Wildlife Refuge System as delineated on maps, leaflets and/or signs, available at each refuge headquarters or posted at each refuge, or as stated in refuge specific regulations. This regulation does not apply to turkey and deer hunters using buckshot or slugs, except as specifically authorized by refuge specific regulations.

§ 32.7 [Amended]

3. Section 32.7 is amended by alphabetically adding the listing "Key Cave National Wildlife Refuge" to the State of Alabama; by alphabetically adding the listing "Breton National Wildlife Refuge" to the State of Louisiana; by removing the alphabetical listing of "Pond Island National Wildlife Refuge" from the State of Maine; by alphabetically adding the listings "Amagansett National Wildlife Refuge," "Oyster Bay National Wildlife Refuge," "Seatuck National Wildlife Refuge," and "Target Rock National Wildlife Refuge" to the State of New York; by revising the listing of "Tinicum National Environmental Center to read "John Heinz National Wildlife Refuge at Tinicum" in the State of Pennsylvania; by alphabetically adding the listings "Block Island National Wildlife Refuge," "Ninigret National Wildlife Refuge," "Pettaquamscutt Cove National Wildlife Refuge," "Sachuest Point National Wildlife Refuge," and "Trustom Pond National Wildlife Refuge" to the State of Rhode Island; by alphabetically adding the listings "Dungeness National Wildlife Refuge" and "Nisqually National Wildlife Refuge" to the State of Washington; by alphabetically adding the listing "Canaan Valley National Wildlife Refuge" to the State of West Virginia; by alphabetically adding the listings"Guam National Wildlife Refuge" and "Midway Atoll National Wildlife Refuge" to the Pacific Islands Territory.

4. Section 32.20 *Alabama* is amended by revising paragraphs D.1., D.2. and adding paragraph D.4. of Eufaula National Wildlife Refuge; and adding the alphabetical listing of Key Cave National Wildlife Refuge to read as follows:

§ 32.20 Alabama.

* * * * *

Eufaula National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

1. Fishermen may fish, including bowfishing, only during daylight hours on refuge impoundments and waters other than the Walter F. George Reservoir.

2. Fishermen may not frog or trap turtles in impounded waters not contiguous with the Walter F. George Reservoir.

* * * * *

4. Reciprocal license agreements between Alabama and Georgia only apply to waters contiguous with the Walter F. George Reservoir. Fishermen must possess current State of Alabama fishing licenses when fishing in refuge impoundments.

Key Cave National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt mourning doves on designated portions of the refuge subject to the following condition. Permits are required.

B. Upland Game Hunting. Hunters may hunt only quail, squirrel, rabbits, raccoons, and opossum on designated portions of the refuge subject to the following condition: Permits are required.

C. Big Game Hunting. [Reserved]

D. Sport Fishing. [Reserved]

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5. Section 32.24 *California* is amended by revising paragraph C.1. of Clear Lake National Wildlife Refuge to read as follows:

§ 32.24 California.

* * * * *

Clear Lake National Wildlife Refuge

* * * * *

C. Big Game Hunting. * * *

1. Hunters may hunt only in the unit for nine (9) consecutive days beginning on the first Saturday following the third Wednesday in August.

* * * * *

6. Section 32.28 *Florida* is amended by revising paragraph D.3. of Lower Suwannee National Wildlife Refuge; by revising the introductory text of paragraph B. and paragraph D. of St. Marks National Wildlife Refuge; and by revising paragraph D. of Ten Thousand Islands National Wildlife Refuge to read as follows:

§ 32.28 Florida.

* * * * *

Lower Suwannee National Wildlife Refuge

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D. Sport Fishing. * * *

* * * * *

3. Boats may not be left on the refuge overnight.

* * * * *

St. Marks National Wildlife Refuge

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B. Upland Game Hunting. Hunters may hunt squirrel, rabbit, and raccoon on designated areas of the refuge subject to the following condition: Permits are required.

* * * * *

D. Sport Fishing. Anglers may fish and crab on designated areas of the refuge subject to the following conditions:

1. Anglers may fish and crab only from sunrise to sunset.

2. Anglers may only use boats with motors of 10 horsepower or less in refuge pools and lakes.

3. Anglers may only use boats with or without motors on the St. Marks Unit pools from March 15 through October 15.

4. Anglers may take only fish species, and fish limits authorized by State regulations.

5. Anglers may not take frogs or turtles.

6. Anglers may fish and boat in Panacea Unit ponds year round. Anglers may access Panacea Unit ponds in a vehicle only from March 15 through May 15. Anglers may fish and boat in Otter Lake year round.

7. Anglers may not launch commercial boats at the saltwater boat ramp on Co. Rd. 59 (Lighthouse Rd.).

8. Anglers may only take bait fish and non-game fish by hook and line in refuge ponds, lakes, and impoundments.

9. Anglers may not use crab traps in refuge pools and impoundments on the St. Marks Unit.

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Ten Thousand Islands National Wildlife Refuge

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D. Sport Fishing. Anglers may fish only on designated portions of the refuge subject to the following conditions:

1. Anglers may not use airboats, hovercraft, off road vehicles, or personal water craft in freshwater and brackish water wetlands and water bodies.

2. Anglers may fish in freshwater and brackish water creeks and ponds year round from sunrise to sunset. Anglers may enter these areas only from sunrise to sunset.

3. Anglers may fish in tidal waters year round and 24 hours a day.

4. Anglers may not fish with trotlines, gigs, spears, bush hooks, snatch hooks,

crossbows or bows and arrows of any type.

5. Anglers may enter the refuge to crab in freshwater and brackish water areas only from sunrise to sunset. Recreational anglers may use crab pots only in accordance with State regulations, except that crab pots abandoned or not checked after 72 hours are subject to impoundment.

* * * * *

7. Section 32.29 *Georgia* is amended by revising paragraph D.4. and removing paragraph D.5. of Blackbeard Island National Wildlife Refuge; by revising paragraphs D.1., removing paragraph D.2., and renumbering paragraph D.3. as paragraph D.2. of Harris Neck National Wildlife Refuge; by revising paragraphs D.1., D.2., D.4. and adding paragraph D.6. of Savannah National Wildlife Refuge; by revising the introductory text of paragraphs D and D.1., and by removing paragraph D.3. of Wolf Island National Wildlife Refuge to read as follows:

§ 32.29 Georgia.

* * * * *

Blackbeard Island National Wildlife Refuge

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D. Sport Fishing. * * *

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4. Anglers may only bank fish into estuarine waters from sunrise to sunset daily.

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Harris Neck National Wildlife Refuge

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D. Sport Fishing. * * *

1. Anglers may fish in estuarine waters year round from sunrise to sunset daily.

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Savannah National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

1. Anglers may fish in refuge impoundments and canals from March 1 through November 30 annually.

2. Anglers may fish in Black Pond year round.

* * * * *

4. Anglers may bank fish year round in the canal adjacent to the wildlife drive.

* * * * *

6. Anglers may only use non-motorized boats and boats with electric motors.

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Wolf Island National Wildlife Refuge

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D. Sport Fishing. Anglers may fish on designated areas of the refuge subject to the following condition:

1. Anglers may fish year round from sunrise to sunset.

8. Section 32.32 *Illinois* is amended by revising paragraphs A.1., A.2., A.3. and B.3. of Cypress Creek National Wildlife Refuge to read as follows:

§ 32.32 Illinois.

* * * * *

Cypress Creek National Wildlife Refuge

A. Hunting of Migratory Game Birds.

* * *

1. Hunters may dove hunt on sunflower fields only on Mondays, Wednesdays, and Saturdays starting September 1. Hunters may hunt only from noon to 5 pm. Hunters must sign in and out and report daily harvest at registration box. All hunting must be from field borders only. Hunters may not hunt or shoot from the interior of sunflower fields or within 100 yards of roadways. Hunters may not carry or use guns while retrieving downed doves from field interiors.

2. On the Bellrose Waterfowl Reserve—Hunters may not hunt ducks. Hunters may hunt only geese following the closure of the state duck season. Hunters may hunt only on Tuesdays, Thursdays, and Sundays. Hunters may hunt only from sunrise to 1 pm. All hunters must remove blinds and decoys, and be off the unit by 2 pm daily. Hunters may not enter the area prior to 5 am. Hunters may not hunt during special snow goose seasons after the closure of the regular goose season. Hunters may use only temporary or portable blinds; Hunters may not construct pit blinds. No one may hunt within 100 yards of any private property boundary. Distance between hunting parties must be at least 200 yards. All hunters must sign in and out and report daily harvest at the registration box.

3. Hunters must remove boats, decoys, and blinds from the refuge at the conclusion of each days hunt.

* * * * *

B. Upland Game Hunting. * * *

* * * * *

3. Hunters may only use or possessed nontoxic shot while hunting for any permitted birds except wild turkey. Hunters may use lead shot while hunting wild turkey.

* * * * *

9. Section 32.34 *Iowa* is amended by revising the introductory text of paragraph B., and revising paragraph C.2. of Union Slough National Wildlife Refuge to read as follows:

* * * * *

§ 32.34 Iowa.

* * * * *

Union Slough National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt upland game in designated areas of the refuge subject to the following condition: Hunters may only use or possess nontoxic shot while hunting upland game, except wild turkeys. Hunters may possess and use lead shot for wild turkey hunting.

C. Big Game Hunting. * * *

* * * * *

2. Hunters must remove all hunting stands from the refuge at the end of each day's hunt.

* * * * *

10. Section 32.36 *Kentucky* is amended by adding paragraph D.3. of Reelfoot National Wildlife Refuge to read as follows:

§ 32.36 Kentucky.

* * * * *

Reelfoot National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

* * * * *

3. Anglers may not entry the refuge, or use airboats, hovercraft, or jet skis (personal water-craft) on any waters within the refuge boundary.

11. Section 32.37 *Louisiana* is amended by adding Breton National Wildlife Refuge; by revising the introductory text of paragraphs A. and D., of Cameron Prairie National Wildlife Refuge; and by revising the text of paragraphs A. and D. of the Lake Ophelia National Wildlife Refuge to read as follows:

§ 32.37 Louisiana.

* * * * *

Breton National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may fish and crab on designated areas of the refuge subject to the following conditions:

1. Anglers may fish year-round from sunrise to sunset only.

2. Crabbers must tend crabbing equipment at all times.

3. Anglers may not use trotlines, slat traps, or nets.

4. Refuge visitors may not use open fires.

* * * * *

Cameron Prairie National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt waterfowl on designated areas of the refuge subject to the following condition: Refuge permits required.

* * * * *

D. Sport Fishing. Anglers may sport fish on Gibbston Unit. Anglers may sport fish and castnet on the East Cove Unit subject to the following conditions: Any person entering, using or occupying the refuge must abide by all terms and conditions set forth in the appropriate refuge fishing brochure.

* * * * *

Lake Ophelia National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt duck, coots, woodcock, and snipe on designated areas of the refuge subject to the following condition: Hunters must possess a refuge daily permit.

* * * * *

D. Sport Fishing. Anglers may fish on designated areas of the refuge subject to the following condition: Anglers must possess a refuge daily permit.

* * * * *

12. Section 32.38 *Maine* is amended by removing the alphabetical listing of Pond Island National Wildlife Refuge; by adding paragraph A.3., revising the introductory text of B., revising paragraphs B.2., B.3., removing B.4.,revising C. 2., adding C.3. and C.4. of Rachel Carson National Wildlife Refuge; and by revising paragraph D. of Sunkhaze Meadows National Wildlife Refuge to read as follows:

§ 32.38 Maine.

* * * * *

Rachel Carson National Wildlife Refuge

A. Hunting of Migratory Game Birds.

* * *

* * * * *

3. Designated Youth Hunting Areas are open to individuals under 18 who possess a permit. An adult must accompany youths under 15 years of age. Accompanying adults possessing a permit may hunt.

B. Upland Game Hunting. Hunters may hunt pheasants on designated areas of the refuge subject to the following conditions:

* * * * *

2. Hunters during the firearm deer season must wear in a conspicuous manner on head, chest and back a minimum of 400 square inches (10.16 square meters) of solid-colored hunter orange clothing or material.

3. Hunters must possess and use, while in the field, only nontoxic shot.

C. Big Game Hunting. * * *

* * * * *

2. Designated youth hunting areas are open to individuals under 18 who possess a permit. An adult must accompany youths under 15 years of age. Accompanying adults who possess a permit may hunt.

3. Hunters may hunt fox and coyotes during the firearm deer season only.

4. Hunters during the firearm deer season must wear in a conspicuous manner on head, chest and back a minimum of 400 square inches (10.16 square meters) of solid-colored hunter orange clothing or material.

* * * * *

Sunkhaze Meadows National Wildlife Refuge

* * * * *

D. Sport Fishing. Anglers may fish on the waters of and from the banks of Sunkhaze Stream, Birch Stream, and Little Birch Stream, in accordance with state regulations.

13. Section 32.39 *Maryland* is amended by revising paragraph C., and by revising paragraph D. of Eastern Neck National Wildlife Refuge to read as follows:

§ 32.39 Maryland.

* * * * *

Eastern Neck National Wildlife Refuge

* * * * *

C. Big Game Hunting. Hunters may hunt deer and turkey on designated areas of the refuge subject to the following conditions:

1. Refuge permits required.

2. The refuge is open to limited turkey hunting during the state spring turkey season.

3. Hunters may only use archery, shotguns, and muzzleloaders for deer, and shotguns only for turkey.

4. Hunters may not possess loaded weapons in parking areas, blacktopped or graveled roads.

5. Deer hunters must wear in a conspicuous manner on head, chest and back a minimum of 400 square inches of solid colored hunter orange clothing or material.

6. Turkey hunters must wear a hat or cap of hunter orange when moving to or from their blind or hunting position.

D. Sport Fishing. Anglers may saltwater fish from the Eastern Neck Island bridge in accordance with state regulations.

* * * * *

14. Section 32.40 *Massachusetts* is amended by revising the introductory text of paragraph D. of Oxbow National Wildlife Refuge to read as follows:

§ 32.40 Massachusetts.

* * * * *

Oxbow National Wildlife Refuge

* * * * *

D. Sport Fishing. Anglers may fish along the banks of the Nashua River in accordance with state regulations.

* * * * *

15. Section 32.42 *Minnesota* is amended by revising the introductory text of paragraph B., and adding paragraph B.3. of Tamarac National Wildlife Refuge to read as follows:

§ 32.42 Minnesota.

* * * * *

Tamarac National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt ruffed grouse, red, gray and fox squirrel, cottontail rabbit, jackrabbit, snowshoe hare, red fox, raccoon, and striped skunk on designated areas of the refuge subject to the following conditions:

* * * * *

3. Shotgun hunters may only use and possess nontoxic shot while hunting for all upland game species.

* * * * *

16. Amend § 32.43 *Mississippi* by revising paragraphs A., B., and C. of Dahomey National Wildlife Refuge; by revising paragraph D. and removing paragraphs D.1. through D.4. of Hillside National Wildlife Refuge; by revising paragraph D. of Mathews Break National Wildlife Refuge; by revising paragraph D. of Morgan Break National Wildlife Refuge; by revising paragraph D. and removing paragraphs D.1. through D.4. of Panther Swamp National Wildlife Refuge, and adding paragraphs D.4 and D.5. of St. Catherine Creek National Wildlife Refuge to read as follows:

§ 32.43 Mississippi.

* * * * *

Dahomey National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt mourning doves, migratory waterfowl, coots, snipe and woodcock on designated areas of the refuge subject to the following condition: Permits are required.

B. Upland Game Hunting. Hunters may hunt quail, squirrel, rabbit, beaver, raccoon and opossum on designated areas of the refuge subject to the following condition: Permits are required.

C. Big Game Hunting. Hunters may hunt deer and turkey on designated

areas of the refuge subject to the following condition: Permits are required.

* * * * *

Hillside National Wildlife Refuge

* * * * *

D. Sport Fishing. Fishing and frogging are permitted on designated portions of the refuge subject to the following condition: Fishermen must possess a refuge access permit.

Mathews Brake National Wildlife Refuge

* * * * *

D. Sport Fishing. Fishing and frogging are permitted on designated areas of the refuge subject to the following condition: Fishermen must possess a refuge access permit.

Morgan Brake National Wildlife Refuge

* * * * *

D. Sport Fishing. Fishing and frogging is permitted on designated portions of the refuge subject to the following condition: Fishermen must possess a refuge access permit.

* * * * *

Panther Swamp National Wildlife Refuge

* * * * *

D. Sport Fishing. Fishing and frogging is permitted on designated areas of the refuge subject to the following condition: Fishermen must possess a refuge access permit.

* * * * *

St. Catherine Creek National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

* * * * *

4. The use of nets, seines, trotlines or any device for taking fish other than rod and reel is not permitted.

5. Commercial fishing is not permitted.

17. Section 32.45 *Montana* is amended by revising paragraph C of Charles M. Russell National Wildlife Refuge; and revising paragraph C of UL Bend National Wildlife Refuge to read as follows:

* * * * *

§ 32.45 Montana.

* * * * *

Charles M. Russell National Wildlife Refuge

* * * * *

C. Big Game Hunting. Hunters may hunt big game subject to refuge specific regulations as designated in refuge publications.

* * * * *

UL Bend National Wildlife Refuge

* * * * *

C. *Big Game Hunting.* Hunters may hunt big game subject to refuge-specific regulations as designated in refuge publications.

* * * * *

18. Section 32.46 *Nebraska* is amended by revising introductory paragraphs A., B., C. and D. of Valentine National Wildlife Refuge to read as follows:

§ 32.46 Nebraska.

* * * * *

Valentine National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt migratory birds on designated areas of the refuge subject to refuge specific regulations.

B. Upland Game Hunting. Hunters may hunt upland game on designated areas of the refuge subject to refuge specific regulations.

C. Big Game Hunting. Hunters may hunt big game on designated areas of the refuge subject to refuge specific regulations.

D. Sport Fishing. Anglers may fish on designated portions of the refuge subject to refuge specific regulations.

19. Section 32.47 *Nevada* is amended by revising paragraphs D.7 and D.8. of Ruby Lake National Wildlife Refuge; and by revising paragraph D.1. of Sheldon National Wildlife Refuge to read as follows:

§ 32.47 Nevada.

* * * * *

Ruby Lake National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

* * * * *

7. Anglers may not store boats of any kind on the refuge from January 1 through May 31.

8. Anglers may wade and bank fish in the South Marsh only at Brown Dike, the Main Boat Landing, and Narciss Boat Landing from January 1 through July 31 annually. Anglers may wade and bank fish in the entire South Marsh, from August 1 through December 31, annually.

Sheldon National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

1. Big Springs Reservoir, Dufurrena Ponds, and Catnip Reservoir—Anglers may bank fish, fish by wading, or use nonmotorized boats, boats with electric motors, float tubes and similar floatation devices only. Anglers may not fish from motorized boats.

* * * * *

20. Section 32.49 *New Jersey* is amended by adding paragraph A.4., of Cape May National Wildlife Refuge; and by revising paragraph C.2. and removing paragraph C.3. of Great Swamp National Wildlife Refuge to read as follows:

§ 32.49 New Jersey.

* * * * *

Cape May National Wildlife Refuge

A. Hunting of Migratory Game Birds.

* * *

* * * * *

4. Hunters shall possess and use, while in the field, only nontoxic shot.

* * * * *

Great Swamp National Wildlife Refuge

* * * * *

C. Big Game Hunting. * * *

* * * * *

2. Hunters must wear in a conspicuous manner on head, chest and back a minimum of 400 square inches of solid-colored hunter orange clothing or material.

* * * * *

21. Section 32.51 *New York* is amended by adding Amagansett National Wildlife Refuge; revising the introductory text of paragraph D. of Montezuma National Wildlife Refuge; and by adding the alphabetical listings of Oyster Bay National Wildlife Refuge; Seatuck National Wildlife Refuge; and Target Rock National Wildlife Refuge to read as follows:

§ 32.51 New York.

* * * * *

Amagansett National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may surf fish in the Atlantic Ocean from the refuge shoreline in accordance with state regulations.

* * * * *

Montezuma National Wildlife Refuge

* * * * *

D. Sport Fishing. Anglers may access the New York State Barge Canal System waters at only three sites on the refuge: the Seneca River Fishing Access Site, the May's Point Fishing Area, and the Armitage Road Fishing Area. Anglers may either bank fish or boat fish, in accordance with state regulations.

Oyster Bay National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may fish in refuge-controlled waters of Oyster Bay. Anglers may also fish from designated areas on the refuge shoreline at Mill Pond during daylight hours. All fishing within the refuge is in accordance with state regulations.

Seatuck National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may fish in refuge-controlled waters of Great South Bay from boats only. All fishing is in accordance with state regulations.

Target Rock National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may fish in Huntington Bay from the refuge shoreline when the refuge is open to visitors. All fishing is in accordance with state regulations.

* * * * *

22. Section 32.52 *North Carolina* is amended by revising paragraph D. of Pocosin Lakes National Wildlife Refuge to read as follows:

§ 32.52 North Carolina.

* * * * *

Pocosin Lakes National Wildlife Refuge

* * * * *

D. Sport Fishing. Anglers may fish on designated areas of the refuge subject to the following conditions:

1. The refuge portion of New Lake and the Pungo Lake is open to fishing from March 1 to November 1. The public may not access the refuge portion of New Lake and Pungo Unit during the period from November 2 to the end of February. Anglers may fish in all other refuge waters year round.

2. Anglers may bank fish only on the Pungo Unit.

3. Anglers may only fish from sunrise to sunset.

4. Boats may not be left on the refuge overnight.

* * * * *

23. Section 32.53 *North Dakota* is amended by revising paragraph B introductory text of Des Lacs National Wildlife Refuge; by revising paragraph B.1. of Lake Zahl National Wildlife Refuge; by revising paragraph B introductory text and adding paragraph B.1. of Tewaukon National Wildlife Refuge; and by adding paragraph B.3. of Upper Souris National Wildlife Refuge to read as follows:

§ 32.53 North Dakota.

* * * * *

Des Lacs National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt ringnecked pheasants, sharp-tailed grouse, gray partridge, turkey, cottontail rabbit, jackrabbits, snowshoe hares and fox on designated areas of the refuge subject to the following conditions:

* * * * *

Lake Zahl National Wildlife Refuge

* * * * *

B. Upland Game Hunting. * * *

* * * * *

1. Hunters may only possess and use nontoxic shot.

* * * * *

Tewaukon National Wildlife Refuge

* * * * *

B. Hunters may hunt ring-necked pheasants on designated areas of the refuge subject to the following conditions:

1. Hunters may only possess and use nontoxic shot.

* * * * *

Upper Souris National Wildlife Refuge

* * * * *

B. Upland Game Hunting. * * *

* * * * *

3. Hunters may only possess and use nontoxic shot.

* * * * *

24. Section 32.55 *Oklahoma* is amended by adding paragraphs A.4., A.5., revising paragraphs B.3. and B.4. of Little River National Wildlife Refuge; revising paragraphs B. introductory text, B.2., adding paragraph B.3.; and revising paragraph C. introductory text of Optima National Wildlife Refuge; by revising paragraphs D.1. through D.12 of Tishomingo National Wildlife Refuge; revising paragraphs B. introductory text, adding paragraph B.2., revising paragraphs D. introductory text, D.1., D.2.; and removing paragraph D.4. of Washita National Wildlife Refuge; revising paragraph D.5. of Wichita Mountains Wildlife Refuge to read as follows:

§ 32.55 Oklahoma.

* * * * *

Little River National Wildlife Refuge

A. Hunting of Migratory Game Birds.

* * *

* * * * *

4. Hunters must carry refuge hunting permits.

5. Hunters may hunt waterfowl (ducks) only during designated refuge seasons.

B. Upland Game Hunting. * * *

* * * * *

3. Hunters may hunt upland game only during designated refuge seasons.

4. Hunters shall possess and use, while in the field, only nontoxic shot

* * * * *

Optima National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt pheasants, bobwhite and scaled quail, cottontail rabbit and jackrabbit on the refuge in accordance with State hunting regulations subject to the following conditions:

* * * * *

2. Closed during the State gun deer season.

3. Hunting ends at 4:30 p.m. daily.

C. Big Game Hunting. Hunters may hunt white-tailed deer, mule deer and turkey on the refuge in accordance with State hunting regulations subject to the following conditions:

* * * * *

Tishomingo National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

1. Anglers may bank and wade fish with pole and line or rod and reel year-round in areas open for public fishing access.

2. Anglers may use boats from March 1 through September 30 on designated refuge waters and Wildlife Management Unit.

3. Anglers may use trotlines and other set tackle only in the Cumberland Pool and between the natural banks of the Washita River. Anglers must attach set tackle, used in Cumberland Pool, to anchored floats. Anglers may not attach set tackle to sticks, poles, trees, or other fixed objects.

4. Anglers may not use limblines, throwlines, juglines, and yo-yo's.

5. Anglers may not use any containers (jugs, bottles) as floats.

6. Anglers must remove fishing tackle at the end of the boating season.

7. Anglers may no-wake boat fish during the boating season. Anglers may only use line and pole or rod and reel in: (a) open areas south and west of the Cumberland Pool shallow water buoy line; (b) lakes south and west of the

Washita River; and (c) the Wildlife Management Unit.

8. Anglers may night fish from boat (during boating season) on the Cumberland Pool, except not in the no-wake area south and west of the buoy line. Anglers may night fish at the headquarters area, including Sandy Creek Bridge, Murray 2, Nida Point, and the Wildlife Management Unit.

9. Anglers may take bait for personal use while fishing on the refuge in accordance with Oklahoma State law.

10. Anglers may bow fish only in the Wildlife Management Unit.

11. Anglers may not take fish by the use of hands (noodling) in any refuge waters.

12. Anglers may not take frogs, turtles, or mussels.

* * * * *

Washita National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt quail and rabbit on designated areas of the refuge in accordance with State hunting regulations subject to the following conditions:

* * * * *

2. Closed during the State gun deer season.

* * * * *

D. Sport Fishing. Anglers may fish on designated areas of the refuge in accordance with State fishing regulations subject to the following conditions:

1. Anglers may fish from March 15 through October 14 on the Washita River and Foss Reservoir. Anglers may bank fish year round from the refuge boundary south of Lakeview Recreation to Pitts Creek Recreation Area.

2. Anglers may access fishing areas only from designated parking areas and by boat from Foss Reservoir.

* * * * *

Wichita Mountains Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

* * * * *

5. Anglers may use electric trolling motors on boats 14′ or less in length only on Jed Johnson, Rush, Quanah Parker and French Lakes.

* * * * *

25. Amend § 32.56 *Oregon* by revising paragraph B. of Hart Mountain National Wildlife Refuge, by revising paragraph D. of Lewis and Clark National Wildlife Refuge to read as follows:

§ 32.56 Oregon.

* * * * *

Hart Mountain National Wildlife Refuge

* * * * *

B. Upland Game Hunting. Hunters may hunt partridge and coyote on designated areas of the refuge.

* * * * *

Lewis and Clark National Wildlife Refuge

* * * * *

D. Sport Fishing. Anglers may fish in designated areas of the refuge.

* * * * *

26. Section 32.57 *Pennsylvania* is amended by revising the heading of Tinicum National Environmental Center to read as follows:

§ 32.57 Pennsylvania.

* * * * *

John Heinz National Wildlife Refuge at Tinicum

* * * * *

27. Section 32.59 *Rhode Island* is amended by adding an introductory paragraph; by adding the alphabetical listing of Block Island National Wildlife Refuge, Ninigret National Wildlife Refuge, Pettaquamscutt Cove National Wildlife Refuge, Sachuest Point National Wildlife Refuge, and Trustom Pond National Wildlife Refuge to read as follows:

§ 32.59 Rhode Island.

The following refuge units have been opened for hunting and/or fishing and are listed in alphabetical order with applicable refuge-specific regulations.

Block Island National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may surf fish in the Atlantic Ocean from the refuge shoreline in accordance with state regulations.

Ninigret National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may surf fish in the Atlantic Ocean from the refuge shoreline in accordance with state regulations. Anglers may saltwater fish and shellfish in Ninigret Pond from the refuge shoreline only from sunrise to sunset in accordance with state and refuge regulations.

Pettaquamscutt Cove National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may saltwater fish from the refuge shoreline in accordance with state regulations.

Sachuest Point National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may surf fish in the Atlantic Ocean and Sakonnet River from the refuge shoreline in accordance with state regulations. Additionally, anglers may night-fish after sunset in accordance with state regulations.

Trustom Pond National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt Canada geese and mourning doves on designated areas of the refuge subject to the following conditions: State permits are required.

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may surf fish in the Atlantic Ocean from the refuge shoreline from September 16 to March 31 in accordance with state and refuge regulations.

28. Section 32.60 *South Carolina* is amended by revising paragraph A. of Ace Basin National Wildlife Refuge to read as follows:

§ 32.60 South Carolina.

* * * * *

Ace Basin National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt ducks, geese, and coots on designated areas of the refuge subject to the following condition: Refuge hunting permits required.

* * * * *

29. Section 32.62 *Tennessee* is amended by revising paragraph C. of Lake Isom National Wildlife Refuge; and adding paragraph D.5. of Lower Hatchie National Wildlife Refuge to read as follows:

§ 32.62 Tennessee.

* * * * *

Lake Isom National Wildlife Refuge

* * * * *

C. Big Game Hunting. Hunters may hunt white-tailed deer with archery equipment on designated areas of the refuge subject to the following condition: Permits are required.

* * * * *

Lower Hatchie National Wildlife Refuge

* * * * *

D. Sport Fishing. * * *

* * * * *

5. Anglers may only use non-motorized boats and boats with electric motors on Sunk Lake Public Use Natural Area.

* * * * *

30. Section 32.63 *Texas* is amended by revising paragraphs B.1., and C.1. of Balcones Canyonlands National Wildlife Refuge to read as follows:

* * * * *

Balcones Canyonlands National Wildlife Refuge

* * * * *

B. Upland Game Hunting. * * *

1. Hunting will take place in November, December, and/or January.

* * * * *

C. Big Game Hunting. * * *

1. Hunting will take place in November, December, and/or January.

* * * * *

31. Section 32.66 *Virginia* is amended by revising paragraph C.7., and adding paragraph C.8. of Great Dismal Swamp National Wildlife Refuge to read as follows:

§ 32.66 Virginia.

* * * * *

Great Dismal Swamp National Wildlife Refuge

* * * * *

C. Big Game Hunting. * * *

* * * * *

7. Hunters may not shoot onto or across a refuge road including roads closed to vehicles.

8. Hunters may not possess alcoholic beverages.

* * * * *

32. Section 32.67 *Washington* is amended by adding the alphabetical listing of Dungeness National Wildlife Refuge and Nisqually National Wildlife Refuge; adding paragraphs A.6., and B.5. of Toppenish National Wildlife Refuge; amended by adding paragraph C. introductory text and C.1. of Umatilla National Wildlife Refuge to read as follows:

§ 32.67 Washington.

* * * * *

Dungeness National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may salt water fish on designated areas of the refuge.

* * * * *

Nisqually National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may salt water fish on designated areas of the refuge.

* * * * *

Toppenish National Wildlife Refuge

A. Hunting of Migratory Game Birds. * * *

* * * * *

6. Hunters may hunt on Wednesdays, Saturdays, Sundays, Thanksgiving day, Christmas day, and New Years day only.

B. Upland Game Hunting. * * *

* * * * *

5. Hunters may hunt on Wednesdays, Saturdays, Sundays, Thanksgiving day, Christmas day, and New Years day only.

* * * * *

Umatilla National Wildlife Refuge

C. Big Game Hunting. Hunters may hunt deer on designated areas of the refuge subject to the following condition:

1. Hunting by permit only.

* * * * *

33. Section 32.68 *West Virginia* is amended by alphabetically listing Canaan Valley National Wildlife Refuge to read as follows:

§ 32.68 West Virginia.

* * * * *

Canaan Valley National Wildlife Refuge

A. Hunting of Migratory Game Birds. Hunters may hunt migratory game birds on designated areas of the refuge subject to the following conditions:

1. Hunters must sign and be in the possession of a refuge conditional hunting permit at all times while hunting on the refuge.

B. Upland Game Hunting. Hunters may hunt upland (small) game on designated areas of the refuge subject to the following conditions:

1. Hunters must sign and be in the possession of a refuge conditional hunting permit at all times while hunting on the refuge.

2. Shotgun hunters may use or possess only nontoxic shot while hunting upland (small) game on the refuge.

C. Big Game Hunting. Hunters may hunt big game on designated areas of the refuge subject to the following conditions:

1. Hunters must sign and be in the possession of a refuge conditional hunting permit at all times while hunting on the refuge.

D. Sport Fishing. [Reserved]

* * * * *

34. Section 32.69 *Wisconsin* is amended by adding paragraph B.4., and revising paragraph C.5. of Necedah National Wildlife Refuge to read as follows:

§ 32.69 Wisconsin.

* * * * *

Necedah National Wildlife Refuge

* * * * *

B. Upland Game Hunting. * * *

* * * * *

4. Dogs may be used only when hunting upland game birds and waterfowl.

C. Big Game Hunting. * * *

5. Refuge Area 3 is open to deer hunting during the state's gun, muzzle loader, and late archery season.

* * * * *

35. Section 32.71 *Pacific Islands Territory* is amended by adding the alphabetical listing of Guam National Wildlife Refuge, Kilauea Point National Wildlife Refuge, and Midway Atoll National Wildlife Refuge to read as follows:

§ 32.71 Pacific Islands Territory.

* * * * *

Guam National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may salt water fish on designated areas of the refuge.

* * * * *

Kilauea Point National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may salt water fish on designated areas of the refuge.

Midway Atoll National Wildlife Refuge

A. Hunting of Migratory Game Birds. [Reserved]

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. [Reserved]

D. Sport Fishing. Anglers may fish and lobster only in accordance with a refuge fishing leaflet available at refuge headquarters.

Dated: July 14, 1998.

Donald J. Barry,

Assistant Secretary for Fish and Wildlife and Parks.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 072098C]

New England Fishery Management Council; Public Meeting

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

ACTION: Public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a 2-day public meeting on August 10 and August 11, 1998, to consider actions affecting New England fisheries in the exclusive economic zone.

DATES: The meeting will be held on Monday, August 10, 1998, at 9 a.m. and on Tuesday, August 11, at 8:30 a.m.

ADDRESSES: The meeting will be held at the Peabody Marriott Hotel, 8A Centennial Drive, Peabody, MA 01960; telephone (978) 977–9700. Requests for special accommodations should be addressed to the New England Fishery Management Council, 5 Broadway, Saugus, MA 01906–1097; telephone: (781) 231–0422.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council (781) 231–0422.

SUPPLEMENTARY INFORMATION:

Monday, August 10, 1998

There will be a Stock Assessment Public Review Workshop on the status of haddock, Gulf of Maine cod, Georges Bank cod and Georges Bank yellowtail flounder, Southern New England yellowtail flounder, Atlantic herring, scup, black sea bass, and ocean quahogs. A special agenda item will be the initiation of consideration of emergency action for Gulf of Maine cod. The Groundfish Committee will then review public comments and committee and advisory panel recommendations on Amendment 9 to the Fishery Management Plan (FMP) for the Northeast Multispecies Fishery. The measures being considered for final approval at this meeting are associated with new overfishing definitions and the specification of optimum yield (OY) as required by the Sustainable Fisheries Act, rebuilding winter flounder stocks, conserving Atlantic halibut, mesh size changes to reduce the bycatch of flounders, and a prohibition of streetsweeper trawl gear. The committee will also review other issues under its consideration: The inclusion of cusk and wolffish in the FMP management unit, the transfer of days-at-sea (DAS), and the upcoming annual FMP adjustment (including measures to protect Gulf of Maine cod).

During the afternoon session, the Council will approve a public hearing document for the whiting amendment to the Northeast Multispecies FMP, including any new options brought before the Council, and the associated Draft Supplemental Environmental Impact Statement. Measures in the public hearing document will include revised overfishing definitions and the specification of OY, a moratorium on commercial whiting permits, restrictions on the transfer of whiting and red hake at sea, options for management through whiting DAS, and management alternatives for northern and southern management areas and the Cultivator Shoal fishery. The Habitat Committee will review public comments received on the Essential Fish Habitat (EFH) Amendment followed by consideration and approval of final designations for EFH and Habitat Areas of Particular Concern (HAPC), including management measures associated with the juvenile cod HAPCs. The day will conclude with the Herring Committee report, during which the Council will review public comments, committee and advisory panel recommendations, and vote on final management measures for inclusion in the Atlantic Herring FMP.

August 11, 1998

During the Sea Scallop Committee Report, there will be a briefing on the Council's Scientific and Statistical Committee review of the sea scallop overfishing definition, scientific information on which management measures are based, and the stock rebuilding proposals under consideration for inclusion in Amendment 7 to the Atlantic Sea Scallop FMP. There will also be consideration of committee and advisory panel recommendations and public comments on the Amendment 7 proposals to rebuild stocks, followed by approval of measures by the Council. The report will include an update on the status of the experimental fishery for scallops in the Georges Bank closed areas. During the Monkfish Committee Report, the Council will review and approve the final Monkfish FMP documents for submission to the Secretary of Commerce. Following the election of 1998–99 Council officers, the Interspecies Committee will ask for approval of an amendment that would improve consistency among New England and Mid-Atlantic Council fishery management plans concerning vessel permitting and upgrading. This action would amend the New England Council's Atlantic Sea Scallop, Northeast Multispecies and American Lobster Plans and the Mid-Atlantic Council's Summer Flounder, Scup, and Black Sea Bass Plan, the Atlantic Mackerel, Squid and Butterfish Plan, and the Atlantic Surf Clam and Ocean Quahog Plan. Comments on the NMFS draft report to Congress titled "Proposed Implementation of a Fishing Vessel Registration and Fisheries Management Information System" will also be approved. The Mid-Atlantic Plans Committee will ask for approval of a Council position on mackerel joint venture allocations, summer flounder discards, and other issues, as well as seek approval of a public hearing document for dogfish management measures. Following any other outstanding business, the day will conclude with reports from the Council Chairman, Executive Director, NMFS Northeast Region Administrator, Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, and representatives of the Coast Guard and the Atlantic States Marine Fisheries Commission.

Although other issues not contained in this agenda may come before this Council for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: July 21, 1998.

Bruce C. Morehead,

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

[FR Doc. 98–19989 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 63, No. 143
Monday, July 27, 1998

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.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Grant Exclusive License; Correction Notice

AGENCY: Agricultural Research Service, USDA.

ACTION: Correction to notice of intent to grant exclusive license.

SUMMARY: In notice document published in the issue of Monday, July 13, 1998, (63 FR 37512) the Serial No. 07/550,310 was erroneous. This notice corrects the exclusive grant license to Satake USA Inc., of Modesto, California, as follows:

On page 37512, in the second column, first paragraph of the USDA notice, the Serial No. was incorrect. The correct Serial No. is 08/550,310.

Richard M. Parry, Jr.,

Assistant Administrator.

[FR Doc. 98–19909 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 98–071–1]

Availability of Environmental Assessments and Findings of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that four environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the field testing of genetically engineered organisms. The environmental assessments provide a basis for our conclusion that the field testing of the genetically engineered organisms will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared for these field tests.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to telephone before visiting on (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Assistant Director, Scientific Services, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1237; (301) 734–7710. For copies of the environmental assessments and findings of no significant impact, contact Ms. Linda Lightle at (301) 734–8231; e-mail: Linda.Lightle@usda.gov. Please refer to the permit numbers listed below when ordering the documents.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 (referred to below as the regulations) regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained or a notification acknowledged before a regulated article may be introduced into the United States. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, and release into the environment of a regulated article.

In the course of reviewing each permit application, the Animal and Plant Health Inspection Service (APHIS) assessed the impact on the environment that releasing the organisms under the conditions described in the permit application would have. APHIS has issued permits for the field testing of the organisms listed below after concluding that the organisms will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment. The environmental assessments and findings of no significant impact, which are based on data submitted by the applicant and on a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

Environmental assessments and findings of no significant impact have been prepared by APHIS relative to the issuance of permits to allow the field testing of the following genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
98–117–03r	Limagrain Genetics Research.	6–10–98	Corn genetically engineered to express the human serum albumin protein.	Illinois, Iowa.
98–117–04r	Limagrain Genetics Research.	6–12–98	Corn genetically engineered to express the rabies virus G glycoprotein.	Indiana.
98–117–01r	Limagrain Genetics Research.	6–12–98	Corn genetically engineered to express human hemoglobin protein chains.	Illinois.
98–117–02r	Limagrain Genetics Research.	6–12–98	Corn genetically engineered to express a human procollagen type chain protein.	Indiana.

The environmental assessments and findings of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA)(42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 22nd day of July 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–19996 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Saveno DeBorgiac Timber Sales and Road Rehabilitation; Superior Ranger District, Lolo National Forest; Mineral County, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement (EIS) to disclose the environmental effects of timber harvesting, prescribed burning, road access changes, and watershed rehabilitation in a 38,000 acre area near St. Regis, Montana.

DATES: Initial comments concerning the scope of the analysis should be received in writing no later than August 26, 1998. Comments received during the initial scoping will be considered in the analysis and do not need to be resubmitted during this comment time period.

ADDRESSES: Send written comments to Cindy Chapman Enstrom, District Ranger, Superior Ranger District, Box 460, Superior, MT 59872.

FOR FURTHER INFORMATION CONTACT: Ron Mason, Saveno DeBorgiac Interdisciplinary Team Leader, Superior Ranger District, as above, or phone: (406) 822–4233.

SUPPLEMENTARY INFORMATION: The responsible official who will make decisions based on this EIS is Charles C. Wildes, Forest Supervisor, Lolo National Forest, Building 24 Fort Missoula, Missoula, MT 59804. He will decide on this proposal after considering comments and responses, environmental consequences discussed in the Final EIS, and applicable laws, regulations, and policies. The decision and reasons for the decision will be documented in a Record of Decision.

The Forest Service proposed to harvest about 33,000 hundred cubic feet of timber from about 1700 acres (about 1030 of those acres to be burned after harvest), to reconstruct or recondition about 7.5 miles of road and stabilize and/or obliterate about 10.3 miles of existing road (primarily to mitigate existing water quality and fish habitat impacts), and to add new yearlong road closures to about 7.3 miles of currently open roads. New road construction would be limited to about 2.5 miles of permanent road and about 3.4 miles of temporary road.

Lands affected are within the Twin Creek, Savenac Creek, Timber Creek, McManus Creek and Packer Creek drainages, tributary to the St. Regis River, between Saltese and DeBorgia, Montana. The project area is bounded by Interstate 90 to the south and the divide between Plains/Thompson Falls and superior Ranger Districts to the north.

The purpose of this proposal is to carry out the goals and direction given in the Lolo National Forest Land and Resource Management Plan with ecosystem management principles. Key elements of the purpose and need are:

(1) Maintain existing elk security habitat;

(2) Modify stand structures in lodgepole pine to reduce susceptibility to mountain pine beetle;

(3) Accelerate succession in mid seral, moist mixed conifer stands where potential exists to develop late seral, multi-storied structures with old growth characteristics;

(4) Replace the ponderosa pine communities which developed from poorly adapted seed from other states. The trees were planted in the early 1900's. These stands are experiencing extensive mortality from diseases, and are also increasingly susceptible to bark beetle attacks. These communities are also naturally reproducing, and degrading the locally adapted gene pool;

(5) Develop stand structures that are equivalent to single story, moisture limited conditions resembling structures developed from very frequent, low intensity ground fires. The resulting stand structures will enhance growth and development of ponderosa pine, western larch and Douglas-fir stands;

(6) The St. Regis River is a priority watershed for bull trout recovery; we will protect the species and seek opportunities to enhance and restore habitat;

(7) The St. Regis River is a Water Quality Limited Segment (WQLS). Increased sediment has resulted in the "cold water fishery" to be only partially supported. The proposal seeks opportunities to eliminate erosion and control sediment sources to improve water quality in the streams entering the St. Regis River; and

(8) Provide forest products in support of forest plan goals.

The decision to be made is to what extent, if at all, the Forest Service should conduct timber harvest, prescribed burning, road construction or reconstruction, road reclamation, and road closure in the Twin Creek, Savenac Creek, Timber Creek, McManus Creek and Packer Creek drainages, given the above purpose and need. This is a site specific project decision, not a general management plan nor a programmatic analysis.

Public scoping has been conducted on this proposal and the alternatives developed for this proposal.

While quite a number of issues have been identified for environmental effects analysis, the following issues are the one which so far have been found significant enough to guide alternative development and provide focus for the EIS.

(1) Water quality and fisheries habitat effects resulting from timber harvest and road construction and rehabilitation activities;

(2) Forest health issues pertaining to even-aged management and restoration; and

(3) Economic effects on local communities resulting from different access methods and resulting timber values.

The proposed action could have both beneficial and adverse effects on these resources. In addition to the proposed action, a range of alternatives have been developed in response to issues identified during scoping. Alternatives planned for detailed study are:

(1) No action; none of the proposed activities would be implemented.

(2) Restoration of offsite ponderosa pine stands. Mid-seral stands will be treated to develop multi-storied stands with large trees, and dry sites with a history of high fire frequency will be thinned to develop open stands of ponderosa pine, Douglas-fir and larch. Approximately 77 percent of the volume will be helicopter yarded, 12 percent will be tractor yarded and 11 percent will skyline yarded.

Road work	Approximate miles
Construction, new roads	0.0

Road work	Approximate miles
Reconstruction, existing roads	2.7
Reclamation, existing roads	12.9
Construct and obliterate temporary roads	0.0
Reconstruct and reclaim, existing road	0.0
Change travel management	7.3

(3) Then lodgepole pine stands to make them resistant to mountain pine beetle attacks. Harvest from existing roads and from short-term and temporary roads on gentle ridgetops and upper sidelopes, harvest with no evenaged management cuts. Approximately 1 percent of the volume will be helicopter yarded, 64 percent will be tractor yarded and 35 percent will skyline yarded.

Road work	Approximate miles
Construction, new roads	0.0
Reconstruction, existing roads	2.7
Reclamation, existing roads	8.6
Construct and obliterate temporary roads	3.4
Reconstruct and reclaim, existing road	4.3
Change travel management	7.3

(4) Restoration of offsite ponderosa pine stands. Mid-seral stands will be treated to develop multi-storied stands with large trees, and dry sites with a history of high fire frequency will be thinned to develop open stands of ponderosa pine, Douglas-fir and larch. Thin lodgepole pine stands to make them more resistant to mountain pine beetle attacks. Approximately 43 percent of the volume will be helicopter yarded, 33 percent will be tractor yarded and 24 percent will skyline yarded.

Road work	Approximate miles
Construction, new roads	2.5
Reconstruction, existing roads	2.7
Reclamation, existing roads	6.7
Construct and obliterate temporary roads	3.4
Reconstruct and reclaim, existing road	0.4
Change travel management	0.0

(5) Restoration of offsite ponderosa pine stands. Mid-seral stands will be treated to develop multi-storied stands with large trees, and dry sites with a history of high fire frequency will be thinned to develop open stands of ponderosa pine, Douglas-fir and larch. Thin lodgepole pine stands to make them more resistant to mountain pine beetle attacks. Approximately 20 percent of the volume will be helicopter yarded, 45 percent will be tractor yarded and 35 percent will skyline yarded.

Road work	Approximate miles
Construction, new roads	2.5
Reconstruction, existing roads	3.2
Reclamation, existing roads	2.6
Construct and obliterate temporary roads	3.4
Reconstruct and reclaim, existing road	4.3
Change travel management	0.0

Public participation is important to the analysis. People may visit with Forest Service officials at any time during the analysis and prior to the decision. No formal scoping meetings are planned. However, two periods are specifically designated for comments on the analysis:

(1) During this scoping process; and

(2) During the draft EIS comment period.

During the scoping process, the Forest Service is seeking information and comments from Federal, State, and local agencies and other individuals or organizations who may be interested in or affected by the proposed action. A scoping document will be mailed to parties known to be interested in the proposed action. The agency invites written comments and suggestions on this action, particularly in terms of issues and alternatives.

The Forest Service will continue to involve the public and will inform interested and affected parties as to how they may participate and contribute to the final decision. Another formal opportunity for response will be provided following completion of a draft EIS.

The draft EIS should be available for review in March, 1999. The final EIS is scheduled for completion in June, 1999.

The comment period on the draft EIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register.**

The Forest Service believes it is important, at this early stage, to give reviewers notice of several 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 it is meaningful and alerts the agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 533 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but 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 Heritage* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important those interested in this proposed action participate by the close of the 45 day comment period so substantive comments and objections are 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 environmental impact statement 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.

I am the responsible official for this environmental impact statement. My address is Lolo National Forest, Building 24, Fort Missoula, Missoula MT 59804.

Authority: 40 CFR 1508.220.

Dated: July 10, 1998.

Charles C. Wildes,

Forest Supervisor.

[FR Doc. 98–19726 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Task Force on Agricultural Air Quality

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Task Force on Agricultural Air Quality will hold a teleconference to discuss the relationship between agricultural production and air quality. The meeting is open to the public.

DATES: The teleconference will convene Tuesday, August 18, 1998, at 11:20 a.m. EDT and continue until 5:00 p.m. EDT. Written material and requests to make presentations should reach the Natural Resources Conservation Service on or before August 14, 1998.

ADDRESSES: Written material and requests to make presentations should be sent to George Bluhm, University of California, Land, Air, Water Resources, 151 Hoagland Hall, Davis, CA 95616–6827.

FOR FURTHER INFORMATION CONTACT: George Bluhm, Designated Federal Official, telephone (530) 752–1018, fax (530) 752–1552, email bluhm@crocker.ucdavis.edu.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. Additional information about the Task Force on Agricultural Air Quality, including any revised agendas for the August 18, 1998, meeting that may appear after this **Federal Register** Notice is published, may be found on the World Wide Web at http://www.nhq.nrcs.usda.gov/faca/aaqtf.html.

Participants are advised that the entire proceedings of the teleconference will be recorded. Minutes from the teleconference will be published and available to the public after October 1, 1998.

Teleconference Access Instructions

In order to determine the number of phone lines needed for this teleconference, members of the public wishing to participate are asked to contact the Natural Resources Conservation Service in Washington, D.C. at (202) 720–4716 for access numbers and dialing instructions.

Draft Agenda of the August 18, 1998, Meeting

A. Opening Remarks
   1. Call the meeting to order and explain the meeting process—George Bluhm, Designated Federal Official
   2. Opening remarks of the Chair—Pearlie Reed

B. Past Actions
   1. Air quality research needs subcommittee report—Jim Trotter
   a. National Research Council activities—Tim Strickland
   2. Agricultural burning subcommittee report—Robert Quinn
   3. Model MOU for voluntary compliance with bad actor clause—Dennis Tristao and Manuel Cunha
   4. Recognition of committee for past efforts—Pearlie Reed

C. New Issues
   1. Reconstitution of the AAQTF charter—Gary Margheim
   2. Reconstitution of the AAQTF membership—Gary Margheim
   3. Suggested date and location of a future meeting—committee

D. Public Input

E. Adjourn

Procedural

This meeting is open to the public. At the discretion of the Chair, members of the public may provide input during the August 18, 1998 teleconference. Persons wishing to make oral presentations should notify George Bluhm no later than August 14, 1998.

If a person submitting material would like a copy distributed to each member of the committee in advance of the teleconference, that person should submit material to Jeff Graham, curator of Task Force documents, by August 17, 1998. Material should be in electronic format suitable for posting to the Internet. Mr. Graham may be reached via phone at (202) 720–1858 or email at *jeff.graham@usda.gov*. Handouts for presentations to Task Force members will be posted to the Web address listed above before the meeting, as they become available.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact George Bluhm as soon as possible.

Dated: July 21, 1998.

Thomas A. Weber,

Deputy Chief for Science and Technology.

[FR Doc. 98–19998 Filed 7–24–98; 8:45 am]

BILLING CODE 3014–16–P

ASSASSINATION RECORDS REVIEW BOARD

Sunshine Act Meeting; Formal Determinations and Additional Releases

AGENCY: Assassination Records Review Board.

ACTION: Notice.

SUMMARY: The Assassination Records Review Board (Review Board) met in closed meetings on July 8, 1998 and July 20, 1998, and made formal determinations on the release of records under the President John F. Kennedy Assassination Records Collection Act of 1992 (JFK Act). By issuing this notice, the Review Board complies with the section of the JFK Act that requires the Review Board to publish the results of its decisions in the **Federal Register** within 14 days of the date of the decision.

FOR FURTHER INFORMATION CONTACT: Peter Voth, Assassination Records Review Board, Second Floor, Washington, D.C. 20530, (202) 724–0088, fax (202) 724–0457. The public may obtain an electronic copy of the complete document-by-document determinations by contacting <Eileen—Sullivan@jfk-arrb.gov≤.

SUPPLEMENTARY INFORMATION: This notice complies with the requirements of the President John F. Kennedy Assassination Records Collection Act of 1992, 44 U.S.C. § 2107.9(c)(4)(A) (1992). On July 8, 1998, the Review Board made formal determinations on records it reviewed under the JFK Act.

Notice of Formal Determinations

4 Church Committee Documents: Postponed in Part until 10/2003
15 Church Committee Documents: Postponed in Part until 10/2017
2 CIA Documents: Postponed in Part until 05/2001
909 CIA Documents: Postponed in Part until 10/2017
37 DOJ Documents: Postponed in Part until 10/2017
1 FBI Document: Open in Full 6 Ford Library Documents: Postponed in Part until 10/2017
10 JCS Documents: Postponed in Part until 10/2017
8 NSC Documents: Postponed in Part until 10/2017
326 US ARMY Documents: Postponed in Part until 10/2017

Notice of Other Releases

After consultation with appropriate Federal agencies, the Review Board announces that documents from the following agencies are now being opened in full: 92 CIA documents; 3 Ford Library documents; 18 NSC documents; 182 U.S. Army (Califano) documents; 242 U.S. Army (IRR) documents.

On July 20, 1998, the Review Board made formal determinations on records it reviewed under the JFK Act.

Notice of Formal Determinations

3 CIA Documents: Postponed in Part until 05/2001
1 CIA Document: Postponed in Part until 10/2003
704 CIA Documents: Postponed in Part until 10/2017
7 FBI Documents: Open in Full
229 FBI Documents: Postponed in Part until 10/2017
1 Ford Library Document: Open in Full
11 Ford Library Documents: Postponed in Part until 10/2017
5 HSCA Documents: Postponed in Part until 10/2017

40 NSC Documents: Postponed in Part until 10/2017
392 US ARMY Documents: Postponed in Part until 10/2017

Notice of Other Releases

After consultation with appropriate Federal agencies, the Review Board announces that documents from the following agencies are now being opened in full: 1087 FBI documents; 4 Ford Library documents; 48 NSC documents; 10 U.S. Army (Califano) documents; 302 U.S. Army (IRR) documents.

Notice of Corrections

On December 15, 1997 the Review Board made formal determinations that were published in the December 24, 1997 Federal Register (FR Doc. 97–33529, 60 FR 12345). For that Notice make the following corrections:

Record identification number	Previously published	Corrected data
119–10021–10357	1; 10/2017	0; n/a
119–10022–10395	1; 10/2017	0; n/a
119–10022–10074	1; 10/2017	0; n/a

Dated: July 22, 1998.

T. Jeremy Gunn,

Executive Director.

[FR Doc. 98–20092 Filed 7–23–98; 11:27 am]

BILLING CODE 6118–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 USC Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Applications and Reports for Registration as a Tanner or Agent.

Agency Form Number(s): None.

OMB Approval Number: 0648–0179.

Type of Request: Extension of a currently approved collection.

Burden: 154 hours.

Number of Respondents: 77.

Avg. Hours Per Response: 2 hours.

Needs and Uses: The Marine Mammal Protection Act exempts Alaskan natives from the prohibitions from taking, killing, or injuring marine mammals without a permit or exemption if the taking is done for subsistence or for creating and selling authentic native articles of handicraft or clothing. Non-natives who wish to act as a tanner or an agent for such products must register with NOAA and submit certain records. The information obtained is used for law enforcement purposes.

Affected Public: Businesses or other for-profit organizations.

Frequency: On occasion, annually.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, NW, Washington, DC 20503.

Dated: July 22, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 98–19940 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 USC Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Western Alaska Community Development Quota Program.

Agency Form Number(s): None.

OMB Approval Number: 0648–0269.

Type of Request: Revision of a currently approved collection.

Burden: 3,495 hours.

Number of Respondents: 59.

Avg. Hours Per Response: Ranges between 4 and 520 hours depending on the requirement.

Needs and Uses: The collection of information is needed to administer and manage harvests of groundfish and halibut under the Western Alaska Community Development Quota (CDQ) Program for the groundfish fisheries off Alaska. The information collected will be used to determine whether communities applying for allocations under the CDQ program meet administrative requirements, whether vessels and processors harvesting CDQ species meet equipment and operational requirements, and to monitor whether quotas have been harvested or exceeded.

Affected Public: Not-for-profit institutions, businesses or other for-profit organizations, state, local or tribal government.

Frequency: On occasion, weekly, annually, recordkeeping.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, NW, Washington, DC 20503.

Dated: July 22, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 98–19941 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–820]

Amended Order and Final Determination of Sales at Less Than Fair Value: Ferrosilicon From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amendment to Final Determination of Antidumping Duty

Investigation in Accordance with Decision upon Remand.

SUMMARY: On July 20, 1995, the United States Court of International Trade (the CIT) remanded to the Department of Commerce (the Department) the final determination and the amended final determination in the antidumping duty investigation of ferrosilicon from Brazil. *See Aimcor et al.* v. *United States et al.*, Slip Op. 95–130 (CIT July 20, 1995). On January 17, 1996, the Department filed its results of redetermination pursuant to the CIT's order, and on May 21, 1996, the CIT affirmed the Final Remand Determination. That decision was appealed. The petitioner cross-appealed. On April 9, 1998, the CAFC affirmed the decision of the CIT. As there is now a final and conclusive court decision in this action, we will instruct the Customs Service to collect a cash deposit of 42.17 percent for subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice, from "all other" manufacturers, producers or exporters. The cash deposit rates calculated for CBCC and Minasligas as a result of the remand have been superseded by subsequent administrative reviews for these companies.

EFFECTIVE DATE: July 27, 1998.

FOR FURTHER INFORMATION CONTACT: Kate Johnson or David J. Goldberger, Office 5, AD/CVD Enforcement Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone: (202) 482–4929 or (202) 482–4136, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions in effect as of December 31, 1994. In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations codified at 19 CFR Part 353 (1994).

Background

On January 6, 1994, the Department published in the **Federal Register** the *Final Determination of Sales at Less-Than-Fair-Value: Ferrosilicon from Brazil* (59 FR 732) (*Final Determination*). On February 23, 1994, the Department published the *Amended Final Determination of Sales at Less-Than-Fair-Value: Ferrosilicon from Brazil* (59 FR 8598) (*Amended Final Determination*). Subsequently, AIMCOR and Minasligas filed lawsuits with the CIT, challenging the Department's final determination and amended final determination.

On July 20, 1995, the CIT remanded to the Department the *Final Determination* and *Amended Final Determination*. *See Aimcor, Alabama Silicon, Inc., American Alloys, Inc., Globe Metallurgical, Inc., and American Silicon Technologies* v. *United States and Companhia Ferroligas Minas Gerais-Minasligas*, Slip Op. 95–130 (CIT July 20, 1995). In its remand instructions, the CIT upheld the Department's reduction of home market price by the inflation premium (we determined that the home market price erroneously included an adjustment for anticipated inflation that did not permit a contemporaneous comparison of the home market price at the time of shipment to the replacement cost in the month of shipment) but directed the Department to determine if the amount of the "spread" (the difference between the interest rate and the inflation rate) was sufficiently quantified and, if so, to account for this amount in the home market price. If this data was not found to be sufficiently quantified, the Department was to grant Minasligas an opportunity to provide such data. We determined that the spread reported by Minasligas was not the most appropriate measure of inflation in this case. We used the monthly Wholesale Price Index because it more closely reflected the price increases experienced by the producer due to inflation. Second, the CIT stated that the Department must reconsider its profit calculation in CV because in this hyperinflationary situation, the Department calculated profit based upon an imputed home market credit expense that may be totally unrelated to an appropriate CV. The Court further stated that the Department must explain the rationale for whatever methodology it chose to apply. We recalculated profit after using the weighted average of home market spreads as imputed credit for CV because the spreads most accurately reflect the real interest rate charged to customers during the payment period. Third, the CIT instructed the Department to apply a U.S. dollar-denominated interest rate in calculating Minasligas' imputed U.S. credit expenses. We determined that the company's only evidence of U.S. borrowing is an aircraft lease and, therefore, the only evidence of what credit terms this company would encounter when borrowing in U.S. dollars. Accordingly, for purposes of imputed credit expenses, we used the interest rate on the aircraft lease. Fourth, the CIT directed the Department to request from Minasligas data on the appropriate monetary correction for loans, and if that data was inadequate or not provided, to reconsider our selection of best information available. Also, we were to reconsider whether the Department's interest expense adjustment and the selection, if any, of an adjustment for monetary correction for loans understated Minasligas' interest expenses included in COP and CV. We recalculated the net interest expense ratio for the combined companies (Delp and Minasligas) based on the actual interest expense incurred consistent with our normal methodology. We restated the cost of sales used in the denominator of the net interest expense ratio by using the wholesale price inflation index. We applied the actual interest expense ratio to the replacement cost of manufacturing for each month of the period of investigation. Fifth, the CIT directed the Department to determine whether Minasligas' value-added taxes on the inputs at issue were fully recovered prior to exportation of the subject merchandise. On September 13, 1995, the CIT determined that the fifth issue also pertained to CBCC. The parties were unable to submit data to enable us to determine whether the taxes paid on inputs for any specific sale were recovered. Therefore, there was insufficient evidence to conclude that the taxes were fully recovered and we considered them a cost and included them in the cost of production.

On January 17, 1996, the Department filed its results of redetermination pursuant to the CIT's remand. As a result of the redetermination upon remand, the dumping margin for Minasligas changed from 3.46 percent to 19.73 percent, the dumping margin for CBCC changed from 15.53 to 17.93 percent, and the All Others rate changed from 35.95 to 42.17 percent. On May 21, 1996, the CIT affirmed the Department's results of the remand redetermination. *See AIMCOR* v. *United States*, Slip Op. 96–79 (CIT May 21, 1996). That decision was appealed by both AIMCOR and Minasligas. Specifically, Minasligas challenged the inclusion of Brazilian value-added taxes as part of the cost of materials in determining CV. AIMCOR cross-appealed, challenging the interest rate used by the Department to calculate Minasligas' U.S. credit expenses. On April 9, 1998, the CAFC affirmed the decision of the CIT. As there is now a final and conclusive court decision in this action, we are amending our

amended final determination in this matter.

Amended Final Determination

Pursuant to section 19 U.S.C. 1516A(e) of the Act, we are now amending the amended final determination on the antidumping duty order on ferrosilicon from Brazil. As a result of the remand redetermination, the recalculated final weighted-average margins are as follows:

Manufacturer/ producer/exporter	Customers ID No.	Margin percentage
CBCC	A–351–820–001	17.93
Minasligas	A–351–820–003	19.73
All Others	A–351–820–000	42.17

Assessment Instructions

On January 19, 1996, the Court granted an injunction preventing liquidation of entries made on or after August 16, 1993, at the less-than-fair-value (LTFV) or amended LTFV cash deposit rates for CBCC, Minasligas, as well as "all others" (except Italmagnesio S.A. Industria e Comercia, which was not covered by the injunction), and required that any unreviewed entries be liquidated at the rates determined in the litigation. We will, therefore, instruct Customs to liquidate unreviewed entries of Minasligas, CBCC and "all others," which were entered at the LTFV cash deposit rates, at the rates listed above.

This determination is issued and published in accordance with section 736(a)(1) of the Act and 19 CFR 353.20(a)(4)(1994).

Dated: July 17, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 98–20013 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–836]

Polyvinyl Alcohol From Japan: Final Results of Changed Circumstances Antidumping Duty Review, and Revocation in Part of Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of changed circumstances antidumping duty review, and revocation in part of antidumping duty order.

SUMMARY: On April 30, 1998, the Department published a notice of initiation of a changed circumstances antidumping duty review and preliminary results of the review with intent to revoke, in part, the antidumping duty order on polyvinyl alcohol from Japan. On June 16, 1998, the Department published a notice amending the preliminary results of the changed circumstances antidumping duty review, the scope of which included polyvinyl alcohol for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement. We are now revoking this order in part, with regard to polyvinyl alcohol from Japan for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement, based on the fact that domestic parties have expressed no further interest in the relief provided by the order with respect to the importation or sale of polyvinyl alcohol for use in the manner prescribed above.

EFFECTIVE DATE: July 27, 1998.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended ("the Act"), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act ("URAA"). In addition, unless otherwise indicated, all citations to the Department of Commerce's ("the Department") regulations are to the regulations at 19 CFR Part 351, 62 FR 27296 (May 19, 1997).

FOR FURTHER INFORMATION CONTACT: Brian Smith or Brian Ledgerwood, Office of AD/CVD Enforcement, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–1766 or (202) 482–3836, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 12, 1998, Colorcon, Inc. ("Colorcon") requested that the Department conduct a changed circumstances review and revoke, in part, the antidumping duty order with respect to polyvinyl alcohol ("PVA") from Japan for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement. Colorcon included in its request a statement from the petitioner dated October 30, 1997, expressing (i) no objection to a changed circumstances review, and (ii) no further interest in maintaining the antidumping duty order with respect to PVA imported from Japan for use in the manner described above.

We preliminarily determined that the petitioner's affirmative statement of no interest constituted changed circumstances sufficient to warrant a review and partial revocation of this order. Consequently, on April 30, 1998, the Department published a notice of initiation and preliminary results of changed circumstances antidumping duty review with an intent to revoke this order in part (63 FR 23722). In that notice, we stated that we intend to revoke in part, the antidumping duty order as it relates to "imports of PVA for use as a pharmaceutical excipient or for use in the manufacture of film coating systems which are components of a drug or dietary supplement." Subsequently, it came to the Department's attention that our description of the type of PVA subject to the proposed revocation did not accurately reflect the description contained in the petitioner's expression of no further interest. In particular, the Department's description of the product subject to revocation did not include PVA "for use in the manufacture of an excipient." As a result, we amended our preliminary results published on April 30, 1998, to clarify our description of the type of PVA subject to the proposed revocation. On June 16, 1998, the Department published a notice amending the preliminary results of the changed circumstances antidumping duty review with an intent to revoke the order in part (63 FR 32809). We gave interested parties an opportunity to comment on the amended preliminary results of this changed circumstances review. We received no comments.

Scope of Review

The product covered by this review is PVA. PVA is a dry, white to cream-colored, water-soluble synthetic polymer. Excluded from this review are PVAs covalently bonded with acetoacetylate, carboxylic acid, or sulfonic acid uniformly present on all polymer chains in a concentration equal to or greater than two mole percent, and PVAs covalently bonded with silane uniformly present on all polymer chains in a concentration equal to or greater than one-tenth of one mole percent. PVA in fiber form is not included in the scope of this review.

The merchandise under review is currently classifiable under subheading 3905.30.00 of the *Harmonized Tariff Schedule of the United States*

("HTSUS"). Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope is dispositive.

Final Results of Review; Partial Revocation of Antidumping Duty Order

The affirmative statement of no interest by the petitioner in PVA from Japan for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement, constitutes changed circumstances sufficient to warrant partial revocation of this order. Therefore, the Department is partially revoking the order on PVA from Japan for use in the manner prescribed above, in accordance with sections 751 (b) and (d) and 782(h) of the Act and 19 CFR 351.222(g)(i). This partial revocation applies to all entries of the subject merchandise entered or withdrawn from the warehouse for consumption on or after May 1, 1998.

The Department will instruct the Customs Service ("Customs") to proceed with liquidation, without regard to antidumping duties, of all unliquidated entries of PVA from Japan for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement entered, or withdrawn from the warehouse, for consumption on or after May 1, 1998. The Department will further instruct Customs to refund with interest any estimated duties collected with respect to unliquidated entries of PVA from Japan for use in the manner prescribed above, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this changed circumstances review, in accordance with Section 778 of the Act.

This notice also serves as a final reminder to parties subject to administrative protection orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d)(1997). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This changed circumstances review, partial revocation of the antidumping duty order, and notice are in accordance with sections 751 (b) and (d) and 782(h) of the Act and sections 351.216, 351.221(c)(3), and 351.222(g) of the Department's regulations.

Dated: July 20, 1998.

Joseph A. Spetrini,

Assistant Secretary for Import Administration.

[FR Doc. 98–20012 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Cornell University; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW, Washington, DC.

Docket Number: 98–028. *Applicant:* Cornell University, Ithaca, NY 14853–1501. *Instrument:* Electron Microprobe, Model JXA–8900R. *Manufacturer:* Narishige Scientific, Japan. *Intended Use:* See notice at 63 FR 31737, June 10, 1998.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides characterization of elemental composition and structure in surfaces with resolution down to 1 μm. The National Institute of Standards and Technology advised July 26, 1996 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use (comparable case).

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 98–19904 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Rutgers-The State University of New Jersey; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This is a decision pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW, Washington, DC.

Decision: Denied. Applicant has failed to establish that domestic instruments of equivalent scientific value to the foreign instrument for the intended purposes are not available.

Reasons: Section 301.5(e)(4) of the regulations requires the denial of applications that have been denied without prejudice to resubmission if they are not resubmitted within the specified time period. This is the case for the following docket.

Docket Number: 97–101. *Applicant:* Rutgers-The State University of New Jersey, Piscataway, NJ 08855. *Instrument:* Automated Thermal Conductivity and Specific Heat System, Model EMT 101. *Manufacturer:* Termis Ltd., C.I.S. *Date of Denial Without Prejudice to Resubmission:* April 28, 1998.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 98–20014 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of California, Berkeley; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 98–025. *Applicant:* University of California, Berkeley, Berkeley, CA 94720. *Instrument:* Electron Detector. *Manufacturer:* Gammadata/Scienta AB, Sweden.

Intended Use: See notice at 63 FR 27562, May 19, 1998.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides angular resolution of 0.02 degree with significant throughput. The Brookhaven National Laboratory advised July 2, 1998 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 98–19902 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of California, Davis; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW, Washington, DC.

Docket Number: 98–026. *Applicant:* University of California, Davis, Davis, CA 95616. *Instrument:* Optical Imaging System, Model ORA 2001. *Manufacturer:* Optical Imaging, United Kingdom. *Intended Use:* See notice at 63 FR 31737, June 10, 1998.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides ability to perform optical imaging to map brain activity in laboratory animals. The National Institutes of Health advises in its memorandum dated June 8, 1998 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 98–19903 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of California, San Diego; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW, Washington, DC.

Docket Number: 98–029. *Applicant:* University of California, San Diego, San Diego, CA 92121. *Instrument:* Wave Measurement Equipment. *Manufacturer:* Datawell bv, The Netherlands. *Intended Use:* See notice at 63 FR 31737, June 10, 1998.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides: (1) more reliable wave direction estimates at frequencies under 1.0 Hz and over 3.0 Hz with less variability within the range, and (2) better wave spread estimates than comparable domestic equipment. Two domestic manufacturers of similar equipment advised April 23, 1997 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use (comparable case).

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 98–19905 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Feedback Forms for WebMetrics

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506 (c)(2)(A)).

DATES: Written comments must be submitted on or before September 25, 1998.

ADDRESSES: Direct written comment to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Sharon Laskowski, National Institute of Standards and Technology (NIST), Building 225, Room A216, Gaithersburg, MD 20899.

SUPPLEMENTARY INFORMATION:

I. Abstract

This submission under the Paperwork Reduction Act represents a request for a new collection by NIST. The NIST WebMetrics Tool Suite contains rapid, remote, and automated tools to help in producing usable web sites. The NIST WebMetrics Tool Suite consists of three tools: the Static Analyzer Tool (WebSAT), the Category Analysis Tool (WebCAT), and the Visual Instrumenter Tool (WebVIP).

WebSAT checks the Hypertext Markup Language (HTML) of a web page against numerous usability guidelines. The output from WebSAT consists of identification of potential usability problems which should be investigated further through user testing.

WebCAT lets the usability engineer quickly construct and conduct a simple category analysis across the web.

WebVIP lets the usability engineer rapidly instrument a web site for local or remote testing by employing visual instrumenting as well as automated techniques.

Users of the NIST WebMetrics tools may provide NIST with comments on

the tools through the use of the automated feedback forms, "Feedback Forms for NIST WebMetrics", which are accessible from the NIST WebMetrics web site. The feedback forms allow users to comment on any problems they had with using the tools, the helpfulness of the tools, and suggestions for the functionality of the tools. Users are not obligated to provide comments in order to access and use the tools. Comments are strictly voluntary.

II. Method of Collection

Applicants will submit information to NIST via the NIST WebMetrics web site.

III. Data

OMB Number: None.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Businesses or other for-profit, individuals or households, Federal Government, state or local government.

Estimated Number of Respondents: 200.

Estimated Time Per Response: 10 minutes.

Estimated Total Annual Cost: The estimate of the total annual cost to submit this information for fiscal year 1998 and future years is $0. There is no cost since no capital expenditures are required. The only cost is a person's time.

IV. Request for Comments

Comments are invited 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 (including hours and costs) of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: July 21, 1998.

Linda Engelmeier,

Department Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 98–19910 Filed 7–24–98: 8:45am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Coastal Zone Management: Federal Consistency Appeal by Rick Bellew From an Objection by the State of Alabama

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of appeal and request for comments.

By letter dated November 17, 1997, Mr. Rick Bellew (Appellant), filed with the Secretary of Commerce (Secretary) a notice of appeal pursuant to section 307(c)(3)(A) of the Coastal Zone Management Act of 1972 (CZMA), as amended, 16 U.S.C. 1451 *et seq.*, and the Department of Commerce's implementing regulations, 15 C.F.R. Part 930, Subpart H. The appeal is taken from an objection by the State of Alabama (State) to the Appellant's consistency certification for a permit to dredge a ten-foot wide by 420-foot long channel to a three-foot depth. According to a survey submitted by Appellant, approximately 185 linear feet of the proposed channel is vegetated by shoalgrass.

The CZMA provides that a timely objection by a state precludes any federal agency from issuing licenses or permits for the activity unless the Secretary finds that the activity is either "consistent with the objectives" of the CZMA (Ground I) or "necessary in the interest of national security" (Ground II). Section 307(c)(3)(A). To make such a determination, the Secretary must find that the proposed project satisfies the requirements of 15 CFR 930.121 or 930.122.

The Appellant requests that the Secretary override the State's consistency objections based on Ground I. To make the determination that the proposed activity is "consistent with the objectives" of the CZMA, the Secretary must find that: (1) the proposed activity furthers one or more of the national objectives or purposes contained in §§ 302 or 303 of the CZMA, (2) the adverse effects of the proposed activity do not outweigh its contribution to the national interest, (3) the proposed activity will not violate the Clean Air Act or the Federal Water Pollution Control Act, and (4) no reasonable alternative is available that would permit the activity to be conducted in a manner consistent with the State's coastal management program. 15 CFR 930.121.

Public comments are invited on the findings that the Secretary must make as set forth in the regulations at 15 CFR 930.121. Comments are due within 30 days of the publication of this notice and should be sent to Ms. Pamela Lawrence, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1305 East-West Highway, Room 6111, Silver Spring, MD 20910. Copies of comments will also be forwarded to the Appellant and the State.

All nonconfidential documents submitted in this appeal are available for public inspection during business hours at the offices of the State and the Office of the Assistant General Counsel for Ocean Services.

FOR ADDITIONAL INFORMATION CONTACT: Ms. Pamela Lawrence, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1305 East-West Highway, Room 6111, Silver Spring, MD 20910, 301–713–2967.

(Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance)

Dated: July 14, 1998.

Monica Medina,

General Counsel.

[FR Doc. 98–19911 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071598H]

Caribbean Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Caribbean Fishery Management Council (Council) and its Administrative Committee will hold meetings.

DATES: The Council meetings will be held on August 12–13, 1998. The Administrative Committee meeting will be on August 11, 1998.

ADDRESSES: All meetings will be held at the Windward Passage Hotel, in Charlotte Amalie, St. Thomas, U.S. Virgin Islands.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 268 Munoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico 00918–2577; telephone: (787) 766–5926; fax: (787) 766–6239.

SUPPLEMENTARY INFORMATION: The Caribbean Fishery Management Council will hold its 94th regular public meeting to discuss the Draft Amendment Number 1 to the Fishery Management Plan for Corals and Reef Associated Plants and Invertebrates of Puerto Rico and the United States Virgin Islands for Establishing a Marine Conservation District. The Council will be taking final action on the establishing of a proposed "no-take" marine conservation district in the exclusive economic zone, U.S.V.I.

The Administrative Committee will meet on Tuesday, August 11, 1998, from 2:00 p.m. to 5:00 p.m., to discuss administrative matters regarding Council operation.

The Council will convene on Wednesday, August 12, 1998, from 9:00 a.m. to 5:00 p.m., and on Thursday August February 13, 1998, from 9:00 a.m. till noon, approximately.

The meetings are open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral and written statements regarding agenda issues.

Although other issues not contained in this agenda may come before the Council for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or requests for sign language interpretation or other auxiliary aids, please contact Mr. Miguel A. Rolon at the Council (see **FOR FURTHER INFORMATION CONTACT** for address) at least 5 days prior to the meeting dates.

Dated: July 20, 1998.

Gary C. Matlock,

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

[FR Doc. 98–19990 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071498A]

Incidental Taking of Marine Mammals; Acoustic Harassment

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

ACTION: Notice of workshop on acoustic criteria.

SUMMARY: NMFS announces that it will convene a panel of independent experts in marine acoustics to discuss various technical aspects of the problem of marine mammals and anthropogenic noise. While the proceedings are open to the general public for observation, the public's ability to interact with the expert panel will be limited to specified times during the proceedings.

DATES: The workshop will be held September 9 through September 11, 1998, from 9 a.m. until 5 p.m. each day.

ADDRESSES: The Workshop will be held at the Silver Spring Metro Center Building 4, NOAA Science Center, 1301 East-West Highway, Silver Spring, MD.

FOR FURTHER INFORMATION CONTACT: Roger Gentry or Kenneth R. Hollingshead, Office of Protected Resources, NMFS, telephone (301) 713–2055.

SUPPLEMENTARY INFORMATION: Anthropogenic sounds in the marine environment are increasing over the span of decades, with possible adverse impacts on the marine biota, in particular marine mammals. These sounds come from shipping, military (and civilian) explosives, seismic profiling (both oil and gas exploration and for seismic/geological hazards), government, commercial, and private sonars, dredging, drilling and pile driving, military activities, use of acoustic deterrence, and some scientific research. Some sounds may be loud enough to cause physical injury to marine mammals. The Marine Mammal Protection Act (MMPA) defines "take" to include "harass." Harassment includes a disturbance or a disruption of behavioral patterns, including migration, breathing, nursing, breeding, feeding, or sheltering (16 U.S.C. 1362(18)). While it is clear that certain takings (e.g., those that cause serious injury or mortality or result in large scale displacements of a marine mammal population) require an authorization under the MMPA (unless exempted), it is less clear what level of anthropogenic sounds might cause behavioral modification or affect hearing sufficient to require authorizations under the MMPA and the Endangered Species Act. Additionally, at this time scientific data demonstrating that certain sounds result in the harassment of marine mammals are lacking, and it is not known to what extent NMFS should apply data from surrogate species to marine mammals.

The workshop will consist of experts in the fields of animal bioacoustics, underwater sound, and animal behavior. The workshop will consider whether different criteria are needed for explosions, pulsed sound, intermittent sound, and continuous sound, the preferred units in which to report these levels, and other approaches as alternatives to proximity for estimating the effects of sound on marine mammals.

Dated: July 21, 1998.

Patricia A. Montanio,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–19992 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071598G]

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold joint meetings of its Habitat Committee and Coral Advisory Panel and its Habitat and Environmental Protection Advisory Panel.

DATES: The meetings will be held from August 11-13, 1998. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meeting will be held at the Town & Country Inn, 2008 Savannah Highway, Charleston, SC; telephone: (843) 571-1000.

Council address: South Atlantic Fishery Management Council, One Southpark Circle, Suite 306; Charleston, SC 29407-4699.

FOR FURTHER INFORMATION CONTACT: Susan Buchanan, Public Information Officer; telephone: (843) 571-4366; fax: (843) 769-4520; email: susan.buchanan@noaa.gov

SUPPLEMENTARY INFORMATION:

Meeting Dates

August 11, 1998, 1:00 p.m. to 5:00 p.m.

The Habitat Committee, Coral and Habitat & Environmental Protection Advisory Panels will hear an overview of the development of the Council's actions to meet the requirements of the Sustainable Fisheries Act regarding essential fish habitat, bycatch, overfishing and fishingcommunities, and an overview of further necessary action to meet these requirements, review comments received during public hearing and informal review comments on the Council's Habitat Plan and Habitat Comprehensive Amendment and the Sustainable Fisheries Act Amendment,and Review and provide advisory panel and committee comments on the Draft Calico Scallop Fishery Management Plan.

August 12, 1998, 8:30 a.m. to 5:00 p.m.

The committee and advisory panels will review and provide comments to the Council on the following Council documents: the Draft Sargassum Plan, the Draft Habitat Plan, the Draft Habitat Amendment, and the Sustainable Fisheries Act Amendment. The advisory panels will then develop final advisory panel recommendations on these documents to the Council.

August 13, 1998, 8:30 a.m. to 12:00 noon

The committee and advisory panels will meet to develop final committee recommendations to the Council regarding the aforementioned documents in this Notice, and discuss other business.

Although other issues not contained in this agenda may come before these groups for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by August 4,1998.

Dated: July 20, 1998.

Gary C. Matlock,

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

[FR Doc. 98–19991 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071598B]

Marine Mammals; File No. 782–1455

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

ACTION: Issuance of permit amendment.

SUMMARY: Notice is hereby given that Permit No. 782–1455, issued to Dr. Douglas P. DeMaster, Director, National Marine Mammal Laboratory, National Marine Fisheries Service, 7600 Sand Point Way, NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0070, was amended.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits and Documentation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130 Silver Spring, MD 20910 (301/713–2289);

Regional Administrator, Alaska Region, National Marine Fisheries Service, NOAA, P.O. Box 21668, Juneau, AK 99802–1668 (907/586–7221; and

Regional Administrator, Southwest Region, National Marine Fisheries Service, NOAA, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: Sara Shapiro or Ruth Johnson, 301/713–2289.

SUPPLEMENTARY INFORMATION: The subject amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of § 216.39 of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the provisions of § 222.25 of the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR part 222), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The amendment authorizes the National Marine Mammal Laboratory to obtain and maintain northern fur seal (*Callorhinus ursinus*) scientific specimens collected from the native subsistence harvest, authorizes harassment of northern fur seals while collecting/necropsying dead pups throughout the duration of the Permit, and changes the due date of the annual reports from December 31 to March 31 every year the permit is active.

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 species which is the subject of this permit, and (3) is

consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: July 20, 1998.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–19988 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. 980713169–8167–01]

Dissemination of Patent and Trademark Information on the PTO's Web Site

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice and request for public comments.

SUMMARY: The Patent and Trademark Office (PTO) plans to expand the searchable database offerings on its World-Wide Web (Web) site by adding additional patent data and by including trademark data. This expansion will provide Web access to the full text of patents granted since 1976 and to the trademark text data for registered and pending marks. The PTO also plans to incorporate patent and trademark image data and trademark data for inactive marks as part of its expanded Web offering. The PTO requests public comments on its decision to expand its Web site offerings.

DATES: To ensure consideration, written comments must be submitted on or before August 26, 1998.

ADDRESSES: Address comments to the Commissioner of Patents and Trademarks, Attention: Wesley H. Gewehr, Administrator for Information Dissemination, Crystal Park 3, Suite 451, Washington, DC 20231; or fax to 703–306–2737; or e-mail to jane.myers@uspto.gov. Comments will be available for public inspection in the Office of Electronic Information Products, Crystal Park 3, Suite 441, 2231 Crystal Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Jane S. Myers, Office of Electronic Information Products, by telephone at 703–306–2600; by fax at 703–306–2737;

by e-mail to jane.myers@uspto.gov; or by mail to Patent and Trademark Office, Office of Electronic Information Products, Crystal Park 3, Suite 441, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The PTO has been directed to disseminate patent and trademark information using automated methods. See 35 USC 41(i)(2). The PTO currently provides the public with on-line access, for a fee, to internal patent and trademark automated search systems in its public search facilities located in Crystal City, VA. Thirty-one Patent and Trademark Depository Libraries (PTDLs) offer on-line access to PTO's automated patent full-text search system, and three Partnership PTDLs offer on-line access to PTO's automated trademark text and image search system and to the automated patent image retrieval system. The PTO also provides access to subsets of its patent and trademark databases on CD-ROMs in the PTO's public search facilities and at 83 PTDLs located throughout the country. The PTO sells its CD-ROM products to the public, and the Government Printing Office makes them available to the Federal Depository Libraries. Although the PTO has provided World-Wide Web access to searchable patent bibliographic data since November 1995, neither searchable trademark data, the full text of patents, nor patent and trademark image data are currently available on the PTO Web site.

The PTO hereby provides notice to the public of its plans to expand searchable patent data and to begin offering searchable trademark data on its Web site. In August of this year, the PTO plans to provide free Web access to the trademark text data that is currently available on the PTO's Cassis CD-ROM products—Trademarks Registered and Trademarks Pending—covering active registered and pending marks. In November 1998, this trademark offering will include the "clipped" images associated with these marks. In the future, this searchable trademark database will be expanded to include inactive (abandoned, cancelled and expired) marks and some additional data elements associated with those inactive marks, and will be updated more frequently to reflect more current conditions of the trademark database. Also in November 1998, the PTO plans to expand its patent database offering on the Web to include free access to the full text of all patents issued since 1976. In March 1999, the patent offering will allow users free access to the full page images of patents identified. On-line ordering of patent documents issued since 1976 for electronic delivery, for a fee, is planned for March 1999. Any such fee will be established by taking into consideration applicable government policy, OMB circular A–130, the Paperwork Reduction Act, and any other applicable statutes. The PTO requests public comments on its plans to expand its Web site offerings.

Dated: July 21, 1998.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 98–19993 Filed 7–24–98; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Department of Defense, Advisory Group on Electron Devices.

ACTION: Notice.

SUMMARY: Working Group B (Microelectronics) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Friday, September 11, 1998.

ADDRESSES: The meeting will be held Palisades Institute for Research Service, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Timothy Doyle, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director Defense Research and Engineering (DDR&E), and through the DDR&E, to the Director Defense Advanced Research Projects Agency and the Militaryd Departments in plannign and managing an effective research and development program in the field of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military proposes to initiate with industry, universities or in their laboratories. The microelectronics area includes such programs on semiconductor materials, integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C. App. 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: July 21, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–19949 Filed 7–24–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Department of Defense, Advisory Group on Electron Devices.

ACTION: Notice.

SUMMARY: Working Group A (Microwave Devices) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Wednesday, September 9, 1998.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: David Cox, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency (ARPA) and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave devices, electronic warfare devices, millimeter wave devices, and passive devices. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C.

App. 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: July 21, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–19950 Filed 7–24–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Department of Defense, Advisory Group on Electron Devices.

ACTION: Notice.

SUMMARY: The DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Thursday, September 10, 1998.

ADDRESSES: The meting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. Eliot Cohen, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The AGED meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The agenda for this meeting will include programs on Radiation Hardened Devices, Microwave Tubes, Displays and Lasers. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C. App. Section 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(l)(1994), and that accordingly, this meeting will be closed to the public.

Dated: July 21, 1998.

L.M. Bynum,

Alternate, OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–19951 Filed 7–24–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Department of Defense, Advisory Group on Electron Devices.

ACTION: Notice.

SUMMARY: Working Group C (Electro-Optics) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Tuesday, August 25, 1998.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Elise Rabin, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The Working Group C meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This opto-electronic device area includes such programs as imaging device, infrared detectors and lasers. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C. App. Section 10(d)(1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1)(1994), and that accordingly, this meeting will be closed to the public.

Dated: July 21, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–19952 Filed 7–24–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Army

Proposed Collection; Comment Request

AGENCY: Deputy Chief of Staff for Personnel (DAPE–ZXI–RM).

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 25, 1998.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Department of the Army, United States Military Academy, West Point, New York 10996 ATTN: (Joseph E. Dineen). Consideration will be given to all comments received within 60 days of the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Department of the Army Reports clearance officer at (703) 614–0454.

Title: Candidate Procedures, USMA Forms, 21–26, 21–23, 21–25, 21–16, 21–14, 21–8, 5–520, 5–518, 5–497, FL 481, FL 546, FL 5–2, FL 5–26, FL 5–515, FL 480–1, FL 520, FL 261, OMB Control Number 0702–0061.

Needs and Uses: West Point candidates provide personal background

information which allows the West Point Admissions Committee to make subjective judgment on non-academic experiences. Data are also used by West Point's Office of Institutional Research for correlation with success in graduation and military careers.

Affected Public: Individuals or households.

Annual Burden Hours: 129,265.

Number of Respondents: 91,875.

Responses Per Respondent: 1.

Average Burden Per Response: 14 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: West Point candidates provide personal background information which allows the West Point Admissions committee to make subjective judgment on academic and non-academic experiences to determine qualification for admission to West Point. Approximately 12,000 to 13,000 applicant files are opened each year and about 4,500 are evaluated by the Admissions Committee during each admissions cycle.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 98–19919 Filed 7–24–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Proposed Collection; Comment Request

AGENCY: Deputy Chief of Staff for Personnel (DAPE–ZXI–RM).

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 25, 1998.

ADDRESSES: Written comments and recommendations on the proposed information collection should not be sent to Department of the Army, United States Military Academy, West Point, New York 10996, ATTN: (Joseph E. Dineen). Consideration will be given to all comments received within 60 days of the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Department of the Army Reports clearance officer at (703) 614–0454.

Title: Offered Candidate Procedures, USMA Forms, 534, 5–499, 5–490, 2–66, 847, 5–489, 5–519, 8–2, 6–154, 5–515, 5–26, 5–516, FL 480–1, OMB Control Number 0702–0062.

Needs and uses: West Point candidates provide personal background information which allows the West Point Admissions Committee to make subjective judgment on non-academic experiences. Data are also used by West Point's Office of Institutional Research for correlation with success in graduation and military careers.

Affected public: Individuals or households.

Annual Burden Hours: 1,383.

Number of Respondents: 16,600.

Responses Per Respondent: 1.

Average Burden Per Response: 5 minutes..

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: The Admissions Office and other agencies at the U.S. Military Academy require information on candidates who receive an offer of admission to enable them to order supplies, clothes, eye glasses and prepare travel arrangement for the incoming class. All information collected on candidates is stored in locked rooms with restricted access to authorized personnel only.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 98–19920 Filed 7–24–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Proposed Collection; Comment Request

AGENCY: Deputy Chief of Staff for Personnel (DAPE–ZXI–RM).

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 25, 1998.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Department of the Army, United States Military Academy, West Point, New York 10996 ATTN: (Joseph E. Dineen). Consideration will be given to all comments received within 60 days of the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Department of the Army Reports clearance officer at (703) 614–0454.

Title: Pre-Candidate Procedures, USMA Forms, 375, 723, 450, 21–12, 21–27, 381, OMB Control Number 0702–0060.

Needs And Uses: West Point candidates provide personal background information which allows the West Point Admissions Committee to make subjective judgment on non-academic experiences. Data are also used by West Point's Office of Institutional Research for correlation with success in graduation and military careers.

Affected Public: Individuals or households.

Annual Burden Hours: 8,258.

Number of Respondents: 65,100.

Responses Per Respondent: 1.

Average Burden Per Response: 9 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: Student information is obtained through the use of business reply cards on posters and in publications, permitting potential candidates to request information on the

U.S. Military Academy. This initial student information received is retained in a file until an additional response is received by potential candidates. The purpose of this activity is to obtain a group of applicants who eventually may be evaluated for admission to West Point.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 98–19921 Filed 7–24–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

ARMS Initiative Implementation

AGENCY: Armament Retooling and Manufacturing Support (ARMS) Executive Advisory Committee (EAC).

ACTION: Notice of meeting.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of the next meeting of the Armament Retooling and Manufacturing Support (ARMS) Executive Advisory Committee (EAC). The EAC is chartered to develop new and innovative methods to maintain the government-owned, contractor-operated ammunition industrial base and retain critical skills for a national emergency. This meeting will update attendees on the status of ongoing actions with decisions being made to close out or continue these actions. Topics for this meeting include ARMS Loan Guarantee Program, Funding Status, Data Base establishment, and revisions to 10 U.S.C. 2692. This meeting is open to the public.

DATES OF MEETING: August 12–13, 1998.

PLACE OF MEETING: The Monte Carlo, 3770 Las Vegas Boulevard South, Law Vegas, Nevada 89109.

TIME OF MEETING: 8:00 a.m.–5:00 p.m. on August 13, and 8:00 a.m.–1:00 p.m. on August 13.

FOR FURTHER INFORMATION CONTACT: Mr. Elwood H. Weber, ARMS Task Force, HQ Army Materiel Command, 5001 Eisenhower Avenue, Alexandria, Virginia 22333; Phone (703) 617–9788.

SUPPLEMENTARY INFORMATION: Participants are encouraged to make reservations immediately by calling (800) 311–8999. Be sure to mention that you will be attending the "ARMS PPTF #15" meeting to obtain the negotiated group rate of $59.00 per night (plus 9% room tax). Request you contact Mike Perez on the ARMS Team, telephone (309) 782–3360 or Mr. Mike Lopez at (309) 782–4090, if you will be attending the meeting, so that our roster of attendees is accurate. This number may also be used if other assistance regarding the ARMS meeting is required.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 98–19918 Filed 7–24–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Special Weapons Agency (DSWA); Membership of the Defense Special Weapons Agency Performance Review Board

AGENCY: Department of Defense, Defense Special Weapons Agency.

ACTION: Notice of membership of the Defense Special Weapons Agency Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) of the Defense Special Weapons Agency. The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). The Performance Review Board shall provide fair and impartial review of Senior Executive Service performance appraisals and make recommendations regarding performance and performance awards to the Director, Defense Special Weapons Agency.

EFFECTIVE DATE: The effective date of service for the appointees of the DSWA PRB is on or about 28 July 1998.

FOR FURTHER INFORMATION CONTACT: D. DIAL-ALFRED, Civilian Personnel Management Division (MPC), (703) 325–1106, Defense Special Weapons Agency, Alexandria, Virginia 22310–3398.

SUPPLEMENTARY INFORMATION: The names and titles of the members of the DSWA PRB are set forth below. All are DSWA officials unless otherwise identified:

Dr. George W. Ullrich, Deputy Director
Mr. David G. Freeman, Director, Acquisition Management Office
Mr. Michael K. Evenson, Deputy Director, Operations Directorate
Mr. Timothy X. Morgan, Director, Programs & Budget, Special Operations and Low-Intensity Conflict, Office of the Assistant Secretary Office of Defense
Mr. James R. Dominy, Associate Director for Comptroller Information Systems, Office of the Under Secretary of Defense (Comptroller)

The following DSWA officials will serve as alternate members of the DSWA PRB, as appropriate.

Mr. Robert L. Brittigan, General Counsel
Mr. Frederick S. Celec, Deputy Assistant to the Secretary of Defense (Nuclear Matters).
Dr. Kent L. Goering, Chief, Hard Target Defeat Program Office
Mr. Richard L. Gullickson, Chief, Simulation and Test Division
Dr. Don A. Linger, Director for Programs
Mr. Clifton B. McFarland, Jr., Director for Weapons Effects
Mr. Vayl S. Oxford, Director for Counterproliferation Programs
Mrs. Joan Ma Pierre, Director for Electronics and Systems
Dr. Michael J. Shore, Chief, Special Programs Office
Mr. Robert C. Webb, Chief, Electronics Technology Division
Dr. Leon A. Wittwer, Chief Weapons Lethality Division

Dated: July 21, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–19953 Filed 7–24–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Request for Proposals for the Archaeological Investigation of the Civil War Submarine H.L. Hunley, Lost off the Coast of Charleston, South Carolina on February 17, 1864, After Successfully Attacking the USS Housatonic

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its Request for Proposals for the archaeological investigation of the H.L. Hunley. In 1996 the Department of the Navy entered into a Programmatic Agreement under Section 106 of the National Historic Preservation Act for the management of this historic shipwreck. Other parties to the Programmatic Agreement are the General Services Administration, the Advisory Council on Historic Preservation, the South Carolina Hunley Commission, and the South Carolina State Historic Preservation Officer. The Programmatic Agreement requires decisions on the suitability of proposals for recovery and presentation of the Hunley be made by the Navy and the South Carolina Hunley Commission after obtaining the recommendations of members of the Hunley Oversight Committee. The Committee is an interagency group consisting of the Navy, the Department of the Interior, the General Services

Administration, the National Oceanic and Atmospheric Administration, the Smithsonian Institution, and the Advisory Council on Historic Preservation. The Committee will also consider any public comments.

The Programmatic Agreement provides for individuals and organizations to submit proposals regarding the archeological investigation of the Hunley.

Any party interested in implementing any of the following aspects of archeological investigation of the Hunley that includes: (1) data recovery at the site; (2) raising of the vessel; (3) recovery and treatment of human remains; (4) conservation and curation; (5) public participation and education during the archeological investigation; and (6) future exhibition and interpretation, must submit a comprehensive proposal and an overall financial plan to the Navy. The proposal must also include an abstract suitable for public distribution and comment.

The Navy will provide abstracts of all proposals it receives to the Hunley Oversight Committee and organizations identified by the Navy, in consultation with the National Park Service and the South Carolina Hunley Commission, as potentially having an interest in the conduct of archeological investigations of the Hunley.

Upon request, the Navy will provide these organizations with copies of entire proposals, excluding any proprietary data. Parties interested in conducting any of the archeological investigation of the Hunley will be required to bid upon a Request for Proposal and enter into a contract with the South Carolina Hunley Commission. Initial contracts will cover the following: data recovery at the site; raising of the vessel; recovery and treatment of human remains; and initial conservation of the vessel. Preference will be given to contractors who can provide a comprehensive plan for these management aspects. Contracts for the recovery and preservation will be with the South Carolina Hunley Commission.

DATES: Anyone wishing to submit an initial proposal to the Navy must submit it by November 1, 1998. The Navy will request that the South Carolina Hunley Commission provide information regarding the contracting process that includes instructions on obtaining a copy of the Request for Proposals and the dates for submitting responses to it. The Navy shall share any comments on the Programmatic Agreement with other parties to it.

ADDRESSES: Copies of the Programmatic Agreement are available from: The Naval Historical Center, Underwater Archaeology Branch, Washington Navy Yard, 901 M Street SE, Washington, DC 20374–5060, or, the Naval Historical Center Homepage:

http://www.history.navy.mil

FOR FURTHER INFORMATION CONTACT: Dr. Robert S. Neyland, Underwater Archaeologist, Naval Historical Center, Underwater Archaeology Branch, Washington Navy Yard, 901 M Street SE, Washington, DC 20374–5060, telephone (202) 433–9784.

Authority: 16 U.S.C. 470, 36 CFR Part 800.

Dated: July 16, 1998.

Lou Rae Langevin,

LT, JAGC, USN, Alternate Federal Register Liaison Officer.

[FR Doc. 98–19980 Filed 7–24–98; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Invention for Licensing; Government-Owned Invention

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy and is available for licensing by the Department of the Navy.

Patent Application entitled "Surface-Laminated Piezoelectric-Film Sound Transducer," filed October 18, 1993, Navy Case No. 75510, U.S. Patent Application Ser. No. 08/136,856.

ADDRESSES: Requests for copies of the patent application cited should be directed to the Office of Naval Research, ONR 00CC, Ballston Tower One, 800 North Quincy Street, Arlington, Virginia 22217–5660, and must include the Navy Case number.

FOR FURTHER INFORMATION CONTACT: Mr. R. J. Erickson, Staff Patent Attorney, Office of Naval Research, ONR 00CC, Ballston Tower One, 800 North Quincy Street, Arlington, Virginia 22217–5660, telephone (703) 696–4001.

Authority: 35 U.S.C. 207, 37 CFR Part 404.

Dated: July 16, 1998.

Lou Rae Langevin,

LT, JAGC, USN, Alternate Federal Register Liaison Officer.

[FR Doc. 98–19981 Filed 7–24–98; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent to Grant Exclusive Patent License; Engineering Technology, Inc.

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Engineering Technology, Inc. a revocable, nonassignable, exclusive license in the United States to practice the Government owned invention described in U.S. Patent No. 5,351,623 entitled "Explosive Simulator" issued October 4, 1994.

DATES: Anyone wishing to object to the grant of this license must file written objections along with supporting evidence, if any, not later than September 25, 1998.

ADDRESSES: Written objections are to be filed with the Office of Naval Research, ONR 00CC, Ballston Tower One, 800 North Quincy Street, Arlington, Virginia 22217–5660.

FOR FURTHER INFORMATION CONTACT: Mr. R. J. Erickson, Staff Patent Attorney, Office of Naval Research, ONR 00CC, Ballston Tower One, 800 North Quincy Street, Arlington, Virginia 22217–5660, telephone (703) 696–4001.

Authority: 35 U.S.C. 207, 37 CFR Part 404.

Dated: July 16, 1998.

Lou Rae Langevin,

LT, JAGC, USN, Alternate Federal Liaison Officer.

[FR Doc. 98–19979 Filed 7–24–98; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Idaho Operations Office; Notice of Intent To Solicit Applications for Financial Assistance Awards

AGENCY: Department of Energy.

ACTION: Notice of Solicitation for Financial Assistance Number DE–PS07–98ID13679—Geothermal Direct Use Drilling Program.

SUMMARY: The U.S. Department of Energy (DOE) is seeking applications for cost-shared well drilling for wells that can supply geothermal fluid to one or more of the direct use applications, and for sites where there is strong evidence of a verified geothermal resource. This solicitation focuses on the following direct use applications: space heating for commercial, industrial, or Government buildings, or multi-family dwellings; district heating systems;

greenhouses; aquaculture; and industrial uses. Geothermal heat pumps, also known as ground-source heat pumps, are not included in this solicitation. The ultimate goal is to increase the utilization of the United States' geothermal resources for direct use by reducing the risk inherent in well drilling. It is expected that cost-sharing wells will result in successful, exemplary direct use application projects that will, in turn, stimulate the development of additional direct use projects.

DATES: The anticipated issuance date of the solicitation is July 28, 1998. The solicitation and application forms and instructions may be accessed via the Internet at *http://www.id.doe.gov/doeid/solicit.html* and *http://www.id.doe.gov/doeid/application.html*, respectively. The website is the agency preferred method for interested parties to obtain the solicitation and application information. Interested parties requiring hardcopies should request them in writing (preferably via e-mail) from the Contract Specialist below. The website will be the official notification medium for any possible changes in the solicitation. All interested parties should monitor the website during the application period.

ADDRESSES: Applications shall be submitted to: U.S. DOE, Idaho Operations Office, Procurement Services Division, Attention: Wendy Huggins, SOL DE–PS07–98ID13679, 850 Energy Drive, MS 1221, Idaho Falls, ID 83401–1563.

FOR FURTHER INFORMATION CONTACT: Contact Wendy Huggins, Contract Specialist, at: Tele: (208) 526–2808, Fax: (208) 526–5548, E-mail: hugginwl@id.doe.gov

SUPPLEMENTARY INFORMATION: The solicitation will be issued pursuant to 10 CFR 600.6(a) with no eligibility restrictions. The statutory authorities for the issuance of this solicitation are Public Law 93–410, the Geothermal Energy Research, Development & Demonstration Act of 1974 and the Energy Policy Act (EPAct) of 1992. The Catalog of Federal Domestic Assistance Number for this program is 81.087. Approximately $500,000 to $700,000 in federal funds may be available to totally fund this program's selected projects. DOE anticipates making more than one grant award with a duration of one to three years. A minimum of 25% non-federal cost-share is required for the well drilling and completion activities.

Issued in Idaho Falls, Idaho, July 14, 1998.

R. Jeffrey Hoyles,

Director, Procurement Services Division.

[FR Doc. 98–19976 Filed 7–24–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah Gaseous Diffusion Plant.

DATES: Thursday, August 20, 1998: 5:30 p.m.–10:00 p.m.

ADDRESSES: Paducah Information Age Park Resource Center, 2000 McCracken Boulevard, Paducah, Kentucky.

FOR FURTHER INFORMATION CONTACT: Myrna E. Redfield, Site-Specific Advisory Board Coordinator, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (502) 441–6815.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

5:30 p.m.—Call to Order
5:45 p.m.—Approve Meeting Minutes
6:00 p.m.—Public Comment/Questions
6:30 p.m.—Presentations
7:30 p.m.—Break
7:45 p.m.—Presentations
9:00 p.m.—Public Comment
9:30 p.m.—Administrative Issues
10:00 p.m.—Adjourn

Copies of the final agenda will be available at the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Myrna E. Redfield at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments as the first item on the meeting agenda.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information and Reading Room at 175 Freedom Boulevard, Highway 60, Kevil, Kentucky between 8:00 a.m. and 5:00 p.m. on Monday through Friday, or by writing to Carlos Alvarado, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, or by calling him at (502) 441–6804.

Issued at Washington, DC, on July 21, 1998.

Althea T. Vanzego,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 98–19977 Filed 7–24–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford Site

AGENCY: Department of Energy.

ACTION: Meeting cancellation notice.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act Pub. L. No. 92–463, 86 Stat. 770), a notice is hereby given of the cancellation of the open Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford Site meeting, which was scheduled to be held on Thursday, August 6, 1998, from 9:00 a.m.–5:00 p.m., and Friday, August 7, 1998, from 8:30 a.m.–4:00 p.m., at the Ridpath Hotel, W. 515 Sprague, Spokane, Washington has been canceled. This meeting was announced in the **Federal Register** on Thursday, July 2, 1998 (63 FR 36216).

Issued at Washington, DC, on July 21, 1998.

Althea T. Vanzego,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 98–19978 Filed 7–24–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–665–000]

Colorado Interstate Gas Company; Notice of Request Under Blanket Authorization

July 21, 1998.

Take notice that on July 10, 1998, Colorado Interstate Gas Company (CIG), P.O. Box 1087, Colorado Springs, Colorado 80944, filed in Docket No. CP98–665–000 a request pursuant to Sections 157.205 and 157.216 and 211 of the Commission's Regulations under the National Gas Act (18 CFR 157.205, 157.216, and 211) for authorization to remove an existing 6-inch meter run formally used for receipt of gas from the Roggen Processing Plant and to replace it with a 2-inch meter tube to deliver gas to Duke Energy Field Services, Inc. (Duke) pursuant to CIG's Blanket Certificate issued in Docket No. CP83–21–000, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

CIG states that the 6-inch meter facility was originally installed to receive gas from the Roggen Processing Plant (closed in the summer of 1997) which provided pipeline quality gas for Duke's gathering system compressor station in Weld county, Colorado. CIG now proposes to remove the existing 6-inch meter tube and replace it with a 2-inch meter tube to be used to deliver gas for fuel gas at Duke's gathering system compressor station.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19957 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–664–000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

July 21, 1998.

Take notice that on July 10, 1998, Columbia Gas Transmission Corporation (Columbia), 12801 Fair Lakes Parkway Fairfax, Virginia 22030–0146, filed in Docket No. CP98–664–000 a request pursuant to Sections 157.205, 157.212 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212 and 157.216) for authorization to upgrade an existing point of delivery by abandoning and replacing certain facilities in Henrico County, Virginia, under Columbia's blanket certificate issued in Docket No. CP83–76–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Columbia states that it proposes to upgrade its existing West Richmond point of delivery for firm transportation service and will provide the service pursuant to Columbia's blanket certificate issued in Docket No. CP86–240–000 under existing rate schedules and within certificated entitlements.

Columbia states the proposed upgrade of the existing West Richmond point of delivery has been requested by the City of Richmond (COR) to provide additional firm transportation service for residential and commercial customers. Columbia states that COR has not requested an increase in its total firm entitlements in conjunction with this upgrade request, and therefore, there will be no impact on Columbia's existing peak day obligations to its other customers as a result of the proposed upgrade.

Columbia states that as part of the upgrade, it proposes to abandon certain facilities in order to increase the Maximum Daily Delivery obligations by 4,000 Dth/Day and increase the Maximum pressure at the existing West Richmond point of delivery. Columbia states that COR will install new measurement and regulation facilities at the current site and Columbia will install electronic measurement at the new station.

Columbia states that it will comply with all of the environmental requirements of Section 157.206(d) of the Commission's Regulations prior to the construction of any facilities due to the upgrade.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19956 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GP98–39–000]

Finney-Kearny County Gas Venture and Westgate Greenland, L.P.; Notice of Petition for Extension of Time Pending Verification of Extent of Refund Liability

July 21, 1998.

Take notice that, on July 7, 1998, Finney-Kearny County Gas Venture (Finney-Kearny) and Westgate Greenland, L.P. (Westgate) filed a petition requesting an extension of time to make Kansas ad valorem tax refunds to K N Interstate Gas Transmission Company (KNI). Finney-Kearny and Westgate assert that KNI has certain factual data that they have requested and that they need to verify whether they owe KNI any Kansas ad valorem tax refunds. Finney-Kearny and Westgate do not describe the information that they seek from KNI, but state simply that KNI has not provided the "full factual data" they previously requested. Therefore, Finney-Kearny and Westgate request that they be granted an extension of time to make refunds until the later of: 1) 90 days; or 2) 30 days after the date that KNI submits the full factual data sought by Finney-Kearny and Westgate. Finney-Kearny and Westgate's petition is on file with the Commission and open to public inspection.

The Commission, by order issued September 10, 1997, in Docket No. RP97–369–000,[1] on remand from the D.C. Circuit Court of Appeals,[2] required First Sellers to refund Kansas ad valorem tax reimbursements to pipelines, with interest, for the period from 1983 to 1988, by March 9, 1998. In its January 28, 1998 Order Clarifying Procedures [82 FERC ¶ 61,059 (1998)], the Commission stated that producers (i.e., First Sellers) could file dispute resolution requests with the Commission, asking the Commission to resolve the dispute with the pipeline over the amount of Kansas ad valorem tax refunds owed.

Any person desiring to comment on or make any protest with respect to the above-referenced petition should, on or before August 11, 1998, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to the proceeding, or to participate as a party in any hearing therein, must file a motion to intervene in accordance with the Commission's Rules.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19961 Filed 7–24–98; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–117–000]

K N Interstate Gas Transmission Company; Notice of Informal Settlement Conference

July 21, 1998.

Take notice that an informal settlement conference in this proceeding will be convened on Tuesday, August 18, and Wednesday, August 19, 1998, at 10:00 a.m. The settlement conference will be held at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, for the purpose of exploring the possible settlement of the above referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Thomas J. Burgess at 208–2058 or Lorna J. Hadlock at 208–0737.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19964 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2047–004]

Niagara Mohawk Power Corporation; Notice of Filing for Application

July 21, 1998.

Take notice that on June 23, 1998, the Niagara Mohawk Power Corporation filed an application to relicense the Stewarts Bridge Hydroelectric Project No. 2047.

The Stewarts Bridge Project is located on the Sacandaga River, in Saratoga County, New York. The project includes an earth dam about 1,650 feet long and 112 feet high with a concrete gated spillway and penstock intake structure; a reservoir of about 475 acres at elevation 705 feet USGS datum; a steel penstock to a brick powerhouse with one generator rated at 30,000 kW; an outdoor transformer, switching station and 400-foot-long transmission line; and appurtenant facilities. The licensee proposes no changes in operation or new construction for the project. The current operating license expires July 1, 2000.

To facilitate on going discussions to settle issues at projects in the Sacandaga-Hudson River Basin, including the Stewart's Bridge Project, requirements for compliance with Sections 16.8(c)(5)–(10) have been waived and modified. Niagara Mohawk Power Corporation has until October 15, 1998 to comply with Sections 16.8(c)(8) and 16.8(f). Therefore, if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merits, a request for the study, together with justification for such request in accordance with section 4.32 of the Commission's regulations, must be filed no later than November 30, 1998.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19962 Filed 7–24–98; 8:45am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–666–000]

Northwest Pipeline Corporation; Notice of Request Under Blanket Authorization

July 21, 1998.

Take notice that on July 13, 1998, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP98–666–000 a request pursuant to Sections 157.205, 157.211 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, and 157.216) for authorization to abandon existing regulator facilities and constructing and operating upgraded replacement regulator facilities in Spokane County, Washington under Northwest's blanket certificate issued in Docket No. CP82–433–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

The upgrade is being requested because of a request by Washington Water Power Gas Company for increased delivery pressure. As a result of the upgrade, the maximum design delivery capacity of the meter station will increase from 34,945 to approximately 37,450 Dth per day at 250 psig and the station will be able to deliver gas at 400 psig when operating conditions are suitable. The total cost of the upgrade will be approximately $32,075.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn

[1] See 80 FERC ¶ 61,264 (1997); order denying rehearing issued January 28, 1998, 82 FERC ¶ 61,058 (1998).

[2] *Public Service Company of Colorado* v. *FERC*, 91 F.3d 1478 (D.C. 1996), cert. denied, Nos. 96–954 and 96–1230 (65 U.S.L.W. 3751 and 3754, May 12, 1997).

within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19958 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Transcontinental Gas Pipe Line Corporation; Notice of Request Under Blanket Authorization

[Docket No. CP98–667–000]

July 21, 1998.

Take notice that on July 13, 1998, Transcontinental Gas Pipe Line Corporation (Transco), Post Office Box 1396, Houston, Texas 77251, filed in Docket No. CP98–667–000, a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.211) for authorization to construct and operate a production area sales tap for Burlington Resources Offshore, Inc. (Burlington), under Transco's blanket certificate issued in Docket No. CP82–426–000, pursuant to Section 7(c) of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Transco proposes to install and operate a new sales tap to Burlington on an existing production platform in Block 196, Eugene Island Area, Offshore Louisiana. Transco says the gas will be delivered through an existing valve on the piping on the platform. Transco relates that it will install, own and operate electronic flow measurement (EFM) equipment; while Burlington will install, own and operate a meter tube.

Transco has estimated that the total cost of the proposed facilities will be $32,000,00. Burlington will reimburse Transco for all costs associated with such facilities.

Transco states that the new sales tap will be used by Burlington to receive up to 1,000 Mcf of gas per day from Transco on an interruptible basis. Transco says such gas will be used by Burlington for gas lift purposes at Eugene Island Block 196. Transco relates that the transportation service will be rendered to Burlington through this new tap pursuant to Transco's Rate Schedule IT and Part 284(G) of the Commission's Regulations. Transco states that the addition of this tap will have no significant impact on Transco's peak day or annual deliveries and is not prohibited Transco's FERC Gas Tariff.

Transco relates that the installation and operation of Transco's facilities will be performed in compliance with the environmental requirements set forth in Section 157.206(d) of the Commission's Regulations and that Transco will obtain all required clearances prior to the commencement of installation.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized affective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19959 Filed 6–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–670–000]

Williston Basin Interstate Pipeline Company; Notice of Request Under Blanket Authorization

July 21, 1998.

Take notice that on July 15, 1998, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed in Docket No. CP98–670–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.211) for authorization to utilize an existing tap in Morton County, North Dakota to effectuate additional natural gas deliveries to an existing customer. Williston Basin makes such request under its blanket certificate issued in Docket Nos. CP82–487–000, *et al.* pursuant to Section 7 of the National Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Williston Basic states that it recently received a request from Montana-Dakota Utility Company (Montana-Dakota), a local distribution customer, for authorization to add additional end-use customers to an existing transmission line tap in Morton County, North Dakota. Williston Basin is proposing herein to utilize this existing tap to effectuate additional natural gas transportation deliveries to Montana-Dakota for other than right-of-way grantor use. It is stated that Williston Basin plans to provide natural gas transportation deliveries to Montana-Dakota for ultimate use by the additional end-use customers under Rate Schedules FT–1 and/or IT–1.

The estimated additional volume to be delivered is 110 dekatherms per year. It is averred that the proposed service will not have a significant effect on Williston Basin's peak day or annual requirements. Williston Basin indicates that its tariff does not prohibit the addition of new delivery points, and that the volumes proposed to be delivered are within the contractual entitlements of Montana-Dakota.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If not protest is filed within the time allowed thereof, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is tiled and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19960 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL98–7–002, et al.]

Wisconsin Power & Light Company, et al.; Electric Rate and Corporate Regulation Filings

July 20, 1998.

Take notice that the following filings have been made with the Commission:

1. Wisconsin Power & Light Company

[Docket No. EL98–7–002]

Take notice that on July 1, 1998, Wisconsin Power & Light Company tendered for filing its compliance in the above-referenced docket.

Comment date: August 7, 1998, in accordance with Standard Paragraph E at the end of this notice.

2. Florida Power & Light Company

[Docket No. ER98–3728–000]

Take notice that on July 14, 1998, Florida Power & Light Company (FPL), tendered for filing proposed service agreements with Tennessee Valley Authority for Short-Term Firm transmission service under FPL's Open Access Transmission Tariff.

FPL requests that the proposed service agreement be permitted to become effective on July 1, 1998.

FPL states that this filing is in accordance with Part 35 of the Commission's Regulations.

Comment date: August 3, 1998, in accordance with Standard Paragraph E at the end of this notice.

3. MIECO, Inc.

[Docket No. ER98–3735–000]

Take notice that on July 14, 1998, MIECO, Inc., tendered for filing a letter from the Executive Committee of the Western Systems Power Pool (WSPP) dated February 26, 1998, indicating that MIECO had completed all the steps for pool membership. MIECO requests that the Commission amend the WSPP Agreement to include it as a member.

MIECO requests an effective date of February 26, 1998 for the proposed amendment. Accordingly, MIECO requests waiver of the Commission's notice requirements for good cause shown.

Copies of the filing were served upon the WSPP Executive Committee.

Comment date: August 3, 1998, in accordance with Standard Paragraph E at the end of this notice.

4. Southwest Power Pool

[Docket No. ER98–3736–000]

Take notice that on July 14, 1998, Southwest Power Pool (SPP), tendered for filing eight executed service agreements for short-term firm point-to-point transmission service and Non-Firm Point-To-Point Firm Transmission Service under the SPP Open Access Transmission Tariff.

Copies of this filing were served upon each of the parties to these agreements.

Comment date: August 3, 1998, in accordance with Standard Paragraph E at the end of this notice.

5. East Texas Electric Cooperative, Inc.

[Docket No. ER98–3737–000]

Take notice that on July 15, 1998, East Texas Electric Cooperative, Inc. (ETEC), tendered for filing proposed changes in its Rate Schedule ETEC–1. The proposed changes amend Rate Schedule ETEC–1 by (i) revising the existing Demand Charge to exclude purchased power, production and fuel costs, and (ii) implementing a Power Supply Demand Charge and Power Supply Energy Charge to recover all purchased power, production and fuel costs.

Copies of the filing were served on the public utility's customers and the Public Utility Commission of Texas.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

6. American Electric Power Service Corporation

[Docket No. ER98–3738–000]

Take notice that on July 15, 1998, the American Electric Power Service Corporation (AEPSC), tendered for filing blanket service agreements under the Wholesale Market Tariff of the AEP Operating Companies (Power Sales Tariff). The Power Sales Tariff was accepted for filing effective October 10, 1997 and has been designated AEP Operating Companies' FERC Electric Tariff Original Volume No. 5.

AEPSC respectfully requests waiver of notice to permit the service agreements to be made effective for service as specified in the submittal letter to the Commission with this filing.

A copy of the filing was served upon the Parties and the State Utility Regulatory Commissions of Indiana, Kentucky, Michigan, Ohio, Tennessee, Virginia and West Virginia.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

7. Southern Company Services, Inc.

[Docket No. ER98–3739–000]

Take notice that on July 15, 1998, Alabama Power Company (APC), filed proposed changes to Rate Schedule MUN–1 of FERC Electric Tariff, Original Volume No. 1 of Alabama Power Company. The proposed changes will provide the affected customers a rate reduction. In addition, the filing proposes to revise Rate Schedule MUN–1's provisions for terminating service at any given delivery point. APC has requested an effective date of April 30, 1998. The filing also contain corresponding Statements of Consent from the affected Customers.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

8. Cinergy Services, Inc.

[Docket No. ER98–3740–000]

Take notice that on July 15, 1998, Cinergy Services, Inc. (Cinergy), tendered for filing a Firm Point-To-Point Transmission Service Agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff), entered into between Cinergy and PG&E Energy Trading—Power, L.P., (PG&E).

Cinergy and PG&E are requesting an effective date of June 15, 1998.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

9. Idaho Power Company

[Docket No. ER98–3743–000]

Take notice that on July 15, 1998, Idaho Power Company (IPC), tendered for filing with the Federal Energy Regulatory Commission a Service Agreement under Idaho Power Company FERC Electric Tariff No. 6, Market Rate Power Sales Tariff, between Idaho Power Company and American Electric Power Service Corporation.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

10. Public Service Company of New Mexico

[Docket No. ER98–3744–000]

Take notice that on July 15, 1998, Public Service Company of New Mexico (PNM), tendered for filing a mutual netting/close-out agreement between PNM and Vitol Gas & Electric, LLC (Vitol). PNM requested waiver of the Commission's notice requirement so that service under the PNM/Vitol netting agreement may be effective as of July 17, 1998.

Copies of the filing were served on Vitol and the New Mexico Public Utility Commission.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

11. Ohio Power Company

[Docket No. ER98–3745–000]

Take notice that on July 15, 1998, the American Electric Power Service Corporation acting as agent for Ohio Power Company (Ohio Power), tendered for filing a letter from the Executive Committee of the Western Systems Power Pool (WSPP), indicating that Ohio Power had completed all the steps for pool membership. Ohio Power requests that the Commission amend the WSPP Agreement to include it as a member.

Ohio Power requests an effective date of June 1, 1998, for the proposed amendment. Accordingly, Ohio Power respectively requests waiver of the Commission's notice requirements.

Copies of the filing were served upon the WSPP Executive Committee.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

12. Portland General Electric Company

[Docket No. ER98–3746–000]

Take notice that on July 15, 1998, Portland General Electric Company (PGE), tendered for filing under FERC Electric Tariff, Second Revised Volume No. 2, an unexecuted Service Agreement with American Electric Power.

PGE respectfully requests that the Commission allow the Service Agreement to become effective June 2, 1998. PGE will be required to refund the time value of any revenues collected from the effective date of the Service Agreement through September 14, 1998, to account for the prior-notice requirement under 18 CFR Section 35.3.

A copy of this filing was caused to be served upon American Electric Power as noted in the filing letter.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

13. Pacific Gas and Electric Company

[Docket No. ER98–3747–000]

Take notice that on July 15, 1998, Pacific Gas and Electric Company (PG&E), tendered for filing a Quitclaim Conveyance Agreement with the City and County of San Francisco (City), pursuant to which PG&E is transferring title to and ownership of a transformer and associated equipment to the City. These facilities were constructed for the City's sole benefit, and the ownership transfer agreement was completed before the facilities' operation date.

Copies of this filing have been served upon the City and the California Public Utilities Commission.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

14. California Independent System Operator Corporation

[Docket No. ER98–3760–000]

Take notice that on July 15, 1998, the California Independent System Operator Corporation (ISO), tendered for filing a clarification filing, which includes revisions and corrections to the ISO Tariff (including the ISO Protocols).

The ISO states that this filing has been served on all parties listed on the official service list in Docket Nos. EC96-19–003 and ER96–1663–003.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

15. Montaup Electric Company

[Docket No. ER98–3761–000]

Take notice that on July 15, 1998, Montaup Electric Company (Montaup), tendered for filing an Amendment to an October 24, 1997, agreement by and between Montaup and The Pascoag Fire District (Pascoag), which was accepted and approved by the Commission on March 19, 1997, as part of Montaup's restructuring settlement filed in Docket Nos. ER97–2800 et al.

Montaup states that the purpose of this filing is to accelerate Pascoag's contract termination charge (CTC), payment obligation such that the total amount due under the Agreement can be satisfied through a single lump sum payment.

Copies of the filing were served upon Montaup's jurisdictional customers and upon affected state agencies.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

16. Florida Power & Light Company

[Docket No. ER98–3762–000]

Take notice that on July 15, 1998, Florida Power & Light Company (FPL), filed a unexecuted Service Agreement with Orlando Utilities Commission for service pursuant to FPL's Market Based Rates Tariff.

FPL requests that the Service Agreements be made effective on June 18, 1998.

Comment date: August 4, 1998, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. 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. Copies of these filings are on file with the Commission and are available for public inspection.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19965 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Filed With the Commission

July 21, 1998.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of Application:* Transfer of Licenses.

b. *Projects Nos.:* (1) 2142–027, (2) 2194–002, (3) 2283–019, (4) 2284–019, (5) 2302–045, (6) 2322–028, (7) 2325–031, (8) 2329–026, (9) 2335–018, (10) 2519–026, (11) 2527–006, (12) 2528–052, (13) 2529–015, (14) 2530–020, (15) 2531–024, (16) 2552–035, (17) 2556–012, (18) 2557–009, (19) 2559–010, (20) 2612–008, (21) 2615–028, (22) 3133–013, and (23) 9340–027.

c. *Date filed:* June 26, 1998.

d. *Applicants:* Central Maine Power Company (CMP), Union Water Power Company (UWP), and FPL Energy Maine Hydro LLC (FPLE).

e. and f. *Name and Location of Projects:* (1) Indian Pond (Harris): Kennebec River in Somerset and Piscataquis Counties, Maine; (2) Bar Mills: Saco River in York County, Maine; (3) Gulf Island-Deer Rips: Androscoggin River in Androscoggin County, Maine; (4) Brunswick: Androscoggin River in Cumberland and Sagadahoc Counties, Maine; (5) Lewiston Falls: Androscoggin River in Androscoggin County, Maine; (6) Shawmut: Kennebec River in Kennebec and Somerset Counties, Maine; (7)

Weston, (8) Wyman, and (9) Williams: Kennebec River in Somerset County, Maine; (10) North Gorham: Presumpscot River in Cumberland County, Maine; (11) Skelton and (12) Cataract: Saco River in York County, Maine; (13) Bonny Eagle: Saco River in York and Cumberland Counties, Maine; (14) Hiram: Saco River in Oxford and Cumberland Counties, Maine; (15) West Buxton: Saco River in York and Cumberland Counties, Maine; (16) Fort Halifax: Sebasticook River in Kennebec County, Maine; (17) Union Gas, (18) Rice Rips, and (19) Oakland: Messalonskee River in Kennebec County, Maine; (20) Flagstaff: Dead River in Franklin and Somerset Counties, Maine; (21) Brassua: Moose River in Somerset County, Maine; (22) Errol: Androscoggin River in Oxford County, Maine, and Coos County, New Hampshire; and (23) Kezar Falls: Ossipee River in York and Cumberland Counties, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contacts:*

For CMP: Mr. Michael A. Murphy, Central Maine Power Company, 41 Anthony Avenue, Augusta, ME 04330, (207) 621–4499.

For UP: Mr. Normand V. Rodrigue, Union Water Power Company, 150 Main Street, Lewiston, ME 04240, (207) 784–4501.

For FPLE: Mr. James B. Vasille, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036, (202) 429–6297.

i. *FERC Contact:* James Hunter, (202) 219–2839.

j. *Comment Date:* September 4, 1998.

k. *Description of Transfer:* Transfer of the licenses for these projects to FPLE is being sought in connection with the divestiture by CMP and UMP of substantially all their hydropower resources, pursuant to Maine Public Law 1997, ch. 316, 35–A § 3204, *et seq.* (An Act to Restructure the State's Electric Industry). CMP, as co-licensee of Brassua, and UP, as co-licensee of Errol, seek to transfer their interest in the storage facilities for those projects to FPLE, leaving unaffected the respective co-licensees' interest in the generating facilities. The Union Gas, Rice Rips, and Oakland Projects, on the Messalonskee River, were found non-jurisdictional on August 6, 1997. At its July 15, 1998, meeting, the Commission, in Docket UL96–7–003, *et al.*, reversed the prior findings and concluded that the projects were required to be licensed.

The transfer application was filed within five years of the expiration of the licenses for Projects Nos. 2142, 2283, and 2612, the last two of which are the subject of pending relicense applications. In Hydroelectric Relicensing Regulations Under the Federal Power Act (54 Fed. Reg. 23,756; FERC Stats. and Regs. Preambles 1986–1990 30,854 at p. 31,437), the Commission declined to forbid all license transfers during the last five years of an existing license, and instead indicated that it would scrutinize all such transfer requests to determine if the transfer's primary purpose was to give the transferee an advantage in relicensing (id, at p. 31,438 n. 318). The transfer would lead to the substitution of the transferee for the transferor as the applicant in the relicensing proceedings for Projects Nos. 2283 and 2612.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. 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 Sections 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.

C1. 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 is in response. Any of these documents must be filed by providing the original and 8 copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426. Motions to intervene must also be served upon each representative of the applicant specified in the particular application.

D2. Agency Comments—The Commission invites federal, state, and local agencies to file comments on the described application. (Agencies may obtain a copy of the application directly from the applicant.) If an agency does not file comments within the time specified for filing comments, the Commission will presume that the agency has none. One copy of an agency's comments must also be sent to the applicant's representatives.

David P. Boergers,

Acting Secretary.

[FR Doc. 98–19963 Filed 7–24–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

July 22, 1998.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: July 29, 1998, 10:00 a.m.

PLACE: Room 2C, 888 First Street, N.E., Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* Note—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: David P. Boergers, Acting Secretary, Telephone (202) 208–0400. For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the reference and information center.

Consent Agenda—Hydro; 703rd Meeting—July 29, 1998; Regular Meeting (10:00 a.m.)

CAH–1.

DOCKET# P–2357, 007, WISCONSIN ELECTRIC POWER COMPANY
OTHER#S P–2394, 010, WISCONSIN ELECTRIC POWER COMPANY

CAH–2.

DOCKET# P–2436, 085, CONSUMERS ENERGY COMPANY
OTHER#S P–2447, 083, CONSUMERS ENERGY COMPANY
P–2448, 088, CONSUMERS ENERGY COMPANY
P–2449, 083, CONSUMERS ENERGY COMPANY
P–2450, 081, CONSUMERS ENERGY COMPANY
P–2451, 077, CONSUMERS ENERGY COMPANY
P–2452, 093, CONSUMERS ENERGY COMPANY
P–2453, 082, CONSUMERS ENERGY COMPANY
P–2468, 079, CONSUMERS ENERGY COMPANY
P–2580, 108, CONSUMERS ENERGY COMPANY

P–2599, 088, CONSUMERS ENERGY COMPANY
CAH–3.
DOCKET# P–2680, 039, CONSUMERS ENERGY COMPANY AND THE DETROIT EDISON COMPANY
CAH–4.
DOCKET# P–10819, 002, IDAHO WATER RESOURCE BOARD

Consent Agenda—Electric

CAE–1.
DOCKET# ER98–3014, 000, PJM INTERCONNECTION, L.L.C.
CAE–2.
DOCKET# ER98–3207, 000, MONTAUP ELECTRIC COMPANY
CAE–3.
OMITTED
CAE–4.
DOCKET# ER98–498, 000, ROCKY MOUNTAIN RESERVE GROUP
OTHER#S ER98–3347, 000, PUBLIC SERVICE COMPANY OF COLORADO
ER98–3351, 000, BLACK HILLS CORPORATION
ER98–3358, 000, UTILICORP UNITED INC.
CAE–5.
DOCKET# ER98–3220, 000, CAROLINA POWER & LIGHT COMPANY
CAE–6.
DOCKET# ER98–3285, 000, AMEREN SERVICES COMPANY, AS AGENT FOR UNION ELECTRIC COMPANY AND CENTRAL ILLINOIS PUBLIC SERVICE COMPANY
CAE–7.
DOCKET# EL98–1, 001, CENTRAL ILLINOIS PUBLIC SERVICE COMPANY
CAE–8.
DOCKET# ER97–2398, 002, DUKE POWER COMPANY
CAE–9.
DOCKET# ER98–3177, 000, SOUTHWESTERN ELECTRIC POWER COMPANY
OTHER#S EL98–63, 000, SOUTHWESTERN ELECTRIC POWER COMPANY
CAE–10.
DOCKET# ER98–556, 004, PACIFIC GAS & ELECTRIC COMPANY
CAE–11.
DOCKET# ER96–399, 001, NORTHERN INDIANA PUBLIC SERVICE COMPANY
CAE–12.
DOCKET# FA91–47, 001, PUBLIC SERVICE COMPANY OF COLORADO
CAE–13.
DOCKET# TX94–4, 000, TEX-LA ELECTRIC COOPERATIVE OF TEXAS, INC.
OTHER#S ER94–1385, 000, WEST TEXAS UTILITIES COMPANY
ER94–1385, 001, WEST TEXAS UTILITIES COMPANY
TX94–4, 001, TEX-LA ELECTRIC COOPERATIVE OF TEXAS, INC.
TX94–4, 002, TEX-LA ELECTRIC COOPERATIVE OF TEXAS, INC.
CAE–14.
DOCKET# EL91–29, 000, SOUTHERN COMPANY SERVICES, INC.
CAE–15.
DOCKET# ER96–1428, 000, PP&L, INC.
OTHER#S ER96–1428, 001, PP&L, INC.
OA96–142, 000, PP&L, INC.
CAE–16.
DOCKET# ER98–2233, 001, NEW ENGLAND POWER COMPANY
CAE–17.
DOCKET# ER98–270, 002, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.
OTHER#S ER98–1631, 002, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.
CAE–18.
DOCKET# ER98–1163, 001, SOUTHWEST POWER POOL
CAE–19.
DOCKET# EL98–2, 001, WISCONSIN PUBLIC POWER INC. SYSTEM V. WISCONSIN PUBLIC SERVICE CORPORATION
OTHER#S EL98–7, 001, WISCONSIN PUBLIC SERVICE CORPORATION V. WISCONSIN POWER & LIGHT COMPANY AND WISCONSIN PUBLIC POWER INC. SYSTEM
EL98–11, 001, WISCONSIN PUBLIC POWER INC. SYSTEM V. WISCONSIN POWER & LIGHT COMPANY
CAE–20.
DOCKET# ER90–373, 005, NORTHEAST UTILITIES SERVICE COMPANY
OTHER#S EL90–39, 002, CONNECTICUT LIGHT & POWER COMPANY AND WESTERN MASSACHUSETTS ELECTRIC COMPANY
ER90–390, 005, NORTHEAST UTILITIES SERVICE COMPANY
CAE–21.
DOCKET# ER86–645, 009, BOSTON EDISON COMPANY
CAE–22.
DOCKET# ER98–1285, 001, PUBLIC SERVICE COMPANY OF NEW MEXICO
CAE–23.
DOCKET# EL98–21, 000, CONSUMER ENERGY COMPANY
OTHER#S EL98–30, 000, THE NARRAGANSETT ELECTRIC COMPANY
EL98–42, 000, THE MASSACHUSETTS DEPARTMENT OF TELE-COMMUNICATIONS AND ENERGY
CAE–24.
DOCKET# EL98–49, 000, CITIZENS UTILITIES COMPANY
CAE–25.
DOCKET# EL96–70, 000, PACIFIC GAS & ELECTRIC COMPANY V. RED TOP COGENERATION, L.P.
OTHER#S QF84–329, 001, RED TOP COGENERATION, L.P.
CAE–26.
DOCKET# DR97–3, 000, OHIO EDISON COMPANY, CLEVELAND ELECTRIC ILLUMINATING COMPANY, PENNSYLVANIA POWER COMPANY AND TOLEDO EDISON COMPANY
OTHER#S DR97–4, 000, CONSUMERS ENERGY COMPANY
DR98–7, 000, GEORGIA POWER COMPANY
DR98–32, 000, CENTRAL POWER AND LIGHT COMPANY
DR98–44, 000, KANSAS CITY POWER & LIGHT COMPANY
CAE–27.
DOCKET# EL98–6, 000, OLD DOMINION ELECTRIC COOPERATIVE V. PUBLIC SERVICE ELECTRIC AND GAS COMPANY
CAE–28.
DOCKET# RM98–3, 000, OPEN ACCESS SAME-TIME INFORMATION SYSTEM
CAE–29.
DOCKET# OA97–117, 001, ALLEGHENY POWER SERVICE CORPORATION, MONONGAHELA POWER COMPANY. THE POTOMAC EDISON COMPANY AND WEST PENN POWER COMPANY
OTHER#S OA97–125, 002, CENTRAL HUDSON GAS & ELECTRIC CORPORATION
OA97–126, 002, ILLINOIS POWER COMPANY
OA97–158, 001, NIAGARA MOHAWK POWER CORPORATION
OA97–216, 002, WISCONSIN ELECTRIC POWER COMPANY
OA97–278, 002, NEW YORK STATE ELECTRIC & GAS CORPORATION
OA97–279, 001, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.
OA97–284, 001, NORTHEAST UTILITIES SERVICE COMPANY, CONNECTICUT LIGHT & POWER COMPANY, HOLYOKE WATER POWER COMPANY AND HOLYOKE POWER & ELECTRIC CO.
OA97–313, 001, MIDAMERICAN ENERGY COMPANY
OA97–408, 002, AMERICAN ELECTRIC POWER SERVICE CORPORATION, APPALACHIAN POWER COMPANY AND COLUMBUS SOUTHERN POWER COMPANY, ET AL.
OA97–411, 002, PACIFICORP
OA97–429, 001, PUBLIC SERVICE ELECTRIC & GAS COMPANY
OA97–429, 002, PUBLIC SERVICE ELECTRIC & GAS COMPANY
OA97–430, 002, EL PASO ELECTRIC COMPANY
OA97–431, 002, BOSTON EDISON COMPANY
OA97–434, 001, CONSUMERS ENERGY COMPANY
OA97–445, 002, SOUTHERN CALIFORNIA EDISON COMPANY
OA97–449, 001, PUGET SOUND ENERGY, INC.
OA97–459, 002, COMMONWEALTH EDISON COMPANY AND COMMONWEALTH EDISON COMPANY OF INDIANA, INC.
OA97–459, 004, COMMONWEALTH EDISON COMPANY AND COMMONWEALTH EDISON COMPANY OF INDIANA, INC.

Consent Agenda—Gas and Oil

CAG–1.
DOCKET# PR98–10, 000, PACIFIC GAS AND ELECTRIC COMPANY
CAG–2.
DOCKET# RP98–258, 000, SABINE PIPE LINE COMPANY
CAG–3.
DOCKET# RP98–274, 000, BLACK MARLIN PIPELINE COMPANY
CAG–4.
DOCKET# RP98–327, 000, MIDWESTERN GAS TRANSMISSION COMPANY
CAG–5.

DOCKET# RP98–328, 000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–6.
DOCKET# RP98–331, 000, MIDWESTERN GAS TRANSMISSION COMPANY
CAG–7.
DOCKET# RP98–332, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–8.
DOCKET# RP98–333, 000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–9.
DOCKET# RP98–343, 000, DAUPHIN ISLAND GATHERING PARTNERS
OTHER#S RP98–343, 001, DAUPHIN ISLAND GATHERING PARTNERS
CAG–10. OMITTED
CAG–11.
DOCKET# RP98–253, 000, WILLISTON BASIN INTERSTATE PIPELINE COMPANY
CAG–12.
DOCKET# RP98–260, 000, WYOMING INTERSTATE COMPANY, LTD.
CAG–13.
DOCKET# RP98–263, 000, QUESTAR PIPELINE COMPANY
CAG–14.
DOCKET# RP98–264, 000, OVERTHRUST PIPELINE COMPANY
CAG–15.
DOCKET# RP98–269, 000, WYOMING INTERSTATE COMPANY, LTD.
CAG–16.
DOCKET# RP98–270, 000, YOUNG GAS STORAGE COMPANY, LTD.
CAG–17.
DOCKET# RP98–290, 000, VIKING GAS TRANSMISSION COMPANY
CAG–18.
DOCKET# RP98–291, 000, TRANSWESTERN PIPELINE COMPANY
CAG–19.
DOCKET# RP98–292, 000, NORTHERN NATURAL GAS COMPANY
CAG–20.
DOCKET# RP98–293, 000, WILLIAMS GAS PIPELINES CENTRAL, INC
OTHER#S RP89–183, 082, WILLIAMS GAS PIPELINES CENTRAL, INC
CAG–21.
DOCKET# RP98–294, 000, NORTHERN BORDER PIPELINE COMPANY
CAG–22.
DOCKET# RP98–295, 000, FLORIDA GAS TRANSMISSION COMPANY
CAG–23.
DOCKET# RP98–298, 000, BLACK MARLIN PIPELINE COMPANY
CAG–24.
DOCKET# RP98–310, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–25.
DOCKET# RP98–311, 000, EL PASO NATURAL GAS COMPANY
CAG–26.
DOCKET# RP98–313, 000, MOJAVE PIPELINE COMPANY
CAG–27.
DOCKET# RP98–329, 000, MOBILE BAY PIPELINE COMPANY
OTHER#S RP98–335, 000, MOBILE BAY PIPELINE COMPANY
CAG–28.
DOCKET# RP98–330, 000, KOCH GATEWAY PIPELINE COMPANY
OTHER#S RP98–336, 000, KOCH GATEWAY PIPELINE COMPANY
CAG–29. OMITTED
CAG–30.
DOCKET# TM98–2–53 002, K N INTERSTATE GAS TRANSMISSION COMPANY
CAG–31. OMITTED
CAG–32.
DOCKET# SA98–76, 000, EDWIN A. CORNELL
CAG–33.
DOCKET# RP98–320, 000, TRANSCOLORADO GAS TRANSMISSION COMPANY
CAG–34.
DOCKET# PR98–9, 000, TEKAS PIPELINE, L.L.C.
CAG–35.
DOCKET# RP91–143, 046, GREAT LAKES GAS TRANSMISSION LIMITED PARTNERSHIP
CAG–36.
DOCKET# RP98–99, 001, TENNESSEE GAS PIPELINE COMPANY
OTHER#S RP98–99, 002, TENNESSEE GAS PIPELINE COMPANY
CAG–37.
DOCKET# RP98–206, 000, ATLANTA GAS LIGHT COMPANY
CAG–38.
DOCKET# RP97–126, 000, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
CAG–39.
DOCKET# RP97–373, 012, KOCH GATEWAY PIPELINE COMPANY
CAG–40.
DOCKET# RP96–272, 006, NORTHERN NATURAL GAS COMPANY
CAG–41.
DOCKET# RP97–108, 002, KOCH GATEWAY PIPELINE COMPANY
CAG–42.
DOCKET# RP97–275, 008, NORTHERN NATURAL GAS COMPANY
OTHER#S TM97–2–59, 006, NORTHERN NATURAL GAS COMPANY
CAG–43.
DOCKET# RP97–373, 013, KOCH GATEWAY PIPELINE COMPANY
CAG–44.
DOCKET# RP98–12, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
OTHER#S RP89–183, 075, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–12, 001, WILLIAMS GAS PIPELINES CENTRAL, INC.
CAG–45. OMITTED
CAG–46.
DOCKET# SA98–15, 000, MARK A. GOWER
CAG–47.
DOCKET# SA98–78, 000, TOTAL MINATOME CORPORATION
CAG–48.
DOCKET# RP98–341, 000, NORTHERN NATURAL GAS COMPANY
CAG–49.
DOCKET# GP97–6, 000, PLAINS PETROLEUM COMPANY AND PLAINS PETROLEUM OPERATING COMPANY
OTHER#S GP98–25, 000, PLAINS PETROLEUM COMPANY AND PLAINS PETROLUEM OPERATING COMPANY
CAG–50.
DOCKET# RP95–364, 000, WILLISTON BASIN INTERSTATE PIPELINE COMPANY
CAG–51.
DOCKET# RP98–39, 007, NORTHERN NATURAL GAS COMPANY
OTHER'S GP98–5, 001, MOBIL OIL CORPORATION
GP98–8, 001, OXY USA INC.
GP98–12, 001, AMOCO PRODUCTION COMPANY
GP98–14, 001, ANADARKO PETROLEUM CORPORATION
GP98–20, 001, UNION PACIFIC RESOURCES COMPANY
RP98–38, 004, NATURAL GAS PIPELINE COMPANY OF AMERICA
RP98–40, 006, PANHANDLE EASTERN PIPE LINE COMPANY
RP98–42, 006, ANR PIPELINE COMPANY
RP98–43, 005, ANADARKO GATHERING COMPANY
RP98–44, 003, EL PASO NATURAL GAS COMPANY
RP98–52, 006, WILLIAMS NATURAL GAS COMPANY
RP98–53, 006, K N INTERSTATE GAS TRANSMISSION COMPANY
RP98–54, 007, COLORADO INTERSTATE GAS COMPANY
CAG–52.
DOCKET# RP97–374, 002, NORTHWEST PIPELINE CORPORATION
CAG–53.
DOCKET# RP98–105, 006, WILLIAMS GAS PIPELINES CENTRAL, INC.
OTHER#S RP89–183, 080, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP94–365, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP96–173, 000, WILLIAMS GAS PIPELINES CENTRAL, INC. ET AL.
RP97–407, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP97–484, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–12, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–105, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–105, 007, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–105, 008, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–165, 002, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–165, 003, WILLIAMS GAS PIPELINES CENTRAL, INC.
RP98–319, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
CAG–54.
DOCKET# RP98–208, 002, WILLIAMS GAS PIPELINES CENTRAL, INC.
OTHER#S RP98–208, 001, WILLIAMS GAS PIPELINES CENTRAL, INC.
CAG–55.
DOCKET# RP98–117, 001, K N INTERSTATE GAS TRANSMISSION COMPANY
OTHER#S RP98–90, 002, K N INTERSTATE GAS TRANSMISSION COMPANY
CAG–56.
DOCKET# RP98–188, 001, TENNESSEE GAS PIPELINE COMPANY
CAG–57.

DOCKET# RP97–444, 001, HORSEHEAD RESOURCE DEVELOPMENT COMPANY, INC. V. TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–58.
DOCKET RP98–53, 003, K N INTERSTATE GAS TRANSMISSION COMPANY
OTHER#S GP98–2, 000, AMOCO PRODUCTION COMPANY
GP98–15, 000, OXY USA, INC.
GP98–19, 000, UNION PACIFIC RESOURCES CORPORATION
CAG–59.
DOCKET# IS98–7, 004, MOBIL ALASKA PIPELINE COMPANY
CAG–60.
DOCKET# OR98–13, 000, TOSCO CORPORATION V. SFPP, L.P.
OTHER#S OR98–1, 000, ARCO PRODUCTS COMPANY V. SFPP, L.P.
CAG–61.
DOCKET# MG98–1, 001, NATIONAL FUEL GAS SUPPLY CORPORATION
CAG–62.
DOCKET# MG98–11, 000, WESTERN GAS INTERSTATE COMPANY
CAG–63.
DOCKET# RM98–7, 000, REPORTING INTERSTATE NATURAL GAS PIPELINE MARKETING AFFILIATES ON THE INTERNET
CAG–64.
DOCKET# CP96–809, 004, MARITIMES & NORTHEAST PIPELINE, L.L.C.
OTHER#S CP96–178, 005, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–809, 000, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–809, 002, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–809, 003, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–810, 000, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP96–810, 001, MARITIMES & NORTHEAST PIPELINE, L.L.C.
CP97–238, 005, MARITIMES & NORTHEAST PIPELINE, L.L.C. AND PORTLAND NATURAL GAS TRANSMISSION SYSTEM
CAG–65.
DOCKET# CP97–71, 001, ANR PIPELINE COMPANY
OTHER#S CP96–790, 001, NAUTILUS PIPELINE COMPANY, L.L.C.
CP96–790, 002, NAUTILUS PIPELINE COMPANY, L.L.C.
CP96–791, 001, NAUTILUS PIPELINE COMPANY, L.L.C.
CP96–791, 002, NAUTILUS PIPELINE COMPANY, L.L.C.
CP96–792, 001, NAUTILUS PIPELINE COMPANY, L.L.C.
CP97–71, 000, ANR PIPELINE COMPANY
CAG–66.
DOCKET# CP98–21, 000, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–67.
DOCKET# CP93–117, 002, SAN DIEGO GAS & ELECTRIC COMPANY
CAG–68.
DOCKET# CP98–247, 000, MIDCOAST INTERSTATE TRANSMISSION, INC.
CAG–69.
DOCKET# CP98–168, 000, WILLIAMS GAS PIPELINES CENTRAL, INC.
CAG–70.
DOCKET# CP97–330, 000, QUESTAR PIPELINE COMPANY
CAG–71.
DOCKET# CP98–220, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–72.
DOCKET# CP98–63, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–73.
DOCKET# CP98–99, 000, ALGONQUIN GAS TRANSMISSION COMPANY
CAG–74.
DOCKET# CP98–512, 000, DESTIN PIPELINE COMPANY, L.L.C.
CAG–75.
DOCKET# CP98–541, 000, NORTHERN LIGHTS, INC.
CAG–76.
DOCKET# CP98–74, 000, ANR PIPELINE COMPANY V. TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–77.
DOCKET# CP98–527, 000, MOUNTAINEER GAS COMPANY V. COLUMBIA NATURAL RESOURCES, INC.
OTHER'S CP96–385, 000, COLUMBIA NATURAL RESOURCES, INC.
CP96–386, 000, COLUMBIA GAS TRANSMISSION CORPORATION
CP97–127, 000, COLUMBIA GAS TRANSMISSION CORPORATION
CAG–78.
DOCKET# CP94–29, 003, PAIUTE PIPELINE COMPANY
CAG–79.
DOCKET# CP98–43, 000, PG&E-TEX, L.P.
OTHER'S CP98–13, 000, TRANSWESTERN PIPELINE COMPANY
CP98–14, 000, NORTHERN NATURAL GAS COMPANY
CP98–14, 001, NORTHERN NATURAL GAS COMPANY

Hydro Agenda

H–1.
DOCKET# P–460, 001, CITY OF TACOMA, WASHINGTON
OTHER'S P–460, 009, CITY OF TACOMA, WASHINGTON
ORDER ON APPLICATION FOR SUBSEQUENT LICENSE.
H–2.
DOCKET# P–1417, 001, CENTRAL NEBRASKA PUBLIC POWER AND IRRIGATION DISTRICT
ORDER ON APPLICATION FOR NEW LICENSE.
H–3.
DOCKET# P–1835, 013, NEBRASKA PUBLIC POWER DISTRICT
ORDER ON APPLICATION FOR NEW LICENSE.
H–4.
DOCKET# P–1417, 053, CENTRAL NEBRASKA PUBLIC POWER AND IRRIGATION DISTRICT
OTHER'S P–1417, 001, CENTRAL NEBRASKA PUBLIC POWER AND IRRIGATION DISTRICT
P–1835, 013, NEBRASKA PUBLIC POWER DISTRICT
P–1835, 185, NEBRASKA PUBLIC POWER DISTRICT
ORDER ON OFFER OF SETTLEMENT AND APPLICATIONS FOR NEW LICENSES.

Electric Agenda

E–1.
RESERVED

Regular Agenda—Miscellaneous

M–1.
DOCKET# RM98–13, 000, COMPLAINT PROCEDURES
NOTICE OF PROPOSED RULEMAKING.
M–2.
OMITTED

Oil and Gas Agenda

I.
PIPELINE RATE MATTERS
PR–1A.
DOCKET# RM98–10, 000, REGULATION OF SHORT-TERM NATURAL GAS TRANSPORTATION SERVICES
NOTICE OF PROPOSED RULEMAKING.
PR–1B.
DOCKET# RM98–12, 000, REGULATION OF INTERSTATE NATURAL GAS TRANSPORTATION SERVICES
NOTICE OF INQUIRY.
PR–2A.
DOCKET# RP95–197, 032, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER'S RP95–197, 024, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
RP95–197, 031, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
RP96–44, 007, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
RP96–44, 008, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OPINION NO. 414–A.
PR–2B.
DOCKET# RP93–109, 012, WILLIAMS NATURAL GAS COMPANY
ORDER ON REHEARING.
II.
PIPELINE CERTIFICATE MATTERS
PC–1.
RESERVED

David P. Boergers,

Acting Secretary.

[FR Doc. 98–20098 Filed 7–23–98; 11:27 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–701A; FRL–6017–3]

Notice of Filing of a Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of pesticide petition (PP 6F4664), proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–701A, must be received on or before August 26, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (PM-23) Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location/telephone and e-mail address: Rm. 237, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA, 703–305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–701A] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–701A] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 10, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

Petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Amended Petition

PP 6F4664. In the Federal Register of February 26, 1997 (62 FR 8737) (FRL–5585–2), EPA issued a notice that Rhone-Poulenc Ag Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, proposed pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for the combined residues of the herbicide isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethyl benzoyl) isoxazole] and its metabolites 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione and 2-methylsulphonyl-4-trifluoromethyl benzoic acid, calculated as the parent compound, in or on the raw agricultural commodity field corn at 0.20 parts per million (ppm), field corn, fodder, at 0.50 ppm, field corn, forage at 1.0 ppm; and establishing a tolerance for combined residues of the herbicide isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethyl benzoyl) isoxazole] and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione, calculated as the parent compound, in or on the liver of cattle, goat, hogs, horses, poultry and sheep at 0.40 ppm, meat byproducts (except liver) of cattle, goat, hogs, horses, and sheep at 0.2 ppm and milk at 0.02 ppm.

Rhone-Poulenc Ag Company has submitted to EPA an amended petition (PP 6F4664), proposing to amend 40 CFR part 180 by establishing a tolerance for the combined residues of the herbicide isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethyl benzoyl) isoxazole] and its metabolites 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione and 2-methylsulphonyl-4-trifluoromethyl benzoic acid, calculated as the parent compound, in or on the raw agricultural commodities field corn at 0.20 ppm, field corn, fodder, at 0.50 ppm, field corn, forage at 1.0 ppm; and establishing a tolerance for combined residues of the herbicide isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethyl benzoyl) isoxazole] and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione, calculated as the parent compound, in or on the meat of cattle, goat, hogs, horses, and sheep at 0.20 ppm, liver of cattle, goat, hogs, horses and sheep at 0.50 ppm, meat byproducts (except liver) of cattle, goat, hogs, horses, and sheep at 0.1 ppm, fat of cattle, goat, hogs, horses, and sheep at 0.20 ppm,

liver of poultry at 0.3 ppm, eggs at 0.1 ppm and milk at 0.02 ppm.

[FR Doc. 98–20005 Filed 7–24–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6129–8]

Proposed Second Modification of General NPDES Permit (GP) for Alaskan Mechanical Placer Miners (Permit Number AKG–37–0000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed second modification of a general permit.

SUMMARY: This proposed modification of the GP is intended to regulate activities of mechanical placer mining in the state of Alaska. The proposed modifications are based on the "Withdrawal of Federal Regulations of the Applicability to Alaska's Waters of Human Health Criteria" which was published in the **Federal Register** on March 2, 1998 (63 FR 10140) and became effective on April 1, 1998, and other changes as described in the Fact Sheet.

DATES: Comments must be received by August 26, 1998.

ADDRESSES: Interested persons may submit comments on the proposed modification of the GP to Director, Office of Water; U.S. EPA, Region 10, 1200 Sixth Avenue, OW–135; Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Copies of the Proposed Second Modification of the General Permit and Fact Sheet are available upon request.

Requests may be made to Jeanette Carriveau at (206) 553–1214 or to Cindi Godsey at (907) 271–6561. Requests may also be electronically mailed to: CARRIVEAU.JEANETTE@EPAMAIL.EPA.GOV or GODSEY.CINDI@EPAMAIL.EPA.GOV. Copies of the permit and fact sheet can also be found by visiting the Region 10 website at www.epa.gov/r10earth/offices/water/npdes.html.

SUPPLEMENTARY INFORMATION:

A. Executive Order 12866

The Office of Management and Budget has exempted this action from the review requirements of Executive Order 12866 pursuant to section 6 of that order.

B. Regulatory Flexibility Act

After review of the facts presented in the notice printed above, I hereby certify pursuant to the provision of 5 U.S.C. 605(b) that this modification of the GP will not have a significant impact on a substantial number of small entities. Moreover, the permit reduces a significant administrative burden on regulated sources.

Dated: July 14, 1998.

Roger K. Mochnick,

Acting Director, Office of Water, Region 10.

Fact Sheet—United States Environmental Protection Agency, Region 10, 1200 Sixth Avenue, OW–130, Seattle, Washington 98101, (206) 553–1214

Permit No.: AKG–37–0000

Proposed second modification of the National Pollutant Discharge Elimination System (NPDES) General Permit (GP) to discharge pollutants pursuant to the provisions of the Clean Water Act (CWA) for Alaskan Mechanical Placer Miners.

This fact sheet includes (a) the tentative determination of the Environmental Protection Agency (EPA) to modify the GP, (b) information on public comment, public hearings and appeal, and (c) the conditions and requirements contained in the modification.

Persons wishing to comment on the modifications contained in the proposed GP may do so before the expiration date of the public document. Only the modifications are open to public comment. All written comments should be submitted to EPA as described in the public comments section of the attached public document.

After the expiration date of the public document, the Director, Office of Water, will make final determinations with respect to issuance of the modified GP. The tentative determinations contained in the proposed GP will become final conditions if no substantive comments are received during the public comment period.

A General Permit follows rulemaking procedures so EPA's issuance and promulgation activities must be conducted in accordance with the Administrative Procedure Act (APA). The modified GP will become effective 30 days after publication of the final modified GP in the **Federal Register** according to section 553(d) of the APA. Anyone wishing to appeal the modifications to this GP must do so in court according to 40 CFR 124.71. Interested persons may challenge the amendments, within 120 days of issuance, in the Circuit Court of Appeals of the United States under section 509(b)(1) of the Act.

The proposed NPDES permit and fact sheet are on file and may be inspected and copies made at the above address any time between 8:30 a.m. and 4:00 p.m., Monday through Friday. Copies and other information may be requested by writing to EPA at the above address to the attention of the NPDES Permits Unit, or by calling (206) 553–1214. The proposed GP and fact sheet are also available from the EPA Alaska Operations Office, Room 537, Federal Building, 222 West 7th Avenue, Anchorage, Alaska 99513–7588 or Alaska Operations Office, 410 Willoughby Avenue, Suite 100, Juneau, Alaska 99801 or the Alaska Department of Environmental Conservation (ADEC), Watershed Management Section, 610 University Avenue, Fairbanks, Alaska 99709.

Technical Information

1. Summary of Modifications

The intent of this proposed modification of the GP is to revise the effluent limitation for arsenic based on a change to the state's Water Quality Standards. This has been requested by a Permittee according to the requirements of 40 CFR 124.5 for the reasons specified in 40 CFR 122.62. Also, some additions and deletions of permit language have been made due to the water quality standard change, changes in regulation and the correction of typographical errors. Renumbering of Permit Parts, where necessary, has been done without being noted.

2. Coverage of Modified Permit

It is the intent of EPA to apply the final modified general permit to all facilities previously covered by a general permit for mechanical operations without the submission of a new Notice of Intent (NOI). Upon issuance of the final GP, a copy of the new permit will be sent to each permittee.

3. Description of the Industry

Placer mining involves the mining and extraction of gold or other heavy metals and minerals primarily from alluvial deposits. These deposits may be in existing stream beds or ancient often buried stream deposits, i.e. paleo or fossil placers. Many Alaskan placer deposits consist of unconsolidated clay, sand, gravel, cobble and boulders that contain very small amounts of native gold or other precious metals. Most are stream deposits and occur along present stream valleys or on benches or terraces above existing streams. Beach placer deposits have been and continue to be important producers in Alaska. These deposits, most notable near Nome,

include both submerged and elevated beach placer deposits.

4. Receiving Waters

The receiving waters for the discharges are waters of the United States including tundra wetlands which are classified in 18 AAC 70 as Classes (1)(A), (B), and (C) for use in drinking, culinary, and food processing, agriculture, aquaculture, and industrial water supply; contact and secondary recreation; and growth and propagation of fish, shellfish, other aquatic life and wildlife. Since most of these waterbodies are protected for all uses, the most restrictive water quality standards will be applied in this modified GP.

5. Regulatory Authority

A. State of Alaska Water Quality Standards and Limitations

Section 301(b)(1) of the Act requires the establishment of limitations in permits necessary to meet water quality standards by July 1, 1977. All discharges to state waters must comply with state and local coastal management plans as well as with state water quality standards, including the state's antidegradation policy. Discharges to state waters must also comply with limitations imposed by the state as part of its coastal management program consistency determinations, and of its certification of NPDES permits under section 401 of the Act.

The NPDES regulations at 40 CFR 122.44(d)(1) require that permits include water quality-based limits which "Achieve water quality standards established under section 303 of the CWA, including State narrative criteria for water quality."

B. Section 308 of the Clean Water Act

Under section 308 of the Act and 40 CFR 122.44(i), the Director must require a discharger to conduct monitoring to determine compliance with effluent limitations and to assist in the development of effluent limitations.

6. Specific Permit Conditions

EPA has concluded, based on available sampling data, that arsenic is commonly associated with placer mining wastes. Locally, it is the most abundant toxic metal present. It is for this reason that EPA has determined that arsenic is a pollutant of concern.

This modification of the existing Modified General Permit AKG–37–0000 for Alaskan Mechanical Placer Miners (GP) is based on the "Withdrawal from Federal Regulations of the Applicability to Alaska's Waters of Human Health Criteria" which was published in the Federal Register on March 2, 1998 (63 FR 10140) and became effective on April 1, 1998. This rulemaking withdraws the human health criteria for arsenic. This makes the drinking water maximum contaminant level (MCL) of 50 µg/L the applicable standard protective of the designated uses of the receiving waters covered by the GP.

The effluent limitation proposed for arsenic is a daily maximum limit of 50 µg/L. This is based on the Primary Drinking Water MCL applicable through 18 AAC 70.020(1)(A) for Toxic and other Deleterious Organic and Inorganic Substances. EPA defines the MCL as the "maximum permissible level of a contaminant" (40 CFR 142.2) so it is included as an instantaneous maximum limit.

7. Removals, Changes and Additions

A. Removal of Language

In the previous permit, Permit Part II.B.4. contained language discussing the application of the minimum level (ML) because the effluent limitation was below the method detection level (MDL). Since the proposed effluent limitation of 50 µg/L is above the MDL and the ML, there is no need for the permit to contain this language.

B. Additions

The Commissioner of ADEC, Michele Brown, sent a letter to Robert Perciasepe, Assistant Administrator for EPA's Office of Water, dated October 8, 1997, concerning the State's regulations on using "site specific data to develop appropriate permit limits or site specific criteria to further our statutory mission, which includes protection of public health." Permit Part II.A.1.e. contains new language to address site specific criteria that could be developed that are more stringent than the proposed effluent limitation if concerns are raised to the State by an affected community or individual. EPA is working with the State to generate a mechanism by which a site specific criterion would be developed and implemented.

C. Changes

Permit Part V.B. lists the administrative and civil penalties for a violation of the permit as $10,000 and $25,000, respectively. Changes to $11,000 and $27,500 were noticed in the Federal Register (61 FR 69360, December 31, 1996). To avoid the possibility of different levels being listed in different places, this section has been updated to include generic penalty language.

Permit Part IV.B. has been changed from the Enforcement Unit at mailstop WD–135 to the NPDES Compliance Unit at mailstop OW–133.

Permit Part I.F.4. has been updated from a mailstop of WD–134 to OW–130.

Permit Part I.F.6. contained a typographical error listing Wrangell St. Alias instead of Wrangell St. Elias. This has been corrected.

8. Other Legal Requirements

A. Oil Spill Requirements

Section 311 of the Act prohibits the discharge of oil and hazardous materials in harmful quantities. Routine discharges specifically controlled by a permit are excluded from the provisions of section 311. However, this general permit does not preclude the institution of legal action or relieve permittees from any responsibilities, or penalties for other, unauthorized discharges of oil and hazardous materials which are covered by section 311 of the Act.

B. Coastal Zone Management Act

A determination that the activities allowed by this proposed GP are consistent with the Alaska Coastal Management Plan must be made in accordance with the Coastal Zone Management Act before a final permit will be issued.

C. State Water Quality Standards and State Certification

Whereas state waters are involved in this proposed GP, the provisions of section 401 of the Act will apply. Furthermore, in accordance with 40 CFR 124.01(c)(1), public notice of the proposed GP has been provided to the State of Alaska and Alaska state agencies having jurisdiction over fish, shellfish, and wildlife resources, and over coastal zone management plans.

D. Endangered Species Act

Letters were sent to the U.S. Fish and Wildlife Service (USFW) and to the National Marine Fisheries Service (NMFS) on April 20, 1998, requesting information to the extent the permit modification may affect threatened and endangered species.

References

1. Letter from John Cook to Robert R. Robichaud dated March 25, 1998, requesting that EPA modify the General Permit.

2. Letter from Steve Borell, Executive Director of the Alaska Miners Association, Inc., to Robert R. Robichaud dated March 24, 1998, requesting that EPA modify the General Permit.

3. 63 FR 10142, March 2, 1998—Withdrawal from Federal Regulations of the Applicability to Alaska's Waters of Human Health Criteria.

4. Letter from Michele Brown to Robert Perciasepe dated October 8, 1997.

5. 61 FR 69360, December 31, 1996—Civil Monetary Penalty Inflation Adjustment Rule.

[FR Doc. 98–19831 Filed 7–24–98; 8:45 am]
BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board Action to Approve a Plan of Voluntary Liquidation of AgCo Services Corporation and Cancel the Charter of AgCo Services Corporation

AGENCY: Farm Credit Administration.

ACTION: Notice.

On June 29, 1998, the Farm Credit Administration Board adopted FCA Board Action NV 98–26 authorizing the voluntary liquidation of AgCo Services Corporation (AgCo) without the appointment of a receiver pursuant to 12 CFR 627.2795(a), and the cancellation of AgCo's charter arising out of the voluntary liquidation of AgCo. The text of the FCA Board Action is set forth below: Farm Credit Administration (FCA) Board Action to Cancel the Charter of AGCO Services Corporation.

Whereas, AgCo Services Corporation, chartered under section 4.25 of the Farm Credit Act of 1971 as amended, and originally organized by CoBank, ACB and AgAmerica, FCB for the purpose of consolidating their management information systems and electronic data processing functions, has not performed any of the services for which it was originally chartered for nearly two years;

Whereas, the board of directors of AgCo Services Corporation has submitted a plan of voluntary liquidation pursuant to FCA Regulation 12 CFR 627.2795(a) to liquidate the service corporation;

Whereas, CoBank, ACB of Englewood, Colorado, as the sole remaining shareholder of AgCo Services Corporation, voted to voluntarily liquidate the service corporation pursuant to 12 CFR 627.2795; and

Whereas, CoBank, ACB has agreed to assume all present and future liabilities and responsibilities in whatever form and substance as well as acquire the remaining assets of AgCo Services Corporation;

Now, therefore, it is hereby ordered that:

1. The Charter of the AgCo Services Corporation is hereby canceled.

2. The foregoing FCA Board action shall be effective at 5:00 p.m. EDT on July 22, 1998.

Signed by Marsha Pyle Martin, Chairman, Farm Credit Administration Board, on June 29, 1998.

Dated: July 21, 1998.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 98–19889 Filed 7–24–98; 8:45 am]
BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Submitted to OMB for Review and Approval

July 21, 1998.

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, as required by the Paperwork Reduction Act of 1995, Public Law 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 comments should be submitted on or before August 26, 1998. 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 to Les Smith, Federal Communications Commissions, Room 234, 1919 M St., N.W., Washington, DC 20554 or via internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at 202–418–0217 or via internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0332.

Title: Section 76.614 Cable television system regular monitoring.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents: 9,300.

Estimated Time Per Response: .5 hours–1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden to Respondents: 9,300 hours.

Total Annual Cost to Respondents: $32,550.

Needs and Uses: Section 76.614 requires that cable television operators transmitting carriers in the frequency bands 108–137 and 225–400 MHz shall provide for a program of regular monitoring for signal leakage by substantially covering the plant every three months. This collection (3060–0332) accounts for the paperwork and recordkeeping burden associated with maintaining logs that show the date and location of each leakage source identified, the date on which the leakage was repaired and the probable cause of the leakage. This data are used by cable television systems and the Commission to prevent, locate, and eliminate harmful interference as it occurs, to help assure safe operation of aeronautical and marine radio services and to minimize the possibility of interference to these safety-of-life services. If this collection of information is not conducted, there would be a greater likelihood of harmful interference to aeronautical and safety radio services, Commission efforts to locate and eliminate such interference would be impaired, and there would be a potentially greater risk to safety-of-life and property.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98–19946 Filed 7–24–98; 8:45 am]
BILLING CODE 6712–01–P

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. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

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 21, 1998.

A. Federal Reserve Bank of Richmond (A. Linwood Gill III, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. First Union Corporation, Charlotte, North Carolina; to increase its investment in United Bancshares, Inc., Philadelphia, Pennsylvania, and thereby indirectly acquire nonvoting common stock of United Bank of Philadelphia, Philadelphia, Pennsylvania.

B. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. First American Corporation, Nashville, Tennessee; to merge with Pioneer Bancshares, Inc., Chattanooga, Tennessee, and thereby indirectly acquire Pioneer Bank, Chattanooga, Tennessee; Valley Bank, Sweetwater, Tennessee, and Pioneer Bank, FSB, East Ridge, Tennessee.

In connection with this application, Applicant has also applied to engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, July 22, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–19999 Filed 7–24–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Contract Review Meeting

In accordance with Section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), announcement is made of the following technical review committee to meet during the month of August 1998.

Name: Technical Review Committee on the Agency for Health Care Policy and Research SBIR Topic 3000—Computer Decision Support Tools for Evidence-based Medicine.

Date and Time: August 5, 1998, 8:00 a.m.–5:00 p.m.

Place: Hyatt Regency-Bethesda, Tiffany/Cartier Room, One Bethesda Metro Center, Bethesda, Maryland 20814.

This meeting will be closed to the public.

Purpose: The Technical Review Committee's charge is to provide, on behalf of the Agency for Health Care Policy and Research (AHCPR) Contracts Review Committee, recommendations to the Administrator, AHCPR, regarding the technical merit of contract proposals submitted in response to a specific Request for Proposals regarding the AHCPR Research Topic 3000, SBIR-Computer Decision Support Tools for Evidence-based Medicine, announced in the Commerce Business Daily on May 1, 1998.

These contracts constitute the Agency for Health Care Policy and Research's participation in the Small Business Innovative Research Program (SBIR). The programs of the Department of Health and Human Services (HHS), and of certain other Federal agencies are required by statutes to reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development (R&D) for SBIR programs. The purpose of the legislation is to emphasize increased private sector commercialization of technology developed through Federal SBIR R&D; increase small business participation in Federal R&D; and foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program and to expand and improve the SBIR programs.

In Phase I of the SBIR program, each contractor will determine and report the scientific, technical, and commercial merit and feasibility of proposed research or R&D efforts and the ability of that small business concern to carry out this research or R&D with further Federal support in Phase II.

AHCPR issued a Request for Proposal (AHCPR–98–0014) under the SBIR program for Phase I contracts for the specific topic of Computer Decision Support Tools for Evidence-based Medicine. Evidence-based medicine is increasingly providing systematic reviews of the medical literature to improve the care provided to patients. What is lacking are real-time resources to give providers on-site and immediate access to the latest requested evidence. The SBIR contract projects are to produce software that will provide decision support tools and information on demand for clinicians to foster the practice of evidence-based medicine.

Agenda: The Committee meeting will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to the above-referenced Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This action is necessary to safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during this meeting, and to protect the free exchange of views, and avoid undue interference with Committee and Department operations.

This is in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C., Appendix 2, implementing regulations, 41 CFR 101–6.1023 and procurement regulations, 48 CFR 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Kate Rickard, Center for Practice and Technology Assessment, Agency for Health Care Policy and Research, 6010 Executive Boulevard, Suite 304, Rockville, Maryland 20852, telephone (301) 594–2431.

Dated: July 16, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–19901 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Injury Prevention and Control (ACIPC).

Times and Dates: 1 p.m.–4 p.m., August 11, 1998; 8:30 a.m.–3:30 p.m., August 12, 1998.

Place: JW Marriott at Lenox, 3300 Lenox Road, Atlanta, Georgia 30336.

Status: Closed: 1 p.m.–3 p.m., August 11, 1998, and 8:30–9 a.m., August 12, 1998; Open: 3 p.m.–4 p.m., August 11, 1998, and 9 a.m.–3:30 p.m., August 12, 1998.

Purpose: The Committee advises and makes recommendations to the Secretary, the Assistant Secretary for Health, and the Director, CDC, regarding feasible goals for the prevention and control of injury. The Committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee

provides advice on the appropriate balance and mix of intramural and extramural research, including laboratory research, and provides guidance on intramural and extramural scientific program matters, both present and future, particularly from a long-range viewpoint. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee recommends areas of research to be supported by contracts and provides concept review of program proposals and announcements.

Matters to be Discussed: The meeting will convene in closed session from 1 p.m. to 3 p.m. on August 11, 1998. The purpose of this closed session is for the Science and Program Review Work Group (SPRWG) to consider Injury Control Research Center grant applications recommended for further consideration by the CDC Injury Research Grant Review Committee. On August 12, 1998, from 8:30 a.m. to 9 a.m., the meeting will convene in closed session in order for the full Committee to vote on a funding recommendation. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c) (4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463. Following the SPRWG closed session, there will be a program oversight session which will include (1) discussion of the extramural research budget, (2) intramural/extramural program oversight, (3) upcoming program announcements, (4) upcoming Injury Research Grant Review Committee and ACIPC meeting dates, (5) State and Territorial Injury Control Research Center funding/program balance, (6) progress on standing Work Group issues, and (7) extramural research review process. The full Committee will discuss (1) an update from the Director, National Center for Injury Prevention and Control (NCIPC); (2) updates on Safe America/Partnership Council; (3) translation/communicating research findings; and (4) a report from the Science and Program Review Work Group, including a programmatic review of biomechanics.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mr. Thomas E. Blakeney, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341–3724, telephone 770/488–1481.

Dated: July 20, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–19927 Filed 7–24–98; 8:45 am]

BILLING CODE 4161–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Fernald Health Effects Subcommittee.

Times and Dates: 1 p.m.–9 p.m., August 26, 1998; 8:30 a.m.–5 p.m., August 27, 1998.

Place: The Plantation, 9660 Dry Fork Road, Harrison, Ohio 45020, telephone 513/367–5610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for communities, American Indian Tribes, and labor to express concerns and provide advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR on updates regarding the progress of current studies.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Steven A. Adams, Radiation Studies Branch, Division of Environmental Hazards and Health, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: July 20, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–19928 Filed 7–24–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0571]

BASF Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53) as a colorant for polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4611) has been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828–1234. The petition proposes to amend the food additive regulations to provide for the safe use of nickel antimony titanium yellow rutile (C.I. Pigment Yellow 53) as a colorant for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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.

Dated: July 6, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–19894 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0568]

FMC Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that FMC Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3072.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8A4605) has been filed by FMC Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 172.846 (21 CFR 172.846) to provide for the expanded safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups.The agency has determined under 21 CFR 25.32(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.

Dated: July 6, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–19893 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Granulocytes for Transfusion: Research and Clinical Experience; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Granulocytes for Transfusion: Research and Clinical Experience. This workshop, which is cosponsored by FDA and the National Institutes of Health (NIH), will include a discussion of the effects of cytokine administration on normal donors, the functional properties of the transfusion product, the effects of storage conditions on the product, and the safety and effectiveness of the product.

Date and Time: The public workshop will be held on Friday, September 11, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by Wednesday, August 12, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The findings that administration of Granulocyte–Colony Stimulating Factor or Granulocyte–Macrophage Colony Stimulating Factor to normal volunteers results in the peripheral mobilization of high concentrations of granulocytes has renewed an interest in the collection of granulocytes for transfusion. The goals of the workshop are to discuss: (1) The current scientific and clinical experience with cytokine mobilized granulocyte transfusion products; (2) the effects of cytokine administration on normal donors; (3) the functional properties of transfusion product; and (4) studies needed to establish the safety and effectiveness of the transfusion product. The information obtained from these presentations will assist FDA in assessing the safety and effectiveness of the product and will assist NIH in identifying areas in need of further research.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19955 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Evaluation of In Vivo Efficacy of Platelet Transfusion Products and Platelet Substitutes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Evaluation of In Vivo Efficacy of Platelets and Platelet Substitutes. This workshop is cosponsored by FDA, the United States Army, and the National Institutes of Health. The topics to be discussed include: Current methodology for efficacy assessment of transfused platelets; definition of efficacy for platelet substitutes; animal models of platelet efficacy; discussion of the therapeutic "cost versus benefit" of using platelets treated with novel decontamination treatments or stored with novel media/methods, or of using platelet substitutes.

Date and Time: The public workshop will be held on Monday, September 28, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at Wilson Hall, Bldg. 1, National

Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Request for Oral Presentations: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by August 28, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop. Requests for oral presentations should be sent to Jaroslav G. Vostal, Division of Hematology (HFM–335), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–496–2577, FAX 301–402–2780, e-mail "VOSTAL@A1.CBER.FDA.GOV". Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The goals of the workshop include the following: (1) Review current methodology for measuring platelet clinical efficacy; (2) define the clinical efficacy of a platelet transfusion; (3) discuss similarities and differences between intact platelets and platelet substitutes; (4) present animal models used for measuring platelet substitute efficacy; and (5) discuss design of clinical trials to establish clinical efficacy for platelets and platelet substitutes. The information obtained from these presentations will assist FDA in developing standards to evaluate novel platelet products and to assure the safety and effectiveness of these products.I11*Transcripts*: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19896 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0497]

Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation. This workshop, which is cosponsored by FDA and the National Institutes of Health, will include a discussion of the current status of clinical and nonclinical laboratory data to support the development of standards for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cell products; studies to obtain data for product safety and effectiveness; and the notice and request for comments entitled "Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments" that published in the **Federal Register** of January 20, 1998 (63 FR 2985).

Date and Time: The public workshop will be held on Thursday, September 10, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Contact Person: Joseph Wilczek, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–350), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6129, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: The goals of this workshop are to: (1) Discuss the current status of related and unrelated allogeneic peripheral blood hematopoietic stem/progenitor cell collection; (2) discuss the current status of unrelated allogeneic placental/umbilical cord blood banking and transplantation; (3) discuss issues regarding the administration of cytokines to normal donors for the mobilization of peripheral blood hematopoietic stem/progenitor cells and transplantation; and (4) address questions the public may have regarding the notice and request for comments published in the **Federal Register** of January 20, 1998 (63 FR 2985). The information obtained from these presentations will assist FDA and the interested public in developing standards for unrelated allogeneic peripheral blood and placental/umbilical cord blood hematopoietic stem/progenitor cell products.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations, to the contact person by Tuesday, August 11, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for this workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19892 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0049]

Guidance for Industry on Environmental Assessment of Human Drug and Biologics Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." This guidance is intended to provide information on when an environmental assessment (EA) should be submitted in support of a human drug or biologics application

and recommendations on how to prepare EA's.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm". Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5629, or Daniel C. Kearns, Center for Biologics Evaluation and Research (HFM–206), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3031.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental impact of approving drug and biologics applications as an integral part of its regulatory process. Under the President's reinventing Government initiatives announced in April 1995, FDA reevaluated and revised its environmental regulations to reduce the number of EA's required to be submitted by industry and, consequently, the number of findings of no significant impact prepared by the agency under NEPA.

In the **Federal Register** of April 3, 1996 (61 FR 14922) (republished May 1, 1996 (61 FR 19476)), FDA issued for public comment a notice of proposed rulemaking that proposed additional categorical exclusions for those actions the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have determined normally do not individually or cumulatively have a significant effect on the quality of the human environment. The final rule was published in the **Federal Register** of July 29, 1997 (62 FR 40570), and became effective August 28, 1997. This guidance is based on the final rule and supersedes CDER's "Guidance for Industry For the Submission of an Environmental Assessment in Human Drug Applications and Supplements," which published in November 1995.

In the **Federal Register** of February 12, 1998 (63 FR 7174), FDA announced the availability of a draft version of this guidance. The February 12, 1998, document gave interested persons an opportunity to submit comments through April 13, 1998. All comments received during the comment period have been carefully reviewed and incorporated, where appropriate, in this revised guidance.

FDA's regulations in part 25 (21 CFR part 25) specify that environmental assessments must be submitted as part of certain new drug applications, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, investigational new drug applications and for various other actions (see § 25.20), unless the action qualifies for a categorical exclusion.

This guidance provides information on when an EA should be submitted and recommendations on how to prepare EA's for submission to CDER and CBER for these drug or biologics applications. Topics covered include: (1) When categorical exclusions apply, (2) when to submit an EA, (3) the content and format of EA's, (4) specific guidance for the environmental issues that are most likely to be associated with human drugs and biologics, (5) test methods, (6) an applicant's treatment of confidential information submitted in support of an EA, and (7) master files for drugs and biologics.

This guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on environmental assessment of human drug and biologics applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19900 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0563]

CDRH Draft Guidance For Industry: Contents of a Product Development Protocol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft". This draft guidance is not final nor is it in effect at this time. This document provides guidance on the content of product development protocol (PDP) applications, expected actions and timeframes in the development of a product under a PDP, and how changes during the course of product development under a PDP should be handled.

DATES: Written comments must be received by October 26, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft" to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the Dockets Management Branch (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the document number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

For general information on the PDP process, or to comment on this guidance, please contact: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–594–2186.

For information concerning the design control and GMP aspects of this guidance, please contact: Sandy Weininger, Center for Devices and Radiological Health (HFZ–141), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–443–2536, ext. 34.

SUPPLEMENTARY INFORMATION:

I. Background

Section 515(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(f)) provides an alternative to the investigational device exemption (IDE) and PMA processes for class III devices subject to premarket approval. This alternative process, PDP, was not implemented during the early years of FDA's medical device program because it was considered potentially complex and there was a need to focus attention on implementing the core provisions of the Medical Device Amendments of 1976, such as the IDE, premarket approval, 510(k), good manufacturing practices, and problem reporting requirements.

This document provides guidance on the content of PDP applications, expected actions and timeframes in the development of a product under a PDP, and how changes during the course of product development under a PDP should be handled. This draft guidance also provides a framework for interaction between FDA and the applicant; but, because of the wide range of devices that may be developed under the PDP authority, it is unlikely that every element addressed in the guidance will apply to any given device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the PDP process and the relative duties and responsibilities of the agency and the applicant. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

"CDRH Guidance for Industry—Contents of a Product Development Protocol; Draft" is available by fax from CDRH's Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt, press 2, and then enter the document number 473 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH Home Page includes "Guidance for Industry—Contents of a Product Development Protocol; Draft" device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at "http://www.fda.gov/cdrh". The "Guidance for Industry—Contents of a Product Development Protocol; Draft" will be available at "http://www.fda.gov/cdrh/pdp/.html".

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before October 26, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 9, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–19899 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0545]

Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods." The draft guidance document describes the recommended donor suitability criteria and the licensing provisions for the collection of red blood cells using automated methods. The draft guidance document provides recommendations to blood establishments for the use of FDA cleared automated blood cell separators for the collection of both single and double units of red blood cells.

DATE: Written comments may be submitted at any time, however, comments should be submitted by September 25, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods" to the Office of Communication, Training, and Manufacturers Assistance (HFM–40),

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods." The draft guidance document is intended to provide specific recommendations on donor suitability criteria for allogenic and autologous red blood cell donations, on standard operating procedures, and recordkeeping, and describes registration and licensing procedures for the manufacture of double units of red blood cells or single units of red blood cells plus up to two units of fresh frozen plasma.

This draft guidance document represents the agency's current thinking with regard to collecting red blood cells by automated apheresis methods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. This draft guidance document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by September 25, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of this draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW) by connecting to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19897 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4356–N–14]

Notice of Proposed Information Collection: Comment Request

AGENCY: Office of the Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be 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.

DATES: Comments due date: September 25, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: John J. Coonts, Director, Office of Insured Single Family Housing, telephone number (202) 708–3046 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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 agency's estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Requirements for Single Family Mortgage Instruments.

OMB Control Number, if applicable: 2502–0404.

Description of the need for the information and proposed use: The Single Family Mortgage Instruments are the documents used to record the mortgage (or deed of trust) and the mortgage note (or deed of trust note). These are public documents used to protect both the interest of the mortgage borrower as well as the mortgage lender.

Estimation of total number of hours needed to prepare the information. The estimated number of respondents are 8,300, the frequency of responses is variable depending on business activity, with 0.25 hours per response.

Agency form numbers, if applicable: n/a.

Status of the proposed information collection: Extension of currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 20, 1998.

Ira G. Peppercorn,

General Deputy Assistant Secretary for Housing.

[FR Doc. 98–19913 Filed 7–24–98; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4352–N–06]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comment on the subject proposal.

DATES: The due date for comments is: July 31, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB Control Number and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB an information collection package with respect to a Notice announcing the Title VI Loan Guarantee Demonstration Program and a Notice of Funding Availability for Title VI Loan Guarantee Capacity-Building Grants. This information collection package submission to OMB for review is required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to : (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 agency's estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The Department has submitted the proposal for the collection of information to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Department has requested emergency clearance of the collection of information, as described below, with approval being sought by July 27, 1998.

Title of Proposals: Notice of Title VI Loan Guarantee Demonstration Program; Notice of Funding Availability for Title VI Loan Guarantee Capacity-Building Grants.

Description of the need for the information and proposed use: The Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act for Fiscal Year 1998 (FY 1998 HUD Appropriations Act) provided a $5 million appropriation for the funding of a demonstration program which would guarantee up to $45 million in loan guarantees pursuant to Title VI of the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA), which provides the authority to operate a loan guarantee program to fund certain eligible tribal housing activities. Through the demonstration program, HUD is seeking to develop models which will provide innovative ways to enhance economic growth, increase access to private capital, and encourage the investment and participation of traditional financial institutions on Indian reservations and other Native American areas. Indian tribes and tribally Designated Housing Entities (TDHE) are encouraged to form partnerships with investors or financial institutions and submit model Title VI demonstration projects to be evaluated in accordance with the criteria contained in the Notice.

The FY 1998 HUD Appropriations Act also provided $25 million for a rural housing and economic development initiative to test comprehensive approaches to developing job bases through economic development, developing affordable low- and moderate-income rental and home ownership housing, and increasing the investment of both private and nonprofit capital. Grants are authorized, in amounts not to exceed $4 million each, to rural and tribal areas.

The Department has determined that $4 million will be allocated under a Notice of Funding Availability for Title VI Loan Guarantee Capacity-Building Grants to assist organizations providing capacity-building technical assistance to Indian tribes or TDHEs that have been granted a Title VI loan guarantee under the Title VI Demonstration Program.

Members of affected public: Up to 20 Indian tribes or TDHEs, and approximately 10 technical assistance providers, are expected to apply under the Notice and the NOFA.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: Tribes/TDHEs will be able to apply for Title VI loan guarantees at any time until all funds have been obligated. Since this is the first year of operation for the Title VI Program, it is essential that the technical assistance to be provided under the NOFA be in place as the loan guarantee applications are being developed to ensure that the new program is successful. The average amount of time to put together a loan guarantee package is likely to be, on average, 60 hours for the 20 tribes/TDHEs. We anticipate that not more than 10 technical assistance provide will apply under the NOFA, with an average application completion time of 40 hours each. In total, the Department expects this request will have an annual reporting burden of 1,600 hours.

Status of the proposed information collection: Pending OMB approved.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 20, 1998.

David S. Cristy,

Director, IRM Policy and Management Division.

[FR Doc. 98–19914 Filed 7–24–98; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF THE INTERIOR

National Park Service

Retail Sales in Yorktown, Virginia; Notice

AGENCY: National Park Service, Interior.

ACTION: Public Notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a concession contract authorizing retail sales for the public in Yorktown, Virginia within Colonial National Historical Park for a period for five (5) years from date of contract execution.

EFFECTIVE DATE: October 13, 1998.

ADDRESSES: Interested parties should contact National Park Service, Colonial National Historical Park, P.O. Box 210, Yorktown, VA 23690, or phone (757) 898–3400, to obtain a copy of the prospectus describing the requirements of the proposed contract.

SUPPLEMENTARY INFORMATION: This contract has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared.

The existing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expired by limitation of time on December 31, 1990, and therefore pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract, providing that the existing concessioner submits a responsive offer (a timely offer which meets the terms and conditions of the Prospectus). This means that the contract will be awarded to the party submitting the best offer, provided that if the best offer was not submitted by the existing concessioner, then the existing concessioner will be afforded the opportunity to match the best offer. If the existing concessioner agrees to match the best offer, then the contract will be awarded to the existing concessioner.

If the existing concessioner does not submit a responsive offer, the right of preference in renewal shall be considered to have been waived, and the contract will then be awarded to the party that has submitted the best responsive offer.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be received by the Superintendent, Colonial National Historical Park, not later than the seventy-fifth (75th) day following publication of this notice to be considered and evaluated.

Dated: July 17, 1998.

P. Tremblay,

Acting Superintendent, Colonial National Historical Park.

[FR Doc. 98–19968 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent To Issue a Prospectus for the Operation of Two Hostel Facilities at Golden Gate National Recreation Area

SUMMARY: The National Park Service will be releasing a concession Prospectus authorizing continuation of two hostel operations within Golden Gate National Recreation Area. The operations are located at Fort Mason (in San Francisco at the north end of Franklin Street) and Fort Barry (in Marin Headlands northwest of the Golden Gate Bridge). Both operations are year-round and provide modest overnight accommodations for visitors to the park. The facility at Fort Mason can accommodate approximately 155 overnight visitors and the Fort Barry facility can accommodate approximately 66 overnight visitors. Capital improvements to both facilities of approximately $400,000 will be required during the first year of the contract. The average annual gross receipts for the combined operations are approximately $1.7 million dollars. The term of the new contact will be for ten (10) years. There is no requirement to purchase any of the personal and real property from the current concessioner. There is an existing concessioner, which has operated satisfactorily, under the existing concession permits and has a right of preference in renewal.

SUPPLEMENTARY INFORMATION: The cost for purchasing a Prospectus is $30.00 by mail or $25.00 if picked up in person at the below address. Purchasing of the Prospectus will be by check only (NO CASH). The check must be made payable to "National Park Service". A Tax Identification Number (TIN) or Social Security Number (SSN) *MUST be provided on all checks.* Copies can be obtained at the following address: National Park Service, Pacific Great Basin Support Office, Office of Concession Program Management, 600 Harrison Street, Suite 600, San Francisco, California 94107–1372. If purchased by mail, the front of the envelope should be marked "Mailroom Do Not Open". Please include in your request a mailing address indicating where to send the Prospectus. Inquiries may be directed to Ms. Teresa Jackson, Office of Concession Program Management at (415) 427–1369.

Dated: July 17, 1998.

John J. Reynolds,

Regional Director, Pacific West Region.

[FR Doc. 98–19966 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Issue a Prospectus for the Operation of a Coffee Shop at Golden Gate National Recreation Area

SUMMARY: The National Park Service will be releasing a concession Prospectus authorizing continuation of a coffee shop operation at the western edge of San Francisco within Golden Gate National Recreation Area. The operation provides a coffee shop style of food service with limited beer and wine beverages. The facility has a fifty (50) seat capacity. There will be no expansion of the facility during the term of this contract. Improvements to the present structure are required to meet current American Disability Act and health and safety requirements. The operation is year-round and provides service to visiting public from morning to early evening. The average annual gross receipt for the operation is approximately $750,000. The term of the new contract will be for ten (10) years. There is an existing concessioner, which has operated satisfactorily, under the existing concession contract and has a right of preference in renewal.

SUPPLEMENTARY INFORMATION: The cost for purchasing a Prospectus is $30.00 by mail or $25.00 if picked up in person at the below address. Purchasing of the Prospectus will be by check only (NO CASH). The check must be made payable to "National Park Service". A Tax Identification Number (TIN) or Social Security Number (SSN) MUST be provided on all checks. Copies can be obtained at the following address: National Park Service, Pacific Great Basin Support Office, Office of Concession Program Management, 600 Harrison Street, Suite 600, San Francisco, California 94107–1372. If purchased by mail, the front of the envelope should be marked "Mailroom Do Not Open". Please include in your request a mailing address indicating where to send the Prospectus. Inquiries may be directed to Ms. Teresa Jackson, Office of Concession Program Management at (415) 427–1369.

Dated: July 17, 1998.

John J. Reynolds,

Regional Director,

Pacific West Region.

[FR Doc. 98–19967 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Jurisdictional Transfers; Wupatki National Monument

AGENCY: National Park Service.

ACTION: Notice of Transfer of Administrative Jurisdiction, Wupatki National Monument.

SUMMARY: The Bureau of Land Management had administrative jurisdiction over certain lands and/or interests therein within the area generally depicted as "Proposed Addition 168.89 Acres" on the map entitled "Boundary—Wupatki and Sunset Crater National Monuments, Arizona," numbered 322–80,021, and dated April 1989. A May 27, 1998, memorandum from the Arizona State Director of the Bureau of Land Management confirmed the public land records have been noted to show the 168.89 acres as being within Wupatki National Monument, and administrative jurisdiction is transferred to the National Park Service. Notice is hereby given that, pursuant to the provisions of Section 207 of Public Law 104–333, 110 Stat. 4093, administrative jurisdiction on the 168.89 acres is now in the National Park Service, subject to prior existing rights and applicable laws and regulations. The specific lands and/or interests, subject to this notice include 168.89 acres of both surface and mineral interests.

SUPPLEMENTARY INFORMATION: Maps and other documents associated with the transfer of the lands and minerals within the proposed addition to Wupatki National Monument may be reviewed at the Arizona State Office of the Bureau of Land Management, 222 North Central Avenue, Phoenix, Arizona 85004, and at Wupatki National Monument Headquarters, 6400 North Highway 89, Flagstaff, Arizona 86004.

Dated: June 24, 1998.

John E. Cook,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 98–19749 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before July 18, 1998. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, 1849 C St. NW, NC400, Washington, DC 20240. Written comments should be submitted by August 11, 1998.

Carol D. Shull,

Keeper of the National Register.

ALABAMA

Bullock County

Foster House, 201 Kennon St., Union Springs, 98001021

Jefferson County

Smithfield Historic District (Boundary Increase), Roughly along 4th Court and Center St., Birmingham, 98001022

Lauderdale County

College Place Historic District (Boundary Increase), Roughly along W. Lelia and W. Mattie Lou Sts., Florence, 98001030

Rogers Department Store, 117 N. Court St., Florence, 98001025

Lawrence County

Moulton Courthouse Square Historic District, Roughly bounded by Lawrence, Main, Court, and Market Sts., Moulton, 98001026

Madison County

Monte Sano Railroad Workers' House, 4119 Shelby Ave., Huntsville, 98001019

Mobile County

Lower Dauphin Street Commercial District (Boundary Increase III), 310 St. Francis St., Mobile, 98001027

Sumter County

Ward, Dr. H. B., House, 202 4th Ave., Cuba, 98001020

ARIZONA

Coconino County

Krenz—Kerley Trading Post, E. side of Main St., Tuba City, 98001040

Maricopa County

Petroglyph Site AZ U 1:165, Address Restricted, Scottsdale, 98001038

ILLINOIS

Piatt County

North State Street Historic District, Roughly along N. State St., from 300–1100 blk., Monticello, 98001045

Rock Island County

Broadway Historic District, Roughly bounded by 17th and 23rd Sts., 5th and 7th Aves., Lincoln Court, and 12th and 13th Aves., Rock Island, 98001046

INDIANA

Allen County

Pennslyvania Railroad Station, 221 W. Baker St., Fort Wayne, 98001056

Bartholomew County

Heagy, D.W., Farm, 3005 W 200 S, Columbus vicinity, 98001052

Cass County

Place, Willard B., House, 900 E. Broadway, Logansport, 98001050

Clinton County

Frankfort Commercial Historic District, Address Restricted, Frankfort, 98001055

Hendricks County

Jessup, Joel, Farm, Cty Rd. 800 S, near Cty Rd. 1050 E., Friendswood vicinity, 98001049

Marshall County

East Shore Historic District, Roughly, E Shore Dr. from W. 18th Rd.,to the E turn of IN 117, including Maxinkuckee Country Club, Culver vicinity, 98001054

Monroe County

Maple Grove Road Rural Historic District, Roughly, Maple Grove Rd., from Beanblossom Cr. to IN 46, including E half of Lancaster Park subdivision, Bloomington vicinity, 98001051

Orange County

Homestead Hotel, IN 56 between Ballard and First Sts., West Baden Springs, 98001057

St. Joseph County

Mishawaka Carnegie Library, 122 North Hill, Mishawaka, 98001048

Mishawaka Reservoir Caretaker's Residence, 16581 Chandler Blvd., Mishawaka, 98001053

IOWA

Buchanan County

Maas Commercial Building, 209 1st St. E, Independence, 98001047

LOUISIANA

Jefferson Parish

Raziano House, 913 Minor St., Kenner, 98001058

MICHIGAN

Charlevoix County

Boyne City Water Works Building, 210 E. Division St., Boyne City, 98001060

Ottawa County

Olive Township District No. 1 School, 11611 Stanton St., Olive Township, 98001061

St. Clair County

Military Road Historic District, Military St. and Huron Ave., from Court St. to Bard St., Port Huron, 98001059

MISSOURI

Ray County

Mansur, Isaiah, Farmstead Historic District, 17740 MO E., Richmond vicinity, 98001063

N. MARIANA ISLANDS

Rota Municipality

Chugai' Pictograph Site, Address Restricted, Chugai' vicinity, 98001066

NEW JERSEY

Atlantic County

Pitney, Dr. Jonathan, House, 57 N. Shore Rd., Absecon City vicinity, 98001062

Cumberland County

Levoy Theatre, 126–130 N. High St., Millville City, 98001064

NEW YORK

Dutchess County

St. Paul's (Zion's) Evangelical Lutheran Church, 57 S Broadway, Red Hook, 98001065

West Chester County

Flagg, Ethan, House—Blessed Sacrament Monastery, 23 Park Ave., Yonkers, 98001075

VIRGINIA

Page County

Mounty Calvary Lutheran Church, VA 670, approx. 0.5 mi. NE of jct. with VA 689, Luray vicinity, 98001068

Westmoreland County

Johnson, Armstead T., High School, 0.2 mi. NW of jct. of VA 3 and VA 202, Montross vicinity, 98001071

Norfolk Independent City

Taylor, Walter Herron, Elementary School, 1410 Claremont Ave., Norfolk vicinity, 98001067

Salem Independent City

Monterey, 110 High St., Salem, 98001069

Winchester Independent City

Handley, John, High School, 425 Handley Blvd., Winchester, 98001070

WEST VIRGINIA

Cabell County

Liggett and Myers Tobacco Company, 9 27th St., Huntington, 98001073

Jefferson County

Ripon Lodge, US 340, jct. with Withers-Carve Rd., Rippon, 98001074

Tucker County

Thomas Commercial Historic District, Roughly Spruce St. and East Ave. bet. First St. and Third St.; East Ave. W to the North Fork of the Blackwater R., Thomas, 98001072

WYOMING

Teton County

Cascade Canyon Barn (Grand Teton MPS), Cascade Canyon 5mi. upstream from Jenny Lake, Moose vicinity, 98001023

Death Canyon Barn (Grand Teton MPS), 5 mi. NW of Phelps Lake near Alaska Basin, Moose vicinity, 98001024

Double Diamond Dude Ranch Dining Hall (Grand Teton MPS), 5 mi. N of Moose, W side of Teton Park Rd. and Cottonwood Cr., Moose vicinity, 98001028

Highlands Historic District (Grand Teton MPS), 5 mi. N of Park HQ, ¼ mi. W of Teton Park Rd., Moose vicinity, 98001029

Hunter Hereford Ranch Historic District (Grand Teton MPS), SE corner of park, S of Shadow Mt. along Aspen Ridge, Moose vicinity, 98001031

Jenny Lake Boat Concession Facilities (Grand Teton MPS), S end of Jenny Lake, Moose vicinity, 98001032

Jenny Lake CCC Camp NP–4 (Grand Teton MPS), 1/4 mi. S of Jenny Lake, W side of Cottonwood Cr., Moose vicinity, 98001033

Lucas, Geraldine Homestead—Fabian Place Historic District (Grand Teton MPS), 4.5 mi. N of Moose, Moose vicinity, 98001034

Manges Cabin (Grand Teton MPS), S end of park SE of Taggart Lake, Moose vicinity, 98001035

Moran Bay Patrol Cabin (Grand Teton MPS), N bank of Moran Bay on Jackson Lake, Moose vicinity, 98001037

Murie Ranch Historic District (Grand Teton MPS), 1/2 mi. SW of park HQ, Moose vicinity, 98001039

Ramshorn Dude Ranch Lodge (Grand Teton MPS), SE corner of park, 2.5 mi. NW of Kelly, Wy, Moose, 98001041

Snake River Land Company Residence and Office (Grand Teton MPS), West bank of Snake R. 1/4 mi. N of Moran Jct., Moose vicinity, 98001036

Triangle X Barn (Grand Teton MPS), E side of park, N of Shadow Mt., Moose vicinity, 98001042 Upper Granite Canyon Patrol Cabin (Grand Teton MPS), SW corner of park at Granite Canyon, Rendezvous Pass, Moose vicinity, 98001043

[FR Doc. 98–20004 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Quarterly Status Report of Water Service and Repayment Contract Negotiations

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given of proposed contractual actions that are new, modified, discontinued, or completed since the last publication of this notice on April 22, 1998. The January 27, 1998, notice should be used as a reference point to identify changes. This notice is one of a variety of means used to inform the public about proposed contractual actions for capital recovery and management of project resources and facilities. Additional Bureau of Reclamation (Reclamation) announcements of individual contract actions may be published in the **Federal Register** and in newspapers of general circulation in the areas determined by Reclamation to be affected by the proposed action. Announcements may be in the form of news releases, legal notices, official letters, memorandums, or other forms of written material. Meetings, workshops, and/or hearings may also be used, as appropriate, to provide local publicity. The public participation procedures do not apply to proposed contracts for sale of surplus or interim irrigation water for a term of 1 year or less. Either of the contracting parties may invite the public to observe contract proceedings. All public participation procedures will be coordinated with those involved in complying with the National Environmental Policy Act.

ADDRESSES: The identity of the approving officer and other information pertaining to a specific contract proposal may be obtained by calling or writing the appropriate regional office at the address and telephone number given for each region in the supplementary information.

FOR FURTHER INFORMATION CONTACT: Alonzo Knapp, Manager, Reclamation Law, Contracts, and Repayment Office, Bureau of Reclamation, PO Box 25007, Denver, Colorado 80225–0007; telephone 303–445–2889.

SUPPLEMENTARY INFORMATION: Pursuant to section 226 of the Reclamation Reform Act of 1982 (96 Stat. 1273) and 43 CFR 426.20 of the rules and regulations published in *52 FR 11954*, Apr. 13, 1987, Reclamation will publish notice of the proposed or amendatory contract actions for any contract for the delivery of project water for authorized uses in newspapers of general circulation in the affected area at least 60 days prior to contract execution. Pursuant to the "Final Revised Public Participation Procedures" for water resource-related contract negotiations, published in *47 FR 7763*, Feb. 22, 1982, a tabulation is provided of all proposed contractual actions in each of the five Reclamation regions. Each proposed action is, or is expected to be, in some stage of the contract negotiation process in 1998. When contract negotiations are completed, and prior to execution, each proposed contract form must be approved by the Secretary of the Interior, or pursuant to delegated or

redelegated authority, the Commissioner of Reclamation or one of the regional directors. In some instances, congressional review and approval of a report, water rate, or other terms and conditions of the contract may be involved.

Public participation in and receipt of comments on contract proposals will be facilitated by adherence to the following procedures:

1. Only persons authorized to act on behalf of the contracting entities may negotiate the terms and conditions of a specific contract proposal.

2. Advance notice of meetings or hearings will be furnished to those parties that have made a timely written request for such notice to the appropriate regional or project office of Reclamation.

3. Written correspondence regarding proposed contracts may be made available to the general public pursuant to the terms and procedures of the Freedom of Information Act (80 Stat. 383), as amended.

4, Written comments on a proposed contract or contract action must be submitted to the appropriate regional officials at the locations and within the time limits set forth in the advance public notices.

5. All written comments received and testimony presented at any public hearings will be reviewed and summarized by the appropriate regional office for use by the contract approving authority.

6. Copies of specific proposed contracts may be obtained from the appropriate regional director or his designated public contact as they become available for review and comment.

7. In the event modifications are made in the form of a proposed contract, the appropriate regional director shall determine whether republication of the notice and/or extension of the comment period is necessary.

Factors considered in making such a determination shall include, but are not limited to: (i) the significance of the modification, and (ii) the degree of public interest which has been expressed over the course of the negotiations. As a minimum, the regional director shall furnish revised contracts to all parties who requested the contract in response to the initial public notice.

Acronym Definitions Used Herein

(BCP) Boulder Canyon Project
(CAP) Central Arizona Project
(CUP) Central Utah Project
(CVP) Central Valley Project
(CRSP) Colorado River Storage Project
(D&MC) Drainage and Minor Construction
(FR) Federal Register
(IDD) Irrigation and Drainage District
(ID) Irrigation District
(M&I) Municipal and Industrial
(O&M) Operation and Maintenance
(P-SMBP) Pick-Sloan Missouri Basin Program
(R&B) Rehabilitation and Betterment
(PPR) Present Perfected Right
(RRA) Reclamation Reform Act
(NEPA) National Environmental Policy Act
(SOD) Safety of Dams
(SRPA) Small Reclamation Projects Act
(WCUA) Water Conservation and Utilization Act
(WD) Water District

Pacific Northwest Region: Bureau of Reclamation, 1150 North Curtis Road, Boise, Idaho 83706–1234, telephone 208–378–5346.

New contract actions:

22. Juniper Flat District Improvement Company, Wapinitia Project, Oregon: Repayment contract for reimbursable cost of dam safety repairs to Wasco Dam Modified contract actions:

4. West Extension ID, Umatilla Project, Oregon; Pioneer Ditch Company, Boise Project, Idaho; Clark and Edwards Canal and Irrigation Company, Enterprise Canal Company, Ltd., Lenroot Canal Company, Liberty Park Canal Company, Parsons Ditch Company, Poplar ID, Wearyrick Ditch Company, all in the Minidoka Project, Idaho; Juniper Flat District Improvement Company, Wapinitia Project, Oregon; Roza ID, Yakima Project, Washington: Amendatory repayment and water service contracts; purpose is to conform to the RRA (Pub. L. 97–293).

Mid-Pacific Region: Bureau of Reclamation, 2800 Cottage Way, Sacramento, California 95825–1898, telephone 916–979–2401.

New contract actions:

30. Warren Act Contracts, CVP, California: Execution of long-term Warren Act contracts with various entities for conveyance of non-project water in the Delta-Mendota Canal.

Modified contract actions:

8. Glenn-Colusa ID, Sutter Extension WD, Biggs-West Gridley WD, Buena Vista Water Storage District, and the State of California Department of Water Resources, CVP, California: Pursuant to Public Law 102–575, conveyance agreements for the purpose of wheeling refuge water supplies and funding district facility improvements and exchange agreements to provide water for refuge and private wetlands.

Lower Colorado Region: Bureau of Reclamation, PO Box 61470 (Nevada Highway and Park Street), Boulder City, Nevada 89006–1470, telephone 702–293– 8536.

New contract actions:

50. Canyon Forest Village II Corporation, BCP, Arizona: Water delivery contract for the diversion of up to 400 acre-feet of unused Arizona apportionment or surplus apportionment of Colorado River water for domestic use.

51. Gila Project Works, Gila Project, Arizona: Proposed title transfer of facilities and certain lands in the Wellton-Mohawk Division, Arizona, to be transferred from the United States to the Wellton-Mohawk IDD.

52. City of Tucson, CAP, Arizona: Assignment of 9,500 acre-feet of M&I water to First Trust of Arizona.

53. First Trust of Arizona, CAP, Arizona: Partial assignment of 8,852 acre-feet of M&I water to Metropolitan Domestic Water Improvement District.

54. First Trust of Arizona, CAP, Arizona: Partial assignment of 642 acre-feet of M&I water to Oro Valley.

55. Camp Verde Water System, CAP, Arizona: Assignment of 1,443 acre-feet of M&I water to the City of Scottsdale.

56. Cottonwood Water Works, Inc., CAP, Arizona: Assignment of 1,789 acre-feet of M&I water to the City of Scottsdale.

Upper Colorado Region: Bureau of Reclamation, 125 South State Street, Room 6107, Salt Lake City, Utah 84138–1102, telephone 801–524–4419.

New contract actions:

1(f) LeChee Chapter of the Navajo Nation, Glen Canyon Unit, CRSP, Arizona: Long-term contract for 200 acre-feet of water for municipal purposes.

1(g) TransColorado Gas Transmission Company, Aspinall Unit, CRSP, Colorado: One-year contract for 15 acre-feet of water to be used for hydrostatic testing of a natural gas pipeline and dust abatement in construction area.

1(h) Stephens, Walter Daniel, Aspinall Unit, CRSP, Colorado: Contract for 2 acre-feet to support an augmentation plan, Case No. 97CW49, Water Division Court No. 4, State of Colorado, to provide for pond evaporative depletions during the nonirrigation season.

Modified contract actions:

23. Carlsbad ID, Carlsbad Project, New Mexico: Multi-year contract to allow the district to lease water to the New Mexico Interstate Stream Commission to fulfill New Mexico's water obligation to Texas under Supreme Court's Amended Decree in *Texas* v. *New Mexico* 485 U.S. 288(1988).

Completed contract actions:

12. Country Aire Estates, Forrest Groves Estates, and Los Ranchitos,

Florida Project, Colorado: Water service contracts for a total of 86 acre-feet annually of domestic water as replacement water in State of Colorado approved augmentation plans. The water supply for these contracts are flow rights purchased and owned by the United States for project development and are not specifically a part of the project water supply.

22. Carbon Water Conservancy District, Scofield Project, Utah: Amendment to SOD contract to raise contract repayment ceiling on the M&I obligation and replace estimated SOD costs with actuals.

Great Plains Region: Bureau of Reclamation, PO Box 36900, Federal Building, 316 North 26th Street, Billings, Montana 59107–6900, telephone 406–247–7730.

Modified contract actions:

7. City of Rapid City and Rapid Valley Water Conservancy District, Rapid Valley Unit, P–SMBP, South Dakota: Contract renewal for up to 55,000 acre-feet of storage capacity in Pactola Reservoir.

14. Northwest Area Water Supply, North Dakota: Long-term contract for water supply from Garrison Diversion Unit facilities. Basis of negotiation has been approved by Commissioner. Negotiations will begin this summer.

26. Lower Marias Unit, P–SMBP, Montana: Initiating 25-year water service contract for up to 750 acre-feet of storage from Tiber Reservoir to irrigate 250 acres. A 1-year temporary contract has been issued to allow additional time to complete necessary actions required for the long-term contract. Water service contract expired May 31, 1998. Initiating renewal of the long-term water service contract to provide 4,570 acre-feet of storage from Tiber Reservoir to irrigate 2,285 acres. A 1-year interim contract has been issued to continue delivery of water until the necessary actions can be completed to renew the long-term contract.

Completed contract actions:

17. P–SMBP, Nebraska: Water service contracts with the Loup Basin Reclamation District for the Sargent and Farwell IDs in the Middle Loup River Basin in Nebraska will be extended for a period of 4 years in accordance with Public Law 104–326 enacted October 19, 1996. Contract extension has been signed.

29. Belle Fourche Unit, P–SMBP, South Dakota: Negotiations have been held with the Belle Fourche ID to amend their long-term repayment contract deferring their 1997 construction payment and reducing their annual construction payment. Contract amendment has been signed.

32. Greenfields ID, Sun River Project, Montana: Contract for SOD costs for repairs to Pishkun Dike No. 4. A 1-year SOD repayment contract has been issued.

Dated: July 20, 1998.

Margaret W. Sibley,

Director Program Analysis Office.

[FR Doc. 98–19925 Filed 7–24–98; 8:45 am]

BILLING CODE 4310–94–P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of Information Collection Under Review; Application to Register Permanent Residence or Adjust Status and Supplement A to Form I–485.

The Department of Justice, Immigration and Naturalization Service has submitted the following information collection request for review and clearance 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 September 25, 1998.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information 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:* Application to Register Permanent Residence or Adjust Status and Supplement A to Form I–485.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–485 and I–485 Supplement A. Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This form allows an applicant to determine whether he or she must file under section 245 of the Immigration and Nationality Act, and it allows the Service to collect information needed for reports to be made to different government committees.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* I–485 Adult respondents is 160,000 at 5.25 hours per response; I–485 Children respondents is 112,000 at 4.5 hours per response; and I–485 Supplement A respondents is 50,000 at 13 minutes (.216) hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Form I–485 annual burden hours are 1,316,000 and Form I–485 Supplement A annual burden hours are 10,800.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: July 22, 1998.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 98–20000 Filed 7–24–98; 8:45 am]

BILLING CODE 4410–18–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Wednesday, July 19, 1998.

PLACE: Room 6005, 6th Floor, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following:

1. Secretary of Labor on behalf of Bowling v. Mountain Top Trucking Co., Docket Nos. KENT 95–604–D, etc. (Issues include whether the judge erred in determining that coal truck drivers did not establish that they were constructively discharged and whether the judge abused his discretion in finding that a discriminatee's back pay award should be reduced because he did not mitigate his damages by requesting the Secretary of Labor to reopen his previously withdrawn application for temporary reinstatement.)

TIME AND DATE: 2:00 p.m., Wednesday, July 29, 1998.

PLACE: Room 6005, 6th Floor, 1730 K Street, N.W., Washington, D.C.

STATUS: Closed [Pursuant to 5 U.S.C. § 552b(c)(10)].

MATTERS TO BE CONSIDERED: It was determined by a unanimous vote of the Commission that the Commission consider and act upon the following in closed session:

1. Secretary of Labor on behalf of Bowling v. Mountain Top Trucking Co., Docket Nos. KENT 95–604–D, etc. (See oral argument listing, supra, for issues.)

Any person attending oral argument or an open meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 98–20130 Filed 7–23–98; 1:02 pm]

BILLING CODE 6735–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–287]

Duke Energy Corporation; Notice of Consideration of Issuance of Amendment To Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–55 issued to Duke Energy Corporation (the licensee) for operation of the Oconee Nuclear Station Unit 3 located in Seneca, South Carolina.

If approved, the proposed amendment would extend, on a one-time basis, Technical Specification Surveillance 4.18.3 for hydraulic and mechanical snubber testing. The tests are required to be performed at a frequency of 18 months, with a maximum allowed frequency of 22 months, 15 days. The proposed amendment would extend this to a maximum of 25 months to coincide with the revised start date of the Oconee, Unit 3, refueling outage. The start date for the refueling outage has been delayed due to the management decision to extend the present operating cycle, which resulted in the surveillances becoming due prior to the start of the refueling outage.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves 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. 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:

This proposed change has been evaluated against the standards in 10 CFR 50.92 and has been determined to involve no significant hazards, in 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?

No. A review of the previous two hydraulic and mechanical snubber functional tests, discussed in this amendment request concluded that no adverse effects should occur as a result of the one-time extension. As a consequence, there should be no adverse affects to the piping systems and components which are restrained by snubbers for seismic and pipe whip events.

There is a high level of confidence that the snubbers should be available to perform their intended function during the requested extension period. Thus, the probability and consequences of an accident previously evaluated will not be significantly increased.

2. Create the possibility of a new or different kind of accident from the accidents previously evaluated?

No. Since the one-time extension should not cause any adverse effects on the snubbers' capability to restrain piping systems and components, a new or different kind of accident from the accidents which were previously evaluated will not occur. The snubbers should be available to perform their intended function during the requested extension period.

3. Involve a significant reduction in a margin of safety?

No. The margin of safety will not be significantly reduced by this amendment request because the snubbers and the systems supported by the snubbers should be available to perform their intended function during the requested extension period. In addition, the review of functional tests which are discussed in the amendment request concluded that no adverse effects should occur as a result of the one-time extension.

Duke [Duke Energy Corporation] has concluded, based on the above information, that there are no significant hazards involved in this amendment request.

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.

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. 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 6D59, 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 NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By August 26, 1998, 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 Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina. 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 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 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: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Mr. J. Michael McGarry, III, Winston and Strawn, 1200 17th Street, NW., Washington, DC, 20005, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the 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 dated July 20, 1998, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

Dated at Rockville, Maryland, this 21st day of July 1998.

For the Nuclear Regulatory Commission.

David E. LaBarge,

Senior Project Manager, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 98–19971 Filed 7–24–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 070–3073]

Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Finding of No Significant Impact Related to Amendment of Materials License No. SNM–1999, Kerr-McGee Corporation, Cushing Refinery Site, Cushing, Oklahoma.

The U.S. Nuclear Regulatory Commission (hereafter referred to as NRC) is considering issuing a license amendment to Materials License No. SNM–1999, held by the Kerr-McGee Corporation (Kerr-McGee or the licensee), to authorize remediation of Acid Sludge Pit 4 located on its Cushing refinery site (Cushing site located in Cushing, Oklahoma), and authorize placement of radioactive contaminated material into the radioactive material storage area (RMSA).

Summary of Environmental Assessment

Background

Kerr-McGee has environmental responsibility for a former refinery site near the city of Cushing, Oklahoma. The refinery opened around 1912 and was purchased by Kerr-McGee in 1956. During the early 1960s, in addition to petroleum processing, Kerr-McGee processed uranium fuel and thorium metal in several buildings onsite under licenses issued by the Atomic Energy Commission (AEC). The uranium fuel and thorium processing area was decommissioned, the property and facilities were released for unrestricted use, and the license was terminated by the AEC. Kerr-McGee continued to operate the refinery until 1972, at which time it was torn down. In May 1990 Kerr-McGee entered into a Consent Order with the Oklahoma State Department of Health (now referred to as the Oklahoma Department of Environmental Quality; ODEQ), addressing the investigation and remediation of the Cushing refinery site. The ODEQ Consent Order divided the site work into radiological and non-radiological remediation efforts. The non-radiological remediation is being performed in a manner similar to the Federal Superfund Remedial Investigation/Feasibility Study (RI/FS) process. On April 6, 1993, NRC issued Materials License SNM–1999 to Kerr-McGee Corporation, for the radiological decommissioning of its Cushing site. This license authorized the licensee to possess radioactive contaminated soil, sludge, sediment, trash, building rubble, and any other radioactively contaminated material, at its Cushing site.

Proposed Action

One of the refinery acid sludge pits being remediated under the ODEQ Consent Order contains thorium contamination in one corner of the pit. This affected pit is designated as Acid Sludge Pit 4. The licensee proposed to remediate Acid Sludge Pit 4 based on the experience gained from remediating non-radiologically contaminated acid sludge pits. The licensee would establish a 50-by-50-foot grid system over the surface of Acid Sludge Pit 4, referenced to the site-wide grid system. A layer of reagent (agricultural lime) would be placed over each grid block. The acidic sludge in each block would be neutralized to a pH of approximately five to six by adding and mixing in the reagent to depth. The mixing process should produce a relatively homogeneous material. The licensee plans to surface-scan this material in 18-inch lifts, to determine if material exceeds NRC's Branch Technical Position (BTP) (46 **Federal Register** 52061) Disposal Option 1 for thorium concentrations. Material that exceeds this Option 1 limit would be transported to the RMSA. Once this material is in the RMSA the licensee plans to package and transport this material to a licensed offsite disposal facility, the Envirocare Low-Level Radioactive Waste Disposal Site in Clive, Utah, for disposal. Material that meets the Option 1 limit would be excavated, stabilized by blending in cement kiln dust or similar reagent, and transported to the onsite Other Industrial Waste (OIW) disposal cell. The licensee plans to perform a final survey of the material, once it is placed in the OIW disposal cell, to confirm that the material meets NRC's release criteria, Option 1 limit.

There are five acid sludge pits located on the Cushing site. These acid sludge pits contain acidic hydrocarbon sludge from an earlier lubricating oil manufacturing operation. The waste is primarily heavy hydrocarbon containing sulfuric acid (typically 15 to 20 percent). The northwest corner of Acid Sludge Pit 4 also contains thorium-contaminated material in concentrations that exceed current remediation criteria and pose a long-term risk to the environment. The other acid sludge pits do not contain radiologically contaminated material. Phase One of the non-radiological effort is remediation of the five acid sludge pits. The RI/FS process was completed and reviewed by the ODEQ and local citizens. The ODEQ issued a record of decision for the acidic sludge pits requiring neutralization, excavation, and placement in an onsite engineered disposal cell.

License Condition 11.B.1 authorized construction of the RMSA but prohibited use of the RMSA until the licensee demonstrated that liquid effluent releases would be in compliance with the requirements of 10 CFR Part 20. The licensee requested License Condition 11.B.1 be amended to allow radioactive contaminated material to be placed into the RMSA. The licensee also provided its proposed RMSA liquid effluent monitoring program.

In addition to the RMSA the licensee plans to construct an Acid Sludge Pit 4 storm water retention pond (retention pond). The purpose of the retention pond is to collect surface water runoff caused by rainstorm events that may occur during the several week period while the licensee will be performing Acid Sludge Pit 4 remediation activities in zones 1 and 2 (known contaminated or possibly contaminated areas, respectively). Therefore, surface water runoff that may contain radiologically contaminated material from a rainstorm event would be collected and monitored prior to release from this area. The licensee plans to use the same liquid effluent monitoring procedures prior to release of liquid from the retention pond as it plans to use for monitoring RMSA liquid effluent releases. Finally, both the RMSA and the retention pond use a common discharge point in Skull Creek.

The Need for Proposed Action

This proposed action is necessary to remove radiologically-contaminated material from Acid Sludge Pit 4. This action will facilitate compliance with the Consent Order, and remediation of Acid Sludge Pit 4 for release for unrestricted use, a necessary action for termination of Materials License SNM–1999.

Alternative to Proposed Action

An alternative to the proposed action is a no-action alternative. No action would mean that Acid Sludge Pit 4 would not be remediated now. This would prevent the licensee from complying with the ODEQ Consent Order. Also, this conflicts with NRC's requirement, in 10 CFR 40.42, of timely remediation at sites that have ceased operation. Although there is no immediate threat to the public health and safety from this site, not undertaking remediation at this time does not solve the regulatory and potential long-term health and safety problems associated with storing this

waste. No action now would delay remediation until some time in the future, when costs could be much higher than they are today. It is even possible that no disposal option will be available in the future if the current low-level radioactive waste disposal facilities are closed and no new ones are opened. Therefore, the no-action alternative is not acceptable.

Environmental Impacts of Proposed Action

The 10 CFR Part 20 liquid effluent release limits are based on a total effective dose equivalent of 50 mrem if the radionuclide were ingested continuously over the course of a year. The licensee has committed to maintain annual cumulative averaging less than 20 percent of the effluent limits stipulated in Appendix B of 10 CFR Part 20. The Cushing license SNM–1999 will be conditioned to reflect this commitment. The licensee's analysis indicates that the actual releases will likely be less than one percent of the effluent limits. If the licensee did release liquid effluents at one percent of the 10 CFR Part 20 release limits and if a member of the public were able to directly consume this contaminated liquid effluent, that member of the public would receive a total effective dose of less than 0.5 mrem/year. Further, if the licensee released liquid effluents at 20 percent of the 10 CFR Part 20 release limits and if a member of the public were able to directly consume this contaminated liquid effluent, that member of the public would receive a total effective dose of less than 10 mrem/year. Therefore, effluent releases from the RMSA will be limited to an annual average of not more than 20 percent of the 10 CFR Part 20 limit and, in accordance with ALARA, any discharge above 20 percent of the limit will be investigated and corrective measures will be taken and documented. This condition will ensure that the maximum potential dose to a member of the public is less than 10 mrem/year. Therefore, the impact on the human environment due to the release of potentially radioactive contaminated liquid effluent from either the RMSA or the retention pond is insignificant.

Further, the low-level waste disposal facility, Envirocare, eligible to receive this waste, is regulated under State of Utah rules for land disposal of radioactive wastes, which provide for long-term institutional control and minimize the potential for human intrusion and other environmental impacts. Therefore, NRC staff believes that disposing of the Acid Sludge Pit 4 radiologically contaminated wastes at the Envirocare facility will not cause any significant impacts on the human environment and is acceptable. The conditions and restrictions placed on the Envirocare facility, combined with the facility design provisions and its location, provide an acceptable level of protection of human health and safety and the environment.

Conclusions

Based on NRC staff's evaluation of the licensee's Acid Sludge Pit 4 remediation plan and placement of radioactive contaminated material into the RMSA, NRC staff has determined that the proposed plan and use of the RMSA complies with NRC's public and occupational dose and effluent limits, and that authorizing the proposed activities by license amendment would not be a major Federal action significantly affecting the quality of the human environment. NRC staff concludes that a finding of no significant impact is justified and appropriate, and that an environmental impact statement is not required. In accordance with the requirements of Subpart L of 10 CFR Part 2, an Opportunity for a Hearing was offered.[1]

Finding of No Significant Impact

Pursuant to 10 CFR Part 51, NRC has prepared an environmental assessment related to the issuance of a license amendment to Materials License SNM–1999, authorizing remediation of Acid Sludge Pit 4 and placement of radioactive contaminated material into the RMSA. On the basis of this environmental assessment, NRC has concluded that this licensing action would not have any significant effect on the quality of the human environment and does not warrant the preparation of an environmental impact statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

Further Information

For further details with respect to this action, the Environmental Assessment and other documents related to this proposed action are available for public inspection and copying at NRC's Public Document Room at the Gelman Building, 2120 L Street NW., Washington, DC.

Dated at Rockville, Maryland, this 15th day of July 1998.

For the Nuclear Regulatory Commission.

Lawrence G. Bell,

Acting Chief, Low-Level Waste and Decommissioning Projects Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–19972 Filed 7–24–98; 8:45 am]

BILLING CODE 7590–01–P

[1] 60 **Federal Register** 46318 (September 6, 1995).

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATES: Wednesday, July 29, 1998.

PLACE: NRC Headquarters, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of July 27

Wednesday, July 29

2:00 p.m.

Briefing on Operating Reactors and Fuel Facilities (Public meeting)

4:00 p.m.

Affirmation Session (Public meeting)

*(Please note: This item will be affirmed immediately following the conclusion of the preceding meeting.)

a: Private Fuel Storage, L.L.C.; Atomic Safety and Licensing Board Memorandum and Order, LBP–98–7 (April 22, 1998)

(Tentative)

*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: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.htm

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 it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661). 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 wmh@nrc.gov or dkw@nrc.gov.

Annette L. Vietti-Cook,

Acting Secretary, Office of the Secretary.

[FR Doc. 98–20102 Filed 7–23–98; 11:30 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued for public comment a proposed revision of a guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide, temporarily identified by its task number, DG–8022 (which should be mentioned in all correspondence concerning this draft guide), is a proposed Revision 1 to Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." The guide is in Division 8, "Occupational Health." This proposed revision is being developed to provide updated guidance on the elements of a respiratory protection program that is acceptable to the NRC. This draft guide provides guidance that is in conformance with the proposed revision to 10 CFR part 20, "Standards for Protection Against Radiation," of Subpart H, "Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas," which was published recently.

The draft guide has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on Draft Regulatory Guide DG–8022. The related NUREG–0041, "Manual of Respiratory Protection Against Airborne Radioactive Material," is currently being revised to be consistent with the revision to part 20. Comments and suggestions are also solicited regarding the scope and content of this NUREG. Comments may be accompanied by additional relevant information or supporting data. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by September 30, 1998.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301)415–5905; e-mail CAG@nrc.gov.

Although a time limit is given for comments on this draft guide, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC. Requests for single copies of draft or final guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Reproduction and Distribution Services Section; or by fax at (301)415–2289; or GRW1@NRC.GOV by email. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this 16th day of July 1998.

For the Nuclear Regulatory Commission.

John W. Craig,

Director, Division of Regulatory Applications, Office of Nuclear Regulatory Research.

[FR Doc. 98–19969 Filed 7–24–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued for public comment a draft of a guide planned for its Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide, temporarily identified by its task number, DG–1069 (which should be mentioned in all correspondence concerning this draft guide), is titled "Fire Protection Program for Nuclear Power Plants During Decommissioning and Permanent Shutdown." The guide is intended for Division 1, "Power Reactors." This draft guide is being developed to describe methods acceptable to the NRC staff for complying with the NRC's regulations regarding fire protection programs during decommissioning for licensees who have permanently shut down their operations.

The draft guide has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on Draft Regulatory Guide DG–1069. Comments would be particularly welcome on whether there is a need for additional guidance on the content of fire hazard analyses.

Comments may be accompanied by additional relevant information or supporting data. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by October 5, 1998.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905; e-mail CAG@nrc.gov.

Although a time limit is given for comments on this draft guide, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC. Requests for single copies of draft or final guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section; or by fax at (301) 415–5272. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this 15th day of July 1998.

For the Nuclear Regulatory Commission.

John W. Craig,

Director, Division of Regulatory Applications, Office of Nuclear Regulatory Research.

[FR Doc. 98–19970 Filed 7–24–98; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Sunshine Act Meeting

TIMES AND DATES: 1:00 p.m., Monday, August 3, 1998; 8:30 a.m., Tuesday, August 4, 1998.

PLACE: Harrisburg, Pennsylvania, at the U.S. Postal Service Processing and Distribution Center, 1425 Crooked Hill Road, in the Second Floor Conference Room 219.

STATUS: August 3 (Closed); August 4 (Open).

MATTERS TO BE CONSIDERED:

Monday, August 3—1:00 p.m. (Closed)

1. Compensation issues.

Tuesday, August 4—8:30 a.m. (Open)

1. Minutes of the Previous Meeting, June 29–30, 1998.
2. Remarks of the Postmaster General/ Chief Executive Officer.
3. Consideration of Amendments to BOG Bylaws.
4. Quarterly Report on Service Performance.
5. Quarterly Report on Financial Results.
6. Report on the Allegheny Area and Harrisburg Performance Cluster.
7. Capital Investments.
   a. 416 Truck Tractors.
   b. Forwarding Control Systems for the Computerized Forwarding Systems
   c. 54 Small Parcel and Bundle Sorters.
   D. Identification Code Sort and Pilot Development Management-Integrated Operations Management.
   e. Chicago, Illinois, Busse Surface Hub Modification.
   f. Self Service Vending Equipment
8. Tentative Agenda for the August 31–September 1, 1998, meeting in Washington, D.C.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Koerber, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, S.W., Washington, D.C. 20260–1000. Telephone (202) 268–480.

Thomas J. Koerber,

Secretary.

[FR Doc. 98–20148 Filed 7–23–98; 2:39 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26897]

Filing Under the Public Utility Holding Company Act of 1935, as amended ("Act")

July 20, 1998.

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 amendments is/are available for public inspection through the Commission's Office 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 13, 1998, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declaration(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of fact 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 13, 1998, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Sempra Energy, et al. (70–9333)

Sempra Energy ("Sempra"), located at 101 Ash Street, San Diego, California 92101, an exempt holding company under section 3(a)(1) of the Act, and an indirect subsidiary of Sempra, Frontier Pacific, Inc. ('Frontier Pacific"), located at 555 West Fifth Street, Suite 2900, Los Angeles, California 90013–1001, have filed an application under sections 3(a)(1), 9(a)(2), and 10 of the Act.

Applicants seek authority for Frontier Pacific to acquire up to 90.1% of the outstanding shares of Frontier Energy, LLC ("Frontier Energy"), a North Carolina partnership that will construct, own and operate a gas utility distribution system in North Carolina. The remaining membership interests in Frontier Energy would be acquired by a third party, Frontier Utilities of North Carolina, Inc. ("Frontier Utilities".[1]) In addition, applicants are seeking an order under section 3(a)(1) exempting Sempra, Frontier Pacific, and each of their subsidiary companies from all provisions of the Act, except section 9(a)(2).

Sempra has two principal subsidiaries, Pacific Enterprises ("Pacific") and Enova Corporation ("Enova"), each of which is an exempt holding company under section 3(a)(1) of the Act. Pacific's sole utility subsidiary is Southern California Gas Company ("SoCalGas"), which purchases, transports and distributes natural gas in southern California. As of December 31, 1997, Pacific reported consolidated total assets of $4.977 billion, of which approximately $3.154 billion consisted of net gas utility plant. For the year ended December 31, 1997, Pacific reported $2.738 billion in operating revenues (including revenues from transportation-only customers) and $184 million in net income.

Enova's sole utility subsidiary is San Diego Gas & Electric Company ("SDG&E"), which provides electric and natural gas service in San Diego and surrounding areas. As of December 31, 1997, Enova reported consolidated total assets of $5.2 billion, of which approximately $2.49 billion consists of net electric plant and $449 million consists of net gas utility plant. For the year ended December 31, 1997, Enova reported operating revenues of $2.2 billion (81.6% from electricity sales and 18.4% from gas sales) (including revenues from transportation only customers), and $252 million in net income. Both SoCalGas and SDG&E are subject to the jurisdiction of the California Public Utility Commission.

Frontier Pacific, which will directly acquire interests in Frontier Energy, currently is a wholly owned subsidiary of Sempra Energy Solutions, LLC ("Solutions"), itself an indirect subsidiary of Sempra.[2] However, applicants state that Solutions will transfer the common stock of Frontier Pacific to Sempra prior to the issuance of any order in this filing.

By orders dated January 27, 1996, August 16, 1996, and March 27, 1997, the North Carolina Utilities Commission ("NCUC") granted Frontier Utilities certificates of public convenience and necessity ("Certificates") to construct, test, market, own and operate a new

[1] Frontier Utilities is an indirect subsidiary of ARB, Inc., a closely held California corporation. ARB, Inc. is not now a "holding company" or an "affiliate" of any "holding company" or "public-utility company," as defined in section 2 of the Act.

[2] Solutions currently is jointly owned by Pacific and Enova.

natural gas distribution system in seven counties in northwestern North Carolina. By order dated March 9, 1998, the NCUC approved various proposals by Frontier Utilities and Frontier Energy related to the financing for the construction of this gas system, including participation by Frontier Pacific as an equity investor in Frontier Energy.[3] In addition, the NCUC authorized Frontier Utilities to transfer the Certificates to Frontier Energy.

Frontier Energy commenced construction in four of the counties during the second quarter of 1998. When complete, the system in these counties will consist of approximately 140 miles of transmission mains, including a 40 mile lateral tap off the interstate pipeline facilities of Transcontinental Gas Pipe Line Corp. and at least 320 miles of distribution mains. Construction in the other counties will commence at a later date. Applicants state that attributable income from Frontier Energy will contribute less than 1% of Sempra's consolidated income on a *pro forma* basis.

Following the proposed transactions, Sempra and each of its public utility subsidiaries, except Frontier Energy and Frontier Pacific, will be organized in California. Frontier Energy and Frontier Pacific will be organized in North Carolina. Applicants contend that they, and each of their subsidiaries, will qualify for a section 3(a)(1) exemption upon consummation of the proposed transactions.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19982 Filed 7–24–98; 8:45 am]

BILLING CODE 8010–01–M

[3] Specifically, the NCUC authorized Frontier Pacific and Frontier Utilities to contribute approximately $12 million of equity and capital to Frontier Energy. In addition, the NCUC authorized Frontier Energy to borrow $40 million, subject to certain conditions.

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–23323; 812–11172]

Weiss, Peck & Greer Funds Trust, et al.; Notice of Application

July 21, 1998.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under Section 6(c) of the Investment Company Act of 1940 (the "Act") from Section 15(a) of the Act.

SUMMARY OF APPLICATION: The requested order would permit the implementation, without prior shareholder approval, of new investment advisory and subadvisory agreements (the "New Advisory Agreements") for a period of up to 90 days following the consummation of the acquisition of the outstanding membership interests of Weiss, Peck & Greer, L.L.C. ("WPG") by Robeco Groep N.V. ("Robeco") (but in no event later than October 31, 1998) (the "Interim Period"). The order would also permit payment of all fees earned under the new advisory agreements during the Interim Period following shareholder approval.

APPLICANTS: Weiss, Peck & Greer Funds Trust, on behalf of WPG Government Money Market Fund, WPG Tax Free Money Market Fund, WPG Core Bond Fund, WPG Intermediate Municipal Bond Fund, and WPG Quantitative Equity Fund; Tomorrow Funds Retirement Trust, on behalf of Tomorrow Long-term Retirement Fund, Tomorrow Medium-Term Retirement Fund, and Tomorrow Short-Term Retirement Fund; SEI Tax Exempt Trust, on behalf of SEI Institutional Tax Free Portfolio, SEI Pennsylvania Tax Free Portfolio, SEI California Tax Free Portfolio, and SEI Tax Free Portfolio; Weiss, Peck & Greer International Fund ("International Fund"); WPG Growth and Income Fund; WPG Growth Fund. WPG Tudor Fund; and RWB/WPG U.S. Large Stock Fund (collectively, the "Funds"); and WPG.

FILING DATES: The application was filed on June 15, 1998, and amended on July 17, 1998.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 18, 1998, and should be accompanied by proof of service on applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants: if to Weiss, Peck & Greer Funds Trust; Tomorrow Funds Retirement Trust; Weiss, Peck & Greer International Fund; WPG Growth and Income Fund; WPG Growth Fund; WPG Tudor Fund; RWB/WPG U.S. Large Stock Fund; or WPG, One New York Plaza, New York, NY 10004; if to SEI Tax Exempt Trust, One Freedom Valley Drive, Oaks, PA 19456.

FOR FURTHER INFORMATION CONTACT: Timothy R. Kane, Staff Attorney, at (202) 942–0615, or Edward P. Macdonald, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 25049 (tel. 202–942–8090).

Applicants' Representations

1. Each Fund is either an open-end management investment company registered under the Act or a series of the company. Weiss, Peck and Greer Funds Trust currently offers five series: WPG Government Money Market Fund, WPG Tax Free Money Market Fund, WPG Intermediate Municipal Bond Fund, WPG Core Bond Fund, and WPG Quantitative Equity Fund. Tomorrow Funds Retirement Trust includes, for purposes of this application, three Series: Tomorrow Long-term Retirement Fund, Tomorrow Medium-Term Retirement Fund, and Tomorrow Short-term Retirement Fund. SEI Tax Exempt Trust includes, for purposes of this application, four series: SEI Institutional Tax Free Portfolio, SEI Pennsylvania Tax Free Portfolio, SEI California Tax Free Portfolio, and SEI Tax Free Portfolio. Each of the other Funds is a single series investment company. Tomorrow Funds Retirement Trust and RWB/WPG U.S. Large Stock Fund are organized as Delaware business trusts. All the other Funds are organized as Massachusetts business trusts.

2. WPG serves as the investment adviser to each Fund pursuant to a separate investment advisory agreement and is an investment adviser registered under the Investment Advisers Act of 1940 ("Advisers Act"). Hill Samuel Asset Management Limited ("Hill Samuel") serves as the investment subadviser to the International Fund pursuant to an investment subadvisory agreement (together with the investment advisory agreements, the "Current Advisory Agreements") and is an investment adviser registered under the Advisers Act.

3. The owners of the outstanding voting securities of WPG ("Sellers")

have agreed to sell to Robeco all of their interests in WPG (the "Acquisition"). After the Acquisition, WPG will be a wholly-owned subsidiary of Robeco. The Acquisition is expected to close during the third quarter of 1998.

4. The Acquisition will result in the assignment and automatic termination of the Current Advisory Agreements. The Board of Trustees ("Board"), including a majority of the Independent Trustees ("Independent Trustees"), of SEI Tax Exempt Trust met on May 18 and June 10, 1998, and approved the New Advisory Agreements between WPG and each of the SEI Funds.[1] The Boards, including a majority of the Independent Trustees, of the WPG Funds met on May 19, 1998, and approved he New Advisory Agreements between WPG and each of the WPG Funds and among Hill Samuel, WPG, and the International Fund. Each New Advisory Agreement contains the same terms and conditions as its corresponding Current Advisory Agreement except for the dates of execution, effectiveness, and termination and the inclusion of escrow arrangements, discussed below.[2]

5. Applicants propose to enter into an escrow arrangement with an unaffiliated escrow agent. Fees earned by WPG during the Interim Period under the New Advisory Agreements would be paid into an interest-bearing escrow account. The escrow agent would release the monies in the escrow account attributable to a Fund (a) to WPG only upon shareholder approval of the New Advisory Agreement by the Fund's shareholders, or (b) to the Fund if the Interim Period has ended and the New Advisory Agreement is not approved by shareholders. Before the escrow agent releases the monies, the Board of the appropriate Fund would be notified.

Applicant's Legal Analysis

1. Section 15(a) of the Act makes it unlawful for any person to serve or act as investment adviser of a registered investment company, except pursuant to a written contract that has been approved by the vote of a majority of the outstanding voting securities of such registered company, and that such written contract provide for automatic termination in the event of its "assignment." Section 2(a)(4) of the Act defines "assignment" to include any direct or indirect transfer of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor.

2. Applicants state that upon consummation of the Acquisition, Robeco will acquire all of WPG's outstanding voting securities, resulting in the "assignment" and termination of each Current Advisory Agreement.

3. Rule 15a–4 under the Act provides, among other things, that if an investment advisory contract with an investment company is terminated by assignment, an investment adviser may act as such for the company pursuant to a written contract that has not been approved by that company's shareholders during the 120-day period following such termination, *provided that* (1) The new contract is approved by that company's board of directors, including a majority of the non-interested directors; (2) the compensation to be paid under the new contract does not exceed the compensation that would have been paid under the contract most recently approved by the company's shareholders; and (3) neither the adviser nor any controlling person of the adviser "directly or indirectly receive[s] money or other benefit" in connection with the assignment. However, applicants state that they cannot rely on Rule 15a–4 because the Sellers will be receiving a benefit from the Acquisition.

4. Section 6(c) of the Act provides that the SEC may exempt any person, security, or transaction, from any provision of the Act if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an order under Section 6(c) of the Act to permit the implementation, without prior shareholder approval, of the New Advisory Agreements.

5. Applicants state that the form and timing of the Acquisition were determined in response to a number of business factors primarily unrelated to the Funds. Applicants assert that there is insufficient time to obtain shareholder approval of the New Advisory Agreements before the Acquisition is consummated. Applicants further assert that the requested relief would prevent any disruption in the delivery of investment advisory services to the Funds during the Interim Period.

6. Applicants state that the Boards, including a majority of the Independent Trustees, after evaluation and with the advice of counsel, voted to approve the New Advisory Agreements to become effective upon the termination of the Current Advisory Agreements and to submit the New Advisory Agreements to the shareholders of each of the Funds for approval. The Boards received from WPG information reasonably necessary to evaluate, among other things, the terms of the New Advisory Agreements and determined that the New Advisory Agreements were in the best interests of the Funds and their respective shareholders.

7. Fees earned by WPG during the Interim Period would be paid into an interest-bearing account maintained by an independent escrow agent who would release the monies either to WPG upon shareholder approval of the New Advisory Agreement, or to the Fund if the Interim Period has ended and the shareholders have not approved the New Advisory Agreement.

8. Applicants state that the requisite shareholder meetings are scheduled to be held on July 29, 1998, for all Funds. Applicants further state that the requested relief would facilitate the orderly and reasonable consideration of the New Advisory Agreements with respect to those Funds for which a quorum of shareholders has not been obtained.

9. Applicants submit that the scope and quality of services provided to the Funds during the Interim Period will not be diminished. The applicants represent that, during the Interim Period, each Fund will receive advisory services of at least equivalent scope and quality, and such services will be provided by the same personnel (including managing directors and portfolio managers) under the New Advisory Agreements as it received under the Current Advisory Agreements. Further, the New Advisory Agreements have the same terms and conditions as the Current Advisory Agreements, except for the dates of execution, effectiveness, and termination and the inclusion of escrow arrangements.

Applicant's Conditions

Applicants agree that any order of the SEC granting the requested relief will be subject to the following conditions:

1. The New Advisory Agreements will have the same terms and conditions as the Current Advisory Agreements, except in each case for the dates of

[1] In this notice, the SEI Tax Exempt Trust is occassionally referred to as the "SEI Funds," and all other Funds are occassionally referred to as the "WPG Funds."

[2] The New Advisory Agreements approved by the Boards of the WPG Funds do not include the escrow arrangements. The Boards of the WPG Funds will meet on July 22, 1998, to consider including the escrow arrangements. Applicants acknowledge that, with respect to each WPG Fund's New Advisory Agreement, they may not rely on the requested order unless the respective Boards, including a majority of the Independent Trustees, approve including the escrow provisions in the New Advisory Agreements prior to the consummation of the Acquisition.

execution, effectiveness, and termination and the inclusion of escrow arrangements.

2. Fees earned by WPG during the Interim Period under the New Advisory Agreements will be maintained in interest-bearing escrow accounts with an unaffiliated escrow agent, and the amounts in such accounts (including interest earned on such amounts) will be paid (a) to WPG only upon approval of the New Advisory Agreements by the Funds' respective shareholders or (b) in the absence of such approval by shareholders of a Fund, to such Fund.

3. The Funds will hold special meetings of shareholders to vote on the approval or disapproval of the New Advisory Agreements on or before October 31, 1998.

4. WPG will bear the costs relating to the preparation and filing of this application and the costs relating to the solicitation of the approvals of the Funds' shareholders of the New Advisory Agreements necessitated by the Acquisition; *provided, however,* that the Funds may bear a portion of the cost of soliciting shareholders approval for proposals unrelated to the Acquisition.

5. WPG will take all appropriate actions to ensure that the scope and quality of advisory and other services provided to the Funds during the Interim Period under the New Advisory Agreements will be at least equivalent, in the judgment of the Boards, including a majority of the Independent Trustees, to the scope and quality of services provided under the Current Advisory Agreements. In the event of any material change in personnel providing services pursuant to the New Advisory Agreements during the Interim Period, WPG will apprise and consult the Boards of the affected Funds to assure that such Board, including a majority of the Independent Trustees, are satisfied that the services provided by WPG will not be diminished in scope or quality.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19983 Filed 7–24–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40228; File No. SR–Amex–98–24]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange, Inc. Relating to the Listing and Trading of Merrill Lynch EuroFund Market Index Target Term Securities

July 17, 1998.

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 June 30, 1998, the American Stock Exchange, Inc. ("Exchange" or "Amex") 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 seeks to list and trade under Section 107A of the Exchange's Company Guide, Merrill Lynch EuroFund Market Index Target Term Securities SM ("MITTS® Securities"). The value of the MITTS Securities will be based in whole or in part on changes in the value of the Merrill Lynch EuroFund Index ("EuroFund Index").

The text of the proposed rule change is available at the Office of the Secretary, the Exchange and at the Commission.

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under Section 107A of the Exchange's *Company Guide,* the Exchange may approve for listing and trading securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures, or warrants.[3] The Exchange seeks to list the MITTS Securities for trading under Section 107A of the Exchange's *Company Guide.* The MITTS Securities are structured as mutual fund linked notes, the value of which will be linked, in whole or in part, to the adjusted total return value of Class B Shares of the Merrill Lynch EuroFund ("EuroFund"),[4] a mutual fund registered under the Investment Company Act of 1940. The EuroFund is a "diversified company" as defined in Section 5(b) of the Investment Company Act of 1940[5] and the securities held by the EuroFund are issued by companies based in five or more countries.

The Exchange represents that MITTS Securities will be senior, unsecured debt securities that will conform to the listing guidelines under Section 107A of the Exchange's *Company Guide.* Although a specific maturity date will not be established until the time of the offering, the MITTS Securities will provide for a maturity of between two and seven years from the date of issuance. MITTS Securities may provide for periodic payments and/or payments at maturity based in whole or in part on changes in the value of the EuroFund Index, an index based on the adjusted total return of the Class B Shares of the EuroFund.[6] At maturity, holders of the

[3] Securities Exchange Act Release No. 27753 (Mar. 1, 1990), 55 FR 8626 (Mar. 8, 1990).

[4] According to the prospectus prepared by the underwriter, the Eurofund is a diversified, open-end management company that seeks to provide shareholders with capital appreciation primarily through investment in equities of corporations domiciled in European countries. While there are no prescribed limits on geographic distribution within the European community, it currently is anticipated that a majority of the EuroFund's assets will be invested in equity securities of issuers domiciled in Western European countries. Current income from dividends and interest will not be an important consideration in selecting portfolio securities. The Eurofund expects that under normal market conditions at least 80% of its net assets will be invested in European corporate securities, primarily common stocks, and debt and preferred securities convertible into common stocks.

[5] 15 U.S.C. 80a–5(b).

[6] The EuroFund Index will measure the adjusted total return value of Class B Shares of the EuroFund. The total return value reflects the change in net asset value of Class B Shares of the

Continued

MITTS Securities will receive not less than 100% of the initial issue price in either the value of Class D Shares of the EuroFund or cash.

a. *Description of the MITTS Securities and the Underlying Merrill Lynch EuroFund.* Similar to equity linked term notes that are listed for trading pursuant to Section 107B of the Exchange's *Company Guide*, the MITTS Securities will have a limited term of between two and seven years. In addition: (i) both the issue (MITTS Securities) and the issuer (Merrill Lynch & Co., Inc.) meet the general criteria set forth in Section 107A of the Exchange's *Company Guide*; (ii) the issuer has a minimum tangible net worth in excess of $250,000,000 and otherwise substantially exceeds the earnings requirements set forth in Section 101(A) of the Exchange's *Company Guide*; (iii) the EuroFund has total net assets of approximately $2.16 billion; and (iv) the EuroFund's net asset value ("NAV") is reported each day through the facilities of the National Association of Securities Dealers Automated Quotation System ("Nasdaq"). The continued listing guidelines governing the MITTS Securities are set forth in Sections 1001 through 1003 of the Exchange's *Company Guide*. In particular, Section 1003(b) regarding suspensions and delistings with respect to limited distribution and reduced market value will apply to MITTS Securities.

b. *Calculation and Dissemination of Net Asset and Index Values.* The EuroFund Index shall measure the adjusted total return of Class B Shares of the EuroFund. Such amount shall be equal to the change in price of EuroFund Class B Shares, plus cash dividends and distributions paid on EuroFund Class B Shares, less a percentage equal to approximately 2.25%–2.75%, each year, of the value of the EuroFund Index. The percentage reduction of the EuroFund Index will be applied to the total return of EuroFund Class B Shares on a pro rata basis each calendar day. This adjusted total return value will be disseminated once a day over the Consolidated Tape Association's Network B.[7]

In addition to the dissemination of the adjusted total return value, the EuroFund's NAV will be disseminated through the facilities of Nasdaq. If the EuroFund does not comply with Rule 22c–1 under the Investment Company Ac tof 1940,[8] which requires daily computation of a fund's current NAV, the Exchange will use the last available price in its calculation.

c. *Settlement of MITTS Securities.* Although the value of MITTS Securities will be calculated using EuroFund Class B Shares, MITTS Securities will settle in Class D Shares of the EuroFund. Under the proposal, MITTS Securities will settle by delivery of the number of Class D Shares of the EuroFund equal in value to the principal amount ($10 per MITTS Security) plus the Supplemental Redemption Amount,[9] if any, based on the NAV for Class D Shares determined on a specified data prior to the stated maturity of the MITTS Securities.[10] If the issuer is unable to deliver the Class D Shares because the EuroFund is not issuing Class D Shares to new investors in the EuroFund as of the date immediately prior to the stated maturity date, it will pay the equivalent amount in cash.

d. *Exchange Rule Applicable to MITTS.* Because MITTS Securities are linked to a portfolio of equity securities, the Exchange's equity floor trading rules and regular equity trading hours (9:30 a.m. to 4:00 p.m. Eastern Standard Time) will govern the trading of MITTS Securities. In addition, MITTS Securities will be subject to the equity margin rules of the Exchange.

In accordance with Exchange Rule 411, the Exchange shall impose a duty of due diligence on its members and member firms to determine the essential facts relating to customers prior to their purchasing and trading MITTS Securities. Furthermore, consistent with the offering of other structured products, the Exchange will distribute a circular to its membership prior to the commencement of trading in MITTS Securities to provide guidance regarding member frim compliance responsibilities, including appropriate suitability criteria and/or guidelines. The circular shall require that before a member, member organization, or employee of such member organization, undertakes to recommend a transaction in a MITT Security, such member or member organization should make a determination that the MITTS Security is suitable for such customer. As part of that determination, the person making the recommendation should have a reasonable basis for believing at the time of making the recommendation, that the customer has such knowledge and experience in financial matters that they may be capable of evaluating the risks and the special characteristics of the recommended transaction, including those highlighted, and that the customer is financially able to bear the risks of the recommended transaction. Lastly, as with other structured products, the Exchange will closely monitor activity in MITTS Securities to identify and deter any potential improper trading activity in the MITTS Securities.

2. *Statutory Basis*

The Exchange believes the proposed rule change in consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5),[12] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in facilitating transactions in securities, and remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

EuroFund, plus cash dividends and distributions paid on those shares. The Amex will calculate the EuroFund Index value each day by reducing the EuroFund Index value by a percentage equal to the pro rata portion of an annual reduction factor. The annual reduction factor is expected to be between 2.25% and 2.75% and will be determined on the date that the MITTS Securities are priced for initial sale to the public. Holders of Class B Shares receive the value of their shares plus cash dividends and distributions paid on those shares less fees. Holders of the MITTS Securities receive at maturity the principal amount of their investment plus a Supplemental Redemption Amount based on the adjusted total return of Class B Shares of the Eurofund (as described above) which may be lower than what a holder of Class B EuroFund Shares might receive. The Amex represents that 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 MITTS Securities.

[7] The Exchange represents that the EuroFund's value is updated only at the close of trading each day because that is the only time when the EuroFund's NAV is determined and disseminated. The Exchange believes this should not pose an obstacle to the trading of the MITTS Securities, anymore than it prevents investors from entering intra-day orders to purchase or redeem shares of the EuroFund's itself at a closing NAV that is unknown as the time the orders are entered.

[8] 17 CFR 270.22c–1.

[9] The Supplemental Redemption Amount, which may not be less than zero, will equal the principal amount ($10) multiplied by the percentage difference between the ending value of the EuroFund Index and the starting value [$10 ((ending EuroFund Index value—starting EuroFund Index value)/starting EuroFund Index value)]. The ending and starting EuroFund Index values used to calculate the Supplemental Redemption Amount shall reflect the application of the annual reduction fee.

[10] The specified date shall be two business days prior to the stated maturity of the MITTS Securities. Telephone conversation between Sharon Lawson, Senior Special Counsel, Division of Market Regulation, Commission; Cliare McGrath, Vice President and Special Counsel, Exchange; and Thomas Lee, Vice President of Customized Investments, Merrill Lynch (July 16, 1998).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange did not solicit or receive written comments with respects 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 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 the 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 is consistent with the Act. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submissions, all subsequent amendments, all written statement 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 persons, other than those that may be withheld from the public in accordance with the provisions of U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Amex–98–24 and should be submitted by August 17, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19987 Filed 7–24–98; 8:45 am]

BILLING CODE 8010–01–M

[13] 17 CFR 200.20–3(c)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40235; File No. SR–CHX–98–09]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by The Chicago Stock Exchange, Incorporated Amending the SuperMax and Enhanced SuperMax Algorithms

July 17, 1998.

I. Background

On April 20, 1998, noticed is hereby given that on April 20, 1998, the Chicago Stock Exchange, Incorporated ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] The proposed rule change was published for comment in the **Federal Register**.[2] The Commission granted accelerated approval to part of the proposal, the new SuperMAX algorithm, on a temporary basis until August 20, 1998. No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change on a permanent basis.

II. Description of the Proposal

The Exchange proposes to amend its SuperMax and Enhanced SuperMAX programs, located in subsections (c) and (e) of Rule 37 of Article XX. Specifically, the Exchange is proposing new algorithms to provide automated price improvement under SuperMax and Enhanced SuperMAX in 1/16th point markets.[3]

In 1997, virtually every registered national securities exchange and national securities association changed their minimum trading variation to one sixteenth of a point or smaller. Although the CHX made some technical changes to its SuperMax and Enhanced SuperMax programs at that time in light of assumptions as to the smallest minimum variation that were contained in the text of the SuperMax and Enhanced SuperMax rules, the CHX did not change the algorithms to reflect the additional price improvement opportunities that are available because of trading in sixteenths.[4] The purpose of the proposed rule change is to amend the existing programs to both simplify the price improvement algorithms and increase the number of orders that are eligible for price improvement due to the smaller minimum trading variation.[5]

Under the new simplified algorithm for SuperMax, small agency market orders[6] would now be eligible for price improvement if the market for the security is quoted with a spread of 1/8 of a point or greater (rather than the 1/4 point spread that is required under the existing rule). In addition, the double-up/double-down concept has been eliminated. The simplified algorithm will now provide 1/16th of a point price improvement from the Intermarket Trading System ("ITS") best bid or offer ("BBO") if an execution at the ITS BBO would be at least 1/8th point higher than (for a buy order) or lower than (for a sell order) the last primary market sale. Basically price improvement is given under certain circumstances when the security is trading between the spread. All other aspects of the existing algorithm, including operating time, timing of execution, applicability to odd-lots, and out of range situations, remain the same.

With respect to Enhanced SuperMax, the Exchange proposes to make this program an add-on feature for securities for which the SuperMax program has already been activated, rather than a stand-alone program. As stated in the Exchange's Report on the operation of the Enhanced SuperMax program that was provided to the Commission in advance of the Commission's permanent approval of Enhanced SuperMax program, taken as a whole, the existing SuperMax program provides more price improvement than the existing Enhanced SuperMax program. The Exchange believes that interconnecting the two programs will encourage more specialists to enable the SuperMax program, with greater resulting price improvement, since the Enhanced SuperMax program will only be available when SuperMax is enable.

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 40017 (May 20, 1998), 63 FR 29277 (May 28, 1998).

[3] Both the SuperMAX and Enhanced SuperMAX programs have been approved by the Commission on a permanent basis. *See* Securities Exchange Act Release No. 32631 (July 14, 1993), 58 FR 39069 (July 21, 1993) (File No. SR–MSE–93–10) (Order approving SuperMax on a permanent basis), Securities Exchange Act Release No. 38338 (February 26, 1997), 62 FR 10102 (March 5, 1997) (File No. SR–CHX–97–02) (Order approving Exchange SuperMax on a permanent basis).

[4] *See* Securities Exchange Act Release No. 38816 (July 3, 1997), 62 FR 37325 (July 11, 1997) (File No. SR–CHX–97–18).

[5] Rather than amending the existing text of the SuperMax and Exchange SuperMax rules, the text of the existing rule has been deleted and replaced with new language. This was done to permit the Exchange to re-write the rule, with non-substantive changes, to clarify some language in the old rule that may have been ambiguous.

[6] Under the proposal, small agency market orders for SuperMax would be orders from 100 shares to 499 shares (or a greater amount chosen by the specialist).

Currently, some specialists have only turned on the Exchange Super Max program without enabling the SuperMax program.

Under the new simplified algorithm for Enhanced SuperMax, small agency market orders[7] would be eligible for price improvement if the market for the security is quoted with a spread of 3/16 of a point (rather than the 1/4 point spread that is required under the existing rule). In addition, the double-up/double down concept currently in place to determine whether an order is stopped has been eliminated. The simplified algorithm will now "stop" an eligible order at the ITS BBO if an execution at the ITS BBO would be at least 1/8 point higher than (for a buy order) or lower than (for a sell order) the last primary market sale. (This stopping algorithm is identical to the new algorithm above for SuperMax.) Once stopped, an order would receive 1/16 price improvement over the stopped price if the next primary market sale occurs before the end of the Time Out Period and the sale is at least 1/8 of a point lower than (for a buy order) or higher than (for a sell order) the stopped price. As is the case for SuperMax, all other aspects of the existing algorithm, including operating time, timing of execution, applicability to odd-lots, and out of range situations, remain the same.

III. Discussion

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. Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[8] which requires that the rules of an exchange be designed, among other things, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

On May 22, 1995, the Commission approved a proposed rule change of the CHX that allows specialists on the Exchange, through the Exchange's MAX system, to provide order execution guarantees that are more favorable than those required under CHX Rule 37(a), Article XX.[9] That approval order contemplated that the CHX would file with the Commission specific modifications to the parameters of MAX that are required to implement various options available under this new rule.

The Commission believes, in light of the industry's move to trading in finer increments last year, that CHX's modification to price improvement algorithms will provide investors a meaningful opportunity for price improvement when securities trading in 1/16's have a spread of 1/8 point or greater. In addition, the Commission finds that the new SuperMAX and Enhanced SuperMAX rules provide greater price improvement opportunities for investors because the criteria for when such opportunities are available has been simplified.[10] The Commission believes that, because the opportunity for price improvement is automatic and without any specialist intervention, SuperMAX and Enhanced SuperMAX facilitate order interaction and enhance customer orders consistent with Section 6(b)(5) of the Act. The Commission notes that while SuperMAX and Enhanced SuperMAX are voluntary programs that specialists choose to participate in for Dual Trading System issues,[11] providing a greater number of investors an opportunity to achieve price improvement is compatible with the views on best execution expressed in the Order Handling release.[12]

IV. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change, SR–CHX–98–09, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange. In addition, in approving this rule, the Commission notes that it has also considered the proposed rule's impact on efficiency, competition, and capital formation.

It is therefore ordered, pursuant to Section 19(b)(2), of the Act,[13] that the proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19986 Filed 7–24–98; 8:45 am]

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[7] Under the proposal, small agency market orders for Enhanced SuperMax would be orders from 500 shares to 2099 shares (or a greater amount chosen by the specialist). Notwithstanding the 500 share minimum order size contained in the rule, the smallest size order eligible for Enhanced SuperMax must always be at least one share greater than the largest size order in such security that is eligible for SuperMax. In other words, if a specialist voluntarily increases the maximum order size for SuperMax, the minimum order size for Enhanced SuperMax must be increased accordingly.

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 35753 (May 22, 1995), 60 FR 28007 (May 26, 1995) (File No. SR–CHX–95–08).

[10] The Exchange has compared the proposed changes to SuperMax with the existing SuperMax algorithm and believes that the new algorithm will provide price improvement to a greater number of trades. using data for January 1998, the Exchange determined that the proposed changes to the algorithm would have resulted in over 32,000 trades receiving price improvement (for a total savings of $329,000 to customers), as opposed to the 5800 trades that received price improvement (for a total savings of $126,000 to customers) under the existing SuperMax program. This means that the changes to SuperMax would have resulted in customers receiving $203,000 additional dollars of price improvement over the Exchange's existing SuperMax algorithm.

[11] Dual Trading issues are issues traded on the CHX, either through listing on the CHX or pursuant to unlisted trading privileges, and are also listed on either the New York Stock Exchange or the American Stock Exchange.

[12] *See* Securities Exchange Act Release No. 37619A (September 6, 1996), 61 FR 48290 (September 12, 1996).

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40230; File No. SR–MSRB–97–14]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Granting Approval of Proposed Rule Change Relating to Rule G–32, on Disclosures in Connection With New Issues

July 17, 1998.

I. Introduction

On March 12, 1998,[1] the Municipal Securities Rulemaking Board ("Board" or "MSRB") submitted to the Securities and Exchange Commission ("Commission" or "SEC"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[2] and Rule 19b–4 thereunder,[3] a proposed rule change to amend Rule G–32, on disclosures in connection with new issues. The proposed rule change strengthens the provisions of the rule relating to dissemination of official statements among dealers and incorporates a long-standing Board interpretation relating to disclosures required to be made to customers in connection with negotiated sales of new issue municipal securities. Notice of the

[1] The Board initially filed this proposal on December 22, 1997. However, an amendment was filed to restore rule language that the initial proposal deleted. The Board filed Amendment No. 1 on this date.

[2] 15 U.S.C. 78s(b)(1).

[3] 17 CFR 240.19b–4.

proposed rule change appeared in the Federal Register on April 28, 1998.[4] This order approves the proposed rule change.

II. Description of the Proposal

Rule G–32, on disclosures in connection with new issues, provides that no broker, dealer or municipal securities dealer ("dealer") shall sell any new issue municipal securities to a customer unless that dealer delivers to the customer, no later than the settlement of the transaction, a copy of the official statement in final form, if one is being prepared. In connection with a negotiated sale of new issue municipal securities, dealers are also required to deliver to their customers, by no later than settlement with the customer, information regarding, among other things, the initial offering price for each maturity in the new issue (termed the "Offering Price Disclosure Provision"). Managing underwriters and other dealers that sell new issue municipal securities to purchasing dealers are required to furnish copies of the official statement to such purchasing dealers upon request, and dealers acting as financial advisors are also required to ensure that official statements are made available to the underwriters in a timely manner (termed the "Dealer Dissemination Provisions").

The Dealer Dissemination Provisions

All dealers that sell new issue municipal securities to customers, not just dealers that participate in the underwriting of the new issue, are required to deliver official statements to their customers by no later than settlement of their transactions. The Dealer Dissemination Provisions clarify that the onus is on the selling dealer to make official statements for new issues available to all dealers so that they may fulfill their customer delivery obligation under the rule. Dealers that are not part of the underwriting group have indicated from time to time that they have had some difficulty in obtaining official statements from the managing underwriter or other selling dealers on a timely basis. Thus, the amended Dealer Dissemination Provisions of Rule G–32 provide a specific timeframe and method for delivery of official statements to purchasing dealers.

The rule language outlining the managing underwriter's primary dissemination responsibilities has been modified for clarity. The amended rule language adds a requirement that the official statement be sent by the managing underwriter to the purchasing dealer no later than the business day after the request or, if the official statement has not been received from the issuer or its agent, the business day after receipt. The managing underwriters would be required to send official statements by first class mail or other equally prompt means unless the purchasing dealer arranges some other method of delivery at its own expense.[5] The amendments also add a requirement that the selling dealer send the official statement to the purchasing dealer within the same timeframe and by the same means as would be required of the managing underwriter.

The proposed rule change retains the existing requirement under Rule G–32 that a dealer acting as financial advisor that prepares an official statement on behalf of an issuer must make that official statement available to the managing or sole underwriter, but would change the timing for such availability from "promptly after the award is made," as provided in the current rule, to "promptly after the issuer approves distribution" of the official statement in final form. The amendment ensures that, once the official statement is completed and approved by the issuer for distribution, dealers acting as financial advisors will be obligated to commence the dissemination process promptly.[6] Issuers using the services of non-dealer financial advisors are urged to hold these financial advisors to the same standards for prompt delivery of official statements to the underwriters, as those of regulated financial advisors.

The Offering Price Disclosure Provision

Since January 1983,[7] the Board has interpreted the Offering Price Disclosure Provision to require that the initial offering price of all maturities of a new issue of municipal securities in a negotiated offering must be disclosed to customers, even for maturities that are not reoffered. The amendment to the Offering Price Disclosure Provision of Rule G–32 incorporates into the rule language this long-standing Board interpretation. The application of the Offering Price Disclosure Provision to maturities that are not reoffered allows customers to determine whether the price they paid for a new issue municipal security is substantially different from the price being paid by presale purchasers.

III. Discussion

The Commission believes the proposed rule change is consistent with the Act and the rules and regulations promulgated thereunder.[8] Specifically, the Commission believes that approval of the proposed rule change is consistent with Section 15B(b)(2)(C)[9] of the Act. This proposed rule change should help dealers comply with their obligation to deliver official statements to their customers by settlement and should more effectively ensure rapid dissemination of official statements to customers and to the marketplace generally, than has been occurring under the past version of the rule.[10] Incorporating a specific timeframe in the Dealer Dissemination Provisions injects accountability in the disclosure process. Compliance will be based on objective factors, not a dealer's interpretation of a vague standard. Furthermore, although the proposed amendment removes specific references in the existing rule to underwriters that

[4] *See* Securities Exchange Act Rel. No. 39904 (April 22, 1998), 63 FR 23311.

[5] These obligations of the managing underwriter will apply with respect to all purchasing dealers, even where the managing underwriter does not sell the securities to the purchasing dealer.

[6] Of course, this amendment would not relieve dealers acting as financial advisors of their obligations to comply with their contractual arrangements entered into with issuers and with all applicable state and federal statutes, regulations and common law. Thus, in particular, in instances where a dealer, acting as financial advisor, has a contractual or other legal duty to assist an issuer in complying with its contractual obligation to deliver final official statements within the timeframe and in the quantities set forth in Rule 15c2–12(b)(3) under the Act, such obligation would not be diminished by implementation of the amendment.

[7] *See MSRB Reports*, Vol. 3, No. 1 (Jan. 1983), "Rule G–32 + Frequently Asked Questions Concerning Disclosures in Connection with New Issues," at 25–27. *See also MSRB Reports*, Vol. 6, No. 4 (Sept. 1986), "Disclosure Requirements for New Issue Securities: Rule G–32," at 17–20 and *MSRB Reports*, Vol. 16, No. 3 (Sept. 1996), "Disclosures in Connection with New Issues: Rule G–32," at 19–23.

[8] The Commission has considered the proposed rule's impact on efficiency, competition and capital formation. Establishing a specific timeframe by which selling dealers must provide the requisite documentation enhances efficiency as the date for compliance is quantifiable and can be specifically determined. Also, requiring disclosure be made by a specific date to all similarly-situated dealers, eliminates any competitive advantage gained by uneven distribution of the requisite information. 15 U.S.C. 78c(f).

[9] Section 15B(b)(2)(C) requires the Commission to determine that the Board's rules are 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.

[10] Specifically, the provisions of the proposed rule change and of the Bond Market Association's Standard Agreement Among Underwriters would effectively obligate the managing underwriter to send the official statement to syndicate members within one business day of receipt from the issuer. *See supra* note 4, p. 23313, n.5.

prepare official statements on behalf of issuers, the Commission is of the opinion that an underwriter that prepares an official statement on behalf of an issuer would be deemed to have received the official statement from the issuer immediately upon the issuer approving the distribution of the completed official statement in final form.

In codifying its long-standing position in the Offering Price Disclosure Provision, the Board not only improves the information available to customers to determine the cost of their investments, but also improves the historical data analysts use to compare similarly priced and structured deals in various municipalities. The Commission believes disclosure of accurate pricing data should help facilitate competitive pricing in the municipal securities markets.

IV. Conclusion

For the above reason, the Commission believes that the proposed rule change is consistent with the provisions of the Act, and in particular with Section 15B(b)(2)(C).

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–MSRB–97–14), is hereby approved/

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19985 Filed 7–24–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40229; File No. SR–NYSE–98–20]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to an Interpretation of Article IV, Section 14 of the Exchange Constitution

July 17, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 10, 1998, the New York Stock Exchange, Inc. ("NYSE" 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 self-regulatory organization. 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 interpret Article IV, Section 14 of the Exchange Constitution to provide that decisions of the Director of Arbitration regarding jurisdiction and hearing situs are not subject to review by the Exchange's Board of Directors.

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 self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments its received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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

The purpose of the proposed resolution is to interpret Article IV, Section 14 of the Exchange Constitution so that decisions of the Director of Arbitration on issues of jurisdiction and hearings situs are not subject to review by the Exchange's Board at the request of a member, member organization, allied member or approved person. This section of the Exchange Constitution provides that where the Board has delegated its powers to an officer or employee, "a member, member organization, allied member of approved person affected by a decision of any officer or employee * * * may require a review by the Board of such decision." No explicit exception is made for actions taken by the Director of Arbitration. Moreover, this provision is not applicable to persons other than members, member organizations, or allied members of approved persons affected by a decision of the Director of Arbitration. However, Exchange Rule 621 and applicable law provide for the review of the Director's decisions by arbitrators or the courts. In addition, the Board has the authority to interpret the Constitution.[1]

The Director of Arbitration is "charged with the duty of performing all ministerial duties in connection with matters submitted for arbitration."[2] These duties include making the initial decisions regarding jurisdiction and hearing situs.[3] Exchange Rule 613 deals with the situs of a hearing and provides that "[t]he time and place for the initial hearing shall be determined by the Director of Arbitration and each hearing thereafter by the arbitrators."

Article XI, Section 1 of the Exchange Constitution and Exchange Rule 600 establish the jurisdiction of the Exchange's arbitration forum.[4] When a claim is submitted for arbitration at the Exchange, the Director of Arbitration, as part of the "ministerial duties in connection with matters submitted for arbitration," determines whether the claim submitted falls within the parameters of the Exchange's jurisdiction.

The arbitrators are empowered to interpret and determine the applicability of all provisions of the Arbitration Rules[5] and thereby the Exchange believes they can overturn decisions of the Director of Arbitration regarding situs of he first hearing. Decisions of the Director Arbitration regarding jurisdiction are subject to review by the courts.[6]

The NYSE notes that in the past, members have requested, and the Board has granted, review of the Director of Arbitration's decisions on jurisdiction and hearing situs.

The Exchange notes that interlocutory procedural decisions are rarely appealable in judicial and arbitral

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[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

[1] Article IV, Section 13.

[2] Exchange Rule 635.

[3] Exchange Rules 600 and 613.

[4] "Any controversy between parties who are members, allied members or member organizations and any controversy between a member, allied member or member organization and any other person arising out of the business of such member, allied member or member organization, or the dissolution of a member organization, shall at the instance of any such party, be submitted for arbitration in accordance with the provisions of this Constitution and such rules as the Board may from time to time adopt." (Article XI, Sec. 1).

"Any dispute, claim or controversy between a customer or non-member and a member, allied member, member organization and/or associated person arising in connection with the business of such member, allied member, member organization and/or associated person in connection with his activities as an associated person shall be arbitrated under the Constitution and Rules of the New York Stock Exchange, Inc. as provided by any duly executed and enforceable written agreement or upon the demand of the customer or non-member." Exchange Rule 600.

[5] *See* Exchange Rule 621.

[6] *Spear, Leeds & Kellogg* v. *Central Life Assurance Co.*, 85 F.3d 21 (2d Cir. 1996).

processes. Generally, they are reserved for consideration as part of any overall review of the lowest court's or arbitrator's decision. This reservation occurs in part because interlocutory appeals are frequently employed by parties simply to gain tactical advantage in the dispute. In addition, a substantive resolution of the conflict will often moot the procedural issues.

Inasmuch as this review by the Board of staff action is in the nature of an interlocutory appeal, the arbitrators and the courts may subsequently review the Board's decision. This may result in an unnecessary delay in the final resolution of an arbitration claim.

The Exchange notes that as a matter of statutory interpretation, when two statutes speak to the same subject matter, and one is general and the other is specific, the specific is usually interpreted to qualify or control the general. In this case, the Exchange Constitution and Rules, as well as the statutory framework within which alternative dispute resolution processes operate, create a specific scheme for review of administrative decisions of the Director of Arbitration.[7] The Exchange believes that this specific scheme obviates the need for review of the Director's decisions under the Exchange Constitution's general scheme for Board review of staff actions. Accordingly, the Exchange believes it is well within the norms of statutory construction for the Board to interpret the specific scheme for the review of the decisions of the Director to displace the general scheme.

2. Statutory Basis

The Exchange believes that the proposed change is consistent with Section 6(b)(5) of the Act[8] in that it promotes just and equitable principles of trade by insuring that members and member organizations and the public have a fair and impartial forum for the resolution of their disputes.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[7] *See* NYSE Rule 621; see also Federal Arbitration Act, 9 U.S.C. 1 et seq.

[8] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice is **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 self-regulatory organization consents, the Commission will:

(A) By order approve the 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 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. 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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–NYSE–98–20 and should be submitted by August 17, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Jonathan G. Katz,

Secretary.

[FR Doc. 98–19984 Filed 7–24–98; 8:45 am]

BILLING CODE 8010–01–M

[9] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Environmental Impact Statement: FRA Regulation of the Use of Locomotive Horns at Highway-Rail Grade Crossings Nationwide (FRA Docket No. RSGC–7)

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Extension of Comment Period.

SUMMARY: FRA is issuing this notice to advise the public that the comment period for identifying the scope of FRA's planned environmental impact statement (EIS) on a proposed regulation related to the use of locomotive horns at highway-rail grade crossings is extended to August 7, 1998.

FOR FURTHER INFORMATION CONTACT: David Valenstein, Environmental Specialist, Office of Railroad Development, Federal Railroad Administration (RDV 13), 400 Seventh Street, SW (Mail Stop 20), Washington, D.C. 20590, (telephone 202–493–6368).

SUPPLEMENTAL INFORMATION:

Background

On May 26, 1998, the Federal Railroad Administration (FRA) published a notice of intent to prepare an environmental impact statement for the proposed regulation of the use of locomotive horns at rail-highway grade crossings, as required by Section 20153 to title 49 United States Code, (63 Fed. Reg. 28549). Comments on the scope of the environmental document were requested by June 19, 1998. The FRA is extending the period in which comments will be accepted to August 7, 1998.

Scoping and Comments

Comments and suggestions are invited from all interested agencies and the public at large to insure the full range of issues related to the proposed action and all reasonable alternatives are addressed and all significant issues are identified. In particular, FRA is interested in determining whether there are any other reasonable alternatives consistent with the provisions of 49 U.S.C. 20153 and whether there are other areas of environmental concern where there might be the potential for significant impacts, either adverse or favorable, as a result of promulgating the proposed rule. Persons interested in providing comments on the scope of this environmental document should do so by August 7, 1998. Comments can be

sent in writing to Mr. David Valenstein at the address identified above. Comments can also be sent via the Internet at: FRAEIS@fra.dot.gov

The Remaining Environmental Review Process

Comments received on the scope and methodology to be used in preparation of the EIS will be reviewed by FRA to develop the final scope of the environmental review. A draft EIS will be made available to the public for comment, presently scheduled for the late fall 1998. It is FRA's intention that the comment period for the draft EIS will occur during the comment period associated with the proposed rule so that interested agencies and the public can combine their comments and that the environmental issues can be fully considered as FRA develops the final rule. After reviewing comments on the draft EIS, FRA will prepare a final EIS that addresses these comments and incorporates any additional analyses and material deemed necessary. The final EIS will be made available for public review for not less than 30 days before FRA takes any final action on the proposed rule.

Internet

This notice and all subsequent documents prepared as part of this environmental review will be available in the environmental pages of the FRA internet website, located at: *http://www.fra.dot.gov*

Issued in Washington, D.C. on: July 21, 1998.

James T. McQueen,

Assistant Administrator for Railroad Development.

[FR Doc. 98–19915 Filed 7–24–98; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. App. 26, the following railroads have petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR Part 236 as detailed below.

Block Signal Application (BS–AP)–No. 3480

Applicant: Burlington Northern and Santa Fe Railway Company, Mr. William G. Peterson, Director Signal Engineering 4515 Kansas Avenue, Kansas City, Kansas 66106

Burlington Northern and Santa Fe Railway Company seeks approval of the proposed discontinuance and removal of the traffic control system, on the single main track, between North River, Missouri, milepost 8.6 and Maxwell, Missouri, milepost 177.7, on the Illinois Division, Brookfield Subdivision, a distance of approximately 169 miles. The proposal includes the implementation of Track Warrant Control Rules as the method of operation, and conversion of the "Bevier Control Point" to a remote controlled interlocking.

The reason given for the proposed changes is that the severe reductions in train traffic can no longer justify the ongoing maintenance and operation of the signals.

BS–AP–No. 3481

Applicant: Union Pacific Railroad Company, Mr. Phil Abaray, Chief Engineer—Signal/Quality, 1416 Dodge Street, Room 1000, Omaha, Nebraska 68179–1000

Union Pacific Railroad Company seeks approval of the proposed discontinuance and removal of the single direction automatic block signal (ABS) system, on the No. 1 single yard track, between Brooklyn, milepost 767.9 and East Portland, milepost 770.3, on the Brooklyn Subdivision, near Portland Oregon. The proposal includes removal of six automatic block signals and the installation of a new "D" signal at milepost 765.4.

The reason given for the proposed changes is the installation of a bi-directional signal system, on the No. 2 main track between Brooklyn and East Portland, has eliminated the need for the single direction ABS system on the No. 1 yard track.

BS–AP–No. 3482

Applicant: CSX Transportation, Incorporated, Mr. R. M. Kadlick, Chief Engineer Train Control, 500 Water Street (S/C J–350), Jacksonville, Florida 32202

CSX Transportation, Incorporated seeks approval of the proposed modification of the traffic control system, on the two main tracks, at Beech Street, milepost BA–280.5, near Grafton, West Virginia, on the Mountain Subdivision, Cumberland Business Unit, consisting of the conversion of the power-operated switch to hand operation, and removal of absolute controlled signals 29, 31, 33, 37, and 39.

The reason given for the proposed changes is to increase operating efficiency.

BS–AP–No. 3483

Applicants:

CSX Transportation, Incorporated, Mr. R. M. Kadlick, Chief Engineer Train Control, 500 Water Street (S/C J–350), Jacksonville, Florida 32202

Consolidated Rail Corporation, Mr. J. F. Noffsinger, Chief Engineer—C&S Assets, 2001 Market Street, Philadelphia, Pennsylvania 19101–1410

CSX Transportation, Incorporated and Consolidated Rail Corporation, jointly seek approval of the proposed discontinuance and removal of the automatic block signal system and interlocking, on the two main tracks, between milepost BIA–251.9 and milepost BIA–257.6, near Hammond, Indiana, on the Lake Subdivision, Chicago Service Lane. The method of operation will be by a Direct Traffic Control Block System. The proposal includes conversion of the power-operated switches at Whiting Interlocking to hand operation; removal of all existing associated signals; and installation of two eastward inoperative approach signals to "Hick."

The reason given for the proposed changes is to eliminate facilities no longer needed for present day operation.

Rules, Standards, and Instructions Application (RS&I–AP)–No. 1104

Applicants:

CSX Transportation, Incorporated, Mr. R. M. Kadlick, Chief Engineer Train Control, 500 Water Street (S/C J–350), Jacksonville, Florida 32202

National Railroad Passenger Corporation, Mr. Ron Scolaro, Vice President Operations, 60 Massachusetts Avenue, N.E., Washington, D.C. 20002

CSX Transportation, Incorporated (CSXT) and the National Railroad Passenger Corporation (AMTRAK), jointly seek temporary relief from Section 236.566 of the Rules, Standards, and Instructions (49 CFR, Part 236), during the period of September 1, through October 1, 1998, to the extent that the CSXT and AMTRAK, as operating railroads for Virginia Railway Express (VRE), be permitted to operate VRE Manassas trains, without cab signals, in automatic cab signal territory, between Alexandria and "RO," Virginia,

approximately 6.1 miles, on CSXT's RF&P Subdivision, Baltimore Service Lane, associated with the conversion of the existing 60 Hertz cab signal system to the 100 Hertz operating cycle.

The justification for relief is that elimination of the only operating, 60 Hertz system of its kind in the country, and the resulting 100 Hertz operation, will provide more conformity with prevailing cab signals. Also, the requested relief is to minimize the impact to VRE's service during this transition, and permit the securing of needed material and modification of the VRE equipment.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and contain a concise statement of the 8 interest of the Protestant in the proceeding. The original and two copies of the protest shall be filed with the Associate Administrator for Safety, FRA, 400 Seventh Street, S.W., Mail Stop 25, Washington, D.C. 20590 within 30 calendar days of the date of publication of this notice. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC, on July 20, 1998.

George A. Gavalla,

Acting Associate Administrator for Safety.

[FR Doc. 98–19948 Filed 7–24–98; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[IA–33–92]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, IA–33–92 (TD 8507), Information Reporting for Reimbursements of Interest on Qualified Mortgages (§ 1.6050H–2).

DATES: Written comments should be received on or before September 25, 1998 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Information Reporting for Reimbursements of Interest on Qualified Mortgages.

OMB Number: 1545–1339.

Regulation Project Number: IA–33–92.

Abstract: Section 6050H of the Internal Revenue Code relates to the information reporting requirements for reimbursements of interest paid in connection with a qualified mortgage. This information is required by the Internal Revenue Service to encourage compliance with the tax laws relating to the deductibility of payments of mortgage interest. The information is used to determine whether mortgage interest reimbursements have been correctly reported on the tax return of the taxpayer who receives the reimbursement.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

The burden for the collection of information is reflected in the burden for Form 1098, Mortgage Interest Statement.

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 OMB control number. Books or records relating to a collection 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.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. 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 shall 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 to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 20, 1998.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 98–20025 Filed 7–24–98; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–209545–92]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing notice of proposed rulemaking, REG–209545–92, Earnings and Profits of Foreign Corporations (§ 1.964–1(c)(1)(v)).

DATES: Written comments should be received on or before September 25, 1998 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be

directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Earnings and Profits of Foreign Corporations.

OMB Number: 1545–1318.

Regulation Project Number: REG–209545–92 (formerly INTL–18–92).

Abstract: This regulation modifies the computation of earnings and profits of foreign corporations by allowing them to account for inventory costs using capitalization methods used for financial accounting purposes rather than the uniform capitalization rules required by Internal Revenue Code section 263A. The regulation also permits reliance on financial accounting conventions in computing depreciation for foreign corporations deriving less than 20 percent of gross income from U.S. sources and maintaining assets with financial book bases not materially different from tax bases. Use of these simplified rules may result in an accounting method change which would ordinarily require the filing of Form 3115, Application for Change in Accounting Method. However, the regulation waives any Form 3115 filing requirements if certain conditions are met.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

The burden for the collection of information is reflected in the burden for Form 3115, Application for Change in Accounting Method.

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 OMB control number. Books or records relating to a collection 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.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. 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 shall 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 to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 20, 1998.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 98–20026 Filed 7–24–98; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[AC–22: OTS No. 7195]

Peoples Savings Bank, Bordentown, New Jersey; Approval of Conversion Application

Notice is hereby given that on July 16, 1998, the Director, Corporate Activities, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Peoples Savings Bank, Bordentown, New Jersey, to convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, NW, Washington, DC 20552, and the Northeast Regional Office, Office of Thrift Supervision, 10 Exchange Place, 18th Floor, Jersey City, New Jersey 07302.

Dated: July 22, 1998.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 98–19994 Filed 7–24–98; 8:45 am]

BILLING CODE 6720–01–M

federal register

Monday
July 27, 1998

Part II

Department of Education

National Institute on Disability and Rehabilitation Research: Final Funding Priorities (Fiscal Years 1998–1999) for Certain Centers and Projects; Notice

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research; Notice of Final Funding Priorities for Fiscal Years 1998–1999 for Certain Centers and Projects

SUMMARY: The Secretary announces final funding priorities for two Disability and Rehabilitation Research Projects (DRRPs) and three Rehabilitation Research and Training Centers (RRTCs) under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 1998–1999. The Secretary takes this action to focus research attention on areas of national need. These priorities are intended to improve rehabilitation services and outcomes for individuals with disabilities.

EFFECTIVE DATE: This priority takes effect on August 26, 1998.

FOR FURTHER INFORMATION CONTACT: Donna Nangle. Telephone: (202) 205–5880. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–2742. *Internet:* Donna__Nangle@ed.gov

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: This notice contains final priorities under the Disability and Rehabilitation Research Projects and Centers Program for two DRRPs related to a burn data coordinating project and collaborative research for traumatic brain injury (TBI) model systems. This notice also contains final priorities for three RRTCs related to employment opportunities for American Indians, community integration for persons with mental retardation, and policies affecting families of children with disabilities.

These final priorities support the National Education Goal that calls for every adult American to possess the skills necessary to compete in a global economy.

The authority for the Secretary to establish research priorities by reserving funds to support particular research activities is contained in sections 202(g) and 204 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 761a(g) and 762).

Note: This notice of final priorities does *not* solicit applications. A notice inviting applications was published in the **Federal Register** on July 2, 1998 (63 FR 36298).

Analysis of Comments and Changes

On June 8, 1998 the Secretary published in separate parts two notices of proposed priorities in the **Federal Register**. One notice included two proposed priorities related to a burn data coordinating project and collaborative research for traumatic brain injury (TBI) model systems (63 FR 31320–31321). The second notice included three proposed priorities related to employment opportunities for American Indians, community integration for persons with mental retardation, and policies affecting families of children with disabilities (63 FR 31324–313290). The Department of Education received 17 letters commenting on the notices of proposed priorities by the deadline date. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under statutory authority—are not addressed.

Disability and Rehabilitation Research Projects

Priority 1: Burn Data Coordinating Project

Comment: Three commenters identified qualifications that applicants for the Burn Data Coordination Project should possess. The commenters suggested that applicants for the burn data coordinating project should demonstrate: an understanding of burn care, an understanding of the burn model systems database, and the ability and motivation to collaborate with the database currently being generated by the American Burn Association. In addition, the commenters suggested that applicants should have experience in the development, coordination, and management of multi-center databases and possess the technology to respond to idiosyncratic hardware and software needs and issues that each burn model system brings to the common database.

Discussion: An applicant's qualifications are addressed in the peer review process and evaluated on the basis of the competition's selection criteria. The qualifications identified by the commenter will be evaluated in the peer review process. It is unnecessary to include these qualifications in the priority.

Changes: None.

Comment: The Burn Data Coordinating Project should be affiliated with an institution that is currently operating a Burn Model Systems Project.

Discussion: NIDRR recognizes the advantages of having the Burn Data Coordination Project administered by an entity that is affiliated with an institution that is currently operating a Burn Model Systems Project. However, NIDRR does not believe that this affiliation is a prerequisite qualification and is unwilling to limit eligible applicants to current Burn Model Systems projects.

Changes: None.

Comment: One commenter suggested that the Burn Data Coordination Project's autonomy and authority should be clearly defined, strict time frames should be required for transmission of data and other summary reports to the model systems from the data center, and the procedures that are currently being developed to use scannable forms and score certain instruments should be continued.

Discussion: These suggestions relate to the administration of the Burn Data Coordination Project grant and the project's relationship with the Burn Model Systems Projects. Following the awarding of the grant, NIDRR will work cooperatively with the Burn Data Coordination Project and the Burn Model Systems Projects to address and resolve these issues. It is not necessary to revise the priority in order to address these administrative matters.

Changes: None.

Comment: Clarification is needed on the requirement for the Burn Data Coordinating Project to collaborate with the Spinal Cord and TBI Model Systems data collection activities.

Discussion: NIDRR believes that communication between the Burn, Spinal Cord, and TBI Model Systems data collection projects may result in improved performance of their common data collection activities and could lead to mutually beneficial collaborative activities. In order to provide the project with as much discretion as possible, the priority indicates that this collaboration should be carried out "as appropriate."

Changes: None.

Priority 2: Collaborative Research for Traumatic Brain Injury Model Systems

Comment: The priority should be revised to address the needs of individuals in correctional facilities.

Discussion: An applicant could propose to address the needs of individuals with TBI in correctional facilities. The peer review process will evaluate the merits of the proposal. However, NIDRR declines to specify any particular subpopulations of research subjects.

Changes: None.

Comment: The priority should be revised to require projects to use the TBI Model Systems database.

Discussion: NIDRR recognizes the advantages of using the TBI model systems database and expects that a

number of applicants will propose collaborative research projects that use the database. Because there may be highly meritorious collaborative research projects that do not use the database, NIDRR declines to limit the scope of research to only those that use the database.

Changes: None.

Comment: The priority should be revised to require collaboration with more than one Model System.

Discussion: NIDRR recognizes the advantages of collaboration with more than one Model System. However, there may be highly meritorious research projects that involve only one Model System. NIDRR declines to require that applicants collaborate with more than one Model System in order to provide applicants with as much discretion as possible.

Changes: None.

Comment: The meaning of collaboration should be clarified.

Discussion: The selection criteria on collaboration (see 34 CFR 350.54(k)) provide all applicants with guidance on the meaning of collaboration for the purpose of the priority. No further guidance is necessary.

Changes: None.

Comment: Any non-Model System applicant should demonstrate equivalent levels of data quality control as achieved by the Model System.

Discussion: The peer review process will evaluate the merits of the research that applicants propose, including the level of data quality control. It is not necessary to revise the priority in order to address the quality of the data that applicants' propose to collect.

Changes: None.

Comment: The priority should be revised to include collaborative projects on costs of rehabilitative interventions and their relationship to the effects of those interventions.

Discussion: An applicant could propose to address the costs of rehabilitative interventions and their relationship to the effects of those interventions. The peer review process will evaluate the merits of the proposal. However, NIDRR has no basis for requiring all applicants to carry out this research.

Changes: None.

Comment: In the Background statement to the priority, one of the examples of the collaborative research that could be carried out under the priority is assessment and treatment of persons with mild TBI. Individuals with mild TBI are not currently captured by the Model System database. Collaborative research on this topic, though very important, would involve a brand new effort, and one for which existing Model Systems offer no special advantages.

Discussion: The fact that assessment and treatment of persons with mild TBI was one of a number of examples included in the Background statement does not bind or encourage applicants to propose this research.

Changes: None.

Comment: The priority should be revised to acknowledge need for an assessment tool to measure community integration of persons with TBI.

Discussion: An applicant could propose to carry out research contributing to the development of these tools. The peer review process will evaluate the merits of the research. However, NIDRR has no basis for requiring all applicants to carry out this research.

Changes: None.

Rehabilitation Research and Training Centers

Priority 1: Employment Opportunities for American Indians

Comment: The fourth activity should be revised to require the RRTC to provide a technical assistance training program to counseling staff from community based service programs, American Indian Vocational Rehabilitation Projects supported under Section 130 of the Rehabilitation Act, and State VR agencies that serve American Indians.

Discussion: In part, the general RRTC training requirement specifies that the RRTC must provide training to persons with disabilities and their families, service providers, and other appropriate parties in accessible formats on knowledge gained from the Center's research activities. No further requirements are necessary for the RRTC to carry out the training suggested by the commenter.

Changes: None.

Comment: The priority should be expanded to include two new activities: (1) analyzing existing data to determine the specific risk factors for severe disabilities among American Indian people, and developing primary and secondary prevention strategies that address these risk factors in order to achieve long-term reduction in lifestyle risk factors that contribute to disability; and (2) developing and evaluating a model Independent Living Service program.

Discussion: NIDRR acknowledges the importance of the suggested activities, however, the purpose of this RRTC is to improve the employment status of American Indians with disabilities. The suggested activities are not sufficiently related to the purpose of the RRTC to be added to the priority. Also, adding them to the priority is not feasible in light of the resources available to the RRTC.

Changes: None.

Comment: It would be interesting to assess whether American Indians with disabilities seek seasonal subsistence employment such as ricing, fishing, hunting, sheepherding, and berrypicking. The priority should include culturally-specific strategies for employment such as subsistence employment.

Discussion: An applicant could propose to carry out research on subsistence employment. The peer review process will evaluate the merits of the research. However, NIDRR has no basis for requiring all applicants to carry out this research.

Changes: None.

Discussion: The RRTC is expected to be national in scope and address the needs of American Indians with disabilities in all parts of the country.

Changes: None.

Priority 2: Community Integration for Persons With Mental Retardation

Comment: Recreation and leisure should be included in the RRTC's efforts in studying effective and cost-beneficial approaches for community integration.

Discussion: An applicant could propose to integrate recreation and leisure into the research activities of the RRTC. The peer review process will evaluate the merits of the research. However, NIDRR has no basis for requiring all applicants to integrate recreation and leisure into the research activities of the RRTC.

Changes: None.

Disability and Rehabilitation Research Projects

Authority for Disability and Rehabilitation Research Projects (DRRPs) is contained in section 202 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 761a). DRRPs carry out one or more of the following types of activities, as specified in 34 CFR 350.13–350.19: research, development, demonstration, training, dissemination, utilization, and technical assistance. Disability and Rehabilitation Research Projects develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities. In addition, DRRPs improve the effectiveness of services authorized

under the Rehabilitation Act of 1973, as amended.

Priorities: Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet the following priorities. The Secretary will fund under this competition only applications that meet one of these absolute priorities.

Priority 1: Burn Data Coordinating Project

Background. In 1994 NIDRR established the Burn Injury Rehabilitation Model Systems of Care (Burn Model Systems) by awarding three 36-month projects. In 1997 NIDRR reestablished the Burn Model Systems with the award of four 60-month projects. These projects develop and demonstrate a comprehensive, multidisciplinary model system of rehabilitative services for individuals with severe burns, and evaluate the efficacy of that system through the collection and analysis of uniform data on system benefits, costs, and outcomes. The projects study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute care management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services.

The Burn Model Systems projects serve a substantial number of patients, allowing the projects to conduct clinical research and program evaluation. In addition, the Burn Model Systems projects utilize a complex data collection and retrieval program with the capability to analyze the different system components and provide information on project effectiveness and benefits. The projects are intended to establish appropriate, uniform descriptors of rehabilitation care. Information is collected throughout the rehabilitation process. Systematic burn injury care permits long-term follow-up on the course of injury and the identification of continuing needs and results in areas such as functional outcome, health and rehabilitation services, procedures for cost-reimbursement and billing and community integration. The Burn Model Systems projects serve as regional and national models for program development and as information centers for consumers, families, and professionals.

In order to take full advantage of the data collected by individual Burn Model System projects, there is a need for a project to assist the projects in their research efforts and establish and maintain a combined database for short- and long-term outcome evaluations (functional, health, psycho-social and vocational status measures) and financial assessments (rehabilitation, professional and hospital charges) for various burn care and injury rehabilitation strategies.

Priority 1: The Secretary will establish a Burn Data Coordinating Project for the purpose of maintaining a common database of burn care and injury rehabilitation information compiled by the Burn Model Systems projects supported by NIDRR. The project shall:

(1) Establish and maintain a common database through the data collection, entry, transfer, editing, quality control, issues resolution, and integration efforts of NIDRR's Burn Injury Rehabilitation Model Systems' projects;

(2) Provide technical assistance to the Burn Model Systems projects in the compilation of common data values from each Burn Injury Model System into a single quality information database for both joint and site specific management reporting, center evaluations and research analyses;

(3) Develop management reports on each Burn Injury Model System project's database-related activities and on trends that can be combined with and compared to other national data systems for evaluation of burn injury outcomes;

(4) Provide technical assistance to the Burn Model System projects in the preparation of scientific articles by providing statistical and analytical support;

(5) Provide technical assistance to the Burn Model Systems projects in the design, implementation, and analysis of specialized clinical studies that assess new burn injury rehabilitation methodologies; and

(6) Provide technical assistance to the Burn Model Systems projects in the clinical and systems analysis studies by collecting and analyzing data on patient characteristics, diagnoses, causes of injury, interventions, outcomes, and costs within a uniform standardized database.

In carrying out these purposes, the project must:

- As appropriate, collaborate with other model systems (such as spinal cord and traumatic brain injury model systems) data collection activities; and
- Link Burn Injury Model Systems, NIDRR Staff, and the project as required to facilitate database interactions and information dissemination opportunities.

Priority 2: Collaborative Research for Traumatic Brain Injury Model Systems

Background. In 1987 NIDRR funded four research and demonstration projects to establish the Traumatic Brain Injury Model Systems of Care (TBI Model Systems) for individuals in need of comprehensive, multidisciplinary rehabilitative services. At present NIDRR supports five TBI Model Systems projects to study the course of recovery and outcomes following the delivery of a coordinated system of care including emergency care, acute neuro-trauma management, comprehensive inpatient rehabilitation, and long-term interdisciplinary follow-up services. The TBI Model Systems projects collect and analyze uniform data from projects on system benefits, costs, and outcomes.

The TBI Model Systems projects serve a substantial number of individuals, allowing the projects to conduct clinical research and program evaluation, and maximize the potential for project replication. In addition, the systems have a complex data collection and retrieval program with the capability to analyze different system components and provide information on cost effectiveness and benefits. Information is collected throughout the rehabilitation process, permitting long-term follow-up on the course of injury, outcomes, and changes in employment status, community integration, substance abuse and family needs. The TBI Model Systems projects serve as regional and national models for program development and as information centers for consumers, families, and professionals.

On January 21, 1998, NIDRR published a notice in the **Federal Register** inviting applications to establish 10 additional TBI Model Systems projects (63 FR 3240). In conjunction with the establishment of these new TBI Model Systems projects, NIDRR is establishing collaborative research projects to broaden knowledge and encourage multi-institutional studies of outcomes, rehabilitation interventions and service delivery system innovation for individuals with traumatic brain injury. The following are examples of collaborative research topics that the proposed project could carry out: evaluation of emerging pharmacologic interventions; examination of the effects of specific type and intensity of rehabilitative treatments; aging with TBI; secondary conditions of TBI; assessment and treatment in mild traumatic brain injury; impact of environmental factors on long term outcomes; impact of substance abuse on memory; and implications of managed care on availability and type of care for persons with TBI.

Priority 2: The Secretary will establish collaborative research projects for the

purpose of improving the knowledge about rehabilitation outcomes in order to improve the lives of persons with TBI, their families, and caregivers. A collaborative research project shall:

(1) Investigate rehabilitation interventions or service delivery issues; and

(2) Disseminate information based on that investigation to TBI Model Systems projects and other appropriate rehabilitation settings.

In carrying out the purposes of the priority, the project must:

- Collaborate with one or more of the 17 NIDRR TBI Model Systems projects that are directed by the following individuals: (1) Dr. Thomas Novack, University of Alabama—Birmingham, AL, (205) 934–3454; (2) Dr. Karyl Hall, Santa Clara Valley Medical Center—San Jose, CA, (408) 295–9896; (3) Dr. Gale Whiteneck, Craig Hospital—Englewood, CO, (303) 789–8204; (4) Dr. Anthony Stringer, Emory University—Atlanta, GA, (404) 712–5667; (5) Dr. Mel B. Glenn, The Spaulding Rehabilitation Hospital—Boston, MA, (617) 720–6821; (6) Dr. Mitchell Rosenthal, Wayne State University/Rehabilitation Institute of Michigan—Detroit, MI, (313) 745–9769; (7) Dr. James F. Malec, Mayo Foundation—Rochester, MN, (507) 255–5199; (8) Dr. Mark Scherer, Mississippi Methodist Rehabilitation Center—Jackson, MS, (601) 364–3490; (9) Dr. Brick Johnstone, University of Missouri—Columbia, MO, (573) 882–6290; (10) Dr. Mark V. Johnston, Kessler Medical Rehabilitation Research and Education Corporation—West Orange, NJ, (973) 414–4734; (11) Dr. Flora Hammond, Charlotte-Mecklenburg Hospital Authority—Charlotte, NC, (704) 355–4300; (12) Dr. John Corrigan, Ohio State University—Columbus, OH, (614) 293–3830; (13) Dr. Randall M. Chestnut, Oregon Health Services University—Portland, OR, (503) 494–4314; (14) Dr. John Whyte, Moss Rehabilitation Research Institute—Philadelphia, PA, (215) 456–9597; (15) Dr. Walter High, Jr., The Institute for Rehabilitation and Research—Houston, TX, (713) 666–9550; (16) Dr. Jeffrey S. Kreutzer, Medical College of Virginia—Richmond, VA, (804) 828–9055; and (17) Dr. Sureyya S. Dikmen, University of Washington—Seattle, WA, (206) 685–7529; and
- Once a year, participate in the TBI Model Systems project directors' meeting.

Rehabilitation Research and Training Centers

The authority for RRTCs is contained in section 204(b)(2) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760–762). Under this program, the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations, for coordinated research and training activities. These entities must be of sufficient size, scope, and quality to effectively carry out the activities of the Center in an efficient manner consistent with appropriate State and Federal laws. They must demonstrate the ability to carry out the training activities either directly or through another entity that can provide that training.

The Secretary may make awards for up to 60 months through grants or cooperative agreements. The purpose of the awards is for planning and conducting research, training, demonstrations, and related activities leading to the development of methods, procedures, and devices that will benefit individuals with disabilities, especially those with the most severe disabilities.

Description of Rehabilitation Research and Training Centers

RRTCs are operated in collaboration with institutions of higher education or providers of rehabilitation services or other appropriate services. RRTCs serve as centers of national excellence and national or regional resources for providers and individuals with disabilities and the parents, family members, guardians, advocates or authorized representatives of the individuals.

RRTCs conduct coordinated, integrated, and advanced programs of research in rehabilitation targeted toward the production of new knowledge to improve rehabilitation methodology and service delivery systems, to alleviate or stabilize disabling conditions, and to promote maximum social and economic independence of individuals with disabilities.

RRTCs provide training, including graduate, pre-service, and in-service training, to assist individuals to more effectively provide rehabilitation services. They also provide training including graduate, pre-service, and in-service training, for rehabilitation research personnel.

RRTCs serve as informational and technical assistance resources to providers, individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of these individuals through conferences, workshops, public education programs, in-service training programs and similar activities.

RRTCs disseminate materials in alternate formats to ensure that they are accessible to individuals with a range of disabling conditions.

NIDRR encourages all Centers to involve individuals with disabilities and individuals from minority backgrounds as recipients of research training, as well as clinical training.

The Department is particularly interested in ensuring that the expenditure of public funds is justified by the execution of intended activities and the advancement of knowledge and, thus, has built this accountability into the selection criteria. Not later than three years after the establishment of any RRTC, NIDRR will conduct one or more reviews of the activities and achievements of the Center. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment.

General Requirements: The following requirements apply to these RRTCs pursuant to these absolute priorities unless noted otherwise. An applicant's proposal to fulfill these requirements will be assessed using applicable selection criteria in the peer review process:

The RRTC must provide: (1) applied research experience; (2) training on research methodology; and (3) training to persons with disabilities and their families, service providers, and other appropriate parties in accessible formats on knowledge gained from the Center's research activities.

The RRTC must develop and disseminate informational materials based on knowledge gained from the Center's research activities, and disseminate the materials to persons with disabilities, their representatives, service providers, and other interested parties.

The RRTC must involve individuals with disabilities and, if appropriate, their representatives, in planning and implementing its research, training, and dissemination activities, and in evaluating the Center.

The RRTC must conduct a state-of-the-science conference and publish a comprehensive report on the final outcomes of the conference. The report must be published in the fourth year of the grant.

Priorities: Under 34 CFR 75.105(c)(3), the Secretary gives an absolute preference to applications that meet the following priorities. The Secretary will fund under this competition only applications that meet one of these absolute priorities.

Priority 1: Employment Opportunities for American Indians

Background. On August 1, 1997, the U.S. population of American Indians, including Alaskan Native and Aleut, was 2.3 million. This population has the highest rate of disability of any racial or ethnic group. One in three American Indians aged 15 and over reports having a disability; about one in seven reports having a "severe" disability. One in two American Indians aged 65 or over has a severe disability (U.S. Department of Commerce, Bureau of the Census, *Census Facts For Native American Month,* October, 1997). American Indians have the highest unemployment rates, the lowest family incomes, and highest percentage of people living below the poverty level (U. S. Department of Commerce, Bureau of the Census, *Current Population Reports, Special Studies Series,* P 23–189, pg. 51, July, 1995). The nation's several hundred reservations have a 50 percent average unemployment rate (Kalt, J. "Development Strategies for American Indians," *Social Policy Research Bulletin,* pg. 21, fall, 1996).

In addition, American Indians have the most severe health problems of all U.S. groups, including the shortest life expectancy and highest infant mortality rate. American Indians experience alcohol and substance abuse, sensory impairment, diabetes mellitus, learning disabilities, fetal alcohol syndrome, and accidents and injuries at alarming rates when compared to the general population (U.S. General Accounting Office, *Indian Health Service, Basic Services Mostly Available; Substance Abuse Problems Need Attention,* GAO/HRD–93–48, April, 1993). American Indians have the nation's highest school dropout rates and the lowest postsecondary attainment rates. Only 66 percent of American Indians have high school diplomas, compared to a 78 percent rate for whites and Asian-Americans (U. S. Department of Education, Office of Educational Research and Improvement, *National Assessment of Vocational Education, Final Report to Congress, Volume IV Access to Programs and Services for Special Populations,* pg. 70, July, 1994).

Although some data on employment and on disability are available, there is little specific information on employment of American Indians with disabilities. In addition, although general disability rates are available for this population, there is little information on the distribution of disability within the population. Many factors may have an impact on the employment status of, and the delivery of, employment services to American Indians with disabilities. These factors include, but are not limited to health status, poverty, educational level, and availability of culturally relevant vocational rehabilitation services.

State vocational rehabilitation (VR) agencies provide employment services to American Indians with disabilities who meet the eligibility criteria for the Vocational Rehabilitation Services Program authorized by the Rehabilitation Act of 1973 (the Act). In 1996, VR agencies assisted approximately 1600 American Indians with disabilities to achieve an employment outcome. However, data from the Rehabilitation Services Administration (RSA) indicate that American Indians served under the program achieve employment outcomes at a lower rate compared to other populations receiving vocational rehabilitation services *(RSA Case Service Reports, PSA–911,* 1991–1996).

Geographic, cultural, language, and political factors affect the ability of State agencies to deliver services to this population, particularly those individuals residing on reservations. Approximately, one-third of American Indians live on reservations or trust lands. Most reservations have populations of less than one thousand and are located in rural areas. Many of these Indian communities are in isolated areas where poor roads and populations spread out over many miles. In addition, tribes are often sovereign political entities with specific powers of self-governance, thus affecting access to populations on reservations.

In recognition of this problem, Congress amended the Act in 1978 to authorize grants for American Indian Vocational Rehabilitation Service Projects (Section 130 Projects) to support tribal vocational rehabilitation programs. These discretionary grant projects, also administered by RSA, are awarded to the governing bodies of Indian tribes located on Federal and State reservations to provide VR services for American Indians who are individuals with disabilities residing on reservations. There are currently 39 such projects.

Nearly two-thirds of American Indians live in urban areas. Much of the urban Indian population is assimilated and dispersed throughout urban census tracts, making it difficult for Vocational Rehabilitation agencies to identify and serve this population (The National Urban Indian Policy Coalition, *Report to the White House Domestic Policy Council,* April, 1995). The lack of culturally sensitive definitions of disability in national data collection efforts, such as the National Health Interview Survey or the Survey of Income and Program Participation, further complicates this problem.

Cultural and language barriers significantly impede delivery of employment services, including vocational rehabilitation programs. There are 557 federally recognized tribes, speaking about 200 languages and dialects. Cultural barriers affect knowledge, understanding, and acceptance of disability and contemporary medical and health practices. In addition, concepts such as self-sufficiency, self-determination and self-advocacy may have very different meanings across Indian cultures.

Priority 1: The Secretary will establish an RRTC to improve the employment status of American Indians with disabilities. The RRTC shall:

(1) Investigate and analyze existing data, demographic and other, relevant to disability and employment outcomes and recommend methodological improvements to enhance the usefulness and comprehensiveness of such data for the purpose of planning and evaluating employment services, including vocational rehabilitation services (as set forth in 34 CFR 361.48), for Indians with disabilities;

(2) Analyze existing employment and vocational rehabilitation service strategies for American Indians with disabilities and identify those that have produced successful employment outcomes, taking into consideration the actual employment opportunities that exist on and off the reservation, and examine how these strategies might be applied to the Section 130 Projects;

(3) Develop and evaluate model employment services, including vocational rehabilitation services, for American Indians with disabilities, incorporating best practices from the review of existing services, taking into account cultural issues and reflecting needs of American Indians on and off the reservations as well as the Section 130 Projects; and

(4) Disseminate both the recommendations for data collection improvements and the results of the evaluation of model employment services to a range of relevant audiences, using appropriate accessible formats.

In carrying out the purposes of the priority, the RRTC must:

- As appropriate, carry out separate analyses for Indians with disabilities who live on the reservation and for those who live off the reservation; and
- Collaborate with the Section 130 Projects, and coordinate with the

Rehabilitation Services Administration, the Bureau of Indian Affairs and the Indian Health Service, the RRTC on Disability Statistics, and other entities carrying out related research or training activities.

Priority 2: Community Integration for Persons With Mental Retardation

Background. Since 1965, NIDRR has supported research and demonstrations in the area of developmental disabilities, particularly in the area of mental retardation. During these years, researchers have addressed issues involving deinstitutionalization, special education, transition from school to work, supported employment and the overall supports persons with mental retardation need to live in the community.

Based on the 1994–1995 National Health Interview Survey-Disability Supplement on adults living in the general household population and surveys of people in formal residential support programs, about .78 percent or 1,250,000 of the population of the U.S. can be identified as being limited in a major life activity and having a primary or secondary condition of mental retardation. Until the Disability Supplement survey was conducted, information was not available about individuals with mental retardation who are not participants in specialized programs, but live in the community with their families or on their own.

Many persons with mental retardation and their families receive long-term services and supports through State developmental disability authorities (SDDAs) that are funded primarily by the State or Federal Medicaid program. According to the results of a recent membership survey conducted by the National Association of State Directors of Developmental Disabilities Services (NASDDS), many SDDAs are currently designing or launching large scale system change initiatives. This is due, in part, to Medicaid reforms, managed care initiatives and budget constraints. Seventy-one percent of the respondents said that cost containment is a major factor prompting system change. The initiatives differ in their specifics but share several common themes: decentralizing authority to local managing entities; shifting to less categorical budgeting; promoting greater flexibility in the purchase and provision of community services and supports; and embracing self determination to define a new relationship between the system and individuals and their families (NASDDS, *Community Services Reporter*, pg. 3, Jan, 1998).

Since 1981, the Medicaid Home and Community Based Services (HCBS) waiver has facilitated flexibility and service innovation. HCBS waivers afford States the flexibility to develop and implement creative alternatives to placing Medicaid eligible individuals in facilities such as nursing homes. The HCBS waiver program recognizes that many individuals at risk of being placed in a long-term care facility can be supported in their own homes and communities, preserving their independence and ties to family and friends at a cost no higher than that of institutional care. Services that may be provided in HCBS waiver programs are case management, homemaker services, home health aide services, personal care services, adult day health services, habilitation, and respite care. Other services States may request include transportation and meal services. States have the flexibility to design each waiver program and select the mix of waiver services that best meet the needs of the population they wish to serve. HCBS waiver services may be provided statewide or may be limited to specific geographic subdivisions.

However, in the last several years, States have attempted to contain Medicaid spending through the application of managed care approaches. Long-term care services, including Medicaid-funded intermediate care facilities for persons with mental retardation and HCBS waiver services for persons with mental retardation, account for 35 percent of all Medicaid spending. Programs serving persons with mental retardation are not likely to be exempt from these cost containment measures (Center on Human Policy, *Information Package on Managed Care and Long-term Supports for People with Developmental Disabilities*, pg. 3, June, 1997).

There is little information available on the use and outcomes of managed care practices in providing long-term supports to persons with mental retardation. Currently, States are implementing various models to consolidate health and long-term care services under one managed care organization. This approach is intended to be cost-effective and improve service coordination. Under some of these models, support networks for persons with mental retardation that now stand alone, could become subspecialty branches of larger care delivery systems (Ashbaugh, J. and Smith, G., "MCARE Policy Brief," *Integration of Health and Long-term Care Services: A Cure in Search of and Illness,*" No. 1, pg. 12, 1997). Some observers have voiced concern that the use of consolidated models may lead to reduced funding for services. Organizations representing persons with mental retardation have proposed integrated models that combine under a single umbrella organization, health and long-term supports in a configuration uniquely suitable for this population.

Emerging practice suggests that people with mental retardation should play leading roles in determining the substance of their lives and that services should be developed as needed to support their preferences. For example, some current service delivery models may provide new options for individuals and their families to self manage their chosen services through vouchers, individual budgets or cash. The field is moving past traditional service delivery approaches to become more responsive to the demands of service recipients and to promote self determined lifestyles. Services developed around the specific needs and choices of an individual may produce better outcomes and cost savings.

There are a number of emerging models for system redesign. Participant driven managed supports refer to a variety of strategies for administering systems to increase their effectiveness and efficiency, while maintaining a commitment to community integration and self determination (Agosta, J., et al., "MCARE Policy Brief," *Developmental Disability Services at the Century's End: Facing the Challenges Ahead*, No. 2, pg. 4, 1997). The consumer managed care approach assumes that consumers with limited budgets will spend more prudently in order to get the most value for their money and increase their use of natural supports in lieu of public supports. Accordingly, consumer choice will spawn a competitive market economy where those providers representing the most value to all consumers will survive (Smith, G. and Ashhbaugh, J., *Managed Care and People with Developmental Disabilities: A Guidebook*, pg. 8, 1996).

Coupled with States' efforts toward containment of long-term care costs, most States have long waiting lists for services. Waiting lists are expected to grow in the future due to increased longevity and higher expectations of families. After examining state-by-state data regarding the status of requests for residential, day care, vocational and other community support services, a 1997 Arc study found that 218,000 requests for community based support services remained unanswered. In addition to individuals living in institutions and nursing homes, these waiting lists include students exiting

from special education programs and individuals living at home with caregivers. There is a need to understand the methods and procedures that States are using to provide community based services, as well as to identify ways in which service systems can be redesigned to better respond to the needs of persons with mental retardation and their families.

Residential direct care providers (e.g., group home staff members, foster family members, roommates in supported living arrangements) are the primary providers of support, training, supervision and personal assistance to persons with mental retardation in home and community settings (Larson, S. A., et al., "Residential Services Personnel," *Challenges for a Service System in Transition*, pg. 313, 1994). In community residential settings, there have been few attempts to study the effects of staff orientation and in-service training programs on important outcomes for persons with mental retardation as well as on direct service personnel (Larson, S. A., ibid., pg. 326). As the service delivery system changes, training for these providers will be essential. In addition, it will be important to determine what training efforts contribute to the desired outcomes of fuller community participation and autonomy for persons with mental retardation.

Priority 2: The Secretary will establish an RRTC to improve community integration outcomes for individuals with mental retardation. The RRTC shall:

(1) Investigate effective and cost-beneficial approaches to assist families to support members with mental retardation at home, or in homes of their own;

(2) Describe and analyze efforts to redesign policy and services in selected state systems serving persons with mental retardation and their families;

(3) Identify and analyze State policies and practices in the management of Medicaid resources that foster or impede access to supports and services;

(4) Identify and analyze policies that foster or impede (e.g., result in individuals being placed on waiting lists for community-based services) the full participation and integration of persons with mental retardation into their communities;

(5) Analyze the outcomes of the implementation of consumer-controlled services, personal assistance, and individual control-of-service purchasing in areas of quality of life and cost effectiveness; and

(6) Identify outcomes of training for residential direct care providers and the long-term costs and benefits of specific training strategies.

In carrying out the purposes of the priority, the RRTC must coordinate with research and demonstration activities sponsored by the Health Care Financing Administration, the Administration on Developmental Disabilities, the Office of Disability, Aging, and Long-term Care Policy in the Department of Health and Human Services, and other entities carrying out related research or training activities.

Priority 3: Policies Affecting Families of Children With Disabilities

Background. The 1992 National Health Interview Survey (NHIS) estimates that 4 million children and adolescents, or 6.1 percent of the U.S. population under 18 years of age, have disabilities. The NHIS broadly defines disability to include any limitation in activity due to a chronic health condition or impairment. Among children under age five, 2 percent are limited in play activities and among children 5–17, 5.5 percent have school related disabilities. In addition, the NHIS estimates that 3.8 million families, or 5.5 percent of all families, contain one or more children with disabilities.

Families of children with disabilities must interact with at least three large service systems: health care, human and social services, and educational systems. It is often difficult to assess the impact of policies, service systems, and service delivery practices because the organizational structures and the services provided under the auspices of public and private institutions vary. The integration and coordination of these systems can be inferred from the patterns of interagency relationships involving client referrals, information flows and resource exchanges (Morrissey, J. P., et al., "Methods for System-Level Evaluations of Child Mental Health Service Networks" *Outcomes for Children and Youth with Behavioral and Emotional Disorders and Their Families: Programs and Evaluation Best Practices*, pg. 299, 1998). For the purposes this priority, the policies affecting families of children with disabilities include, but are not limited to, those in the areas of health care (including mental health), human and social services (including legal systems such as juvenile services), and public and private education.

Families who have children with disabilities often need assistance with accessing and financing services, information about caring for their child, support from other families, community based respite care, and case management services. Case management services are intended to ensure that services are delivered in an effective and efficient manner. Numerous models of case management currently exist. However, there is little extant research on the effectiveness, either at the family or system level, of case management services for families who have children with disabilities.

Numerous methodological problems limit the study of the complex service systems surrounding children with disabilities and their families. Current methods of measuring service coordination and examining roles in service delivery systems are not structured to assess the needs of children and their families (Koren, P. E., et al., "Service Coordination in Children's Mental Health: An Empirical Study from the Caregivers Perspective," *Journal of Emotional and Behavioral Disorders*, 5(3), pg. 164, 1997). Measurement issues become even more complex when the focus of a study moves from the individual and family level to the State and local service system level or when policy analysis is required. There is currently a shortage of methods for assessing the interrelationship between Federal, State, and local policy, service systems, and outcomes for families of children with disabilities. The limited availability of data and methodological tools needed for scientific measurement of the impact of systemic and policy reforms on families of children with disabilities serves as a barrier to increasing our understanding of the relationship between policy and outcomes. Recent major changes in Federal policies for social services, child care, family preservation and support services, and related educational and health care services may be having profound impacts upon these families.

Changes at the Federal level may be having an impact at the State and local level. However, little is known or documented about the effects of Federal policy changes on State and local service systems and families of children with disabilities.

Under new Federal and State legislation, States have more flexibility to administer human service programs. Policymakers and legislators have new opportunities to shape integrated and flexible programs to better serve the needs of families and their children with and without disabilities. Some States are experimenting with a decategorization of State and Federal funding streams so that local communities can reshape their service systems through the use of vouchers. Some State and local agencies are conducting demonstrations of family

support programs that decentralize public services for families of children with disabilities.

The impact of devolution from a system with authority at the Federal level and management of public services at the State level, to a system of both authority and management at the local level has not been documented. Information is needed on these practices and other interventions, the family benefits associated with these policies and practices, and the consequences of practice and policy change in order to facilitate implementation of policies and programs that are sensitive to the needs of families of children with disabilities and to promote effective models of care for families of children with disabilities.

In addition to policy changes in the social services arena, health care systems are changing rapidly the way they provide services to consumers. Families of children with disabilities, and the health care providers that serve them, are facing many challenges that differ from the coverage and access issues that are present for the general population. Even families of children with disabilities that use few medical services often require special knowledge or accommodations when they do access the health care system. Many States have little or no experience in assuring that their health care providers meet the specialized needs of families of children who have disabilities. These challenges are further complicated by the high cost of services for children with disabilities.

Among children enrolled in Medicaid, the average per-person health care costs in 1992 were seven times higher for disabled than nondisabled children. Compared with nondisabled children in the general population, some disabled children use twice as many physician visits and five times as many ancillary services, such as physical therapy. Under current policies and practices, the potential exists to use medical necessity standards to prevent disabled children from receiving therapy or equipment when they need it to maintain existing levels of functioning (U.S. General Accounting Office, *Medicaid Managed Care: Serving the Disabled Challenges States Programs,* (GAO/HEHS Publication No. 96–136) pg. 16, 1996). Research is needed on health care policies and service delivery practices in order to develop long-term strategies to remove service delivery barriers that exist in the health care system and to facilitate establishment of policies that support access to services for families of children with disabilities.

Frequently, children with disabilities who are participating in special education programs and their families have needs that are addressed by health care or social service agencies. As public schools' regular and special education programs restructure, opportunities may arise to expand successful service delivery strategies and develop new ones to fill in existing gaps in the service delivery systems. The development of integrated, community-based services for children with disabilities and their families is an essential component of this reform effort (Duchnowski, A. J., et al., "Integrated and Collaborative Community Services in Exceptional Student Education," *Special Education Practice: Applying the Knowledge, Affirming the Values and Creating the Future,* pgs. 177–188, 1997).

Many communities have begun initiatives to create more responsive family-centered service delivery systems. Mechanisms for interagency coordination at the State and local levels are necessary to ensure optimal service delivery conditions. Service coordination should involve linkages between education agencies, health care systems, and social services systems. In addition, due to the changing demographics of society, little is known about the influence of culture, ethnicity and socioeconomics on how families seek and receive services for their children with disabilities.

Basic information sharing, coordination and collaboration between agencies that provide services to families of children with disabilities is limited. There is a need to evaluate current best practices in service delivery coordination and collaboration, develop a methodology for analyzing collaboration among agencies, establish principles for coordination and collaboration, and develop performance indicators that foster partnerships.

Priority 3: The Secretary will establish an RRTC to assess the impact of policies on service delivery and outcomes for families of children with disabilities. The RRTC shall:

(1) Develop an analytical framework, including tools for assessing: family characteristics and policies, structure of service systems, service delivery processes, interagency coordination and collaboration, and outcomes for families with disabled children;

(2) Using the methodology developed above, determine the effectiveness of specific policies, implementation strategies, service delivery procedures, and coordination practices in meeting the needs of families of children with disabilities;

(3) Identify the impact of specific characteristics of interagency collaboration and coordination on families of children with disabilities; and

(4) Assess the impact of specific policies on access to services of families from diverse cultural, linguistic, ethnic and socioeconomic backgrounds.

In carrying out these purposes, the RRTC must:

- Disseminate materials and coordinate research and training activities with the Maternal and Child Health Bureau, the Administration on Developmental Disabilities, the Office of Policy and Planning in the Department of Health and Human Services, the Office of Special Education, the Federal Interagency Coordinating Council, and other entities carrying out related research or training activities; and
- Establish practical statistical methodologies and measurement tools that specifically assess the policies affecting families of children with disabilities.

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Program Authority: 29 U.S.C. 760–762.

(Catalog of Federal Domestic Assistance Numbers 84.133B, Rehabilitation Research and Training Centers)

Dated: July 22, 1998.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 98–20009 Filed 7–24–98; 8:45 am]

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federal register

Monday
July 27, 1998

Part III

Department of Housing and Urban Development

Super Notice of Funding Availability (SuperNOFA) for Economic Development and Empowerment Programs; Economic Development Initiative (EDI) Program Funding; Announcement of Intention to Establish Future Community Development Block Grant Risk Reduction Pool Demonstration Using EDI Funds; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4363–N–03]

Super Notice of Funding Availability (SuperNOFA) for Economic Development and Empowerment Programs; Economic Development Initiative (EDI) Program Funding; Announcement of Intention to Establish Future Community Development Block Grant Risk Reduction Pool Demonstration Using EDI Funds

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Funding Availability; Supplemental notice.

SUMMARY: The purposes of this notice are to: (1) announce HUD's intention to establish a Community Development Block Grant (CDBG) Risk Reduction Pool demonstration, as first discussed in the Economic Development Initiative (EDI) Program Section of SuperNOFA II, published on April 30, 1998; (2) notify the public that HUD intends to use $10 million of the $38 million in FY 1998 funds available for the EDI Program to fund the CDBG Risk Reduction Pool demonstration. As a result, $28 million will be available for FY 1998 EDI grants under SuperNOFA II. HUD will issue a future notice that describes the details of the CDBG Risk Reduction Pool demonstration.

Application Due Date

The application due date for EDI Program applicants is unchanged. Completed applications (one original and two copies) must be submitted no later than 12:00 midnight, Eastern time, on July 30, 1998 to the addresses listed in the EDI program section of HUD's Super Notice of Funding Availability for Economic Development and Empowerment Programs (SuperNOFA II), published in the **Federal Register** on April 30, 1998 (63 FR 23876), and in accordance with the procedures of SuperNOFA II. Additionally, all other information concerning the EDI Program, as provided in SuperNOFA II published on April 30, 1998, remains unchanged except for the reduction in available funding for the FY 1998 EDI Program.

FOR FURTHER INFORMATION CONTACT: Stan Gimont or Paul Webster, Financial Management Division, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 7178, Washington, DC 20410; telephone (202) 708–1871 (this is not a toll-free number). Persons with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Economic Development Initiative Program

The Economic Development Initiative (EDI) program was enacted in 1994 and is intended to complement and enhance the Section 108 Loan Guarantee program. The purpose of EDI grant funds is to further minimize the potential loss of future CDBG allocations:

(1) By strengthening the economic feasibility of the projects financed with Section 108 funds (and thereby increasing the probability that the project will generate enough cash to repay the guaranteed loan);

(2) By directly enhancing the security of the guaranteed loan; or

(3) Through a combination of these or other risk mitigation techniques.

SuperNOFA II

On April 30, 1998, HUD published its Super Notice of Funding Availability for Economic Development and Empowerment Programs (SuperNOFA II) (63 FR 23876). SuperNOFA II set forth the consolidated program requirements and application process for ten (10) of HUD's Economic Development and Empowerment Programs, including the EDI Program.

SuperNOFA II announced the availability of approximately $38 million to fund EDI grants. The EDI Program section of SuperNOFA II advised that HUD was considering using $10 million of the available $38 million in EDI funds for a CDBG Risk Reduction Pool demonstration. The EDI Program section provided that, in the event HUD intended to proceed with the risk pool demonstration, $28 million would be available for EDI grants under SuperNOFA II. The EDI Program section of SuperNOFA II also advised that HUD would publish a supplemental **Federal Register** notice announcing its decision to fund a CDBG Risk Reduction Pool demonstration.

CDBG Risk Reduction Pool Demonstration

HUD will issue a future notice that describes the details of the CDBG Risk Reduction Pool demonstration. The notice is expected to be issued at the beginning of calendar year 1999. As discussed in the EDI Program Section of SuperNOFA II, the risk pool mechanism will be an EDI program enhancement designed to reduce the risk that CDBG funds will have to be used to repay Section 108 loans that finance economic development projects. The CDBG Risk Reduction Pool will allow public entities to pool economic development loans and related reserves. The CDBG Risk Reduction Pool will also assist public entities in satisfying the collateral requirements for Section 108 loans. The pool's reserves and incremental cash flows will provide an additional credit enhancement for the Section 108 loan and thereby help satisfy Section 108 additional collateral requirements.

Dated: July 22, 1998.

Saul N. Ramirez, Jr.,

Assistant Secretary for Community Planning and Development.

[FR Doc. 98–20103 Filed 7–23–98; 1:14 pm]

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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period July 1, 1996 to June 30, 1997. The volume issued July 1, 1996, should be retained.

[5] No amendments to this volume were promulgated during the period January 1, 1997 through December 31, 1997. The CFR volume issued as of January 1, 1997 should be retained.

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