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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 272 and 273

[Amdt. No. 303]

Food Stamp Program; Income Exclusion of Certain Charitable Donations

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim rule.

SUMMARY: This action amends Food Stamp Program regulations as a result of the Charitable Assistance and Food Bank Act of 1987 (Pub. L. 100–232), enacted January 5, 1988. In accordance with that Act, the Food Stamp Program must exclude from consideration as income certain cash donations received by food stamp households. This action implements this income exclusion provision.

DATE: This action is retroactively effective to January 5, 1988 and affects eligibility and benefit determinations made on or after February 1, 1988. Thus, this action must be implemented immediately. Comments must be received on or before August 15, 1988.

ADDRESS: Send comments to Certification Rulemaking Section, Eligibility and Monitoring Branch, Program Development Division, Food and Nutrition Service, USDA, Alexandria, Virginia 22302.

FOR FURTHER INFORMATION CONTACT: Judith M. Seymour, (703) 756–3429.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Department has reviewed this action under Executive Order 12291 and Secretary's Memorandum No. 1512–1. It has been determined that the action will not result in an annual effect on the economy of $100 million or more or a major increase in costs or prices for consumers, individuals, industries, Federal, State, or local government agencies, or geographic regions. Additionally, this action will not result in significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Therefore this action has been classified as "not major".

Executive Order 12372

The Food Stamp Program is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule related Notice of 7 CFR Part 3015, Subpart V (48 FR 29115), this Program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Regulatory Flexibility Act

This action has also been reviewed in relation to the requirements of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354, 94 Stat. 1164, September 19, 1980). Anna Kondratas, Administrator of the Food and Nutrition Service, has certified that this rule does not have a significant economic impact on a substantial number of small entities. The requirements will affect the food stamp recipients and the State and local agencies which administer the Program.

Paperwork Reduction Act

This rulemaking does not contain recordkeeping or reporting requirements subject to approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Public Participation and Effective Date

This action is being published without prior notice of proposed rulemaking or an opportunity for public comment prior to publication. Section 2(b) of Pub. L. 100–232 mandates that the amendment made by section 2 is effective on the date the statute was enacted (January 5, 1988) and is not applicable for allotments issued prior to February 1, 1988. Thus, good cause if found for publication less than 30 days prior to the effective date of this rule pursuant to 5 U.S.C. 553(d). Also, since prior notice and public comment procedures cannot be completed before the statutory implementation date and because delays in implementation of the requirement could adversely affect food stamp recipients, Anna Kondratas, Administrator of the Food and Nutrition Service, has determined, pursuant to 5 U.S.C. 553(b), that public comment on this action prior to implementation is impracticable. However, because the Department believes that the rule may be improved by public comment, comments are solicited on this rule for 60 days. All comments received will be analyzed and appropriate changes in the rule will be incorporated in the subsequent publication of a final rule.

Background

Current regulations at 7 CFR 273.9 permit the exclusion of income (such as charitable cash donations) received during the certification period which is received too infrequently or irregularly to be reasonably anticipated but not to exceed $30 in a quarter. Section 2(a)(1) of Pub. L. 100–232 amended section 5(d) of the Food Stamp Act to provide an income exclusion of no more than $300 in a quarter for certain charitable donations. The amendment made by Pub. L. 100–232 specifically provides that cash donations based on need, not to exceed $30 in the aggregate in a quarter, which are received from one or more private nonprofit charitable organizations shall be excluded from consideration as income for Food Stamp Program purposes. Accordingly, this action amends 7 CFR 273.9 to add this income exclusion provision.

The legislation did not provide guidance for determining what should constitute a quarter for the purpose of implementing the $300 quarterly limit required by the statute. It is the Department's view that the use of the Federal fiscal year quarter is the most feasible and least error-prone method and would ensure that the provision is treated consistently nationwide, for all households which receive such donations from private nonprofit charitable organizations. Consequently, this interim rule incorporates a Federal fiscal quarter requirement. The Department is particularly interested in receiving comments and suggestions on this question.

Implementation

In accordance with section 2(b)(1), Pub. L. 100–232 is effective retroactive to the date the statute was enacted (January 5, 1988). The statute further clarifies that the income exclusion provision contained in this action does not apply with respect to allotments issued for any month beginning before the date the statute was enacted. Thus, the exclusion of the specific charitable donations is applicable beginning February 1, 1988. Accordingly, this action amends 7 CFR 272.1 to provide that State agencies implement the provision of this action immediately and that affected households are entitled to an income exclusion under the provision beginning with the second Federal Fiscal Year Quarter of 1988 (January 1988 through March 1988), but not prior to February 1, 1988.

Consequently, in accordance with this action a household which received $100 in January 1988 from a private nonprofit charitable organization, another $100 in February from the organization, and $250 in March from a different private nonprofit charitable organization would be entitled to an income exclusion for the $100 received in February and $200 of the $250 received in March for a total income exclusion of $300 in that quarter.

This action further provides that affected households which were denied benefits because the household's eligibility or benefit calculation during the second Federal fiscal year quarter of 1988 (but not prior to February 1, 1988) did not include the income exclusion provision of this amendment shall be entitled to restored benefits, if otherwise eligible, at the time of recertification, whenever the household requests a review of its case, or when the State agency otherwise becomes aware that a review of a particular case is needed. Restored benefits shall be paid back to February 1, 1988 or the date of the food stamp application, whichever is later.

We recognize that this immediate implementation schedule will cause some difficulties with quality control (QC) reviews. Therefore, this action provides that QC reviewers shall not identify variances resulting solely from implementation or nonimplementation of this rule in cases with review dates between February 1, 1988 and August 31, 1988. For retrospective budgeted cases, QC reviewers shall begin identifying variances when September becomes the budget month. This action further provides that variances shall not be identified in cases where the provisions of this rule were not implemented prior to the QC review when the State agency correctly followed the implementation provisions of this rule.

List of Subjects

7 CFR Part 272

Alaska, Civil rights, Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 273

Administrative practice and procedure, Aliens, Claims, Food stamps, Fraud, Grant programs, social-programs, Penalties, Reporting and recordkeeping requirements, Social Security, Students.

Accordingly, 7 CFR Parts 272 and 273 are amended as follows:

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

1. The authority citation for Parts 272 and 273 continues to read as follows:

Authority: 7 U.S.C. 2011–2029.

2. In § 272.1, a new paragraph (g)(98) is added to read as follows:

§ 272.1 General terms and conditions.

* * * * *

(g) *Implementation.* * * *

(98) *Amendment No. 303.* The income exclusion provision § 273.9(c) of *Amendment No. 303* shall be implemented immediately upon publication of the Amendment as follows:

(i) State agencies must apply the provision of this amendment for any eligibility or benefit calculation made on or after February 1, 1988.

(ii) Affected households which were denied benefits because the household's eligibility or benefit calculation during the second Federal fiscal year quarter of 1988 (but not prior to February 1, 1988) did not include the income exclusion provision of this amendment shall be entitled to restored benefits at the time of recertification, whenever the household requests a review of its case, or when the State agency otherwise becomes aware that a review of a particular case is needed.

(iii) Benefits shall be restored back to February 1, 1988 or the date of the food stamp application, whichever occured later. Restoration shall be made in accordance with § 273.17 except that the twelve-month limit for restoring benefits shall not apply.

(iv) For Quality Control (QC) purposes only, QC reviewers shall not identify variances resulting solely from implementation or nonimplementation of *Amendment No. 303* for cases with review dates between February 1, 1988 and August 31, 1988. For retrospectively budgeted cases, QC reviewers shall begin identifying variances when September becomes the budget month. Variances shall not be identified in cases where *Amendment No. 303* was not implemented prior to the QC review when the State agency correctly followed the implementation provisions of this section.

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

3. In § 273.9, paragraphs (c)(2) through (c)(12) are redesignated as paragraphs (c)(3) through (c)(13) respectively and a new (c)(2) is added to read as follows:

§ 273.9 Income and deductions.

* * * * *

(c) *Income Exclusions.* * * *

(2) Cash donations based on need received on or after February 1, 1988 from one or more private nonprofit charitable organizations, but not to exceed $300 in a Federal fiscal year quarter.

* * * * *

Date: June 9, 1988.

Anna Kondratas,

Administrator.

[FR Doc. 88–13430 Filed 6–14–88; 8:45 am]

BILLING CODE 3410-30-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Enforcement Activities; Counterfeit Drugs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority for enforcement activities to add to the authorities delegated to officers and employees of FDA who have been issued certain FDA official credentials. The amendment delegates authority for seizure of counterfeit drugs under the Federal Food, Drug, and Cosmetic Act (the act), as amended.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Melissa M. Moncavage, Office of Management and Operations (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: FDA is amending § 5.35 *Enforcement activities*

(21 CFR 5.35) to delegate additional authority to FDA officers and employees who have been issued FDA credentials consisting of Form FDA–200A, Identification Record, and Form FDA–200B, Specification of General Authority. The amendment delegates to these officials the authority under section 702(e)(5) of the act to seize counterfeit drugs and equipment, labeling, and other things used or designed for use in making counterfeit drugs. The newly-delegated authority will allow the designated officials to carry out their responsibilities more expeditiously.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552; 7 U.S.C. 2217; 15 U.S.C. 638, 1451 *et seq.*; 21 U.S.C. 41 *et seq.*, 61–63, 141 *et seq.*, 301–392, 467f(b), 679(b), 801 *et seq.*, 823(f), 1031 *et seq.*; 35 U.S.C. 156; 42 U.S.C. 219, 241, 242(a), 242a, 242l, 242o, 243, 262, 263, 263b through 263m, 264, 265, 300u *et seq.*, 1395y and 1395y note, 3246(b)(3), 4831(a), 10007, and 10008; Federal Caustic Poison Act (44 Stat. 1406); Federal Advisory Committee Act (Pub. L. 92–463); E.O. 11490, 11921.

2. Section 5.35 is amended by revising paragraph (a)(1) to read as follows:

§ 5.35 Enforcement activities.

(a) * * *

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the Act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

* * * * *

Dated: June 7, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–13433 Filed 6–14–88; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 172

[Docket No. 86F–0131]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Sucrose Fatty Acid Esters

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sucrose fatty acid esters for preservation of fresh avocados, melons (honeydew and cantaloupe), limes, peaches, plums, banana plantains, and papaya. The agency is taking this action in response to a petition filed by Inotek International Corp.

DATES: Effective June 15, 1988. Objections by July 15, 1988.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 14, 1986 (51 FR 12646), FDA announced that a petition (FAP 6A3914) had been filed by Inotek International Corp., P.O. Box 348, Painesville, OH 44077, proposing that § 172.859 *Sucrose fatty acid esters* (21 CFR 172.859) be amended to provide for the safe use of sucrose fatty acid esters for the preservation of fresh avocados, melons (honeydew and cantaloupe), limes, peaches, plums, banana plantains, and papaya.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the sucrose fatty acid esters are safe for the proposed uses, and that the food additive regulations should be amended as set forth below.

In the **Federal Register** of November 5, 1986 (51 FR 40160), FDA published an amendment of § 172.859 that would permit the use of additional solvents in the manufacture of sucrose fatty acid esters. The agency received an objection to this amendment and is issuing a notice regarding the objection elsewhere in this issue of the **Federal Register**. However, FDA's decision to expand the uses of sucrose fatty esters is distinct from the prior amendment. The agency finds that this action has no bearing on its evaluation of the objection to the November 5, 1986, amendment and therefore is proceeding with this action.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before July 15, 1988, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents

shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, Part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 172.859 is amended by revising paragraph (c)(3) to read as follows:

§ 712.859 Sucrose fatty acid esters.

* * * * *

(c) * * *

(3) As components of protective coatings applied to fresh apples, avocados, bananas, banana plantains, limes, melons (honeydew and cantaloupe), papaya, peaches, pears, pineapples, and plums to retard ripening and spoiling.

* * * * *

Dated: June 9, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13435 Filed 6–14–88; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 172

[Docket No. 84F–0408]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Sucrose Fatty Acid Esters

AGENCY: Food and Drug Administration.

ACTION: Final rule; republication and opportunity to file objections or additional information.

SUMMARY: The Food and Drug Administration (FDA) is republishing, with additional information, a final rule that it published in the **Federal Register** of November 5, 1986 (51 FR 40160), and that amended the food additive regulation on sucrose fatty acid esters (21 CFR 172.859) to provide for the use of dimethyl sulfoxide and isobutyl alcohol solvents in the preparation of such esters. An objection to that final rule with a request for a hearing was filed by Suiker Unie Research, Roosendaal, Holland. The agency is not acting on that objection but instead is clarifying herein the basis for the final rule of November 5, 1986. The agency is also providing a new 30-day period for the submission of objections or of additional information in support of the objection that was previously filed. However, the agency has not stayed the effect of the final rule, and it became effective on November 5, 1986.

DATE: Objections or additional information in support of the previously filed objection by July 15, 1988. The Director of the Office of the Federal Register approved the incorporation by reference of certain publications in 21 CFR 172.859 effective on November 5, 1986.

ADDRESS: Written objections or additional information in support of the previously filed objection to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a final rule in the **Federal Register** of November 5, 1986 (51 FR 40160), to provide for the safe use of sucrose fatty acid esters prepared with the solvents dimethyl sulfoxide and isobutyl alcohol That action was in response to a petition filed by Mitsubishi Chemical Industries, Ltd. (FAP 5A3839).

Suiker Unie Research, P.O. Box 1308, 4700 BH Roosendaal, Holland, filed an objection to the regulation and requested a hearing on each issue raised in that objection. The company's objection made the following points:

(1) The final rule provides for the use of dimethyl sulfoxide in the manufacture of sucrose fatty acid esters.

(2) Dimethyl sulfoxide is an irritant, is toxic, and has never been approved for direct food additive use by FDA.

(3) Manufacturing procedures exist that do not require dimethyl sulfoxide, and hence, there is no reason to increase the risk to the public health by approving this petition.

(4) There is no rationale under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to approve sucrose fatty acid esters as being safe when manufactured with dimethyl sulfoxide.

The objection did not mention isobutyl alcohol, and thus that substance is not discussed in this document.

After FDA received the objection, Mitsubishi Chemical Industries, Ltd., the petitioner, through its attorneys, submitted a letter stating that it "opposes the objections and request for a hearing raised by Suiker Unie Research," and that FDA should deny Suiker Unie Research's request for a hearing and confirm the effectiveness of the order amending 21 CFR 172.859.

The preamble to the November 5, 1986, final rule explained that the agency had evaluated the data presented in the petition and had concluded that the proposed use of dimethyl sulfoxide is safe. Thus, the final rule continued, the food additive regulations would be amended as requested in the petition. That document did not discuss the specific nature of the data evaluated, however. In this document, the agency is republishing the final rule and is explaining in detail why the petitioned use was approved. The agency believes that this course of action is appropriate because FDA considered the factors that Suiker Unie Research relies upon in its objections in the agency's deliberations on whether to grant Mitsubishi's petition. The agency rejected each of these factors in concluding that the use of sucrose fatty acid esters manufactured with dimethyl sulfoxide as a solvent is safe. FDA will set forth the reasons it rejected these factors in this document. The objector and any other interested person will then have an opportunity, if it still believes that a hearing is necessary, to proffer facts that demonstrate that the agency's bases for rejecting these factors were incorrect and thus to justify a hearing on this matter. FDA will describe below the type of showing that must be made to justify a hearing.

The agency is therefore republishing the final rule and providing an additional 30 days for the submission of objections or of additional information in support of the objection that has already been filed. In accordance with its discretion under section 409(f) of the act (21 U.S.C. 348(f)), the agency is not staying the final rule. The agency will consider a stay, however, if one is requested, after it has evaluated any objections or other information filed in response to this **Federal Register** document.

II. Request for a Hearing

FDA will act on any requests for a hearing after it has evaluated the information filed in response to this document. In order to accommodate persons who want to request a hearing, the following information is provided.

Section 409(f) of the Act (21 U.S.C. 348(f)) provides that any person adversely affected by a food additive regulation may file objections, specifying with particularity the provisions of the order "deemed objectionable, stating reasonable grounds therefore," and request a public hearing based upon such objections. However, the Commissioner of Food and Drugs may deny the hearing request if the objections to the regulation do not raise genuine and significant issues of fact that can be resolved at a hearing. Specific criteria for determining whether a request for a hearing is valid are (21 CFR 12.24(b)):

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issues can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issues were resolved in the say sought * * *.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980) *reh. den.* 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973). An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. *Georgia Pacific Corp.* v. *U.S. E.P.A.*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959) *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. See *United States* v. *Consolidated Mines & Smelting Co.*, 445 F.2d 432 (9th Cir. 1971). Stated another way, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." *Pactro Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. See *Citizens for Allegan County, Inc.*, v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.) *cert. denied*, 358 U.S. 872 (1958).

In conclusion, a request for a hearing, in order to be granted, must present sufficient credible evidence to raise a material issue of fact, and this evidence must be capable of resolving the issue in favor of the request.

III. Evaluation of Safety

Mitsubishi Chemical Industries proposed that dimethyl sulfoxide be used in the manufacture of sucrose fatty acid esters, and that any listing regulation provide that the residue of dimethyl sulfoxide in the final product not exceed 2 parts per million (ppm).

To support the limitation of 2 parts per million (ppm) for dimethyl sulfoxide, the petitioner analyzed, by gas-liquid chromatography (GLC), samples of sucrose fatty acid esters that were spiked at 2 ppm dimethyl sulfoxide and compared them to unspiked samples. The recovery rates of the spiked samples were between 90 and 110 percent. Those analyses were validated by GLC of samples spiked at 1, 2, and 4 ppm dimethyl sulfoxide with reported recovery rates between 100 and 120 percent.

In evaluating the petition, FDA examined the analytical methodology the petitioner used to determine the dimethyl sulfoxide residue levels and recovery rates. Based on its examination of the data submitted, FDA found that the methodology is satisfactory for assuring that dimethyl sulfoxide can be reliably detected at 2 ppm in sucrose fatty acid esters.

The agency's conclusion that the use of dimethyl sulfoxide under the petitioned condition of use is safe is based on comparisons of estimates of human exposure to dimethyl sulfoxide from sucrose fatty acid esters manufactured with dimethyl sulfoxide to human exposure to dimethyl sulfoxide from natural food sources and to the acceptable daily intake level for dimethyl sulfoxide calculated from animal studies reported in the literature.

A. Estimated Daily Intake

The agency has calculated an estimated daily intake for dimethyl sulfoxide as part of its assessment of the safety of the use of this chemical in the manufacture of sucrose fatty acid esters. Assuming a maximum concentration of 2 ppm dimethyl sulfoxide in sucrose fatty acid esters, and that all sucrose fatty acid esters on the market are produced by the petitioned process (an unlikely event), the agency calculated that the estimated daily intake of dimethyl sulfoxide from this use would be 1.1 micrograms per person per day.

B. Exposure to Dimethyl Sulfoxide From Natural Food Sources

The petitioner provided evidence that dimethyl sulfoxide is a natural component of fruits, vegetables, grains, and beverages (Ref. 8) and generally occurs at levels not greater than 3 ppm, with levels in black tea being an exception at 16 ppm. Using data from the U.S. Department of Commerce (Bureau of Census, 1976 survey) for coffee consumption as an example of a source of dimethyl sulfoxide (at 3 cups of coffee per person per day), the petitioner calculated a daily intake of naturally occurring dimethyl sulfoxide (2.6 ppm in coffee beans) of 93.6 micrograms per person per day, assuming 12 grams of beans are used to prepare 1 cup of coffee. FDA concurs with this estimate. Based on this estimate, it is clear that the intake of dimethyl sulfoxide from coffee alone far exceeds the 1.1 micrograms per person per day estimated daily intake anticipated from potential dimethyl sulfoxide residues in sucrose fatty acid esters intentionally added to the diet.

C. Acceptable Daily Intake

FDA calculated the acceptable daily intake of dimethyl sulfoxide to be 9 milligrams per kilogram of body weight or 630 milligrams for a 70-kilogram adult. This calculation was based on a study that involved chronic oral administration of dimethyl sulfoxide (Ref. 7). In that study, an aqueous solution (90 percent volume by volume)

of pharmaceutical-grade dimethyl sulfoxide was administered to four groups of rhesus monkeys via gastric intubation, 7 days per week, during a 2-year period. One half of the dose was given in the morning, the other half in the afternoon. Two animals per sex were in the groups treated with 1 and 3 milliliters per kilogram of body weight and 3 animals per sex at 9 milliliters per kilogram. Electrocardiograms, hematologic studies, and chemical analyses of the urine were done. Eye examinations were conducted, and gross, as well as histopathologic, examinations were made terminally. Vogin reported toxicological or pathological changes from oral administration of dimethyl sulfoxide to monkeys at a dose of 1 milliliter per kilogram. Therefore, from this study the no-effect level of dimethyl sulfoxide is approximately 900 milligrams per kilogram. Thus using a 100-fold safety factor, the acceptable daily intake is 9 milligrams per kilogram or 630 milligrams for a 70-kilogram adult.

D. Conclusion on Safety

From the available evidence, the agency found that the estimated daily intake (1.1 micrograms per person per day) of dimethyl sulfoxide from sucrose fatty acid esters manufactured with this chemical would be negligible when compared to the exposure to dimethyl sulfoxide from natural food sources (e.g., coffee at 93.6 micrograms per person per day) and when compared to the acceptable daily intake of dimethyl sulfoxide of 630 milligrams per person per day, as calculated from published toxicological data. Consequently, the agency concluded that the use of dimethyl sulfoxide under the petitioned conditions of use is safe.

IV. Other Issues

Suiker Unie Research raised four issues in its objections to the final rule.

The first issue is the significance that is to be given to the fact that dimethyl sulfoxide is an irritant and is toxic. As discussed above, the agency is aware that dimethyl sulfoxide is a toxic irritant. However, FDA's assessment of the safety of the requested use took into consideration the expected levels of human exposure to dimethyl sulfoxide resulting from the petitioned use as well as the known toxicity of dimethyl sulfoxide. The agency's conclusion is that the level of residue of dimethyl sulfoxide that could get into food as a result of this use is safe.

The second issue is the significance of the fact that dimethyl sulfoxide has never been approved for direct food additive use by FDA. This issue is not relevant. FDA decides whether a food additive is safe based on the conditions of use proposed in a petition. Based upon its evaluation of Mitsubishi's petition, the agency concluded that, except for residues of dimethyl sulfoxide (and isobutyl alcohol), the sucrose fatty acid esters that are the subject of the petition meet the specifications in 21 CFR 172.859 and therefore would be safe for human consumption. As mentioned above under section III.D.—Conclusion on Safety, FDA found that the dimethyl sulfoxide residues in this product are safe based on the finding that the residual level of dimethyl sulfoxide in the sucrose fatty acid esters is below the amount found naturally in certain foods as well as below the amount found to be an acceptable daily intake. Therefore, FDA concludes that the subject food additive is safe even though it contains a constituent that has never been approved for use as a direct food additive.

The third issue is whether because there are other manufacturing procedures for sucrose fatty acid esters that do not require dimethyl sulfoxide, there is any reason to increase the risk to human health by approving this petition. The act does not give FDA the authority to limit the number of manufacturing processes that can be used to produce a food additive. FDA's charge under the act is to decide whether a petitioned use of a food additive is safe, and whether the additive will have the technical effect claimed for it. If so, FDA must grant the petition. FDA found that both of these requirements are met with respect to the petitioned use of sucrose fatty acid esters made with dimethyl sulfoxide and isobutyl alcohol, and thus under the act, FDA is granting Mitsubishi's petition and listing this food additive.

The fourth issue is whether there is a rationale under section 409 of the act to approve sucrose fatty acid esters as being safe when manufactured with dimethyl sulfoxide. FDA has found that there is. This document sets forth the reasons why use of the subject product is safe.

V. Conclusion

In this document FDA has clarified the basis for its decision that sucrose fatty acid esters made using fatty acids made with dimethyl sulfoxide and isobutyl alcohol are safe for use in food under the conditions of use set forth in § 172.859. FDA has decided that the objection does not provide sufficient evidence to warrant the stay of the amendment requested by Suiker Unie Research. However, FDA is republishing the final rule and providing a new 30-day objection period to allow for submission of further evidence that would support the need for a stay of the regulation or for an evidentiary hearing on FDA's decision to list this food additive.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition, the administrative record, and all documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection. Among the documents that the agency has relied upon are the following:

VI. References

1. FAP 5A3839, submission of October 26, 1984.

2. Memorandum: Food Additive Chemistry Evaluation Branch to Petitions Control Branch; January 7, 1985, FAP 5A3839.

3. Memorandum: Food Additives Evaluation Branch to Petitions Control Branch, January 17, 1985, FAP 5A3839.

4. Memorandum: Food Additive Chemistry Evaluation Branch to Direct Additives Branch, September 13, 1985, FAP 5A3839.

5. FAP 5A3839 submission of October 18, 1985.

6. Memorandum: Food Additive Chemistry Evaluation Branch to Direct Additives Branch, November 15, 1985, FAP 5A3839.

7. Vogin, E. E., et al., "Chronic Toxicity of dimethyl sulfoxide in Primates," *Toxicology and Applied Pharmacology*, 16:808–812, 1970.

8. Pearson, T. W., et al., "Natural Occurring Levels of Dimethyl Sulfoxide in Selected Fruits, Vegetables, Grains and Beverages," *Journal of Agricultural and Food Chemistry*, 29:1086–1091, 1981.

Any person who will be adversely affected by this regulation may at any time on or before July 15, 1988, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that

a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference.

For convenience, FDA is republishing in its entirety the test of the final regulation that appeared in the Federal Register of November 5, 1986. This republication of the final rule does not amend the regulation in any way. FDA is republishing the final rule under the Federal Food, Drug, and Cosmetic Act.

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. The last sentence of paragraph (a) and paragraphs (b)(10) and (11) of § 172.859 are republished to read as follows:

§ 172.859 Sucrose fatty acid esters.

* * * * *

(a) * * * Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters.

(b) * * *

(10) The total dimethyl sulfoxide content is not more than 2 parts per million as determined by a method entitled "Determination of Dimethyl Sulfoxide," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(11) The total isobuytl alcohol (2-methyl-1-propanol) content is not more than 10 parts per million as determined by a method entitled "Determination of Isobutyl Alcohol," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. SW., Washington, DC 20408.

* * * * *

Dated: June 9, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–13434 Filed 6–14–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Hyaluronate Sodium Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of the new animal drug application (NADA) filed by Sterivet Laboratories, Ltd. The NADA provides for safe and effective use of hyaluronate sodium injection in treating horses for joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3420.

SUPPLEMENTARY INFORMATION: Sterivet Laboratories, Ltd., 3909 Nashua Dr., Mississauge, ON, Canada L4V 1R3, is sponsor of NADA 140–474 which provides for intraarticular injection of a solution containing 10 milligrams per milliliter of hyaluronate sodium (Synacid™) for treating horses for equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity. The application is approved and the regulation for hyaluronate sodium injection are amended in 21 CFR 522.1145 by adding paragraph (d). The basis for approval is discussed in the freedom of information summary. The regulations in 21 CFR 510.600 are further amended in paragraphs (c)(1) and (c)(2) by revising "Sterivet Laboratories, Inc." to read "Sterivet Laboratories, Ltd."

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, Parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a) (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for "Sterivet Laboratories, Inc.," and in paragraph (c)(2) in the entry for "047408" by removing "Inc." and adding in its place "Ltd."

PART 552—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

4. Section 522.1145 is amended by adding paragraph (d), to read as follows:

§ 522.1145 Hyaluronate sodium injection.

* * * * *

(d)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 047408 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use.* For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(iii) *Limitations.* For intraarticular injection in horses only. Not for use in horses intended for food. Not intended for use in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 6, 1988.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 88-13432 Filed 6-14-88; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Decoquinate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations providing for use of decoquinate in Type C goat feeds to state that the feed may be used for breeding animals. The use in the feed of goats is based on approval of a supplemental new animal drug application (NADA) filed by Rhone-Poulenc, Inc., providing for use of decoquinate for prevention of coccidiosis.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Lubomyr Babiak, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 9, 1987 (52 FR 43061), FDA published a document reflecting approval of supplemental NADA 39-417 filed by Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852. The published document failed to reflect that decoquinate had been approved for use in breeding animals (52 FR 38924; October 20, 1987). This document amends the November 9, 1987, approval to state the feed may be used for breeding animals. Therefore, 21 CFR 558.195(d) is amended to delete the statement prohibiting use in breeding animals.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 558.195 [Amended]

2. Section 558.195 *Decoquinate* is amended in paragraph (d) in the table under "Limitations" in the entry "13.6 (0.00149 pct)" by changing the phrase "do not feed to breeding animals or goats producing milk for food;" to read "do not feed to goats producing milk for food;".

Dated: June 9, 1988.

Richard A. Carnevale,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 88-13470 Filed 6-14-88; 8:45 am]

BILLING CODE 4160-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2676

Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal; Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR Part 2676). The regulation prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219 (c)(1)(D) and 4281(b) of the Employee Retirement Income Security Act of 1974. Section 2676.15(c) of the regulation contains a table setting forth, for each calendar month, a series of interest rates to be used in any valuation performed as of a valuation date within that calendar month. On or about the fifteenth of each month, the PBGC publishes a new entry in the table for the following month, whether or not the rates are changing. This amendment adds to the table the rate series for the month of July 1988.

EFFECTIVE DATE: July 1, 1988.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Attorney, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; 202-778-8820 (202-778-8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

The PBGC finds that notice of and public comment on this amendment would be impracticable and contrary to the public interest, and that there is good cause for making this amendment effective immediately. These findings are based on the need to have the interest rates in this amendment reflect market conditions that are as nearly current as possible and the need to issue the interest rates promptly so that they are available to the public before the beginning of the period to which they apply. (*See* 5 U.S.C. 533 (b) and (d).) Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

The PBGC has also determined that this amendment is not a "major rule" within the meaning of Executive Order 12291 because it will not have an annual effect on the economy of $100 million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 29 CFR Part 2676

Employee benefit plans, Pensions.

In consideration of the foregoing, Part 2676 of Subchapter H of Chapter XXVI of Title 29, Code of Federal Regulations, is amended as follows:

PART 2676—VALUATION OF PLAN BENEFITS AND PLAN ASSETS FOLLOWING MASS WITHDRAWAL

1. The authority citation for Part 2676 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1399(c)(1)(D), and 1441(b)(1).

2. In § 2676.15, paragraph (c) is amended by adding to the end of the table of interest rates therein the following new entry:

§ 2676.15 Interest.

* * * * *

(c) *Interest rates.*

For valuation dates occurring in the month:	The values of I_k are:															
	I_1	I_2	I_3	I_4	I_5	I_6	I_7	I_8	I_9	I_{10}	I_{11}	I_{12}	I_{13}	I_{14}	I_{15}	I_a
July 1988..	.09875	.095	.09	.085	.08	.07375	.07375	07375	.07375	.07375	.0675	.0675	.0675	.0675	.0675	.06

Issued at Washington, DC., on this 6th day of June 1988.

Kathleen P. Utgoff,

Acting Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 88-13425 Filed 6-14-88; 8:45 am]

BILLING CODE 7708-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-30072E; FRL-3396-5]

Tolerance Processing Fees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule increases fees charged for processing tolerance petitions for pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). The change in fees reflects a 2 percent increase in pay for civilian Federal General Schedule (GS) employees in 1988. Additional instructions are also provided concerning payment procedures and proper identification of fees.

EFFECTIVE DATE: July 15, 1988.

FOR FURTHER INFORMATION CONTACT:

By mail: Ken Wetzel, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

Office location and telephone number: Rm. 1002-E, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-1128).

SUPPLEMENTARY INFORMATION: The EPA is charged with administration of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 authorizes the Agency to establish tolerance levels and exemptions from the requirements for tolerances for raw agricultural commodities. Section 408(o) requires that the Agency collect fees as will, in the aggregate, be sufficient to cover the costs of processing petitions for pesticide products, i.e., that the tolerance process be as self-supporting as possible.

The current fee schedule for tolerance petitions (40 CFR 180.33) was published in the **Federal Register** on March 3, 1987 (52 FR 6325) and became effective on April 2, 1987. At that time the fees were increased 3 percent in accordance with a provision in the regulation that provides for automatic annual adjustments to the fees based on annual percentage changes in Federal salaries. The specific language in the regulation is contained in paragraph (o) of § 180.33 and reads as follows:

> (o) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale * * * When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the **Federal Register** as a final rule to become effective thirty days or more after publication, as specified in the rule.

The pay raise in 1988 for Federal General Schedule employees is 2 percent; therefore, the tolerance petition fees are being increased 2 percent. The entire fee schedule, § 180.33, is presented for the reader's convenience. (All fees have been rounded to the nearest $25.00.)

Some petitioners have been forwarding fee payments to the "lockbox" address in Pittsburgh, PA, far in advance of submitting the actual tolerance petition and supporting documentation to the Office of Pesticide Programs in Washington, DC. In the future, the Agency asks that the petition be submitted within 30 days of payment. A statement has been added to paragraph (n) requesting this.

The Agency published a final rule on May 26, 1988 (53 FR 19108) which establishes user fees for registration applications received or postmarked after June 27, 1988. When the registration fees become effective, the Agency asks that separate checks be prepared for each registration and tolerance action requested. Each check should also be labeled "Tolerance Petition Fee" or "Registration Fee", as appropriate. This will simplify Agency recordkeeping and help assure proper credit and avoid unnecessary delays in processing requested tolerance and registration actions. The Agency (Office of Pesticide Programs) plans on issuing a PR Notice to pesticide registrants and applicants which will provide specific payment instructions and procedures.

List of Subjects in 40 CFR Part 180

Administrative practice and procedures, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 1, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 is revised to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.33 is revised to read as follows:

§ 180.33 Fees.

(a) Each petition or request for the establishment of a new tolerance or a tolerance higher than already etablished, shall be accompanied by a fee of $46,325, plus $1,150 for each raw agricultural commodity more than nine on which the establishment of a tolerance is requested, except as provided in paragraphs (b), (d), and (h) of this section.

(b) Each petition or request for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the same pesticide chemical, or for the establishment of a tolerance on additional raw agricultural commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a fee of $10,600 plus $750 for each raw agricultural commodity on which a tolerance is requested.

(c) Each petition or request for an exemption from the requirement of a tolerance or repeal of an exemption shall be accompanied by a fee of $8,525.

(d) Each petition or request for a temporary tolerance or a temporary exemption from the requirement of a tolerance shall be accompanied by a fee of $18,500 except as provided in paragraph (e) of this section. A petition or request to renew or extend such temporary tolerance or temporary exemption shall be accompanied by a fee of $2,625.

(e) A petition or request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level or a higher numerical level shall be accompanied by a fee of $9,250 plus $750 for each raw agricultural commodity on which the temporary tolerance is sought.

(f) Each petition or request for repeal of a tolerance shall be accompanied by a fee of $5,800. Such fee is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be repealed and a fee is paid as required by paragraph (a) of this section.

(g) If a petition or a request is not accepted for processing because it is technically incomplete, the fee, less $1,150 for handling and initial review, shall be returned. If a petition is withdrawn by the petitioner after initial processing, but before significant Agency scientific review has begun, the fee, less $1,150 for handling and initial review, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were being submitted for the first time.

(h) Each petition or request for a crop group tolerance, regardless of the number of raw agricultural commodities involved, shall be accompanied by a fee equal to the fee required by the analogous category for a single tolerance that is not a crop group tolerance, i.e., paragraphs (a) through (f) of this section, without a charge for each commodity where that would otherwise apply.

(i) Objections under section 408(d)(5) of the Act shall be accompanied by a filing fee of $2,325.

(j)(1) In the event of a referral of a petition or proposal under this section to an advisory committee, the costs shall be borne by the person who requests the referral of the data to the advisory committee.

(2) Costs of the advisory committee shall include compensation for experts as provided in § 180.11(c) and the expresses of the secretariat, including the costs of duplicating petitions and other related material referred to the committee.

(3) An advance deposit shall be made in the amount of $23,100 to cover the costs of the advisory committee. Further advance deposits of $23,100 each shall be made upon request of the Administrator when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(k) The person who files a petition for judicial review of an order under section 408(d)(5) or (e) of the Act shall pay the costs of preparing the record on which the order is based unless the person has no financial interest in the petition for judicial review.

(l) No fee under this section will be imposed on the Inter-Regional Research Project Number 4 (IR–4 Program).

(m) The Administrator may waive or refund part or all of any fee imposed by this section if the Administrator determines in his or her sole discretion that such a waiver or refund will promote the public interest or that payment of the fee would work an unreasonable hardship on the person on whom the fee is imposed. A request for waiver or refund of a fee shall be submitted in writing to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division (TS–767C), Washington, DC 20460. A fee of $1,150 shall accompany every request for a waiver or refund, except that the fee under this sentence shall not be imposed on any person who has no financial interest in any action requested by such person under paragraphs (a) through (k) of this section. The fee for requesting a waiver or refund shall be refunded if the request is granted.

(n) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the other of the Environmental Protection Agency. All deposits and fees shall be forwarded to the Environmental Protection Agency, Headquarters Accounting Operations Branch, Office of Pesticide Programs (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. The payments should be specifically labeled "Tolerance Petition Fees" and should be accompanied only by a copy of the letter or petition requesting the tolerance. The actual letter or petition, along with supporting data, shall be forwarded within 30 days of payment to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division, Washington, DC 20460. A petition will not be accepted for processing until the required fees have been submitted. A petition for which a waiver of fees has been requested will not be accepted for processing until the fee has been waived or, if the waiver has been denied, the proper fee is submitted after notice of denial. A request for waiver or refund will not be accepted after scientific review has begun on a petition.

(o) This fee schedule will be changed annually by the same percentage as the precent change in the Federal General Schedule (GS) pay scale. In addition, processing costs and fees will periodically be reviewed and changes will be made to the schedule as necessary. When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the Federal Register as a Final Rule to become effective 30 days or more after publication, as specified in the rule. When changes are made based on periodic reviews, the changes will be subject to public comment.

[FR Doc. 88–13212 Filed 6–14–88; 8:45 am]
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40 CFR Parts 795, 796, and 799

[OPTS–42068D; FRL–3396–8]

Office of Solid Waste Chemicals; Final Test Rule

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule.

SUMMARY: EPA is issuing a final test rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring and/or recommending that manufacturers and processors of 33 chemicals perform testing for human health effects and/or chemical fate in support of EPA's hazardous waste regulatory program under the Resource Conservation and Recovery Act (RCRA) of 1976, as amended. The required health effects testing is a subchronic toxicity study via oral gavage. The required chemical fate testing includes tests to determine one or both of the following: Adsorption characteristics, and hydrolysis rates. EPA is also recommending, but not requiring, anaerobic biodegradation rate testing for 12 chemicals.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on June 29, 1988. This

rule shall become effective on July 29, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M St., SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA which requires and/or recommends testing to obtain needed human health effects and chemical fate data for 33 chemicals that have been identified as hazardous constituents under Appendix VIII of 40 CFR Part 261.

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.), which contains authority for EPA to require the development of data relevant to assessing the risk to health and the environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a) of TSCA, EPA must require testing of a chemical to develop health or environmental data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). Detailed discussions of the statutory section 4 findings are provided in the Agency's first and second proposed test rules which were published in the Federal Register of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

Section 4 of TSCA authorizes EPA to require testing of chemicals whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to human health or the environment but for which existing data are inadequate to reasonably determine or predict such effects.

EPA's Office of Solid Waste (OSW) identified a need for health effects and/or chemical fate data on 73 chemicals in support of its effort under section 3001 of the Resource Conservation and Recovery Act (RCRA) to identify those wastes which may pose a substantial hazard to human health and the environment if improperly managed. Those chemicals were the subject of a proposed TSCA section 4 test rule (May 29, 1987; 52 FR 20336) that included testing for chemical fate and/or human health effects.

The proposed rule containing an overview of the Solid Waste Disposal Act (SWDA), as amended by RCRA, background on EPA's concentration-based listing program under RCRA, a discussion of EPA's TSCA section 4(a) findings, and proposed test standards to be used, including a provisional anaerobic biodegradation test guideline designed by EPA and proposed for comment.

Testing is not being required or recommended at this time for the 40 chemicals listed in the following Table 1, for one or more of the following reasons: (1) There is insufficient economic information available to perform an adequate economic analysis for the chemical (e.g., the chemical may not currently be in production); (2) the proposed testing was scientifically inappropriate because of the chemical's physical properties and/or chemical fate; and/or (3) there is no available information in the three data bases searched by OSW to suggest a potential for exposure to the chemical.

TABLE 1.—CHEMICALS FOR WHICH TESTING WAS PROPOSED, BUT IS NOT BEING REQUIRED OR RECOMMENDED AT THIS TIME

Chemical name	CAS No.
Acetamide,N-(aminothiooxomethyl) [1 2 3]	591-08-2
Ammonium vanadate [2]	7803-55-6
Benzal chloride [2]	98-87-3
p-Benzoquinone [2]	106-51-4
2,2'-Bioxirane [1 2]	1464-53-5
Bromoacetone [1 2]	598-31-2
1-Bromo-4-phenoxy benzene [1 2]	101-55-3
Carbonyl fluoride [2 3]	353-50-4
Chloral [2 3]	75-87-6
2-Chlorobenzotrichloride [1 2 3]	2136-89-2
2-Chloroethyl vinyl ether [1]	110-75-8
Chlornaphazine [1 3]	494-03-1
1-(*o*-Chlorophenyl)thiourea [1 3]	5344-82-1
Cyanogen bromide [2]	506-68-3
Daunomycin [1 3]	20830-81-3
o,o-Diethyl-*S*-methyldithiophosphate [1 2]	3288-58-2
a,a-Dimethylphenethylamine [3]	122-09-8
4,6-Dinitro-*o*-cyclohexylphenol [1 2]	131-89-5
Ethylene-bis-dithiocarbamic acid [1 3]	111-54-4
Glycidylaldehyde [1 3]	765-34-4
Hexachlorophene [3]	70-30-4
Hexaethyl-tetra-phosphate [1]	757-58-4
Isosafrole [3]	120-58-1
Maleic anhydride [2]	108-31-6
Methacrylonitrile [4]	126-98-7
Methyl chlorocarbonate [2]	79-22-1
1-Naphthylamine [3]	134-32-7
Nicotine [3]	54-11-5
Paraldehyde [3]	123-63-7
Phenacetin [3]	62-44-2
n-Phenylthiourea [3]	103-85-5
Phosgene [2]	75-44-5
1-Propanamine [3]	107-10-8
Propanenitrile [3]	107-12-0
Propanenitrile, 3-chloro [1 3]	542-76-7
Saccharin [3]	81-07-2
Tetraethyldithiopyrophosphate [1 3]	3689-24-5
Thiosemicarbazide [1 3]	79-19-6
o-Toluidine hydrochloride [1 3]	636-21-5
Trypan blue [3]	72-57-1

[1 2 3] Refers to reasons 1, 2, and 3, stated in the previous paragraph, why testing is not being required or recommended at this time.

II. Response to Public Comments

Thirty-three sets of written comments pertaining to chemicals subject to this final rule were submitted to EPA (Refs. 1 through 33) by the close of the extended comment period (August 27, 1987). A public meeting was also requested by the Chemical Manufacturers Association (CMA) and was held on September 9, 1987. The comment period was reopened for an additional 30 days on January 14, 1988 to allow time to review additional support data inserted into the public docket. Additional written comments (Refs. 38 through 44, and 49) were received during this time.

The commenters who responded to this proposed rulemaking fall into the following categories: Chemical and/or petroleum producers, trade associations, universities and research centers, Federal and State government organizations, and a public interest group. Comments relevant to chemicals subject to this final rule are discussed below, and divided into four categories: General issues, chemical-specific issues, response to technical comments on the proposed anaerobic biodegradation test guideline, and economic issues.

A. General Issues

1. *Use of TSCA section 4 to obtain data for a RCRA program.* The Procter and Gamble Company in its comments (Refs. 23 and 50) stated its support for EPA's goal of determining appropriate levels at which the land disposal of the listed chemicals should be regulated, but believes that the Agency's use of section 4 of TSCA to accomplish the goal is inappropriate. Its belief is based primarily on the fact that the subject chemicals are listed on Appendix VIII of 40 CFR Part 261, a Part that governs the disposal of hazardous waste under RCRA and has no direct relationship to TSCA.

EPA, CMA (Ref. 2), and the Natural Resources Defense Council (NRDC; Ref. 20), however, disagree with Procter & Gamble Company on this use of TSCA section 4. CMA believes that EPA should consider the toxicities of the constituent chemicals in making specific relisting decisions, and recognizes that "the Agency might issue TSCA section 4 testing requirements as one of the means to obtain such toxicity data." NRDC believes that EPA clearly has the authority to issue a test rule covering groups of chemicals under TSCA section 4, and considers this test rule "a long overdue and welcome application of this authority."

EPA agrees with CMA and NRDC on this issue and notes, as NRDC did in

their comments, that TSCA was enacted in 1976 to fill in some of the regulatory gaps that then existed regarding the assessment and prevention of adverse health and environmental effects from potentially toxic substances. This test rule therefore fulfills the intent of Congress, because RCRA contains such a "regulatory gap": it does not itself contain any analogous authority to TSCA that would permit the Administrator to require testing of chemicals.

Nowhere in TSCA is the gathering of data for regulatory purposes under other statutory programs such as RCRA prohibited or discouraged. Instead, the testing policy of Congress as explicitly mandated by TSCA is as follows:

> It is the policy of the U.S. that (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment, and (2) that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures. (TSCA section 2(b)).

Therefore, EPA believes that: (1) A clear and justifiable need exists for the development of adequate health and environmental data for the chemicals subject to this rule; and (2) TSCA section 4 is an appropriate vehicle through which to obtain such data.

2. *The "may present an unreasonable risk" (section 4(a)(1)(A)(i)) finding.* Many comments were received concerning the basis for the section 4(a)(1)(A) findings of "may present an unreasonable risk of injury to health or the environment" for the chemicals listed in the proposed rule (Refs. 2, 16 through 20, 27, 33, 38 through 44, and 49). Since CMA submitted the most extensive comments on this topic, and many commenters incorporated CMA's comments by reference, those comments will be the primary focus of EPA's response.

a. *Regulation of chemicals as a category.* CMA has stated that "* * * EPA correctly has not proposed that these test rules will apply to a category of chemicals, as that term is defined in TSCA section 26(c)(2), because no such category exists with respect to the 73 chemicals involved," and that "EPA must make each of the section 4(a)(1)(A) findings for each of the 73 chemicals * * *" Monsanto Company also does "not believe that the Agency has the authority to regulate these 73 chemicals as a category, as is being attempted here."

TSCA section 26(c)(2) defines "category of chemical substances" to mean a group of chemical substances which are similar in structure, etc., or "which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances." Therefore, the grouping of chemicals which share a common classification basis, such as hazardous waste constituents, is clearly permitted under TSCA. Thus, while EPA believes that a category approach could legally have been used for the proposed rule, instead EPA chose an individual chemical approach and gathered and made available for comment information to support a section 4(a)(1)(A) finding of "may present an unreasonable risk" for each of the chemicals included in this final rule.

b. *Role of exposure data in section 4(a)(1)(A)(i) findings.* With regard to the rulemaking record, CMA commented that EPA concluded that the 73 chemicals meet the requirements for testing under section 4(a)(1)(A)(i) solely "by virtue of these chemicals being identified as 'hazardous constituents' [under the RCRA program]."

The Agency disagrees with this comment. While all chemicals subject to this final rule are listed on Appendix VIII, this was not the sole criterion used by EPA to meet the requirements for testing under TSCA section 4(a)(1)(A)(i). Other factors listed in the proposed rule include: The nature of potential toxicity, the presence of these chemicals in treatment, storage, or disposal facilities, evidence that existing land fills leak, and the potential for human exposure to these chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization. Also, toxicity data for each of the chemicals are contained in the background document for section 3001, Subtitle C of RCRA, and/or a Health and Environmental Effects Profile (HEEP), contained in the RCRA docket and incorporated by reference into the record for this rulemaking. The one exception is methanethiol; toxicity data for this chemical were inserted into the docket prior to reopening the comment period in December, 1987. Therefore, the section 4(a)(1)(A)(i) finding was not made for these chemical substances solely by virtue of their being identified as hazardous constituents under the RCRA program.

Vulcan Chemicals submitted the comment, "Although it is true that the subject chemicals appear in Appendix VIII, they were not included in Appendix VIII because they presented an unreasonable risk to health or the environment but rather because they presented some degree of toxicity . . . Appendix VIII was established by EPA during the promulgation of the RCRA regulations and the hazardous constituents contained therein are not necessarily of significant toxicity." In response, EPA refers to 40 CFR 261.11(a), which states:

> Substances will be listed on App. VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms.

EPA acknowledges that the "unreasonable risk" standard was not used in listing substances on Appendix VIII, but the Agency believes that the toxicity and exposure data made available for public comment do support a finding that the chemicals subject to this final rule "may present an unreasonable risk." In support of EPA's section 4(a)(1)(A)(i) finding for the subject chemicals in the proposed rule, the Natural Resources Defense Council (NRDC; Ref. 20) believes that the threshold requirement for being listed in Appendix VIII is more than adequate to satisfy the "may present an unreasonable risk to health or the environment" finding required by TSCA, noting that:

> Substances will be listed on Appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. (40 CFR 261.11(a)).

NRDC also believes that since EPA is basing its decision for a test rule using the "unreasonable risk" finding rather than the "substantial exposure" (section 4(a)(1)(B)) finding, there is no requirement for a showing of substantial human exposure. Their comments included a discussion of Congressional intent in designing the TSCA testing program, noting that the "unreasonable risk" standard for testing was to be used to identify "those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effect on health or the environment." H.R. Rep. No. 94-1679, 94th Cong., 2nd Sess. 61 (1976) (Conference Report). NRDC also cited Rep. Murphy, Chairman of the House Subcommittee that drafted TSCA, when explaining when testing would be required using the "may present an unreasonable risk" prong: "If there is reliable preliminary data indicating that a substance may be dangerous, again it would be reasonable to conclude that the chemical may present an unreasonable risk and that additional testing be done." 122 Cong. Rec. H11347 (daily ed., Sept. 28, 1976).

NRDC pointed out in their comments that TSCA section 4(a)(1)(A) "is completely silent on the issue of exposure", and noted that "The conscious choice by Congress to omit any such reference to exposure under the 'unreasonable risk' prong has been consistently interpreted by EPA to require only the potential for exposure." NRDC also cited a previous EPA position concerning exposure and the TSCA section 4(a)(1)(A) findings: "Monitoring or other specific exposure information will be unavailable in many cases, and therefore, the Agency will be compelled to rely upon reasonable conclusions about exposure potential" (50 FR 859; January 7, 1985). NRDC therefore believes the EPA's conclusion in the proposed rule regarding the potential for human exposure to the subject chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization is sufficient to satisfy the first requirement of section 4(a)(1)(A) of TSCA.

CMA, however, in its first set of comments (Ref. 2) stated its belief that the general assertions made by EPA in the proposed rule with regard to the subject chemicals' potential for exposure to humans, i.e., the subject chemicals are constituents of wastes to which humans might be exposed, "falls far short of the legal standards mandated by TSCA section 4(a)." Other industry commenters agreed.

EPA agrees with NRDC that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and acknowledges that EPA has consistently interpreted this finding to require only potential for exposure. However, since relevent data were easily available and obtained within the time allowed for this rulemaking, the Agency made the decision to further support the findings by documenting the potential for exposure to the subject chemicals.

EPA inserted into the docket for this rule, and opened for comment, data that document the presence of the subject chemicals in waste streams and/or ground water, demonstrating potential for significant human exposure. The data have been obtained by searching three data bases used by the Office of Solid Waste: The Industry Studies Data Base (ISDB), the Damage Incident Data Base (DIDB), and the Hazardous Waste Disposal Site (HWDS) Data Base. Many of the chemicals are listed in more than one data base. Much of the data contained in the ISDB is confidential business information (CBI), and is contained in a separate CBI docket. All non-CBI information was made available for review in the OPTS docket (No. 42088C). A brief description of each data base is contained in the notice to reopen the comment period on the proposed rule, 53 FR 911, January 14, 1988.

The data show that tens of thousands of pounds of the subject chemicals are being released annually via disposal. Also, the type of disposal described in the data bases for the subject chemicals, such as deep-well injection, discharge to landfill, or discharge to a POTW (publicly-owned treatment works), indicate potential for leaching and exposure to these chemicals. Indeed, data exist for many of the chemicals which document incidents in which the chemicals have migrated from their place of treatment, storage, or ultimate disposal. It is likely that these data represent only a portion of actual contamination occurrences throughout the country.

SOCMA (Ref. 40) believes that there is no evidence that each of the chemicals subject to the rule is being released into the environment "in quantities sufficient to pose an unreasonable risk, nor has EPA supplied such proof with the latest additions to the docket containing 'exposure data' from three sources * * *" CMA, in response to the exposure data inserted into the rulemaking record, still maintains that EPA must demonstrate that there are identified, relevant exposures of each chemical to humans, and that such exposures result from the pertinent activities involved—in this case, from the disposal either of such substances or of products containing them." Also, CMA maintains that the "risk must be reasonably well characterized, with respect to both its nature (e.g., effects and populations involved) and its likelihood."

The Agency disagrees, because EPA believes that TSCA does not require that EPA "show" or "prove" the existence of unreasonable (or substantial) risk, but rather that EPA find that a given chemical "may present an unreasonable risk." Accordingly, the exposure data inserted into the rulemaking record were intended to demonstrate potential for exposure, rather than prove both the nature of the risk (effects and populations involved), and its likelihood, as suggested by CMA.

A recent court decision (Ausimont U.S.A. Inc. v. EPA; Ref. 45) supports EPA's position on the role of exposure data and risk determination in section 4(a)(1)(A) findings. The decision notes that "the agency must be reasonably discriminate in selecting subjects for testing. But section 4 focuses on investigating areas of uncertainty as a prelude to regulating harmful substances." It continues,

> Although mere scientific curiosity does not form an adequate basis for a rule, as the seriousness of risk becomes known and the extent of exposure increases, the need for testing fades into the necessity for regulatory safeguards. The issue presented here is where in the spectrum this rule falls. In most administrative proceedings, we examine the record to see if there is a foundation for an agency determination of fact; however, here we look to see if the Administrator produced substantial evidence to demonstrate not fact, but doubt and uncertainty.

With regard to risk, the decision notes that the congressional conference committee report on TSCA stated that the purpose of the testing provision is to

> * * * focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects on health or the environment. The Administrator need not show that the substance or mixture does or will present a risk * * * Although cautioning that the agency must act reasonably and prudently, and take into consideration the economic impact of any action, of necessity Congress granted EPA fairly broad discretion in exercising its expertise to determine when data must be produced.

CMA, in their last comment set (Ref. 43) expressed concern that "it appears to be virtually impossible for public commenters to search out chemical-specific information from the three data bases cited by EPA in support of these rules * * *", and that "it is simply not possible for members of the public to review any of the data upon which the Agency currently relies."

The Agency acknowledges that the public does not have full access to the three EPA (and EPA contractor) data bases from which the exposure data were obtained. This is because these data bases contain confidential business information, as claimed by the companies that supplied the data to EPA. CMA itself notes that "at least with respect to one of these data bases, most of its data are proprietary and thus are not legally available to the public." Confidential data, although not available for public review, is not precluded from consideration when making a section 4 finding for testing requirements. Section 14 of TSCA, governing disclosure of data, provides that any confidential data obtained by the Administrator must not be disclosed to the public except under certain circumstances, e.g., in order to protect health or the environment against an

unreasonable risk of injury to health or the environment.

SOCMA and CMA expressed concern about the lack of detail presented in the information obtained from the data bases. Again, much of the information is confidential, such as the type of disposal indicating potential for leaching and exposure to the subject chemicals (deep well injection, discharge to landfill, or discharge to a publicly-owned treatment works), location of sampling, etc. All non-confidential information available from the three EPA data bases was inserted into the rulemaking record for public review.

3. *The "data are insufficient" (section 4(a)(1)(A)(iii)) finding.* CMA asserted in its original set of comments (Ref. 2) that EPA had not demonstrated that there are insufficient data and experience upon which the health or environmental effects of each chemical can reasonably be determined or predicted, as required by TSCA. EPA disagrees with CMA's comments on this issue for all chemicals subject to this final rule with the exception of three chemicals, for which supporting documentation for one endpoint each was missing from the Literature Search and Critique document contained in the public docket for the proposed rule. That information was inserted into the public record and opened for public comment, 53 FR 911.

With regard to the subchronic toxicity endpoint, the July 24, 1987 memorandum from the Office of Research and Development (ORD) to OSW contained in the Literature Search Results and Critique document (OPTS docket 42088A) describes the search strategy used by EPA's ORD. The strategy involved the review of published literature, computerized data bases, and also applicable non-CBI information in the EPA's Office of Toxic Substances and the Office of Pesticide Programs files. No subchronic toxicity data were found for any of the subject chemicals, with the exception of phosgene. A February 9, 1987 memorandum from EPA's Environmental Criteria and Assessment Office to OSW (contained in the Literature Search document) explains why the existing data for phosgene are insufficient to support OSW's concentration-based listing program. Due to other factors, however, EPA is not requiring testing for phosgene (see Unit II.B.15. of this preamble).

CMA incorrectly assumed in its supplemental comments (Ref. 3) that EPA relied on the absence of a Health and Environmental Effect Profile (HEEP) to support the "data are insufficient" finding for this rule. Those HEEP documents included in the docket by reference instead were intended to support the section 4(a)(1)(A)(i) "may present an unreasonable risk" finding.

To identify and evaluate existing chemical fate information relevant to the concentration-based listing program, a literature search was conducted and the report was made available for public comment in the docket. The report objective was to evaluate existing test data on soil sorption coefficients, anaerobic biodegradation (subsurface) rates, and hydrolysis rates for their applicability to the OSW ground water model. EPA was looking for studies that: (1) Provided quantitative data concerning the designated key parameters; and (2) were collected under physical conditions that approximate the ground water environment. The TSCA test guidelines published on September 27, 1985 (50 FR 39252) for hydrolysis as a function of pH 25 °C (40 CFR 796.3500) and sediment and soil adsorption isotherm (40 CFR 796.2750) provide general guidelines for evaluation of the test methods for hydrolysis rate and sorption coefficient, and data developed in general accordance with these guidelines fulfill both criteria (1) and (2). The available EPA test guidelines for biodegradation of chemical compounds do not simulate the ground water environment, and do not yield data representative of the various subsurface environmental conditions prevalent in the United States.

All chemicals were searched for each endpoint for which data were not already "in hand." Excluding one study on sorption coefficients, the results reported either did not provide quantitative test data for the designated parameters or were conducted under conditions not related to ground water environment. In addition, a large number of chemicals were found to have no published information pertinent to the parameters of interest.

SOCMA stated in its comments (Ref. 27) that "much data are indeed available" on many of the proposed chemicals, but that "because these data do not fit in EPA's quantitative modeling procedure developed to accomplish the concentration-based listing program under RCRA, EPA has determined the existing data to be unacceptable." SOCMA believes that the existing data on several of these chemicals should be considered and that EPA should redesign the model to accommodate these available data. SOCMA did not submit any additional (existing) data with its comments.

As pointed out in the preceding paragraph, EPA has reviewed all existing data found through a thorough search of the literature, and concluded that the existing data either do not provide quantitative test data for the key parameters consistent with the nation-wide implementation of the model, or were obtained under conditions not relevant to ground water media—the medium of potential exposure. Therefore, EPA finds that for these identified data gaps, there are insufficient data and experience upon which the health or environmental effects of the subject OSW chemicals can reasonably be determined or predicted on a nation-wide basis.

4. *Use of TSCA sections 8(a) and 8(d).* CMA stated in its original comments (Ref. 2) that the "pursuing a 'fast track' to the rulemakings." EPA "both has failed to meet its statutory obligations under section 4(a), and has contravened the Agency's own policies for issuing section 4 test rules." CMA refers specifically to the fact that EPA did not "call in existing data under TSCA section 8(a) and 8(d), a process cited as "established EPA policy" in CMA's comments.

EPA believes that these sections of TSCA have served as useful tools in the gathering of production, release, health effects, and safety information for many previous test rule candidates, particularly those recommended for testing to EPA by the Interagency Testing Committee (ITC). Sections 8 (a) and (d) are automatically "triggered" at the time a chemical is formally recommended by the ITC for testing consideration and thus data are obtained expeditiously for ITC chemicals. However, the use of the rulemaking authorities under TSCA section 8 for information gathering purposes is not required prior to conducting rulemaking pursuant to TSCA section 4. No such expeditious automatic mechanism exists for non-ITC chemicals, and conventional rulemaking would not have produced section 8 (a) and (d) data on a timely basis. Furthermore, any available studies could have been submitted to EPA in response to the proposed section 4 rule. Finally, EPA's Office of Research and Development conducted a search of existing TSCA section 8(d) files as part of their literature search for subchronic toxicity data.

5. *The "testing is necessary" (section 4(a)(1)(A)(iii)) finding.* CMA noted in their original comments (Ref. 2) that "under section 4(a), EPA may require testing only if the data to be developed" are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal [of the chemical], or that any combination of such activities, does or does not present

an unreasonable risk of injury to health or the environment." CMA believes that EPA did not establish this relationship between the proposed testing and future Agency regulatory determinations concerning unreasonable risks, and that RCRA relisting decisions involve no such determinations.

EPA believes that testing is necessary for each of the chemicals subject to this final rule, as follows from section 4(a)(1)(A) (i) and (ii) findings, to develop data which are relevant to determining whether the disposal of the subject chemicals by various means or various concentrations present an unreasonable risk. The Agency has established that each of these chemicals may present an unreasonable risk, and that for the health effects and chemical fate endpoints of concern, data are either not available or are inadequate for use in the OSW concentration-based listing program. Unit II.A.3. of this preamble contains a discussion of why available data are inadequate and why the particular testing endpoints were determined to be critical to the determination of unreasonable risk of injury to health or the environment through disposal to landfills of certain concentrations of the subject chemicals in waste streams.

6. *Who is subject to testing requirements*—a. *Byproduct and "inadvertent" manufacture.* EPA originally proposed that manufacturers of the subject chemicals as byproducts or impurities be subject to the rule. Procter & Gamble (Refs. 23 and 50), Vulcan Chemicals (Ref. 33), and SOCMA (Ref. 27) believe that the proposed test rule should be revised to exempt companies who manufacture or process the subject chemicals only as byproducts without a separate commercial intent. SOCMA suggested that "in certain limited circumstances it may be appropriate for EPA to propose not to grant a standard section 4 testing exemption to impurity and waste byproduct manufacturers," such as when "no one manufactures or imports the subject chemical and current data show that the subject chemical is being discharged to the environment," or "when the volume of impurities or waste byproducts manufactured is a substantial percentage of the amount of the substance intentionally produced."

Procter & Gamble wrote, "The historical roots of section 4 in the Eckhart Subcommittee work on TSCA were the sharing of the costs of test generation in direct proportion to the economic benefits which producers derived from the chemicals."

EPA does not agree that the intention of Congress to have producers share the cost of testing should be interpreted to exclude producers of byproducts from TSCA section 4 testing requirements. While economic benefit is not derived directly from the production of the subject chemical, the production and disposal of the byproduct are a result of a production process by which the company does derive economic benefit (an indirect benefit). In addition, the potential for significant exposure to a chemical exists through its disposal as a byproduct, such as for the chemicals acetophenone and bis(2-chloroisopropyl)ether subject to this rule, for which environmental release has been documented.

CMA originally recommended (Ref. 2) that EPA adopt a "tiering" approach to the coverage of byproducts and impurities, so that such chemicals would be subject only if the Agency first determines, as part of its test rule implementation, that no persons manufacture (or import) the subject chemicals as primary commercial products.

In their supplemental comments (Ref. 3), however, CMA wrote, "Although we continue to believe that such an approach is viable for these rules, our further consideration of the rules' impacts and analytical requirements leads us to conclude that the Agency should adopt the approach spelled out in these supplemental comments, of limiting testing requirements by the 'known to or reasonably ascertainable by' standard described herein."

CMA acknowledged that "because EPA intends to use the data from these rules as part of the Agency's RCRA relisting activities, and because of the possible involvement of impurities and byproducts in waste-related activities, EPA might be justified in applying the rules to impurities and byproducts in the manner described in these comments."

CMA's major concern with the applicability of the test rule to impurities and byproducts is the "tremendous analytical burdens" which these requirements would impose. CMA believes that the rule would, in effect, require companies to analyze all of their products for each of the chemicals listed in this final rule.

EPA concurs with CMA on this issue, and did not intend under the proposed rule that companies be required to perform analytical work in order to determine whether their manufacturing (and import) operations trigger the final testing requirements. EPA believes a company should be subject to this final rule (with respect to manufacture of the subject chemical solely as byproducts) only if it is known to or reasonably ascertainable by that company that such manufacture takes place.

b. *Impurity manufacture.* EPA proposed that manufacturers of the subject chemicals as impurities be subject to the testing requirements of this rule. While EPA believes that this is logical and appropriate, for the same reasons as stated above for byproduct manufacturers, none of the subject chemicals are produced solely as an impurity, and those produced as impurities are produced by the same companies as byproducts. Therefore, so as not to unduly burden industry and the Agency with applications for exemption from testing, this requirement has been deleted from 40 CFR 799.5055(b).

c. *Nonisolated intermediate manufacture.* Several industry commenters objected to required testing of chemicals produced "solely as nonisolated intermediates." The particular chemicals and companies are identified in Unit II.B. of this preamble, which responds to chemical-specific comments.

While EPA acknowledges that the amount of chemical substance released as a result of this type of production may be less than other types, such as byproducts, manufacturing or processing a chemical as an intermediate does not preclude exposure to that chemical. It is common experience that process waste streams and reactor vessel residues will contain "intermediates." In many instances, these chemicals are released to the environment as fugitive emissions, liquid or solid wastes, and as unreacted feedstock (impurities) in finished products. Furthermore, many intermediates are stored on-site in large quantities until batch reacted on demand for a given product (the same intermediate may be used as feedstock for different products or may be stockpiled until needed). As such, "intermediates" typically exist as chemicals to which there is potential for human exposure. Also, EPA has found data documenting the presence in ground or surface water of the subject chemicals cited by commenters as being produced as nonisolated intermediates, 53 FR 911.

d. *Pesticides.* Two chemicals subject to this final rule, endrin and maleic hydrazide, are not listed in the TSCA Inventory, because their primary use has been (endrin) and is (maleic hydrazide) as pesticides. However, this does not preclude their being subject to this section 4 rule. TSCA section 3(2)(B((ii) exempts from coverage "any pesticide * * * when manufactured, processed, or distributed in commerce for use as a pesticide." This test rule is based on

section 4(a)(1)(A) findings for the subject chemicals, due to potential for unreasonable risk associated with their disposal. The disposal of endrin and maleic hydrazide does not constitute "use as a pesticide," and so is subject to regulation under TSCA. Manufacturers and processors of endrin and maleic hydrazide are thus subject to the testing requirements because the chemicals are disposed of, as discussed above.

e. *Research and development, and/or low volume manufacture.* In the proposed rule, EPA discussed several approaches to dealing with chemicals subject to the rule which may be produced only for research and development (R&D) or in small quantities. The Agency has received several comments on this issue, most concurring with an R&D waiver, and an aggregate production threshold for low volume chemicals. It is now apparent, however, that none of the chemicals subject to the final rule fall into either of these categories. Therefore, EPA has not included any R&D waiver provision in the rule.

7. *Export notification.* Section 12(b) of TSCA requires exporters of chemicals for which final test rules have been issued under section 4 to "notify the Administrator of such exportation or intent to export * * *." SOCMA (Ref. 27) commented that if the Agency fails to grant exemptions from testing to those who manufacture the subject chemicals only as byproducts, EPA will be "inundated by useless section 12(b) notifications," and would present an unacceptable burden to the regulated community and to EPA. CMA (Ref. 2) also believes that the section 12(b) requirements should not apply to the chemicals subject to this final rule, and noted that the intention of this rule is "to provide for the environmentally secure disposal of hazardous wastes." CMA suggests that this is not an export issue, and it "should not trigger the unnecessary and burdensome impacts of reporting under section 12(b)."

While EPA acknowledges that this requirement may be burdensome to industry and the Agency for this rule, it is required under TSCA that section 12(b) apply to all chemicals subject to testing under section 4. EPA is continuing to examine the implementation of section 12(b) and ways to reduce burden in relation to TSCA section 4 rules and the Paperwork Reduction Act.

8. *Testing schedule.* CMA suggested (Ref. 2) that "if EPA is unable to complete the modeling necessary for RCRA relisting until all intended data have been generated, then a consistent testing schedule should be established for all of these parameters. If the proposed anaerobic biodegradation protocol is adopted, a 20-month schedule would be appropriate because that protocol requires up to 64 weeks."

EPA disagrees with this comment. The testing schedule as proposed and now finalized is consistent with the time allotted for the various tests in previous section 4 rules. Also, "staggering" the submission of test results rather than requiring the same schedule for all test parameters will allow the Agency time to review the data.

9. *Confidential business information (CBI).* While CMA acknowledged (Ref. 2) that EPA intends to protect CBI submitted under these rules in the same manner that the Agency protects data submitted under other section 4 rules, CMA expressed concern that the final rule would impose testing requirements upon certain chemicals that were reported for the TSCA section 8(b) Inventory, but whose identities were claimed confidential. This comment is no longer applicable, since no such chemicals are subject to this final rule. All CBI (economic and exposure) associated with this final rule has been protected from disclosure.

10. *Proposed toxicity testing requirement.* Three commenters, NRDC (Ref. 20), SOCMA (Ref. 27), and the U.S. Department of Interior (USDOI) (Ref. 28), addressed issues concerning the proposed toxicity testing. NRDC and USDOI concurred that the health effects testing is warranted; however, NRDC believes that the proposed 90-day subchronic toxicity study is grossly inadequate to determine the adverse health effects of the chemicals in question.

NRDC recommended that a series of additional tests be performed to fully ascertain carcinogenic, mutagenic, and neurotoxic effects of these chemicals. First, NRDC advised EPA to replace the 90-day subchronic test in favor of a two-year chronic toxicity test. NRDC maintained that the 90-day test is not adequate to determine long-term effects from prolonged exposure. Second, NRDC urged the adoption of a tiered testing plan that would incorporate:

a. Initial analysis of each chemical to determine whether there exist structural analogues which are carcinogens, mutagens, neurotoxins, or are associated with reproductive effects, and whether the chemical is an alkylating agent.

b. A battery of mutagenicity tests for all chemicals.

c. Satellite tests for carcinogenicity, adverse reproductive effects, and neurotoxicity. NRDC maintained that the plan contained in its comment would fully characterize a chemical's chronic toxicity.

On the other hand, SOCMA recommended that the Agency reevaluate the requirement to perform the 90-day subchronic test in view of chemicals on the list that are not amenable to testing by this method and the impact of testing on the regulated community.

EPA acknowledges NRDC's comment regarding the scope of tests required to fully characterize a given chemical's toxic potential. However, the purpose of this test rule is to obtain data in support of OSW's concentration-based (relisting) program. OSW has determined that relistings can be accomplished using toxicity data from a 90-day study. The Agency maintains that a well-designed and conducted subchronic animal study is minimally sufficient for developing a human reference dose (RfD) for chronic (systemic) toxicity.

With regard to SOCMA's comments, chemicals which are not suited to this method are no longer designated for testing, as discussed in Unit II.B. of this preamble. The impact on the testing community is discussed in the final Economic Analysis for this rule and in Units II.D. and IV. of this preamble.

USDOI wrote that the subchronic toxicity study as proposed is appropriate only for mammalian systems; this test would fail to provide toxicity information for aquatic organisms. USDOI asked that the proposed rule be amended to include testing of invertebrates and fish species and suggested that EPA adopt: (1) A *Daphnia magna* life cycle (21-day renewal) chronic toxicity test; and (2) a fish life cycle toxicity test.

EPA agrees with USDOI's comment that acquiring and using toxicity data for aquatic organisms is necessary. In fact, the Agency is developing a method for assessing the ecological impacts of hazardous waste constituents. However, the Agency believes that it is premature to require the aquatic toxicity tests recommended by USDOI at this time since EPA does not have a well-defined, quantitative process for using aquatic toxicity information in establishing concentration-based listings.

11. *Biodegradation testing should be made optional.* Several commenters addressed EPA's solicitation of comments on whether the proposed anaerobic biodegradation testing should be optional rather than required. Some of these commenters said that manufacturers should be given the opportunity to forego biodegradation testing, thereby tacitly accepting

establishment of lower relisting concentrations by assuming "zero biodegradation." Only one commenter (NRDC; Ref. 20) stated that biodegradation testing should not be made optional.

EPA has decided not to require the biodegradation test, because it is an expensive test and EPA can fully protect the environment by assuming zero biodegradation (a worst case condition) in the absence of data. In the future, if data becomes available that can be used to more accurately predict a chemical's biodegradation rate, then a non-zero value may be used. Thus, individual manufacturers will be able to decide whether the benefits of developing a more realistic estimate, i.e., for each chemical, performing the test and having the data used in the chemical fate and transport model, is worth the cost of conducting the test, or whether it is more cost-effective to not perform the test and have EPA utilize a model which assumes no biodegradation of that chemical. Persons who must make the decision whether or not to test are reminded that, although the protocol contains only a single assay, it can in many respects be considered at tiered test. Because of the way time points were selected, compounds that degrade rapidly will require a minimum amount of effort, whereas compounds that do not degrade over the 64-week period will require samples at all time periods to be analyzed. This approach has been clarified in the revised (final) protocol. The Agency believes that any alternative (non-tiered) approach would be less cost-effective and more time consuming than the tiered approach described in the protocol.

12. *Chemical fate testing should be "tiered."* Several commenters said that EPA should not require the entire battery of chemical fate testing described in the proposed rule. According to one commenter, it would be more cost-effective to replace the requirements to test for biodegradation, hydrolysis, and soil absorption with a tiered approach to testing. Such an approach would allow affected manufacturers to utilize screening tests to determine whether a more definitive test is indicated.

The objective of the biodegradation protocol is to provide anaerobic degradation rate constants for chemicals listed in the test rule. These rates are to be used in EPA's quantitative modeling procedures to evaluate potential exposure due to groundwater contamination. The key to this protocol is the development of rate constants appropriate for the evaluation of groundwater contamination. Although not of the usual tiered design, the protocol does use a tiered approach. The test has been designed so that, when the test chemical concentration has been reduced by 95 percent the test is terminated. Therefore the test is tiered on the specific time intervals after which samples would have to be taken. In the protocol, samples are to be analyzed at 0, 4, 8, 16, 32 and 64 weeks. If the chemical is completely degraded by week 4, the remaining four samples do not have to be completed. This would reduce the analytical portion of the protocol by 66.6 percent and the microbiological analyses by 33.3 percent. This would effectively reduce the cost of the protocol by more than 25 percent for rapidly degraded chemicals. In light of these considerations, EPA believes that in many cases for chemicals subject to this final rule, it would be advantageous for manufacturers and processors to perform this test for their chemicals. A screening test was considered; however, due to the duration of the adaptation period, the amount of time necessary to complete a screening test could be extensive. Performance of the screening test could result in a significant delay in providing results of the full test, if it were determined that one was needed. Also, the cost savings of such a screening test would not be significant. Therefore, incentive for conducting such a test is reduced.

B. Chemical-Specific Comments

1. *Bis(2-chloroethoxy) methane.* Morton Thiokol, Inc. (MTI) (Ref. 19) commented that the studies specified for bis(2-chloroethoxy) methane in the proposed rule, i.e., subchronic toxicity, hydrolysis, and biodegradation tests, are unwarranted. MTI believes that it is the only manufacturer and processor of this compound. MTI stated that bis(2-chloroethoxy) methane is a site-limited intermediate confined in a completely enclosed system, and it is consumed entirely in the production of polysulfide rubber polymers. According to MTI, all wastes associated with the production of polysulfide rubber are deep-well injected, and thus MTI asserted that there is virtually no human exposure to bis(2-chloroethoxy) methane.

EPA does not believe that the practice of deep-well injection necessarily precludes human exposure. Also, MTI did acknowledge in its comment that past disposal practices (other than deep-well injection) at the company's Moss Point, Mississippi, plant have contaminated the groundwater with bis(2-chloroethoxy) methane at levels as high as 5 mg/L. In addition, wastes from other sources which contain bis(2-chloroethoxy) methane as an impurity may currently be land disposed, and thus could pose a risk to human health and the environment. Finally, as MTI pointed out, bis(2-chloroethoxy) methane has been measured in groundwater at a superfund site in Plumsted Township, New Jersey, thus providing additional evidence that the land disposal of bis(2-chloroethoxy) methane-containing waste can lead to its entry into the human-accessible environment. Therefore, the Agency has retained the specific test requirements for bis(2-chloroethoxy) methane.

2. *Benzal chloride.* Monsanto Co. (Ref. 18) objected to requiring testing on benzal chloride because it is a chemical that rapidly hydrolyzes, and thus the biodegradation testing would not provide meaningful results.

The Agency agrees that the compound hydrolyzes very quickly and thus biodegradation testing is unnecessary. This chemical has not been included among the chemicals recommended for biodegradation testing.

3. *4-Chlorobenzotrichloride.* Occidental Chemical (Ref. 21) submitted information to EPA on 4-chlorobenzotrichloride to support its objections to the proposed health effects testing. Occidental's hydrolysis data indicate that the chemical has an aqueous half-life of 2 minutes at 25 °C. According to Occidental, oral exposure is not a relevant route of exposure for this chemical since it is unlikely that waste leachate, surface, or groundwater would contain 4-chlorobenzotrichloride, because of its short half-life. Occidental also believes that 4-chlorobenzotrichloride is not amenable to the oral gavage toxicity study because hydrolysis would occur in the gastrointestinal tract and thus reduce the effective exposure to 4-chlorobenzotrichloride.

EPA recognizes that the reported rapid hydrolysis of 4-chlorobenzotrichloride would result in water not being a significant medium of exposure to the chemical. However, the Agency disagrees with Occidental's assertion that oral exposure is not a relevant route for 4-chlorobenzotrichloride. The ingestion of 4-chlorobenzotrichloride-contaminated soil (particularly by children) is a potential route of oral exposure. The Agency requires oral toxicity data to assess the associated health hazard.

As for Occidental's concern regarding the technical feasibility of the gavage study, the finding that 4-chlorobenzotrichloride is rapidly hydrolyzed in water does not preclude

the use of another medium, such as corn oil, as the gavage vehicle.

Occidental also objected to chemical fate testing for this chemical because it will hydrolyze before soil addition/equilibration, and that biodegradation is not expected to be an important fate process. Aqueous hydrolysis testing for this chemical conducted by this commenter has been submitted to EPA.

The Agency agrees that, owing to this chemical's relatively rapid hydrolysis, it is an inappropriate candidate for biodegradation testing and has removed this chemical from the list of chemicals subject to hydrolysis, biodegradation, and soil sorption testing.

4. *Dibutyl phthalate.* (CMA (Ref. 5 and 38) objected to TSCA section 4 biodegradation testing for this chemical, saying that there was no evidence of direct exposure to this chemical as a result of waste disposal activities, and that there was no evidence to conclude that exposure to this chemical at waste sites presents a serious risk of adverse health or environmental effects. The Phthalate Esters Program Panel of CMA "does not dispute that DBP may be found at detectable levels at some waste disposal sites. However, without evidence of concentration levels or of migration away from the sites at detectable levels, there can be no basis for finding that waste disposal activities involving DBP may present an unreasonable risk of injury."

The Agency disagrees with these comments. As explained in Unit II.A.2.b. of this preamble, EPA believes that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and has consistently interpreted this finding to require only potential for exposure. EPA believes that the data contained in the record for dibutyl phthalate documents potential for exposure to this chemical.

CMA (Ref. 38) also commented that "EPA had not identified any adverse health or environmental effects that are reasonably likely to occur as a result of environmental exposure to DBP."

Although a specific health or environmental effect of concern has not been identified for this chemical, the listing of this chemical as a hazardous constituent in Appendix VIII of RCRA, the toxicity data supporting that listing, and the toxicity data supporting this rule summarized in a Health and Environmental Effects Profile (HEEP), all indicate a concern for the general toxicity of this chemical. This concern creates uncertainties with regard to the degree of risk associated with the disposal of wastes that contain dibutyl phthalate as a constituent. EPA requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

CMA (Ref. 38) stated that "the development of anaerobic biodegradation data will not assist EPA in improving its ability to assess the risk these chemicals present to human health or the environment," referring to the chemicals dibutyl phthalate and dimethyl phthalate (DMP). CMA continues, "Moreover, biodegradation data in fact are already available for both DMP and DBP, and the Agency has not explained why additional data are needed or how such data might be used."

EPA disagrees with these comments. As is explained in Units II.A.3. and II.C.2. of this preamble, and was stated in the proposed test rule for these chemicals, the objective of the anaerobic biodegradation protocol finalized in this rule is to provide anaerobic biodegradation rate constants for chemicals. These rates will be used in EPA's subsurface fate and transport model to evaluate the potential risk to human health and the environment from migration of these chemicals in subsurface conditions prevalent in the United States. Units II.A.3. and II.C.2. explain why existing data developed under alternative protocols are not adequate for EPA's determination of whether the disposal of these chemicals by various means or various concentrations presents an unreasonable risk. Biodegradation testing for DBP is recommended, but not required.

5. *Dichlorobenzenes.* Monsanto Co. (Ref. 18) objected to TSCA section 4 testing for these chemcials because EPA had not demonstrated the necessary findings to develop a test rule under TSCA section 4(a).

The Agency disagrees. In addition to available toxicity data, the Agency has data on the occurrence of the chemicals in regulated and unregulated waste streams and in contaminated soil, groundwater, and surface water and has provided that data for public comment, 53 FR 911. Thus, the Agency finds that disposal of the dichlorobenzenes may present an unreasonable risk of injury to human health and/or the environment. Testing is required and recommended for 1,2-dichlorobenzene; for 1,3- and 1,4-dichlorobenzene, no testing is required, but the optional anaerobic biodegradation test is recommended. A detailed discussion of the findings is presented in Units II.A.2.3., and 5. of this preamble.

6. *1,1-Dichloroethane.* Vulcan Chemicals (Ref. 33) objected to testing for this chemical, saying that it is produced as a nonisolated intermediate.

The Agency disagrees. Simply stating that a chemical is produced as a "nonisolated intermediate" does not preclude release of the chemical to the environment as a component of a waste stream or as an impurity in a finished product (see Unit II.A.6.C. of this preamble).

The Agency believes that 1,1-dichloroethane will have a hydrolysis half-life of greater than 10 years in the environment. The Agency needs data on the hydrolysis and anaerobic biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

7. *2,3-Dichloropropanol.* Eastman Kodak Co. (Ref. 9) objected to testing for this chemical, saying that it is produced in very small quantities (average of 20 kg/yr since 1980) and that a significant adverse economic impact would result if a test rule was imposed.

The Agency disagrees. Although Eastman Kodak Co. produces only a small amount of 2,3-dichloropropanol annually, this compound and 1,3-dichloro-2-propanol, collectively known as dichlorohydrins, are produced as intermediates during the conversion of allyl chloride to epichlorohydrin (Ref. 34). Dow Chemical at Freeport, TX and Shell Chemical at Deer Park, TX are the sole producers of epichlorohydrin using this process. Domestic production of epichlorohydrin using this process was estimated at 440 million pounds in 1984 (Ref. 35). Additional market information obtained subsequent to publication of the proposed rule and incorporated into the revised economic analysis (available for comment January 14, 1988) indicate that the potential for adverse economic impact is low for 2,3-dichloropropanol.

The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, and requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

8. *Dimethyl phthalate.* CMA (Ref. 5 and 38) objected to TSCA section 4 biodegradation testing for this chemical, saying that there was no evidence of direct exposure to this chemical as a result of waste disposal activities, and that there was no evidence to conclude that exposure to this chemical at waste sites presents a serious risk of adverse health or environmental effects.

The Agency disagrees with these comments. As discussed in Unit II.A.2.b. of this preamble, the data indicating the presence of this chemical in regulated and unregulated waste streams, in

groundwater contaminated by releases from RCRA and CERCLA sites, and contaminated soil, groundwater, or surface water resulting from hazardous waste mismanagement incidents documents potential for exposure.

Other comments made by CMA for this chemical (Ref. 38) are the same as the comments submitted for dibutyl phthalate and are addressed in Unit II.B.4. of this preamble. The Agency requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

9. *Endrin.* Velsicol Chemical Corp. (Ref. 32) said that the chemical is no longer manufactured and did not have TSCA-regulated uses when previously manufactured. As a result of its uses which did not fall under TSCA, this commenter believed that it could not have been subject to a TSCA section 4 rulemaking.

This issue has been addressed in Unit II.A.6.d. of this preamble. Confidential data exist which support section 4 rulemaking for this chemical by showing that these chemicals are disposed of, and that potential for exposure exists.

10. *Maleic anhydride.* Maleic Anhydride Consortium (Ref. 16) and Dow Chemical Co. (Ref. 8) noted that there is substantial documentation indicating that this chemical hydrolyzes very rapidly. These commenters felt that maleic anhydride is therefore an inappropriate candidate for soil sorption and biodegradation testing.

The Agency agrees and has removed this chemical from the list of chemicals to be tested for hydrolysis, biodegradation, and soil sorption testing.

11. *Malononitrile.* Lonza, Inc. (Ref. 15) commented that malononitrile, a chemical intermediate imported by the commenter in small amounts (161,800 lbs in 1986) and sold exclusively to the pharmaceutical industry for use in manufacturing several products, should not be tested because it is not land disposed. According to Lonza, malononitrile is consumed during the production of these pharmaceutical products, and, because of its toxicity, is treated to ensure that none remains in the products. The commenter also said that Lonza (as importer) and the pharmaceutical purchasers (as processors) would reclaim any off-specification malononitrile because it is very expensive. Finally, Lonza stated that it would withdraw malononitrile from the market should the rule become final because it cannot justify the expense of the required tests, especially in view of the company's position that malononitrile should be banned from land disposal.

The Agency maintains that malononitrile should undergo the specified tests. In its comment, Lonza said that its material safety data sheet for this chemical states that malononitrile, because of its toxicity, should be disposed of by incineration. However, this recommendation does not necessarily ensure that the users or processors of the chemical are actually incinerating their off-specification material. In fact, malononitrile's presence in unregulated wastes, as documented by the Agency in its January, 1988 notice, published in the Federal Register of January 14, 1988 (53 FR 911), suggests that it may currently be land disposed, and thus, could potentially enter the environment.

Without data on the biodegradation and soil sorption potential of malononitrile, the Agency cannot assess its persistence. Furthermore, without additional data on the toxic potential of this chemical, EPA cannot adequately characterize its effects on health.

12. *Methyl chloride.* The Methyl Chloride Industry Association (Ref. 17 and 42) and Vulcan Chemicals (Ref. 49) objected to testing for this chemical, saying that EPA has not justified its section 4 "may present an unreasonable risk" finding, and had not given full consideration to an earlier proposed test rule (1980) for this chemical that was withdrawn.

The Agency disagrees with these comments. Although a previous (1980) section 4 proposed rule was withdrawn for this chemical, the Agency now has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contaminated by release from RCRA and CERCLA sites, and in contamination resulting from hazardous waste mismanagement incidents.

In addition, as explained in Unit II.A.2.b. of this preamble, EPA believes that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and has consistently interpreted this finding to require only potential for exposure. EPA believes that the data contained in the record for methyl chloride documents potential for exposure to this chemical.

Vulcan Chemicals (Ref. 33) noted that this chemical is produced as a nonisolated intermediate and is normally a gas under ambient conditions. Although methyl chloride has a very low boiling point, the Henry's Law constant for the chemical is .04 atm-m^3/mole (Ref. 46). Henry's Law constant is a ratio of the chemical's vapor pressure to its solubility in water, and provides an indication of whether or not the chemical will be present in groundwater. Due to the value of Henry's Law constant for methyl chloride, and the fact that it has been found in waste streams, the Agency requests data on this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

13. *p-Nitroaniline.* Monsanto Co. (Ref. 18) opposed the testing of this chemical because it is a small volume chemical intermediate, and there is very little economic justification to support the testing as it has been proposed.

The Agency disagrees. The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contaminated release from RCRA and CERCLA sites, and in contamination resulting from hazardous waste mismanagement incidents. Thus, despite the fact that *p*-nitroaniline may be a small volume intermediate, it appears that its manufacture and disposal result in the potential for human exposure. The Agency requests biodegradation data on this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

14. *p-Nitrophenol.* Monsanto Co. (Ref. 18) commented that EPA should exempt *p*-nitrophenol from the required subchronic toxicity test. Given the very small amount of *p*-nitrophenol manufactured for TSCA-regulated purposes, Monsanto said it would cease the TSCA-related production of this chemical if the rule is finalized as proposed. The commenter said that the majority of its *p*-nitrophenol is manufactured as an intermediate in the production of an FDA-regulated product. Monsanto urged the Agency to use existing health effects data to make decisions regarding relisting, and directed EPA to the health effects summary of its *p*-nitrophenol material safety data sheet.

EPA reviewed the above-mentioned summary and concluded that the information discussed is inadequate for quantitative use. Monsanto's information consists of: (1) Very limited, qualitative statements regarding the adverse effects of occupational exposure to the chemical; (2) the results of two acute rodent studies (inhalation and gavage); and (3) several negative mutagenicity or genotoxic activity tests. The Agency requires, at the very minimum, a well-designed and conducted subchronic study for use in deriving an RfD. Such a study does not currently exist for *p*-nitrophenol. Therefore, EPA is requiring that one be performed.

With regard to the amount of *p*-nitrophenol manufactured for TSCA-regulated purposes, the Agency disagrees with Monsanto's comment. EPA's finding is based on the section 4(a)(1)(A) "may present an unreasonable risk" finding, and not the section 4(a)(1)(B) "substantial production and release" finding; therefore, the TSCA production need not be substantial. Also, the Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contamination from RCRA and CERCLA sites, and in contamination resulting from hazardous waste management incidents. The Agency needs data on this chemical in order to accurately model environmental conditions that are protective of human health and the environment.

15. *Phosgene.* CMA (Ref. 6), Dow (Ref. 8), Olin (Ref. 22), and Vulcan (Ref. 33), objected to including phosgene in the list of chemicals subject to health effects and chemical fate testing. Olin and CMA commented that phosgene is a gas which is manufactured and used in closed-system production units. Vulcan also stated that phosgene is a trace byproduct formed during the production of chlorinated hydrocarbons, and is normally contained within the process unit. The commenters pointed out that a solid phosgene waste is not produced. CMA argued that the entire concept of a subchronic toxicity study for phosgene is inappropriate: Phosgene would react with water in the lung tissue to form carbon dioxide and hydrochloric acid if a toxicity study were conducted via inhalation. If phosgene were administered via oral gavage using water as the vehicle, the chemicals studied would be mostly carbon dioxide and hydrochloric acid, not phosgene.

The Agency concurs that phosgene is an inappropriate candidate for an oral subchronic toxicity study. At ambient temperature, phosgene is normally a gas, and thus it is not in a physical state suited for the oral gavage test protocol. Even if conditions existed whereby phosgene could be introduced into a gavage vehicle, the high reactivity of this chemical would make it nearly impossible to maintain the integrity of the dosing solution. Therefore, EPA is eliminating phosgene from the toxicity testing requirements.

The commenters noted that this chemical is highly reactive and that the proposed chemical fate testing is scientifically inappropriate.

The Agency agrees that this chemical is an inappropriate candidate for the proposed environmental fate testing based on its reactivity and has removed it from the list of compounds to be tested for hydrolysis, biodegradation, and soil sorption.

16. *Phthalic anhydride.* CMA (Ref. 4) objected to TSCA section 4 testing for this chemical because it believed that EPA had not demonstrated that there is evidence of measurable exposure as a result of waste disposal activities, and EPA had not linked health or environmental effects to this chemical from environmental exposure.

The Agency disagrees. The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams and in contaminated soil, groundwater, or surface water resulting from hazardous waste mismanagement incidents. The Agency needs data on this chemical to accurately model environmental conditions so that regulations can be developed that are protective of human health and the environment.

17. *2-Picoline.* Lonza Inc. (Ref. 15) objected to testing of this chemical because it is potentially used up in the production of agricultural chemicals and pharmaceuticals and would be unlikely to be discarded.

The Agency disagrees. There is currently no regulation which places a prohibition on disposal of this chemical on land, and the Agency has data indicating the presence of this chemical in regulated and unregulated waste streams. The Agency requests data on this chemical to accurately model environmental conditions so that regulations can be developed that are protective of human health and the environment.

C. Biodegradation Protocol

Comments on the EPA-developed anaerobic biodegradation testing protocol were received from 15 sources including trade associations, chemical producers, universities, and State and Federal government organizations. Due to the number of commenters, and the similarity of many of their comments, individual commenters will not be identified by name for each issue.

1. *Protocol not peer-reviewed or validated.* Several commenters stated that the proposed protocol is unacceptable because it was neither peer-reviewed nor validated. One commenter stated that the anaerobic biodegradation protocol has not been subjected to the rigorous internal and external peer review that is usually required of TSCA test guidelines. Another commenter stated that manufacturers would be unwilling to undertake validation of this protocol at this stage of development.

In response, EPA notes that this protocol for obtaining microbiological transformation rate data for chemicals in the subsurface environment represents input from government, industry, and academic scientists who attended a workshop on methods to evaluate microbiological process rates, held in 1986. The protocol was developed based on ideas presented by attendees of this workshop. Also, the purpose of proposing the test protocol in the **Federal Register** was to solicit a peer review. This process has given the public the opportunity to review the documents that support this protocol; in addition, procedures used in the protocol are in current practice as parts of other peer-reviewed protocols, and have appeared in journals and are referenced in the text of this rulemaking.

2. *Use of established protocols.* Several commenters suggested that the proposed biodegradation protocol be abandoned in favor of other established protocols.

The Agency disagrees. The objective of the proposed protocol is to provide anaerobic biodegradation rate constants for chemicals in wastes. These rates will be used in EPA's subsurface fate and transport model to evaluate the potential risk to human health and the environment from migration of these chemicals in subsurface conditions prevalent in the United States. The alternative protocols (40 CFR 796.3150; FIFRA Pesticide Guideline Subdivision N, October 1982, Guideline 1672–2; OECD Guideline 304a, anaerobic) that have been suggested do not meet these conditions. Each of the alternative protocols either: (1) Does not use subsurface materials representing subsurface in-situ conditions as their microbial source; (2) was not developed to produce rate data but was qualitative in nature (except for OECD Guideline 304a); (3) does not provide biodegradation rate constants representative of varying subsurface environmental conditions in the United States; and/or (4) adds nutrients to enhance activity, which may lead to a significant overestimation of biodegradation potential.

3. *Cost of conducting test is "prohibitive", and was underestimated.* According to several commenters, the cost of implementing the proposed anaerobic biodegradation guidelines is prohibitive. They also believe that the economic impact analysis performed for the tests substantially underestimates the real costs to conduct the studies. In addition, according to several commenters, costs of biomass measurements, test concentration

determinations, travel, equipment associated with soil and groundwater sampling, and the cost of locating sampling sites were not factored into the economic impact analysis performed by the Agency.

EPA has estimated the costs of the proposed protocol and assessed the impact of the testing costs on each chemical. The cost of the testing was not found to be prohibitive. The economic analysis accompanying this rulemaking contains a more complete discussion of this conclusion.

Biomass measurements were not included in the cost estimate for the proposed rule; however, the cost of conducting the test has been reestimated for the final rule, and this new cost reflects the cost of the requisite biomass measurements. In addition, costs for analytical chemistry determinations have been added to the test cost estimate for the final rule. The revised analysis was made available for public comment on January 14, 1988 (53 FR 911).

EPA believes that the costs of test concentration determinations will be relatively small. According to § 795.54(b)(2)(iii) of the proposed rule, the test concentration determinations are based upon two factors, the health-based level and the chemical's solubility. In many cases, these data will be readily available and there will be no cost involved in their determination. In some cases, the health-based level will be determined and/or the chemical's solubility will be estimated. The costs for these determinations will be small.

The costs associated with sample collection (specifically, travel, equipment associated with sampling, and the cost of locating sampling sites) are now also included in the cost estimate for the test protocol in the final rule.

4. *Rate of anaerobic vs. aerobic degradation.* The assumption that anaerobic biodegradation is slower than aerobic metabolism and that anaerobic rates can be used as a conservative estimate for biodegradation was challenged by several commenters.

The Agency agrees that anaerobic activity is not always the slowest activity, but it is less likely that data collected under anaerobic conditions would lead to an overestimation of the degradation rate. In the subsurface, aerobic degradation is probably controlled by the influx of oxygen. Thus, the mass transport of oxygen would be the rate limiting step. In the laboratory, oxygen would probably not be the rate limiting step, so degradation rates obtained in the laboratory are likely to be overestimated. Anaerobic processes are not as easily mass transport-limited, and the degradation rate determined in the laboratory could be equal to, or an underestimation of, the actual degradation rate. The Agency maintains that the use of degradation data from anaerobic processes are more appropriate for obtaining modeling information that can be used to protect human health and the environment.

5. *Results would be site-specific.* One commenter said that the results of the testing are likely to be site-specific and only indicative of the particular site tested. This would prevent the results of the testing from being useful to the manufacturers; they would be useful only to the Agency's implementation of the subsurface fate and transport model.

The study would be site-specific if only one site were selected for the study. Six sites (having a range of characteristics) are required by the protocol to provide a spectrum of data that provide a range of biodegradation rates expected to be encountered in the subsurface environments of the United States. The subsurface in-situ biodegradation rate for a chemical constituent depends on, among other factors, Eh, pH, temperature, concentration of the chemical in ground water, and soil microorganisms.

6. *Justification of site/sample collection.* Several commenters did not find that EPA had sufficiently justified the requirement for six samples from six sites, saying that the testing routine is impractical, unnecessary, and will not yield the best information.

Six sites (which have a range of characteristics) were selected to provide a spectrum of data that could provide a range of biodegradation rates to be encountered in subsurface environments in the United States. This matrix of biodegradation rates will be used in a subsurface fate and transport model. A nation-wide simulation of the subsurface environmental conditions is needed because the waste containing a chemical constituent can potentially be managed anywhere in the country. The subsurface fate and transport model is implemented to simulate the nation-wide subsurface conditions using the Monte Carlo procedure. The Monte Carlo procedure utilizes these biodegradation rates to represent the subsurface environmental conditions in the country. Ideally, samples from more than six sites are preferred. However, because of the projected burden on the manufacturers of chemicals, the consensus of the biodegradation workshop, comprised of industrial, academic, and government representatives, was that six sites should be adequate. The characteristics of these sites were also developed by the attendees of the workshop. Although the Agency recognizes that it is difficult to identify six sites, it was the consensus of the workshop that six sites could be identified by researching available hydrogeological information from the U.S. Geological Survey as well as State and County geological and groundwater survey reports.

7. *Influence of biotransformation on chemical fate.* Biotransformation will influence the fate of some organic contaminants; this process has not been considered sufficiently in the proposed guidelines, according to several commenters.

The Agency agrees that biotransformation can result in the alteration of the original chemical, producing intermediates. The formation of degradation intermediates should be quantified in microcosm assays for test chemicals that can potentially be transformed to other test chemicals subject to this rule. Table 2 is a list of chemicals which should be analyzed for the specified intermediates. Analysis for degradation intermediates is indicated when the level of test chemical has been reduced by more than 25 percent.

TABLE 2.—REQUIRED PRODUCT ANALYSIS

Test chemical	Potential product
Trichloromethanethiol	Methanethiol.
	Chloromethane (methyl chloride).
Pentachlorobenzene	1,2-Dichlorobenzene.
	1,3-Dichlorobenzene.
	1,4-Dichlorobenzene.
	1,2,4,5-Tetrachlorobenzene.
Bromoform	1,2-Dibromomethane.
1,2,4,5-Tetrachlorobenzene.	1,2-Dichlorobenzene.
	1,3-Dichlorobenzene.
	1,4-Dichlorobenzene.

8. *Interpretation of data under conditions of rapid decay or nutrient-limitation.* The manner in which data will be interpreted in the event that decay is very rapid or in cases where a system becomes nutrient-limited was not addressed in the proposed rule, according to one commenter.

The Agency will interpret biotransformation rate data as described in the proposed rule at 52 FR 20354, May 29, 1987. Where decay is very rapid, the number of samples to be analyzed will be reduced and the cost of testing for that chemical will also be reduced. For those chemicals on Table 2 which degrade rapidly, samples will also be analyzed for the appropriate intermediates.

The subsurface environment is generally nutrient-limited. The addition

of nutrients would lead to enhanced degradation rates that would not be representative of actual subsurface conditions.

9. *Discrepancy in number of samples collected.* Several commenters noted a discrepancy in the number of samples to be collected for the required analysis.

The Agency agrees with this comment. The discrepancy in the number of samples has been corrected to indicate that two samples will be collected from each site. Data will be reported for each of the two samples from the six different sites (a total of 12 subsurface samples).

10. *More quality assurance.* Several commenters noted that there needs to be more quality assurance on analytical procedures, i.e., methods of analysis for each chemical should be specified.

The Agency agrees that quality assurance must be part of any testing program. A biodegradation laboratory work conducted should follow EPA's TSCA Good Laboratory Practice standards (40 CFR Part 792). The appropriate analytical methods for measuring the degradation of a given chemical will depend on the concentration of the test chemical and the subsurface material being used. Thus, it would be difficult if not impossible for the Agency to identify a method or series of methods for each chemical. To ensure that the selected techniques are appropriate, the reporting of certain quality assurance data, such as reproducibility, precision, and recovery have been added to the protocol.

11. *Number of samples required.* One commenter said that too many samples are required for this protocol, while others indicated that there was confusion as to how many microcosms were needed.

The Agency agrees that the protocol as written in the proposed rule was confusing as to number of microcosms required. The following flow chart (Table 3) clearly illustrates the number of microcosms necessary to test a chemical.

Table 3.—Required Number of Microcosm Assays for Each Chemical

Six Sites
(x Two samples per site)
12 Samples
(x Two for sulfate and methanogenic conditions)
24 Microcosms
(x Two for control and active microcosms)
48 Microcosms
(x Three for three concentrations)
144 Microcosms
(x Six for six times periods)
864 = Total Number of Active and Control Microcosms

12. *Determination of minimum concentration.* Several commenters questioned the Agency's selection of 22.5 as the multiplier for the health-based level leading to the minimum concentration. Others stated that it is inappropriate to choose a lower level assay on the basis of a health-based level, and that the selection of a low level assay 22.5 times th health-based level was not justified.

The minimum concentration is the permissible leachate concentration that can be released from a waste disposal site as determined by the EPA modeling approach. Concentrations below this figure would constitute a permissible release and therefore microbiological data would not be needed. The figure of 22.5 was the estimated multiplier to determine the permissible concentration of a contaminant that can leach from a disposal site. The number 22.5 has been revised and the updated multiplier will be 30.

13. *Measure of anaerobicity.* Several commenters noted that the test does not require a measure of anaerobicity and is not designed to ensure that anaerobicity will be maintained in samples.

The Agency agrees with these commenters and has added a measure of anaerobicity to the protocol.

14. *Development of aerobic and microaerophyllic test systems.* Two commenters encouraged EPA to develop aerobic and microaerophyllic test systems in addition to developing an anaerobic biodegradation protocol, saying that these mechanisms are important subsurface attenuation processes and their inclusion would improve anaerobic biodegradation modeling results.

The Agency agrees that aerobic and microaerophyllic processes are important. However, as explained in Unit II.C.4. of this preamble, aerobic degradation rates obtained in the laboratory are often overestimations of actual subsurface aerobic rates. The Agency maintains that modeling subsurface environmental conditions using anaerobic degradation rates is more appropriate and that use of the modeling results based on the anaerobic degradation rates for the development of regulations will be more protective of human health and the environment.

15. *Inclusion of a denitrifying condition.* One commenter suggested that the rule would be improved if a denitrifying condition was included in the testing.

The Agency has not found denitrifying conditions to be representative of the majority of disposal sites in the United States. In addition, denitrifying conditions can lead to more rapid rates of biodegradation for many chemicals. Overestimation of biodegradation rates is inconsistent with the Agency's objective of protecting human health and the environment.

16. *Identification of units for reporting results.* One commenter asked that the units for reporting degradation rate, and characteristics of subsurface and groundwater should be stated clearly.

The Agency agrees, and the protocol has been modified to identify the units for reporting data in the protocol; e.g., residual test chemical (mg/gm dry wt. sediment), redox potential (Eh, standard hydrogen electrode [SHE]), dissolved oxygen (mg/L), etc.

17. *Volatile chemicals.* One commenter said that bottles should be filled to the top for volatile chemicals.

The Agency agrees with this comment. The protocol has been amended to indicate that for all volatile and non-volatile chemicals, the assay bottles should be filled to the top, while maintaining the ratio of dry weight of sediment to volume. Nonvolatile chemicals are included in this amendment, to avoid discrepancy as to what is or is not considered volatile.

18. *Clarification of "dry weight".* One commenter asked that the Agency clarify the term "dry weight."

The term has been modified in the protocol to mean oven dry weight (103 °C).

19. *Biomass measurements.* Several commenters said that there was no justification provided for requiring biomass measurements in the protocol.

The Agency agrees. Biomass measurements were included to ensure comparability of results between subsurface material samples. Rate constants from sediment samples having significantly high or low bacterial populations would be considered suspect. In addition, the ratio of sulfate-reducting and methanogenic organisms are indicative of redox potential of the environment. The protocol has been modified to reflect this.

20. *Adaptation period.* Two commenters questioned how the adaptation period is to be used in this protocol.

The adaptation period is the length of time before biodegradation of the chemical is observed. The adaptation period will be subtracted from the sampling time in which less than 5 percent of the original substrate is detected. This difference will be divided by two to obtain a conservative half-life. This method will be used to determine half-life in the event that insufficient

data for half-life determination are obtained during testing.

21. *Total organic carbon.* One commenter requested that total organic carbon be analyzed as part of the protocol.

The Agency agrees and has added the analysis of total organic carbon to the protocol.

22. *Choice of 1.0 mL sample size, and dilution series.* One commenter questioned the selection of a 1 milliliter (mL) sample size, and the dilution series included in the protocol for enumeration of heterotrophic bacteria.

Sample sizes are chosen which are large enough to ensure a representative sample, yet small enough to be practical. The Agency has reviewed the sampling procedure in the protocol, and has changed the initial sampling size from 1 mL to 10 mL to ensure that a representative sample is obtained.

Due to the change in initial sampling size, the dilution series described in the revised protocol differs from the series described in the proposed protocol by a power of ten. The dilution series described in the protocol is a recommended guideline; however, it is the responsibility of the laboratory scientist to obtain the correct dilution series for bacterial enumeration.

23. *Use of Wilson method.* Two commenters noted that the use of the method described by Wilson et al., does not preclude oxygen from the subsurface material.

This method has been replaced by an updated method that prevents oxygen contamination of subsurface material, and is reflected in the revised protocol. This updated method is described in Zapico et al. (Ref. 36).

24. *Use of positive control.* Several commenters suggested that the Agency include a positive control in the protocol.

The Agency disagrees with this comment. A positive control is used to indicate if general microbial activity is present in the sediment. An indication of general microbial activity can be obtained by measuring the quantity of microorganisms in the aquifer material. This procedure is already included in the protocol.

25. *Assumption of aerobic metabolism.* One commenter stated that the assumption that "two parts of oxygen are required to completely metabolize one part of an organic compound" may not be conservative.

The Agency disagrees. The assumption of two parts of oxygen is appropriate if one is not attempting to underestimate the approximate ratio. However, the Agency has removed reference to this ratio from the protocol to avoid misinterpretation.

26. *Use of Teflon®-coated silica septa.* Several commenters stated that it was a mistake to specify that Teflon®-coated silica septa be used, because such septa do not maintain anaerobic conditions.

The Agency agrees that Teflon®-coated septa are inappropriate if samples are to be stored outside of an anaerobic chamber, and the protocol has been amended to require the use of 0.5 to 1 cm thick butyl rubber stoppers coated with Teflon®. The requirement to incubate bottles upside down has also been removed from the protocol.

27. *Guidelines for sulfidogenic and methanogenic enumeration techniques.* One commenter noted that the protocol contained elaborate descriptions of more common laboratory techniques, while guidelines for sulfidogenic and methanogenic enumeration techniques are only referenced.

EPA has provided references for two anaerobic enumeration techniques, and does not believe it is necessary to describe them in detail in the protocol. Sulfidogenic enumeration techniques are described in Pankhurst (1971; Ref. 47), and methanogenic enumeration techniques are described in Jones et al. (1982; Ref. 48).

28. *Cutoff levels.* One commenter questioned the 5 percent and 64-week cutoff levels.

If the cut-off level is 5 percent and the reaction gets to 6 percent and the chemical does not degrade further, the protocol would then be completed. The Agency acknowledges that no matter what cut-off point is established, the problem of what should happen if degradation approaches the point but does not surpass it still exists. The 5 percent cut-off level was selected to ensure that degradation of the chemical was essentially complete, and that the reaction did not simply stop when only a portion of the test chemical had been degraded.

29. *Kinetics.* One commenter questioned why kinetics are not obtained, saying that this will result in limited utility of test findings.

The protocol was designed to develop degradation rates that can be used to model environmental conditions so that regulations can be developed which are protective of human health and the environment. A conservative half-life for degradation of a chemical can be estimated by dividing by two the difference between the last sampling time where no detectable degradation had occurred and the sampling time where less than 5 percent of the original substrate is detected. The adaptation period would then be the time over which no detectable degradation of the chemical was observed. This point has been further clarified in the final protocol.

30. *Loss of chemical: Measurement.* One commenter said that the loss of a chemical should not be equated to carbon dioxide and methane production.

The Agency agrees with this comment. The stoichiometry of conversion of the subject chemicals to methane and carbon dioxide is unknown. Therefore, it would not be possible to determine the residual levels of a chemical from carbon dioxide and methane measurements. The amount of residual test chemical will be measured directly.

31. *Adequacy of enumeration techniques.* One commenter said that enumeration techniques may be inadequate.

The Agency recognizes that no enumeration technique is completely accurate. However, if they are consistent from one study to the next, those data can be used in a qualitative manner to indicate the reproducibility of the subsurface samples used in estimating the degradation of the different chemicals to be analyzed. The enumeration of microorganisms in this protocol is primarily for quality assurance and quality control.

32. *Organisms from overlying strata.* One commenter questioned whether organisms from overlying strata would interfere with the protocol.

The purpose of the protocol is to determine the degradation of organic chemicals in subsurface materials. The Agency believes that whether or not the organisms in that material come from the overlying strata is irrelevant.

33. *Modified sampling technique.* A modified sampling technique, developed at the Agency's Environmental Research Laboratory in Ada, Oklahoma, will be presented at the National Water Well Association's Second Outdoor Action and Aquifer Restoration Conference, May 23–26, 1988. Briefly, the modification consists of alterations to hollow-stem auger equipment. A unique sampling tool, referred to as the "Waterloo Cohesionless-Aquifer Core Barrel," for sampling heaving saturated material has been redesigned so the internal vacuum piston can be used in the 4-inch O.D. sample tube. The major alterations consist of a clam-shell cap which is fitted to the bottom of the hollow-stem auger bit replacing the standard center plug. This device serves as a plug for the hollow-stem auger while drilling to a desired depth. Undisturbed samples are collected by lowering the sample tube into the

hollow auger to the closed clam shell, retracting the auger about one foot—thereby opening the clam shell—and then driving the sample tube to the desired depth with a rig-mounted percussion hammer. The redesigned internal piston inside the sample tube is held stationary by a wire line rigidly fixed to the rig. Holding the piston stationary while lowering the sampler creates a vacuum on the noncohesive sample, holding it in the tube during retrieval from the borehole.

After retrieval, the piston is removed, the sampler is mounted in a hydraulic extruder, and samples are pressed from the tube through an attached paring device inside an aseptic glove-box. The glove-box is designed with a regulated nitrogen flow-through purging system and with a diaphragm port where the sampler can be inserted prior to sample extrusion.

Although EPA did not receive comment on the sampling techniques recommended in the protocol, the Agency is making this information on the modified sampling technique available for the benefit of those who decide to conduct the biodegradation study. For further information on this technique, contact EPA, as directed by this preamble.

D. Economic Issues

Several commenters to this rule (Olin Chemicals, Lonza, Inc., Morton Thiokol, Inc., Velsicol Chemical Corp., Monsanto Co., Dow Chemical Co., Eastman Kodak Co., and Regulatory Network, Inc.; Refs. 22, 15, 19, 32, 18, 8, 9, and 16, respectively) submitted data about specific chemicals, including: phosgene, paraldehyde, malononitrile, 2-picoline, bis(2-chloroethoxy) methane, endrin, hexachlorophene, *p*-nitrophenol, *p*-nitroaniline, benzal chloride, 2,3-dichloro-1-propanol, *p*-benzoquinine, and maleic anhydride. These data have been incorporated in the economic analysis accompanying this final rule. Other non-chemical specific comments are addressed below.

1. The economic analysis accompanying the proposed rule addressed only 49 of 73 chemicals included in the rule (CMA; Ref. 2). In this final rule, testing is required and/or recommended for 33 chemicals. Each of these chemicals has been addressed in the economic analysis for the proposed rule or in the revised economic analysis included in the record upon the reopening of the public comment period on January 14, 1988 (53 FR 911).

2. The Agency cannot justify a test rule for chemicals for which insufficient economic data is available to determine potential economic impact (CMA; Ref. 2). No chemicals for which insufficient economic data are available are included in this final rule.

3. The economic impacts upon manufacturers of byproducts, impurities, and other inadvertent chemicals have not been considered (CMA; Ref. 2). No chemicals identified as chemicals that are manufactured solely as an impurity are included in this final rule. The economic impacts upon manufacturers of byproducts have been included in the economic analysis for each chemical identified as being manufactured solely as a byproduct.

4. The Agency must conduct additional analyses beyond the reliance upon direct cost reviews (CMA, Monsanto; Refs. 2 and 18). The Agency disagrees that a more in-depth analysis is necessary for every chemical included in this rule. The economic analysis for this final rule includes a more in-depth analysis where appropriate. The proposed rule specifically asked for public comment on individual chemicals to assist in the evaluation of significant adverse economic impact. In each case in which such information was submitted, that information has been incorporated into the economic assessment for this final rule. In addition, for each chemical for which the probability of adverse economic impact was determined to be high, or for which insufficient information was available at the time of the proposed rule, additional information has been gathered and incorporated into the economic analysis for this final rule. In sum, the Agency disagrees that such information is required in each and every case. For those specific chemicals for which commenters supplied information, or for which the economic analysis indicated a high probability of adverse impact, a greater level of detail has been incorporated into the final analysis.

5. The economic analysis underestimated the potential economic impact from the rule because the testing costs are annualized over 15 years. Companies required to test will incur these costs over a two-year period, and therefore, the economic analysis underestimates the economic impact of the rule (SOCMA; Ref. 27). This commenter fails to draw a critical distinction between the manner in which firms will pay for testing and the manner in which firms will recover the costs of testing. The method incorporated in the economic analysis of this test rule is aimed at determining the latter—the increase in price necessary to recover the testing cost over the life of each chemical product affected by testing. The commenter instead refers to the former—the accounting method employed to pay for the tests. In the economic analysis, test costs are annualized over the assumed market life of the product, to estimate the amount which a firm would have to increase product price in order to recover the testing cost. As explained in the economic analysis, this estimate of product price increase is used as an indicator of the likelihood of adverse economic impact.

6. EPA has not fulfilled its responsibility to show the availability of testing facilities to conduct the biodegradation test (Olin, Dow; Refs. 22 and 8). In response to this comment, EPA has conducted a survey of testing laboratories (Ref. 37) to determine their capability and likely capactity to conduct the biodegradation test according to the protocol finalized in this rule. The conclusion of this survey is that several laboratories are indeed available to conduct the test at costs comparable to those estimated by EPA.

III. Final Test Rule

A. Findings

The required human health effects and chemical fate testing listed in the following Table 4 is based on the authority of section 4(a)(1)(A) of TSCA. Chemicals recommended for optional (not required) biodegradation testing are also listed in this Table.

TABLE 4.—HAZARDOUS WASTE CONSTITUENTS SUBJECT TO OR RECOMMENDED FOR TESTING[1]

Chemical	CAS No.	Subchronic toxicity testing (required)		Hydrolysis testing (required)		Biodegradation testing (optional)		Soil sorption testing (required)	
		No data	Insufficient data	No data	Insufficient data	No data	Insufficient data	No data	Insufficient data
Acetamide, 2-fluoro	640-19-7	X					X		
Acetophenone	98-86-2					X			

TABLE 4.—HAZARDOUS WASTE CONSTITUENTS SUBJECT TO OR RECOMMENDED FOR TESTING[1]—Continued

Chemical	CAS No.	Subchronic toxicity testing (required)		Hydrolysis testing (required)		Biodegradation testing (optional)		Soil sorption testing (required)	
		No data	Insufficient data	No data	Insufficient data	No data	Insufficient data	No data	Insufficient data
Bis(2-chloroethoxy)methane	111-91-1	X			X	X			
Bis(2-chloroisopropyl)ether	108-60-1			X		X			
4-Bromobenzyn cyanide	16532-79-9	X		X		X		X	
Bromoform	75-25-2				X		X		
4-Chlorobenzotrichloride	5216-25-1	X							
2,4-D	94-75-7			X		X			
Dibromomethane	74-95-3			X		X			
Dibutyl phthalate	84-74-2						X		
1,2-Dichlorobenzene	95-50-1			X			X		
1,3-Dichlorobenzene	541-73-1					X			
1,4-Dichlorobenzene	106-46-7						X		
1,1-Dichloroethane	75-34-3			X			X		
1,3-Dichloropropanol	96-23-1	X					X	X	
2,3-Dichloropropanol	616-23-9					X			
Dihydrosafrole	94-58-6			X		X			
Dimethyl phthalate	131-11-3						X		
2,6-Dinitrotoluene	606-20-2						X		
Endrin	72-20-8			X			X		
Ethyl methacrylate	97-63-2			X		X			
Maleic hydrazide	123-33-1			X			X		X
Malononitrile	109-77-3	X				X		X	
Methanethiol	74-93-1						X		X
Methyl chloride	74-87-3				X	X			
p-Nitroaniline	100-01-6						X		
p-Nitrophenol	100-02-7	X				X			
Pentachlorobenzene	608-93-5			X			X		
Pentachloroethane	76-01-7			X		X			
Phthalic anhydride	85-44-9					X			X
2-Picoline	109-06-8						X		
1,2,4,5-Tetrachlorobenzene	95-94-3			X		X			
Trichloromethanethiol	594-42-3	X		X		X		X	

[1] "X" indicates that the test is needed.

EPA finds that the disposal of these 33 chemicals may present an unreasonable risk of injury to health or the environment; that there are insufficient data and experience to determine or predict the effects of disposal on health or the environment; and that testing is necessary to develop these data.

1. *Subject chemicals may present an unreasonable risk of injury to health or the environment.* All of the chemicals subject to this final test rule have been identified as toxic constituents under Appendix VIII of 40 CFR Part 261, and all have as their primary hazardous property either acute or chronic toxicity. Data document the presence of certain chemicals in waste streams and/or ground water, demonstrating potential for human exposure (53 FR 911; January 14, 1988). The data show that tens of thousands of pounds of these chemicals are being released annually via disposal. Also, the type of disposal described in the data bases for the subject chemicals, such as deepwell injection, discharge to landfill, or discharge to a POTW (publicly-owned treatment works), indicate potential for leaching and exposure to these chemicals. Indeed, data exist for many of the chemicals that document incidents in which the chemicals have migrated from their place of treatment, storage, or ultimate disposal. It is likely that these data represent only a portion of actual contamination occurrences throughout the country.

Therefore, EPA believes that these chemicals meet the requirements for testing under section 4(a)(1)(A)(i) of TSCA. By virtue of these chemicals being identified as "hazardous constituents," the nature of potential toxicity, the presence and evidence of these chemicals in the waste streams of treatment, storage, or disposal facilities, evidence that existing landfills leak, and the potential for human exposure to these chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization, the Agency has determined that the disposal of these chemicals may present an unreasonable risk of injury to human health. A detailed discussion of section 4(a)(1)(A)(i) requirements is contained in Unit II.A.2. of this preamble.

2. *Insufficient data to determine or predict.* All of the chemicals included in this rule have been the subject of a thorough search of the published literature and all standard on-line data bases used by different EPA program offices, including the Toxic Substances Control Act Test Submissions (TSCATS) data base, which identifies data submitted under TSCA section 8(d). The chemicals designated for testing in Table 4 are those for which no acceptable data were found. Specific reasons why data were considered to be inadequate are contained in the health effects and chemical fate Literature Search Results and Critique documents in the public record for this rule.

Therefore, under section 4(a)(1)(A)(ii) of TSCA, the Agency has determined that, for each chemical examined, there are insufficient data upon which the effects of disposal of the subject chemicals on human health can be reasonably determined or predicted.

3. *Testing is necessary.* EPA believes that the testing of the subject chemicals is necessary to determine or predict the effects of disposal of these chemicals on human health so that the Agency can establish concentration levels below which a waste would no longer be considered hazardous under Subtitle C of RCRA.

In the concentration-based listing effort, the Agency will use health effects and chemical fate data on each of the waste constituents to predict the concentration limit that would be the

basis for defining the waste as hazardous under Subtitle C of RCRA.

Therefore, EPA finds under section 4(a)(1)(A)(iii) of TSCA that the testing of the chemicals included in this final rule is needed, and that the required health effects and chemical fate studies are capable of developing the necessary information to assess the effects of disposal. EPA also finds that the data resulting from the required studies will be relevant to determining whether the disposal of each chemical presents an unreasonable risk of injury to human health.

B. Required and Recommended Testing and Test Standards

On the basis of these findings, EPA is requiring health effects testing and/or specific chemical fate testing for the chemicals subject to this final rule (see Unit III.A. of this preamble). The chemicals and the specific tests are listed in Table 4, along with a test that is recommended (biodegradation), but not required. The required tests are to be conducted in accordance with: (1) EPA's TSCA Good Laboratory Practice Standards in 40 CFR Part 792; and (2) the specific TSCA test guidelines as enumerated in 40 CFR Parts 798 and 798, as amended in this rule. The optional biodegradation test, if conducted, should be conducted in accordance with the EPA-developed guideline, 40 CFR Part 795.54, finalized in this rule.

EPA is requiring that the chemicals listed in Table 4 under Subchronic Testing be tested using the guideline at 40 CFR 798.2650. The subchronic studies will be performed by the oral gavage route. The rat will be the test species.

EPA requires that the chemicals listed in Table 4 under Soil Sorption Testing be tested using the guideline at 40 CFR 796.2750—*Sediment and soil adsorption isotherm.*

EPA further requires that the chemicals listed in Table 4 under Hydrolysis Testing be tested using the guideline at 40 CFR 796.3500—*Hydrolysis as a function of pH at 25 °C,* as modified in this rule. These modifications do not apply to the hydrolysis test requirements of previous rules, such as for anthraquinone. To make this clear, language has been added to the codified portion of this rule stating that the guidelines and other test methods cited in the anthraquinone test rule are referenced as they existed on July 20, 1987.

The Agency is requiring that the above-referenced health effects and chemical fate test guidelines specified in III.B., and any modifications to those guidelines, be the test standards for the purposes of the required and optional testing for these chemicals. The EPA test guidelines for chemical fate and human health effects testing specify generally accepted minimum conditions for determining chemical fate and human health toxicities for substances such as the subject OSW chemicals to which humans may be exposed.

Persons manufacturing or processing the 32 chemicals for which biodegradation testing is recommended, as indicated in Table 4, have the option of performing the test according to the EPA-developed guideline at 40 CFR 795.54, finalized in this rule, or not performing the test and having EPA assume "zero biodegradation" when formulating regulatory requirements for land disposal of hazardous wastes. A discussion of why this test is optional, rather than required, is contained in Unit II.A.11. of this preamble. The guideline was developed by EPA to obtain information on the biodegradation of chemicals in the subsurface environment.

C. Test Substances

EPA is requiring that the test substance in the required studies for each of the chemicals subject to this test rule be of at least 98 percent purity. The Agency has specified relatively pure substances for testing because it is interested in evaluating the effects attributable to the subject chemicals themselves. This requirement lessens the likelihood that any effects seen are due to other chemicals that may be present.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. Manufacturers and persons who intend to manufacture a chemical are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors and persons who intend to process the chemical are required to test if the findings are based on processing. Manufacturers and processors and persons who intend to manufacture and process a chemical, are required to test if the exposure giving rise to the potential risk occurs during distribution in commerce, use, or disposal of a chemical.

Because EPA has found that existing data are inadequate to assess the health risks from the continued disposal of the chemicals subject to this test rule, EPA is requiring that persons who manufacture, import, and/or process, including byproduct manufacture (defined in 40 CFR 791.3), or who intend to manufacture or process these chemicals at any time from the effective date of the final test rule to the end of the reimbursenent period be subject to the testing requirements contained in this final rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time equal to that which was required to develop data, if more than 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to this rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for the chemicals subject to this final test rule. As noted in Unit III.C. of this

preamble, EPA is interested in evaluating the effects attributable to each of the chemicals themselves and has specified relatively pure substances for testing.

Manufacturers and processors subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking. This does not include manufacturers and processors of the nine chemicals for which no testing is required, but is recommended (biodegradation).

For those who decide to conduct the optional biodegradation test, EPA requests notification, either in the letter of intent to conduct the required testing or a separate letter, that biodegradation testing will be conducted.

E. Reporting Requirements

EPA requires that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) Standards, which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days prior to the initiation of each test.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. Specific reporting requirements for each of the required (and optional) test standards are as follows:

The 90-day subchonic toxicity study on each of the designated chemicals shall be completed and the final results submitted to the Agency within 12 months of the effective date of the final test rule.

The soil sorption study on the designated chemicals shall be completed and the final results submitted to the Agency within 9 months of the effective date of the final test rule.

The hydrolysis studies on the designated chemicals shall be completed and the final results submitted to the Agency within 6 months of the effective date of the final test rule.

A progress report on the subchronic toxicity and biodegradation tests will be required every 6 months from the effective date of the final rule until submission of the final report.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical substance or mixture subject to a section 4 test rule are subject to the export reporting requirement of TSCA section 12(b). Final regulations interpreting the requirement of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of any of the chemicals listed at 40 CFR 790.5055(c) must report to EPA the first annual export of the chemical to any one country. EPA will notify the foreign country about the test rule for the chemical.

If a person decides to conduct the optional biodegradation study on a chemical, the person should notify EPA. Testing should begin within 4 months of the effective date of the final rule and the final results of the study should be submitted to the Agency within 6 months of the completion date of the study, but not exceed 25 months from the effective date of the final rule. Persons who decide not to conduct the test should notify EPA of this decision in writing within 4 months of the effective date of the final rule. This letter implies acknowledgement that EPA will assume "zero biodegradation" for purposes of concentration-based listing of the chemical.

F. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by TSCA or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by TSCA section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *". The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for these OSW chemicals. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, interpretations, and evaluations, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 of TSCA could be subject to a civil penalty of up to $25,000 for each violation, with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular,

this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

IV. Economic Analysis of Final Rule

To assess the potential economic impact for this rule, EPA has prepared an economic analysis report, contained in the public record for this rule, that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required and recommended testing for each of the 33 chemicals (24 with required and/or recommended testing; 9 recommended for optional testing only) and evaluates the potential for significant adverse economic impact as a result of those costs, incorporating an impact measure based upon unit test cost as a percent of price. For those chemicals for which public comments specifically addressed the potential for economic impact, that information has been incorporated into the economic analysis. For each chemical for which the costs of testing estimated in the economic analysis of the proposed rule indicated a high probability of adverse economic impact, a more detailed assessment has been incorporated into the economic analysis for this final rule to more precisely determine whether that chemical has been classified appropriately.

The total testing costs for testing the 33 chemicals are estimated to range from approximately $6.2 million to $8.2 million if companies consent to conduct the optional biodegradation test for each of the 32 chemicals for which that test is requested. The total testing costs for the required tests alone are estimated to range from $665,000 to $937,000. The estimated testing costs for individual chemicals range from $74,000 to $339,000, again, assuming that the biodegradation test is conducted. If some firms that are subject to required testing opt not to conduct the biodegradation test, for some chemicals, testing costs would be as low as $4,300. See the economic analysis contained in the public record for this rule for the estimated testing costs for each chemical.

The economic impact analysis indicates that for 28 of the 33 chemicals, the probability of significant adverse economic impact as a result of the testing costs is very low. Five chemicals have a potential for significant adverse impact on the basis of the estimated testing costs if the manufacturers and processors of each chemical choose to conduct the optional biodegradation test. If the biodegradation test is not conducted for these five chemicals, only two will have a potential for significant impact. The specific chemicals falling into each of these groups may be found in the economic impact analysis in the public docket.

Please refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability for testing services created by section 4 test rules demands. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (PB 82-140773). On the basis of this study, and a survey of laboratories that can conduct the biodegradation test (Ref. 37), the Agency believes that there will be available test facilities and personnel to perform the testing specified in this rule.

VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42088D]. This record includes:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice of EPA's proposed test rule for OSW Chemicals (52 FR 20336; May 29, 1987).

(b) Notice to extend comment period on proposed test rule for OSW Chemicals (52 FR 29395; August 7, 1987).

(c) Notice to reopen comment period on proposed test rule for OSW Chemicals (53 FR 911; January 14, 1988).

(d) TSCA test guidelines final rule (40 CFR Parts 796, 797, and 798; September 27, 1985) and modifications (52 FR 19056; May 20, 1987).

(e) TSCA GLP standards (48 FR 53922; November 29, 1983).

(f) Notice of final rulemaking on data reimbursement (48 FR 31786; July 11, 1983).

(g) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(2) Support documents consisting of:

(a) Literature search results and critique.

(b) Economic impact analysis of NFRM for the chemicals subject to this final rule.

(c) Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (40 U.S.C. 10001).

(d) Identification and Listing of Hazardous Waste (40 CFR Part 261).

(3) Communications consisting of:

(a) Written public comments.

(b) Transcript of public meeting.

(4) Report—Chemical Testing Industry: Profile of Toxicological Testing (October, 1981).

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the TSCA Public Docket Office, Rm. NE-G004, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

B. References

(1) American Petroleum Institute. Robert T. Drew, Ph.D., Director, Health and Environmental Sciences Department. Letter to EPA. (July 28, 1987).

(2) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Attachment: Comments of the Chemical Manufacturers Association on EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (July 28, 1987).

(3) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Attachment: Supplemental Comments of the Chemical Manufacturers Association of EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (August 27, 1987).

(4) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director; CMA Phthalate Esters Panel; et al. Letter to EPA and Comments of CMA Phthalate Esters Panel on the Proposed Biodegradation and Adsorption Testing Requirements for Phthalate Anhydride. (August 27, 1987).

(5) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President, and Technical Director; CMA Phthalate Esters Panel; et al. Comments of CMA Phthalate Esters Panel on the Proposed Biodegradation Testing Requirements for Dimethyl Phthalate and Dibutyl Phthalate. (August 27, 1987).

(6) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director; CMA Phosgene Program Panel; et al. Letter and Attachment: Comments of the CMA Phosgene Program Panel on EPA's Proposed Subchronic Studies Requirements for Phosgene. (August 27, 1987).

(7) Conoco, Inc. Charles E. Downs, Ph.D., Senior Director, Groundwater Programs, Environmental Conservation. Letter to EPA. (July 28, 1987).

(8) The Dow Chemical Company. Robert L. Hagerman, Research Associate. Letter to EPA. (August 26,1987).

(9) Eastman Kodak Company. Robert F. Brothers, Director, Regulatory Affairs. Letter to EPA. (July 23, 1987).

(10) Florida International University, Drinking Water Center, Tamiami Campus. Frances Parsons, Ph.D., Associate Professor. Letter to EPA. (July 8, 1987).

(11) State of Illinois Department of Energy and Natural Resources, Illinois State Water

Survey, Aquatic Chemistry Section. Michael J. Barcelona, Head of Aquatic Chemistry Section. Letter to EPA (July 14, 1987).

(12) Interagency Testing Committee. Robert Brink, Executive Secretary. Memorandum to TSCA Public Information Office. (August 19, 1987).

(13) Interchem, Inc. Harold H. Flegenheimer, Director, Environmental, Health and Safety Affairs. Letter to EPA. (July 15, 1987)

(14) The Johns Hopkins University, Department of Geography and Environmental Engineering. Edward J. Bouwer, Assistant Professor. Letter to EPA. (July 24, 1987).

(15) Lonza, Inc. Michael J. Reale, Ph.D., Director, Hazard Assessment and Environmental Control. Letter and Attachment: Comments on OPTS–42088A Solid Waste Chemicals; Proposed Test Rule. (July 28, 1987).

(16) Maleic Anhydride Consortium. Prepared by Robert J. Fensterheim, Regulatory Network, Inc. Letter and Attachment: Comments of the Maleic Anhydride Consortium on the U.S. Environmental Protection Agency's Solid Waste Chemicals; Proposed Test Rule Document Control Number (OPTS–42088A) 52 FR 20336 (May 29, 1987). (July 28, 1987).

(17) Methyl Chloride Industry Association (MCIA). Prepared by Robert Sussman and Richard Friedman, Counsel, Covington & Burling. Letter and Attachment: Attachment to the Comments of the Methyl Chloride Industry Association of EPA's Proposed Test Rules for 73 Chemicals, Including Testing for Methyl Chloride. Docket No. OPTS–42088A. Attachment also includes Appendices A through J. (July 24, 1987).

(18) Monsanto Company. D.B. Redington, Director, Regulatory Affairs (RCRA) and J.R. Condray, Director, Regulatory Affairs (TSCA). Letter to EPA and attached Material Safety Data Sheets. (July 27, 1987).

(19) Morton Thiokol, Inc. Arthur E. Slesinger, Director, Environmental Affairs. Letter to EPA. (July 24, 1987).

(20) Natural Resources Defense Council. Helen Greer, Robin Whyatt, and Jacqueline Warren. Comments of the Natural Resources Defense Council on Proposed Test Rule for 73 Solid Waste Chemicals, 52 FR 20336 (May 29, 1987). (August 25, 1987).

(21) Occidental Chemical Corporation. Paul E. Gurba, Ph.D., Corporate Toxicologist. Letter to EPA and Attachments: (1) *para*-Chlorobenzene Vapor Thirty Day Inhalation Toxicity Study in Rats (Huntingdon Research Center); (2) *para*-Chlorobenzene Vapor Thirty Day Inhalation Study in Rats—Microscopic Pathology Addendum (Huntingdon Research Center); (3) Hydrolysis Kinetics for *p*-Chlorobenzotrichloride (p-CBTC), (Oxy Chem Technology Center); (4) Hydrolytic Stabilities for alpha, alpha, alpha-trichlorotoluene, *p*-Chloro, alpha, alpha, alphatrichlorotoluene, benzoyl chloride, *p*-chlorobenzoyl chloride, and 3,5-dichlorobenzoyl chloride, (Hooker); and (5) Biodegradability Testing of Organchlorine Compounds (Vom Wasser v. 67). (July 23, 1987).

(22) Olin Chemicals. Nicholas J. Barone, Manager, Regulatory Services. Letter to EPA. (July 21, 1987).

(23) The Procter and Gamble Company. T.W. Mooney, Technical Government Relations. Letter to EPA. (July 28, 1987).

(24) Reilly Tar & Chemical Corporation. Nicholas Wright, Toxicologist, Corporate Environmental Affairs. Letter to EPA. (July 20, 1987).

(25) Rice University Department of Environmental Science and Engineering. J. Michele Thomas, Research Associate. Letter and Attachment: Critique of EPA Method for Microbial Transformation of Subsurface Materials. (June 26, 1987).

(26) Rice University Department of Environmental Science and Engineering. P.B. Bedient. Letter and attachment: Critique of Protocol for Obtaining Microbiological Transformation Rate Data for Chemicals in Subsurface Aquifers. (June 5, 1987).

(27) Synthetic Organic Chemical Manufacturers Association, Inc. Catherine A. Marshall, Director, Legislative and Regulatory Affairs. Letter and Attachment: Synthetic Organic Chemical Manufacturers Association Comments on Section 4 Test Rule for Solid Waste Chemicals, 52 Fed. Reg. 20336 (May 29, 1987) Document Control No. OPTS–42088A. (August 27, 1987).

(28) United States Department of the Interior, Office of Environmental Project Review. Bruce Blanchard, Director, Environmental Project Review. Letter to EPA. (August 12, 1987).

(29) University of California—Riverside, College of Natural and Agricultural Sciences Citrus Research Center and Agricultural Experiment Station, Department of Nematology. C.E. Castro, Chemist and Professor. Letter to EPA. (July 22, 1987).

(30) The University of Oklahoma, Department of Botany and Microbiology. Joseph M. Suflita, Assistant Professor of Microbiology. Letter to EPA and Attachments: (i) "Biodegradation of cresol isomers in anoxic aquifers," In: *Applied and Environmental Microbiology*, vol, 53, No. 4; and (ii) "Extrapolation of biodegradation results to groundwater aquifers reductive dehalogenation of aromatic compounds," In: *Applied and Environmental Microbiology*, vol. 52, No. 4 (July 8, 1987).

(31) Utah Water Research Laboratory. Ronald C. Sims, Ph.D., Head, Division of Environmental Engineering and Associate Professor, and R. Ryan Dupont. Comments on Provisional Chemical Fate Testing Guidelines. (August 25, 1987).

(32) Velsicol Chemical Corporation. Alfred A. Levin, Manager, Toxic Substances Control. Letter to EPA. (July 8, 1987).

(33) Vulcan Chemicals. Thomas A. Robinson, Ph.D., Director, Environmental Affairs. Letter to EPA. (July 17, 1987).

(34) Kirk-Othmer. "Chlorohydrins." In: *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd. ed., vol. 5. New York, NY. Wiley Interscience. pp. 848–864. (1979).

(35) Mannsville Chemical Products. Chemical Products Synopsis-epichlorohydrin. (1984).

(36) Zapico, M.M., Vales, S., and Cherry, J.A. "A wireline piston core barrel for sampling cohesionless sand and gravel below the water table." *Ground Water Monitoring Review*. Summer, Vol. 7, No. 3: 74–82. (1987).

(37) U.S. Environmental Protection Agency. "Survey of laboratories able to conduct anaerobic biodegradation tests." (1988).

(38) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Supplemental Comments of the CMA Phthalate Esters Program Panel on the Proposed Biodegradation Testing Requirements for Dimethyl Phthalate and Dibutyl Phathalate. (February 16, 1988).

(39) Monsanto Company. D.B. Redington, Director, Regulatory Affairs (RCRA) and J.R. Condray, Director, Regulatory Affairs (TSCA). Letter to EPA. (February 12, 1988).

(40) Synthetic Organic Chemical Manufacturers Association, Inc. Catherine A. Marshall, Director, Legislative and Regulatory Affairs. Letter and Attachment: Synthetic Organic Chemical Manufacturers Association Comments on Section 4 Test Rule for Solid Waste Chemicals; Reopening of Comment Period, 53 FR 911 (January 14, 1988) Document Control No. OPTS 42088C. (February 16, 1988).

(41) Eastman Kodak Company. Robert F. Brothers, Director, Regulatory Affairs. Letter to EPA. (February 11, 1988).

(42) Methyl Chloride Industry Association (MCIA). Prepared by Robert Sussman and William Rawson, Counsel, Latham & Watkins. Letter and Attachment: Comments of the Methyl Chloride Industry Association of EPA's Proposed Test Rules for 73 Chemicals, Including Testing for Methyl Chloride. Docket No. OPTS–42088C. (February 16, 1988).

(43) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D. Vice President and Technical Director, et al. Letter to EPA and attachment: Second Supplemental Comments of the Chemical Manufacturers Association of EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (February 16, 1988).

(44) Maleic Anhydride Consortium. Prepared by Robert J. Fensterheim, Regulatory Network, Inc. Letter to EPA re: Solid Waste Chemicals; Reopening of Comment Period on Proposed Test Rule (OPTS–42088C). (February 16, 1988).

(45) Ausimont U.S.A. Inc. v. EPA, No. 87–3502 slip opinion (3rd Cir. 1988) February 1, 1988.

(46) Mabey, W.R., Smith, J.H., Podoll, R.T., Johnson, H.L., Mill, T., Chou, T.W., Gates, J., Partridge, I.W., Jaber, H., and Vandenberg, D. "Aquatic Fate Process Data for Organic Priority Pollutants." SRI International, EPA Report 440/4–81–014. (1982).

(47) Pankhurst, E.S. "The isolation and enumeration of sulphate-reducing bacteria," p. 223–240. In: D.A. Shapton and R.G. Board (eds.), "Isolation of Anaerobes." Academic Press, Inc., New York (1971).

(48) Jones, J.G., B.M. Simon, and Gardener, S. "Factors affecting methanogenesis and associated anaerobic processes in the sediments of a stratified eutrophic lake." Journal of General Microbiology. 128: 1–11 (1982).

(49) Vulcan Chemicals. Thomas A. Robinson, Ph.D., Director, Environmental Affairs. Letter to EPA. (February 12, 1988).

(50) The Procter and Gamble Company. T.W. Mooney, Technical Government Relations. Letter to EPA. (February 12, 1988).

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in costs or prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprise to compete with foreign enterprises.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businessess because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq., Pub. L. 96-511, December 11, 1980), and has assigned OMB control number 2070-0033.

List of Subjects in 40 CFR Parts 795, 796 and 799

Testing, Environmental protection, Hazardous substances, Chemicals, Laboratories, Provisional testing, Recordkeeping and reporting requirements.

Dated: June 3, 1988.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR, Chapter I, is amended as follows:

PART 795—[AMENDED]

1. In Part 795:

a. The authority citation for Part 795 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. Section 795.54 is added, to read as follows:

§ 795.54 Anaerobic microbiological transformation rate data for chemicals in the subsurface environment.

(a) *Introduction.* (1) This guideline describes laboratory methods for developing anaerobic microbiological transformation rate data for organic chemicals in subsurface materials. The method is based on a time-tiered approach. For chemicals that are degraded rapidly, only a portion (the 0, 4, and 8 week sampling periods, for example) of the test will have to be completed; however, for slowly degrading chemicals, the entire test may have to be performed (64 weeks). The data will be used to calculate degradation rate constants for each tested chemical over a range of environmental conditions. The rate constants obtained from testing will be integrated into algorithms to assess the fate of organic chemicals leaching into ground water from waste management facilities.

(2) Anaerobic transformations are evaluated under methanogenic and sulfur-reducing conditions. Aerobic biodegradation was not included in the modeling analysis for two reasons:

(i) Aerobic biodegradation would be limited by the concentration of oxygen in ground water. In the laboratory, oxygen would probably not be limiting, and the resulting degradation rates obtained would possibly be overestimations of actual subsurface degradation rates.

(ii) Aerobic degradation would only occur at the leading edge of a contaminant plume where dispersion and other processes dilute the plume with oxygenated water, as stated in Wilson et al. (1985), in paragraph (d)(24) of this section.

(3) The anaerobic transformation of chemicals in selected subsurface samples shall be estimated from subsurface microcosm studies using methods adapted from procedures recently reported by Wilson et al. (1986), in paragraph (d)(25) of this section. These procedures shall be used to determine the length of the adaptation period (time interval before detectable degradation of the chemical can be observed) and the half-life of the chemical following the adaptation period. Supporting laboratory methods shall be used to measure the levels of residual test chemical, intermediate degradation products, biomass, and other physical-chemical parameters.

(b) *Laboratory procedures*—(1) *Identification of subsurface sampling sites, collection of subsurface materials, and transportation and storage of subsurface materials.*—(i) A minimum of six subsurface sampling sites shall be identified on the basis of two temperatures and three pH values. Three of the sites shall have annual average temperatures near 10 °C, and three of the sites shall have temperatures near 20 °C. These values are chosen to represent the high and low temperatures commonly observed in aquifers and are one standard deviation on either side of the mean temperature of 15 °C. Generally, low temperature sites are located in northern latitude areas of the United States, and high temperatures correspond to southern latitude areas.

(ii) Acidic (pH 4.5 to 6.0), neutral (pH 6.5 to 7.5), and alkaline (pH 8.0 to 9.5) sites shall be selected for each temperature range. These ranges of pH values for ground waters are selected to estimate the effect of pH on microbial degradation capacity and to examine the effect of chemical form on the degradation of chemicals having dissociable hydrogen (i.e., degradation of the protonated and unprotonated forms of the chemical). Ground waters at all sites shall have dissolved-oxygen levels below 0.1 mg/L and sulfate concentrations below 10 mg/L.

(iii) Samples of subsurface materials shall be collected in a manner that protects them from contamination from surface materials and maintains anaerobic conditions. An appropriate procedure has been reported by Wilson et al. (1983), in paragraph (d)(26) of this section. First, a bore hole is drilled to the desired depth with an auger. Then the auger is removed and the sample taken with a wireline piston core barrel, as reported by Zapico et al., 1987, in paragraph (d)(14) of this section. The core barrel is immediately transferred to an anerobic chamber, filled and continually purged with nitrogen gas, and all further manipulations are performed in the chamber. Using aseptic procedures, up to 5 centimeters (cm) of the core is extruded, then broken off to produce an uncontaminated face. A sterile paring device is then installed, and the middle 30 to 35 cm of the core is extruded, paring away the outer 1.0 cm of core material. As a result, the material that had been in contact with the core barrel, and thus might be contaminated with surface microorganisms, is discarded.

Modifications of this technique can be used for samples obtained from deep coring devices when auger equipment is insufficient because of the depth of the aquifer. Subsurface material shall be stored under nitrogen gas and on ice and shall be used in microcosm studies within 7 days of collection.

(iv) Ground waters will be collected from the bore hole used to collect subsurface materials. Ground waters will be pumped to the surface. The bore hole should be purged with argon before pumping begins. The pumping mechanism should be flushed with enough ground water to insure that a representative ground water sample is obtained. This flushing process generally requires a volume equal to 3 to 10 times the volume of water in the bore hole. Once flushing is complete, ground water samples should be collected, and stored under nitrogen and on ice for transport back to the laboratory. Ground waters shall be sterilized by filtration through 0.22 micrometer (μm) membranes on-site in a portable anaerobic chamber filled and continually purged with nitrogen gas. The sterile water shall be stored under nitrogen and on ice, and shall be used in microcosm studies within 7 days of collection.

(v) Two samples shall be collected from each of the 6 sites. Each core sample shall be assayed for test chemical degradation and analyzed for biomass (heterotrophic, sulfate-reducing, and methanogenic) and physical-chemical parameters (pH, cation exchange capacity, total organic carbon, percent base saturation, percent silt, percent sand, percent clay, redox potential, percent ash-free dry weight). Each corresponding ground water sample will be analyzed for pH, dissolved oxygen, dissolved organic carbon, nutrients (sulfate, phosphate, nitrate), conductivity, and temperature.

(2) *Anaerobic Microcosm assay.* (i) Microcosms shall consist of 160-milliliter (mL) serum bottles which have been filled completely with a slurry of subsurface material and ground water (20 grams equivalent dry wt (oven dry wt. 103 °C) solid to 80 mL ground water). One series of serum bottles shall be amended to a level of 200 mg/L sulfate (weight/volume added as sodium sulfate) to stimulate sulfate-reducing conditions. If the level of soluble sulfate falls below 50 mg/L at any sampling time, additional sulfate (200 mg/L, weight/volume) should be added to all remaining sulfate-amended microcosms. Soluble sulfate levels should be measured by the method of Watwood et al. (1986), in paragraph (d)(23) of this section. A second series shall be left unamended to simulate methanogenic conditions. All manipulations in preparing the microcosms shall be performed aseptically under strict anaerobic conditions, as described in Kaspar and Tiedje (1982) in paragraph (d)(10) of this section, or other equivalent methods, and all equipment in contact with the subsurface samples shall be sterilized. Sterile controls shall be prepared by autoclaving the samples for a minimum of 1 hour on each of 3 consecutive days. Test chemical amendments shall be prepared in sterile nitrogen-purged ground water. Sparingly soluble and volatile chemicals shall be added to sterile, nitrogen-purged ground water and then stirred overnight without a head space.

(ii) The active and control microcosms shall be dosed with the test chemical and 0.0002 percent (w/v) Resazurin as a redox indicator, and then each unit shall be immediately sealed with a Teflon®-coated gray butyl rubber septum and crimp seal. As stated previously, all manipulations shall be performed under strict anaerobic conditions, as described in Kaspar and Tiedje (1982) in paragraph (d)(10) of this section, or other equivalent methods. The microcosms shall be stored in the dark at the original in-situ temperature. Active microcosms and control microcosms, randomly selected from the sulfate-amended series and the unamended series, shall be sacrificed and analyzed at 0, 4, 8, 16, 32, and 64 weeks for residual test chemical and the formation of degradation intermediates. Once the residual level of the chemical drops below 5 percent of the initial concentration, analysis of microcosms at subsequent time periods is not required. The active microcosms and control microcosms from both series, at weeks 0, 16, and 64 (or randomly selected from the remaining samples the week following 95 percent degradation of the chemical, if less than week 64) shall also be analyzed for heterotrophic, sulfate-reducing, and methanogenic bacteria.

(iii) Three concentrations of each chemical tested shall be used. The test chemical concentrations should range between a low level of 30 times the health-based level and a level that equates to the chemical's solubility (or to a level that causes inhibition of the test chemical's degradation).

(iv) Biomass measurements shall be made for heterotrophic, sulfate-reducing, and methanogenic bacteria. Biomass measurements have been included to insure comparability of results between samples of subsurface materials. Degradation rates derived from sediment samples having significantly high or low (student "t" test, 90 percent level) bacterial populations would not be considered in subsequent modeling efforts. Also, the ratio of sulfate-reducing organisms to methanogenic organisms would be used to determine if the dominant redox conditions were sulfate-reducing or methanogenic. Anaerobic techniques described by Kaspar and Tiedje (1982), cited in paragraph (d)(10) of this section, or other equivalent methods, shall be used.

(v) Heterotrophic bacterial concentrations shall be measured by a modification of the procedure developed by Molongoski and Klug (1976) and Clark (1965), cited in paragraphs (d)(13) and (d)(6) of this section, respectively. A ten-mL sample taken from the center of the appropriate microcosm, which has been well mixed, shall be aseptically transferred to 100 mL of sterile dilution medium and agitated to suspend the organisms. Ten-mL samples shall then be transferred immediately from the center of the suspension to a 90-mL sterile dilution medium blank to give a 10^{-2} dilution; 10 mL shall be similarly transferred to another 90-mL of sterile dilution medium to obtain a dilution of 10^{-3}. This process shall be repeated to give a dilution series through at least 10^{-7}. Only the 10^{-1} dilution need be prepared from control samples. The dilution series can be modified to include dilutions of greater than 10^{-7}, if necessary, and if sufficient sample is available. From the highest dilution, 0.1-mL portions shall be transferred to the surface of each of three dilute tryptone glucose extract agar plates. The sample shall be spread immediately over the surface of the plates; the process shall be repeated for lower dilutions. Dilute tryptone glucose agar plates shall be prepared by combining 24.0 g tryptone glucose extract agar in 1 liter of distilled water. The mixture shall be autoclaved, and 25 mL of the molten agar shall be transferred to petri plates. Agar plates should be stored in an anaerobic chamber for a minimum of 24 hours before use. The inoculated plates shall be incubated in plastic bags in the glove box, or, if necessary, removed and kept in anaerobic jars. After 14 days of incubation, the plates shall be examined and the total count per gram of dry sediment material shall be determined. If the plates from the most dilute sample show more than 300 colonies, the dilution series was inadequate. In this case, all of the plates shall be discarded, and the process shall be repeated with greater dilutions, as appropriate.

(vi) Sulfate-reducing species shall be enumerated by the MPN (most probable number) technique as described in Pankhurst (1971) in paragraph (d)(15) of this section, or other equivalent method. The dilution series shall be prepared as described for heterotrophic bacteria.

(vii) Methanogenic bacteria shall be enumerated by the MPN technique as described by Jones et al. (1982) in paragraph (d)(9) of this section, or by another equivalent method. The dilution series shall be prepared as described for heterotrophic bacteria.

(3) *Analytical measures of the loss of test chemical and intermediate degradation products.* (i) The loss of test chemical shall be quantified by measuring the residual test chemical. The formation of degradation intermediates shall be quantified in microcosm assays for test chemicals that can potentially be transformed. Analysis for degradation intermediates shall be required when the level of test chemical has been reduced by more than 25 percent. Concentrations of the potential degradation products 1,2-, 1,3-, and 1,4-dichlorobenzene, and 1,2,4,5-tetrachlorobenzene shall be measured in the appropriate microcosms used to analyze the degradation of pentachlorobenzene. The concentration of the potential degradation product dibromomethane shall be measured in the appropriate microcosms used to analyze the degradation of bromoform. The potential degradation products methanethiol and chloromethane (methyl chloride) shall be measured in the appropriate microcosm used to analyze the degradation of trichloromethanethiol. The potential intermediate products 1,2-, 1,3-, and 1,4-dichlorobenzene shall be measured in the appropriate microcosm used to analyze the degradation of 1,2,4,5-tetrachlorobenzene.

(ii) Measurements of test chemical and intermediate degradation products will require organic analytical techniques tailored to the specific test chemical and subsurface material being investigated. Several extraction and purge-trap techniques are available for the recovery of residual test chemicals and degradative intermediates from subsurface materials. Unique analytical procedures would have to be developed or modified for each test chemical and sediment. The following represent examples of such techniques:

(A) Soxlet extraction as described in Anderson et al. (1985), Bossart et al. (1984), Eiceman et al. (1986), Grimalt et al. (1984), and Kjolholt (1985) in paragraphs (d) (2), (3), (7), (8), and (11) of this section, respectively.

(B) Shake flask method as described in Brunner et al. (1985), and Russel and McDuffie (1983) in paragraphs (d) (4) and (16) of this section, respectively.

(C) Sonification as described in Schellenberg et al. (1984) in paragraph (d)(17) of this section.

(D) Homogenization as described in Fowlie and Sulman (1986), Lopez-Avila et al. (1983), Sims et al. (1982), Stott and Tabatabai (1985), and U.S. EPA (1982) in paragraphs (d) (5), (12), (18), (19), and (22) of this section, respectively.

(E) Purge-trap techniques have been described by Wilson et al. (1986) in paragraph (d)(24) of this section.

(iii) These procedures can be readily coupled to gas chromatography (GC) and high-pressure liquid chromatography (HPLC) procedures to quantify the chemicals of interest. Whatever analytical procedure is selected shall follow Good Laboratory Practice Standards of 40 CFR Part 792.

(4) *Characterization of subsurface materials and ground waters.* (i) Subsurface materials shall be classified, described, and characterized as to soil type and physical and chemical properties using standard procedures as described by the Soil Conservation Service (U.S. Department of Agriculture, 1972 and 1975) in paragraphs (d) (20) and (21) of this section, or other equivalent methods. Ten parameters will be measured as follows:

(A) Total organic carbon (TOC).

(B) pH.

(C) Cation exchange capacity.

(D) Percent base saturation.

(E) Percent silt.

(F) Percent sand.

(G) Percent clay.

(H) Redox potential.

(I) Percent ash-free dry weight.

(J) Texture.

(ii) Ground water shall be characterized for the following, by standard water and wastewater methods described by the American Public Health Association (1985) in paragraph (d)(1) of this section, or other equivalent methods:

(A) pH.

(B) Dissolved oxygen.

(C) Dissolved organic carbon.

(D) Nutrients including sulfate, phosphate, and nitrate.

(E) Conductivity.

(F) Temperature.

(iii) The properties of pH, dissolved oxygen, and temperature shall be measured at the site of collection. All other properties shall be measured in the laboratory.

(c) *Data to be reported to the Agency.* Data shall be reported for the two subsurface samples and corresponding ground waters taken from the six different sampling sites.

(1) The following shall be reported for subsurface sediment samples:

(i) Levels of residual test chemicals (mg/gm/dry wt) quantified in each of the randomly selected replicate microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(ii) Numbers of heterotrophic, sulfate-reducing, and methanogenic bacteria (colony forming units (CFU) or most probable number units (MPNU) per gm dry wt) enumerated in each replicate microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(iii) Levels of persistent degradation intermediates identified in microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(iv) Measured values for pH, cation exchange capacity (meg/100 gm dry wt), percent base saturation, percent silt (percent dry wt), percent sand (percent dry wt), percent clay (percent dry wt), redox potential (Eh, Standard Hydrogen Electrode), percent ash free dry weight (percent dry wt), and a description of texture.

(2) For ground water samples, the analysis report shall provide measured values for:

(i) pH.

(ii) Dissolved oxygen (mg/L).

(iii) Dissolved organic carbon (mg/L).

(iv) Nutrients including sulfate (mg/L), phosphate (mg/L), and nitrate (mg/L).

(v) Conductivity (umho, 25 °C).

(vi) Temperature (°C).

(d) *References.* For additional background information cited in this protocol, the following references should be consulted:

(1) American Public Health Association, American Water Works Association, and Water Pollution Control Federation. "Standard methods for the examination of water and wastewater," 16th ed., A.E. Greenberg, R.R. Trussel, and L.C. Clesceri (eds.), American Public Health Association, Washington, DC (1985).

(2) Anderson, J.W., G.H. Herman, D.R. Theilen, and A.F. Weston. "Method verification for determination of tetrachlorodibenzodioxine in soil." *Chemosphere* 14:1115–1126 (1985).

(3) Bossart, I., W.M. Kachal, and R. Bartha. "Fate of hydrocarbons during oil sludge disposal in soil." *Applied and Environmental Microbiology* 47:763–767 (1984).

(4) Brunner, W., F.H. Sutherland, and D.D. Focht. "Enhanced biodegradation of polychlorinated biphenyls in soil by

analog enrichment and bacterial inoculation." *Journal of Environmental Quality* 14:324–328 (1985).

(5) Fowlie, P.J.A., and T.L. Bulman. "Extraction of anthracene and benzo(a)-pyrene from soil." *Analytical Chemistry* 58:721–723 (1986).

(6) Clark, F.E. "Agar-plate method for total microbial count," p. 1460–1466. In: C.A. Black (ed.), "Methods of soil analysis. Part 2. Chemical and Microbiological Properties." American Society of Agronomy, Inc., Madison WI (1965).

(7) Eiceman, G.A., B. Davani, and J. Ingram. "Depth profiles for hydrocarbons and polycyclic aromatic hydrocarbons in soil beneath waste disposal pits from natural gas production." *Environmental Science and Technology.* 20:508–514 (1986).

(8) Grimalt, J., C. Marfil, and J. Albaiges. "Analysis of hydrocarbons in aquatic sediments." *International Journal of Environmental Analytical Chemistry* 18:183–194 (1984).

(9) Jones, J.G., B.M. Simon, and S. Gardener. "Factors affecting methanogenesis and associated anaerobic processes in the sediments of a stratified eutrophic lake." *Journal of General Microbiology* 128:1–11 (1982).

(10) Kaspar, H.F., and J.M. Tiedje. "Anaerobic bacteria and processes," p. 989–1009. In: A.L. Page (ed.), "Methods of Soil Analysis. Part 2. Chemical and Microbiological Properties." American Society of Agronomy, Madison, WI (1982).

(11) Kjolholt, J. "Determination of trace amounts of organophosphorous pesticides and related compounds in soils and sediments using capillary gas chromatography and a nitrogen-phosphorous detector." *Journal of Chromatography* 325:231–238 (1985).

(12) Lopez-Avila, V., R. Northcutt, J. Onstot, M. Wickham, and S. Billets. "Determination of 51 priority organic compounds after extraction from standard reference materials." *Analytical Chemistry* 55:881–889 (1983).

(13) Molongoski, J.J., and M.J. Klug. "Characterization of anaerobic heterotrophic bacteria isolated from freshwater lake sediments." *Applied Environmental Microbiology* 31:83–90 (1976).

(14) Zapico, M.M., S. Vales, and J.S. Cherry. "A wireline piston core barrel for sampling cohesionless sand and gravel below the water table." *Ground Water Monitoring Review.* Summer, Vol. 7, No. 3:74–82 (1987).

(15) Pankhurst, E.S. "The isolation and enumeration of sulphate-reducing bacteria," p. 223–240. In: D.A. Shapton and R.G. Board (eds.), "Isolation of Anaerobes." Academic Press, Inc., New York (1971).

(16) Russell, D.J., and B. McDuffie. "Analysis for phthalate esters in environmental samples: Separation from PCBs and pesticides using dural column chromatography." *International Journal of Environmental Analytical Chemistry* 15:165–183 (1983).

(17) Schellenberg, K., C.L. Leuenberger, and R.P. Schwarzenback. "Sorption of chlorinated phenols by natural sediments and aquifer materials." *Environmental Science and Technology.* 18:652–657 (1984).

(18) Sims, R.C. "Land treatment of polynuclear wastes." Ph.D. dissertation. North Carolina State University, Raleigh, NC (1982).

(19) Stott, D.E., and M.A. Tabatabai. "Identification of phospholipids in soils and sewage sludges by high-performance liquid chromatography." *Journal of Environmental Quality.* 14:107–110 (1985).

(20) United States Department of Agriculture. "Soil survey laboratory methods and procedures for collecting soil samples." *Soil Survey Investigations Report No. 1.* Soil Conservation Service. Soil Survey Investigation (1972).

(21) United States Department of Agriculture. "Soil taxonomy: a basic system of soil classification for making and interpreting soil surveys." *Agricultural Handbook 436.* Soil Conservation Service (1975).

(22) U.S. Environmental Protection Agency. "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods." Second Edition. SW–846. U.S. Environmental Protection Agency, Washington, D.C. (1982).

(23) Watwood, M.E., J.W. Fitzgerald, and J.R. Gosz. Sulfur processing in forest soil and litter along an elevational and vegetative gradient. *Canadian Journal of Forest Resources.* 16:689–695 (1986).

(24) Wilson, J.T., J.F. McNabb, J.W. Cochran, T.H. Wang, M.B. Tomson, and P.B. Bedient. "Influence of microbial adaptation of the fate of organic pollutants in ground water." *Environmental Toxicology and Chemistry.* 4:721–728 (1985).

(25) Wilson, B.H., G.B. Smith, and J.F. Rees. "Biotransformation of selected alkylbenzenes and halogenated aliphatic hydrocarbons in methanogenic aquifer material: A microcosm study." *Environmental Science and Technology.* 20:997–1002 (1986).

(26) Wilson, J.T., J.F. McNabb, D.L. Balwill, and W.C. Ghiorse. "Enumeration and characterization of bacteria indigenous to a shallow water-table aquifer." *Groundwater* 21:134–142 (1983).

PART 796—[AMENDED]

2. In Part 796:

a. The authority citation for Part 796 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. Section 796.3500 is amended by revising the first sentence of paragraph (b)(1)(ii) and revising paragraphs (b)(1)(iii), (iv), (v), (vii), (ix), and (x) and (b)(2)(i) (C)(*1*) and (D) (*1*) and (*2*), to read as follows:

§ 796.3500 Hydrolysis as a function of pH at 25 °C.

* * * * *

(b) * * *

(1) * * *

(ii) *Purity of water.* Reagent-grade water (e.g., water meeting ASTM Type IIA standards or an equivalent grade) shall be used to minimize biodegradation. * * *

(iii) *Sterilization.* All glassware shall be sterilized. Aseptic conditions shall be used in the preparation of all solutions and in carrying out all hydrolysis experiments to eliminate or minimize biodegradation. Glassware can be sterilized in an autoclave or by any other suitable method.

(iv) *Precautions for volatility.* If the chemical is volatile the reaction vessels shall be almost completely filled and sealed.

(v) *Temperature controls.* All hydrolysis reactions shall be carried out at 25 °C (±1 °C) and with the temperature controlled to ±0.1 °C.

* * * * *

(vii) *Concentration of solutions of chemical substances.* The concentration of the test chesical shall be less than one-half the chemical's solubility in water but not greater than 10^{-2} M.

* * * * *

(ix) *Buffer catalysis.* For certain chemicals, buffers may catalyze the hydrolysis reaction. If this is suspected, hydrolysis rate determination shall be carried out with the appropriate buffers and the same experiments repeated at buffer concentrations lowered by at least a factor of five. If the hydrolysis reaction produces a change of greater than 0.05 pH units in the lower concentration buffers at the end of the measurement time, the test chemical concentrations also shall be lowered by at least a factor of five. Alternatively, test chemical concentrations and buffer concentrations may both be lowered simultaneously by a factor of five. A sufficient criterion for minimization of buffer catalysis is an observed equality in the hydrolysis rate constant for two different solutions differing in buffer or

test chemical concentration by a factor of five.

(x) *Photosensitive chemicals.* The solution absorption spectrum can be employed to determine whether a particular chemical is potentially subject to photolytic transformation upon exposure to light. For chemicals that absorb light of wavelengths greater than 290 nm, the hydrolysis experiment shall be carried out in the dark, under amber or red safelights, in amber or red glassware, or employing other suitable methods for preventing photolysis. The absorption spectrum of the chemical in aqueous solution can be measured under § 796.1050.

* * * * *

(2) * * *

(i) * * *

(C) * * *

(1) The concentrations of all the above buffer solutions are the maximum concentration to be employed in carrying out hydrolysis measurements. If the initial concentration of the test chemical is less than 10^{-2}M, the buffer concentration shall be lowered by a corresponding amount; e.g., if the initial test chemical concentration is 10^{-3}M, the concentration of the above buffers shall be reduced by a factor of 10. In addition, for those reactions in which an acid or base is not a reaction product, the minimum buffer concentration necessary for maintaining the pH within +0.05 units shall be employed.

* * * * *

(D) * * *

(1) If the test chemical is readily soluble in water, prepare an aqueous solution of the chemical in the appropriate buffer and determine the concentration of the chemical. Alternatively, a solution of the chemical in water may be prepared and added to an appropriate buffer solution and the concentration of the chemical then determined. In the latter case, the aliquot shall be small enough so that the concentration of the buffer in the final solution and the pH of the solution remain essentially unchanged. Do not employ heat in dissolving the chemical. The final concentration shall not be greater than one-half the chemical's solubility in water and not greater than 10^{-2}M.

(2) If the test chemical is too insoluble in pure water to permit reasonable handling and analytical procedures, it is recommended that the chemical be dissolved in reagent-grade acetonitrile and buffer solution and then added to an aliquot of the acetonitrile solution. Do not employ heat to dissolve the chemical in acetonitrile. The final concentration of the test chemical shall not be greater than one-half the chemical's solubility in water and not greater than 10^{-2}M. In addition, the final concentration of the acetonitrile shall be one volume percent or less.

PART 799—[AMENDED]

3. In Part 799:

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. In § 799.500, by revising paragraph (d) to read as follows:

§ 799.500 Anthraquinone.

* * * * *

(d) *Effective date.* (1) The effective date of this final rule for anthraquinone is July 20, 1987.

(2) The guidelines and other test methods cited in this section are referenced as they exist on July 20, 1987.

* * * * *

c. Subpart D is added, consisting at this time of § 799.5055, to read as follows:

Subpart D—Multichemical Test Rules

§ 799.5055 Hazardous waste constituents subject to testing.

(a) *Identification of test substances.* (1) The table in paragraph (c) of this section identifies those chemical substances that shall be tested in accordance with this section.

(2) Substances of at least 98-percent purity shall be used as the test substances.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacuture (including import or manufacture as a byproduct) or process or intend to manufacture or process one or more of the substances in paragraph (c), other than as an impurity, after July 29, 1988, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data, or submit exemption applications for those substances they manufacture or process, or intend to manufacture or process, as specified in this section, Subpart A of this part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Designation of testing.* The substances identified in the following table by name and CAS number shall be tested in accordance with the designated requirements under paragraphs (d) and (e) of this section. The paragraph numbers listed for a substance refer to the specific testing and reporting requirements specified in paragraphs (d) and (e) of this section.

Chemical name	CAS No.	Required testing under paragraphs (d) and (e) of this section
Acetamide, 2-fluoro	640-19-7	(e)(1)
Bis(2-chloroethoxy)-methane.	111-91-1	(d)(2), (e)(1)
Bis(2-chloroisopropyl)-ether.	108-60-1	(d)(2)
4-Bromobenzyl cyanide.	16532-79-9	(d)(1), (2), (e)(1)
Bromoform	75-25-2	(d)(2)
4-Chlorobenzo-trichloride.	5216-25-1	(e)(1)
2,4-D	94-75-7	(d)(2)
Dibromomethane	74-95-3	(d)(2).
1,2-Dichlorobenzene.	95-50-1	(d)(2)
1,1-Dichloroethane	75-34-3	(d)(2)
1,3-Dichloropropanol.	96-23-1	(d)(1), (e)(1)
Dihydrosafrole	94-58-6	(d)(2)
Endrin	72-20-8	(d)(2)
Ethyl methacrylate	97-63-2	(d)(2)
Maleic hydrazide	123-33-1	(d)(1), (2)
Malononitrile	109-77-3	(d)(1), (e)(1)
Methanethiol	74-93-1	(d)(1)
Methyl chloride	74-87-3	(d)(2)
p-Nitrophenol	100-02-7	(e)(1)
Pentachloroben-zene.	608-93-5	(d)(2)
Pentachloroethane	76-01-7	(d)(2)
Phthalic anhydride	85-44-9	(d)(1)
1,2,4,5-Tetrachloroben-zene.	95-94-3	(d)(2)
Trichloromethan-ethiol.	594-42-3	(d)(1), (2), (e)(1)

(d) *Chemical fate testing*—(1) *Soil adsorption*—(i) *Required testing.* A soil adsorption isotherm test shall be conducted with the substances designated in paragraph (c) of this section in accordance with § 796.2750 of this chapter.

(ii) *Reporting requirements.* The sediment and soil adsorption isotherm tests shall be completed and the final results submitted to the Agency within 9 months of the effective date of the final rule.

(2) *Hydrolysis*—(i) *Required testing.* A test of hydrolysis as a function of pH at 25 °C shall be conducted with the substances designated in paragraph (c) of this section in accordance with § 796.3500 of this chapter.

(ii) *Reporting requirement.* The hydrolysis tests shall be completed and the final results submitted to the Agency within 6 months of the effective date of the final rule.

(e) *Health effects testing*—(1) *Subchronic toxicity*—(i) *Required testing.* An oral gavage subchronic toxicity test shall be conducted in the rat with the substances designated in paragraph (c) of this section in

accordance with § 798.2650 of this chapter.

(ii) *Reporting requirements.* (A) The oral gavage subchronic tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(B) Progress reports for each test shall be submitted to the Agency 6 months after the effective date of the final rule.

(2) [Reserved].

(f) *Effective date.* (1) The effective date of the final rule July 29, 1988.

(2) The guidelines and other test methods cited in this section are referenced here as they exist on June 15, 1988.

[Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.]

[FR Doc. 88–13347 Filed 6–14–88; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 4100

[Circular No. 2604; AA–220–88–4322–02]

Grazing Administration, Exclusive of Alaska; Amendments to the Grazing Regulations; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking; revision, removal and correction.

SUMMARY: The Department of the Interior is making technical amendments to the final amendments to the grazing regulations of the Bureau of Land Management, published on March 29, 1988, in the Federal Register [53 FR 10224]. These amendments clarify and correct the amendatory instructions in that rule.

EFFECTIVE DATE: April 28, 1988.

ADDRESS: Inquiries or suggestions should be sent to: Assistant Director—Land & Renewable Resources (220) Bureau of Land Management, Room 5626, Main Interior Building 1800 C Street, NW., Washington, DC 20240

FOR FURTHER INFORMATION CONTACT: Dee R. Ritchie, (202) 653–9195.

SUPPLEMENTARY INFORMATION: In response to a request from the staff of the Code of Federal Regulations (CFR) to clarify what final changes need to be published in the code, and based on internal review of the existing regulations, the Department of the Interior is making minor technical amendments to the final regulations pertaining to livestock grazing published in the Federal Register on March 29, 1988 (53 FR 10224), and the existing regulations as they are presently published in the CFR. These amendments clarify the final rulemaking by removing and correcting the amendatory instructions in that rule, and the existing regulations by removing three sections which were replaced by other sections in the final regulations of February 21, 1984, but not omitted from the CFR.

The following revisions are made as editorial changes at the request of the CFR staff. On page 10234 amendatory item 16 is revised to inform the public that the language being removed from this item last appeared in the 1983 edition of the CFR and does not appear in the 1987 Code of Federal Regulations. Item number 17 on page 10234 is amended by adding a statement affirming that §§ 4120.2–1(c) and 4130.2(d)(3) are removed in their entirety and that the language being removed does not appear in the current CFR. Item number 18 on page 10234 is amended by correcting the typographical error in the number of the section from § 4120.2–3 to § 4120.2.

Based on internal review of the existing regulations published in the CFR, § 4130.5–1 "Payment of fees", 4130.5–2 "Refunds" and 4130.5–3 "Service charge" are removed in their entirety since they were replaced by, and are similar to, §§ 4130.7–1, 4130.7–2 and 4130.7–3 of the existing regulations. This was first discussed in the proposed rulemaking of May 13, 1983, in the preamble paragraph on § 4130.5 (48 FR 21821), where it was stated that § 4130.5–1 was proposed to be amended, and §§ 4130.5–2 and 4130.5–3 were proposed to be redesignated as § 4130.9–2 and 4130.9–3. However, the amendatory language of that proposed rulemaking and of the subsequent final rulemaking of February 21, 1984 (49 FR 6453), removed only § 4130.5, in the mistaken belief that this included §§ 4130.5–1, 4130.5–2, and 4130.5–3, which were wrongly assumed to be subordinate to, and parts of, § 4130.5. That final rulemaking added § 4130.7–1 "Payment of fees", § 4130.7–2 "Refunds", and § 4130.7–3 "Service charge", while mistakenly leaving in the sections they were to replace. Today's final rulemaking merely corrects the editing mistakes made in 1983 and 1984.

As an editorial change made at the request of the CFR staff, amendatory item 26 on page 10235 is corrected by changing the paragraph under § 4130.7–1 to (e) from (c) which is a typographical error. The word "this" before the term "30 days" is also removed from the tenth line of this paragraph since it does not refer to anything.

Finally, as another editorial change made at the request of the CFR staff, item number 27 on page 10235 is amended by adding a statement affirming that paragraph (a)(3) of § 4140.1 is added in the final rulemaking and that the language is presently not in the CFR. Amendatory instruction number 27a is also added to clarify that paragraphs (b)(7) and (b)(8) of this section are removed in their entirety and the language is presently not in the CFR. These paragraphs were printed to show language that had been removed by the final rulemaking of February 21, 1984, and consequently not printed in the next edition of the CFR. After the edition of the CFR went to press, the court in the case of *Natural Resources Defense Council, Inc. (NRDC) et al. v. Hodel, et al.*, 618 F. Supp. 848 (E.D. Cal. 1985), enjoined the removal of these sections because of procedural failings in the rulemaking process. The proposed rulemaking of May 20, 1987, again proposed the removal of these sections, and the amendment of that proposal printed in the Federal Register on July 20, 1987, and continued in the final rulemaking, published the language of those sections, for information purposes only, to show what was being removed. Additionally, there are existing paragraphs (b)(7) and (b)(8) under § 4140.1 of the CFR which were promulgated by the rulemaking of February 21, 1984, in place of the paragraphs removed. These paragraphs were not affected by the ruling of the court, are not affected by today's rulemaking, and remain in place in the CFR.

The Department of the Interior has that, because this rulemaking only makes clarifying amendments or corrections to the final rulemaking published on March 29, 1988, and removes sections that are similar in the existing regulations, it is a rule of organization, procedure, and practice, and does not require notice and an opportunity for public comment under the Administrative Procedure Act (5 U.S.C. 553(b)(A)). Therefore, this amendment is published as a final rulemaking effective April 28, 1988.

The principal author of this final rulemaking is Mark Lawrence, Division of Legislation and Regulatory Management, Bureau of Land Management.

The Department of the Interior has determined that because this rule is an administrative action, it is not a major rule for purposes of E.O. 12291, and neither an environmental impact

analysis nor a regulatory flexibility analysis is required. This rulemaking does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects for 43 CFR Part 4100

Administrative practice and procedure, Grazing lands, Livestock, Penalties, Range management.

Under the authority of the Taylor Grazing Act of 1934, as amended (43 U.S.C. 315 *et seq.*), the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1701 *et seq.*), and the Public Rangelands Improvement Act of 1978 (43 U.S.C. 1901 *et seq.*), Part 4100, Group 4100, Subchapter D, Chapter II of Title 43 of the Code of Federal Regulations is amended as set forth below:

PART 4100—[AMENDED]

1. The authority citation for Part 4100 continues to read:

Authority: 43 U.S.C. 315, 315a–315r, 43 U.S.C. 1701 *et seq.*, 43 U.S.C. 1181d.

§ 4120.2 [Amended]

2. On page 10234 in the issue of March 29, 1988, in the second column, amendatory item 16 is revised to read as follows:

"16. Section 4120.2 as amended on February 21, 1984 (49 FR 6453), which was enjoined as stated in a notice published December 18, 1985 (50 FR 51522), and which appears in the 1983 edition of the Code of Federal Regulations, is removed. The text of this section does not appear in the 1987 Code of Federal Regulations, although the notice of the District Court decision which enjoined, the regulation appears as an appendix."

§ 4120.2–1 and 4130.2 [Amended]

3. On page 10234 in the issue of March 29, 1988, in the second column, amendatory item 17 is revised to read as follows:

"17. Sections 4120.2–1(c) and 4130.2(d)(3), as amended on February 21, 1984 (49 FR 6453), which were enjoined as stated in a notice published December 18, 1985 (50 FR 51522), and which appear in the 1983 edition of the Code of Federal Regulations, are removed. The text of these sections does not appear in the 1987 Code of Federal Regulations, although the notice of the District Court decision which enjoined the regulation appears as an appendix."

§ 4120.2 [Amended]

4. On page 10234 in the issue of March 29, 1988, in the second column, amendatory item 18 and the heading of the section to be amended are corrected to read as follows:

"18. Section 4120.2 is revised to read as follows:

§ 4120.2 Allotment management plans."

* * * * *

§ 4130.5–1 [Removed]

5. Section 4130.5–1 is removed.

§ 4130.5–2 [Removed]

6. Section 4130.5–2 is removed.

§ 4130.5–3 [Removed]

7. Section 4130.5–3 is removed.

§ 4130.7–1 [Corrected]

8. On page 10235 in the issue of March 29, 1988, in the first column, in § 4130.7–1, paragraph (c) is correctly designated as (e). The word "this" before the term "30 days" in the tenth line of the paragraph is removed.

§ 4140.1 [Amended]

9. On page 10235 in the issue of March 29, 1988, in the first column, amendatory item 27 is corrected to read as follows:

"27. Section 4140.1(a)(3) is revised to read as follows:"

* * * * *

10. Immediately following the text of § 4140.1(a)(3) on page 10235 add the following instruction 27a.

"27a. Sections 4140.1 (b)(7) and (b)(8) as amended on February 21, 1984 (49 FR 6453), which were enjoined as stated in a notice published December 18, 1985 (50 FR 51522), and which appear in the 1983 edition of the Code of Federal Regulations, are removed. The text of these sections does not appear in the 1987 Code of Federal Regulations, although the notice of the District Court decision which enjoined the regulation appears as an appendix."

J. Steven Griles,

Assistant Secretary of the Interior.

June 6, 1988.

[FR Doc. 88–13348 Filed 6–14–88; 8:45 am]

BILLING CODE 4310–84–M

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43 CFR Public Land Order 6683

[AK–932–08–4220–10; F–012721]

Selection of Lands by the State of Alaska; Partial Revocation of Public Land Orders

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes a public land order, as amended, insofar as it affects 1,026.96 acres of public land reserved for use by the Department of the Navy. The land is no longer needed for national defense purposes. This order also revokes a public land order for a utility and transportation corridor insofar as it affects this land. This action will also classify the land as suitable for selection by the State of Alaska, if such land is otherwise available, excluding approximately 65 acres of surface estate which has been transferred by the Department of the Navy to the General Services Administration under the Federal Property and Administrative Services Act of 1949. If the land is not selected by the State, the land will remain closed to all other forms of appropriation and disposition under the public land laws, including the mining and mineral leasing laws, pursuant to PLO No. 5187, as amended.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Sandra C. Thomas, BLM State Office, 701 C Street, Box 13, Anchorage, Alaska 99513, 907–271–5477.

SUPPLEMENTARY INFORMATION: By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, by section 17(d)(1), and section 22(h) of the Alaska Native Claims Settlement Act of December 18, 1971, 85 Stat. 708 and 714; 43 U.S.C. 1616(d)(1), 1621(h)(4), it is ordered as follows:

1. Public Land Order No. 1571, as amended, and PLO No. 5150, as amended, are hereby revoked insofar as they affect the following described land:

Point McIntyre

U.S. Survey No. 4044, Alaska.

The area described contains 1,026.96 acres.

2. Subject to valid existing rights, the land described in paragraph 1, excluding the surface estate of the following described tract, is hereby classified as suitable for and opened to selection by the State of Alaska under either the Alaska Statehood Act of July 7, 1958, 72 Stat. 339, et seq.; 48 U.S.C. prec. 21, or section 906(b) of the Alaska National Interest Lands Conservation Act of December 2, 1980, 94 Stat. 2437–2438; 43 U.S.C. 1635.

The excluded tract is described as:

From U.S. Survey No. 4044, Corner No. 2; go west 40 chains; thence north to the mean high tide line of the Beaufort Sea (approximately 113.5 chains) and set Corner No. 1, the point of beginning.

From Corner No. 1,
South 18 chains and set Corner No. 2;
Thence S. 63°30'W. for 34 chains and set Corner No. 3;
Thence N. 26°30'W. for 9 chains and set Corner No. 4;

Thence N. 32°E. to the mean high tide line of the Beaufort Sea (approximately 28 chains) and set Corner No. 5;
Thence meander the mean high tide line of the Beaufort Sea easterly closing on the Point of Beginning (approximately 20.5 chains).

The area described contains approximately 65 acres.

3. As provided by section 6(g) of the Alaska Statehood Act, the State of Alaska is provided a preference right of selection for the land described in paragraph 2, for a period of ninety-one (91) days from the date of publication of this order, if the land is otherwise available. Any of the land described herein that is not selected by the State of Alaska will continue to be subject to the terms and conditions of PLO No. 5187, and any other withdrawals of record.

June 6, 1988.

J. Steven Griles,

Assistant Secretary of the Interior.

[FR Doc. 88-13499 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-JA-M

43 CFR Public Land Order 6684

[CO-940-08-4220-10; C-43908]

Withdrawal of National Forest System Land for Protection of Recreational Values; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws approximately 1,440 acres of National Forest System land from mining for a period of 50 years for the protection of existing and planned recreational facilities near Breckenridge, Colorado. The land has been and remains open to such other forms of disposition as may by law be made of National Forest System land and to mineral leasing.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215, 303-236-1768.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land, which is under the jurisdiction of the Secretary of Agriculture, is hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2) to protect existing and planned recreational values which are a part of the Breckenridge Ski Area:

Sixth Principal Meridian

Arapaho National Forest

T. 7 S., R. 78 W.,
Sec. 1, lots 5, 6, 9, 10, 11, 12, W½SE¼, and that portion of SW¼ formerly occupied by M.S. 13846 (cancelled);
Sec. 3, S½SE¼ and S½N½SE¼;
Sec. 10, N½NE¼;
Sec. 11, N½, SE¼, and NE¼SW¼;
Sec. 12, N½ and SW¼.

The area described aggregates approximately 1,440 acres of National Forest System land.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of National Forest System land under lease, license, or permit, or governing the disposal of its mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire 50 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be extended.

J. Steven Griles,

Assistant Secretary of the Interior.

June 8, 1988.

[FR Doc. 88-13500 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-JB-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 71146-8001]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure.

SUMMARY: The Director, Alaska Region, NMFS (Regional Director), has determined that the share of the sablefish total allowable catch (TAC) assigned to hook-and-line gear in the Central Regulatory Area will be taken before the end of the fishing year if directed fishing for sablefish with hook-and-line gear is allowed to continue. In order to provide adequate bycatch amounts of sablefish for continued groundfish fishing by persons using hook-and-line gear, the Secretary of Commerce (Secretary) is prohibiting directed fishing for sablefish in the Central Regulatory Area by persons using hook-and-line gear, from 12:00 noon, Alaska Daylight Time (ADT), on June 12, 1988, through December 31, 1988.

DATES: This notice is effective from 12:00 noon on June 12, 1988, ADT, until midnight, Alaska Standard Time, December 31, 1988.

ADDRESS: Comments should be addressed to James W. Brooks, Acting Director, Alaska Region (Regional Director), National Marine Fisheries Service, P.O. Box 21668, Juneau, Alaska 99802.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg, Fishery Management Biologist, NMFS, 907-586-7230.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) governs the groundfish fishery in the exclusive economic zone in the Gulf of Alaska under the Magnuson Fishery Conservation and Management Act (Magnuson Act). Regulations implementing the FMP are at 50 CFR Part 672. Section 672.20(a) of the regulations establishes an optimum yield range of 116,000-800,000 metric tons (mt) for all groundfish species in the Gulf of Alaska. TACs for each target groundfish species and species group are specified annually. For 1988, TACs were established for each of the target groundfish species and species groups and apportioned among the regulatory areas and districts.

Section 672.2 of the regulations defines the Central Regulatory Area in the Gulf of Alaska. The TAC for sablefish is 12,540 mt in this area. Under § 672.24(b)(1) of current regulations, persons fishing with hook-and-line gear may take up to 80 percent of the TAC in this area, or 10,030 mt.

NMFS estimated as many as 300 hook-and-line vessels registered to fish in the Central Regulatory Area. The average fleet catch has been 132 mt of sablefish per day during the period May 31-June 6. As of June 6, about 8,870 mt of sablefish have been landed. Based on the recent catch rate, NMFS projects the hook-and-line catch of sablefish will reach 9,730 mt on June 12. The Regional Director has determined that the remaining 300 mt of the sablefish assigned to hook-and-line gear in the Central Regulatory Area will be needed as bycatch in hook-and-line fisheries for other groundfish for the remainder of the 1988 fishing year.

Therefore, pursuant to § 672.24(b)(3)(i), the Secretary is prohibiting directed fishing for sablefish

with hook-and-line gear in the Central Regulatory Area effective 12:00 noon, ADT, June 12, 1988. Under § 672.2, as amended in 53 FR 7938 (March 11, 1988) and 53 FR 21649 (June 9, 1988), the following is effective through September 5, 1988: "directed fishing" with respect to sablefish caught with hook-and-line gear means fishing that is intended or can reasonably be expected to result in the catching, taking, or harvesting of quantities of sablefish that amount to 4 percent or more of the catch, take, or harvest, or 4 percent or more of the total amount of groundfish or groundfish products on board at any time.

Overharvesting sablefish by vessels using hook-and-line gear and wastage will result unless this notice takes effect promptly. Therefore, NOAA finds for good cause that prior opportunity for public comment on this notice is contrary to the public interest and its effective date should not be delayed.

Public comments on the necessity for this action are invited for a period of 15 days after the effective date of this notice. Public comments on this notice of closure may be submitted to the Regional Director at the address above until June 27, 1988. If written comments are received which oppose or protest this action, the Secretary will reconsider the necessity of ths action, and, as soon as practicable after that reconsideration, will either publish in the **Federal Register** a notice of continued effectiveness of the adjustment, responding to comments received, or modify or rescind the adjustment.

Classification

This action is taken under § 672.24 and is in compliance with Executive Order 12291.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: June 10, 1988.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 88-13492 Filed 6-10-88; 4:27 pm]

BILLING CODE 3510-22-M

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50 CFR Part 675

[Docket No. 71147-8002]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure.

SUMMARY: NOAA announces the closure of the Bering Sea subarea to directed fishing for sablefish under provisions of the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP). This action is necessary to prevent the total allowable catch (TAC) for sablefish in the Bering Sea subarea from being exceeded before the end of the fishing year. The intent of this action is to assure optimum use of groundfish while conserving sablefish stocks.

DATES: This closure is effective from noon Alaska Daylight Time (ADT), June 11, 1988, through December 31, 1988. Comments will be accepted through June 27, 1988.

ADDRESS: Comments should be mailed to James W. Brooks, Acting Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802, or be delivered to Room 453, Federal Building, 709 West Ninth Street, Juneau, Alaska.

FOR FURTHER INFORMATION CONTACT: Janet E. Smoker (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION:

The FMP governs the groundfish fishery in the exclusive economic zone under the Magnuson Fishery Conservation and Management Act. The FMP was developed by the North Pacific Fishery Management Council (Council) and implemented by rules appearing at 50 CFR 611.93 and Part 675.

The initial specifications of Domestic Annual Processing (DAP) for 1988 were based on the needs of the U.S. industry as projected by the Director, Alaska Region, NMFS (Regional Director). Certain species, including sablefish, are considered fully utilized by DAP and only bycatch amounts (37 mt) were made available for Joint Venture Processing (JVP). After fifteen percent of the original TAC (3,400) was placed in the non-specific reserve, as required at § 675.20(a)(3), the initial specification for the Bering Sea sablefish DAP was determined to be 2,890 mt (53 FR 894, January 14, 1988).

In the Bering Sea subarea, the estimated DAP catch to date of sablefish is 1,680 mt. Most of the sablefish catch represents bycatch in DAP fisheries which have taken 120,000 mt of pollock, rock sole, and Pacific cod, although several vessels (both trawlers and longliners) have on occasion conducted directed fisheries for sablefish. Such directed fishing is expected to increase in the Bering Sea subarea when DAP sablefish closures in the Gulf of Alaska are imposed in the next few weeks. When the Bering Sea sablefish TAC is taken, current regulations require that all domestic vessels operating in the Bering Sea area discard sablefish in the same manner as prohibited species. The Regional Director estimates that without a closure on directed fishing for sablefish in the Bering Sea subarea (effective June 11), that at current and anticipated catch rates the entire Bering Sea sablefish TAC (3,400 mt) would be taken by DAP and JVP fisheries by early August. Thus, sablefish taken in fisheries for other groundfish species and discarded as required by regulation would be wasted for the remainder of the year.

Notice of Closure to Directed Fishing

Under § 675.20(a)(7), when the Regional Director determines that the remaining amount of the TAC of any target species is necessary for bycatch in fisheries for other groundfish species, the Secretary will publish a notice in the **Federal Register** prohibiting directed fishing for that species for the remainder of the fishing year.

The Regional Director has determined that the remaining amount of sablefish TAC, 1,720 mt, will be needed for bycatch in DAP fisheries catching up to 560,000 mt of other groundfish species during the remainder of 1988. Therefore, in order to prevent wastage and encourage the full utilization of all sablefish harvested, directed fishing for sablefish by U.S. fishermen in the Bering Sea area must cease, effective noon, ADT, June 11, 1987.

If the sablefish TAC is taken prior to the end of the year, sablefish will become a prohibited species (§ 675.20(a)(8)). Under this circumstance the Secretary may, under § 675.20(a)(9), limit directed fishing for other groundfish by any method including area closures, gear restrictions or prohibition of directed fishing on certain species in order to prevent overfishing of sablefish.

Following the closure of directed fishing for sablefish, U.S. vessels participating in DAP fisheries may continue fishing for other groundfish species and retain sablefish provided that their take of sablefish does not exceed 20 percent of their catch as defined at § 675.2. The best available data indicate that fisheries for other groundfish species, including Pacific cod and Greenland turbot, can be effectively conducted with trawl or hook-and-line gear and experience sablefish bycatches of less than 5 percent of the total catch. If higher bycatches occur, and the remaining sablefish TAC is taken before

the end of the year, sablefish must be treated in the same manner as a prohibited species. In this event, the Secretary may be required under § 675.20(a)(9) to limit or close other fisheries which incidentally take sablefish to prevent overfishing of sablefish.

Classification

The Assistant Administrator for Fisheries, NOAA, finds for good cause that it is impractical and contrary to the public interest to provide prior notice and comment. Immediate effectiveness of this notice is necessary to prevent wastage and encourage the full utilization of all sablefish harvested. However, interested persons are invited to submit comments in writing to the address above for 15 days after the effective date of this notice.

This action is taken under the authority of §§ 675.20(b) and 675.20(a)(7) and complies with Executive Order 12291.

List of Subjects in 50 CFR Part 675

Fish, Fisheries, Reporting and recordkeeping requirements.

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

Dated: June 10, 1988.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 88-13511 Filed 6-10-88; 4:51 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 53, No. 115
Wednesday, June 15, 1988

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

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 87-061]

Citrus in Buffer Zones in Japan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Citrus Fruit regulations by permitting cultivation of nine additional citrus varieties in Japan's Unshu orange buffer zones. After studying recent scientific reports on citrus-canker resistance, we have concluded that the effectiveness of buffer zones planted with citrus varieties at least as canker-resistant as the Unshu orange would remain unchanged; we therefore see no reason to exclude those citrus varieties from Unshu orange buffer zones. While the proposed rule would affect citrus supply and demand in Japan's domestic market, it should not affect the supply of or demand for Unshu oranges grown for export to the United States. We are also proposing to amend the regulations to specify certain requirements concerning buffer zones.

DATE: Consideration will be given only to written comments postmarked or received on or before August 15, 1988.

ADDRESSES: Send an original and three copies of written comments to APHIS, USDA, Room 1143, South Building, P.O. Box 96464, Washington, DC 20090-6464. Please state that your comments refer to Docket Number 87-061. Comments received may be inspected at Room 1141 of the South Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Ed Imai, Senior Staff Officer Biological Assessment Support Staff, PRQ, APHIS, USDA, Room 632, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782; 301-436-8891.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR 319.28 (referred to below as the regulations) restrict the importation of fruits and peel capable of introducing certain citrus diseases, including citrus canker, into the United States. Varieties of species of the genus *Citrus* considered likely to spread any of these destructive diseases to U.S. citrus crops are not permitted to be imported into the United States from foreign areas where these diseases occur.

Unshu oranges, known to be resistant to citrus canker, are grown under a system of safeguards in special citrus canker-free areas in Japan, from which they have been imported into designated states since 1967. The system of safeguards established in the regulations 20 years ago has proven effective, as evidenced by the record of 100-percent canker-free Unshu orange imports.

Plant protection officials from both Japan and the United States jointly monitor conditions in the isolated, canker-free export areas where U.S.-bound Unshu oranges are grown. A number of independent measures secure the controlled environment for cultivating, testing, and packing the oranges. One measure critical to the success of the export program is the buffer zone isolating each Unshu orange export area from potential sources of citrus canker.

The current regulations prohibit cultivation of all non-Unshu citrus in the buffer zones surrounding the export areas. After a review of recent research on citrus varieties resistant to citrus canker, we propose to allow cultivation in the buffer zones of nine citrus varieties with canker resistance equal to or greater than the Unshu orange's. Working independently, the authors of the scientific papers on which we base this proposal arrived at identical conclusions about the high canker-resistance of the nine additional varieties of citrus. None of these citrus varieties would increase the exposure to citrus canker of Unshu oranges in the export areas. We do not propose to allow cultivation in the buffer zones of any variety about which plant pathologists entertain any doubts, or disagree among themselves, as to the variety's resistance to citrus canker. On the basis, then, of the current scientific literature, including tests studied and approved by Plant Protection and Quarantine (PPQ), we propose to allow the following citrus varieties into the buffer zones now limited to Unshu oranges: Buntan Hirado (*Citrus grandis*); Buntan Vietnam (*C. grandis*); Hassaku (*C. hassaku*); Hyuganatsu (*C. tamurana*); Kinkan (*Fortunella* spp. non *Fortunella hindsii*); Kiyomi tangor (hybrid); Orange Hyuga (*C. tamurana*); Ponkan (*C. reticulata*); Unshu (*C. unshiu* Marcovitch [*Citrus reticulata* Blanco var. *unshu*]); and Yuzu (*C. junos*). Further information about the scientific papers on which this proposal is based may be obtained from the PPQ officer whose name appears above under "For Further Information Contact."

Although our regulations now identify Unshu oranges in accordance with the Swingle taxonomic system, which is used in the United States, this proposal provides scientific names for the nine additional varieties in accordance with the Tanaka taxonomic system, which is used in Japan. Because this proposed change deals with regulatory safeguards implemented in Japan, we are using the Tanaka system to identify the citrus varieties here under discussion. We consider this advisable for two reasons: Exact equivalencies for some Japanese citrus varieties identified under the Tanaka taxonomic system do not exist in the Swingle system, and the same Latin nomenclature may identify different fruits under the different taxonomic systems. The Tanaka system unequivocally identifies for the Japanese the citrus varieties we would allow into the buffer zones surrounding the Unshu export areas. (For consistency with other references to Unshu oranges in regulations not affected by this proposed change and to prevent confusion, we identify the Unshu orange under both systems in the proposed rule itself, where it appears as "Unshu (*C. unshiu* Marcovitch, Tanaka [*Citrus reticulata* Blanco var. *unshu*, Swingle])."

In the interest of specificity, we also propose to make the following changes:

(1) We propose to require that buffer zones be inspected and found free of citrus canker and of all prohibited citrus, including the fruit and all other plant material. Qualified plant pathologists representing both the United States and Japan would conduct the authorized

inspections of buffer zones. Similarly, we would made clear that export areas must be inspected and found free of citrus canker and of all citrus other than propagative material of Unshu oranges, and that qualified plant pathologists representing both countries would conduct the authorized inspections.

(2) We propose to change the language that prohibits certain citrus fruits, peel, plants, or budwood in Unshu orange export areas. Currently, this provision states that "In such areas only Unshu oranges may be grown and necessary steps shall be taken to prevent the movement into those areas from any source of fruits, peel, plants or budwood of the genera Citrus and Poncirus, other than propagating material of *Citrus reticulata* Blanco var. Unshu (Satsuma)." We would rephrase this, simply and directly excluding from the export areas all varieties of citrus other than Unshu. Restated, this provision would read: "Only Unshu orange trees may be grown in these areas, which must be kept free of all citrus other than the propagative material of Unshu oranges." This language would also emphasize the responsibility of all parties involved in actively preventing potential sources of citrus canker from naturally or otherwise spreading into the export areas.

(3) We propose to require that buffer zones be 400 meters wide. Although not currently specified in the regulations, buffer zones surrounding the canker-free export areas are 400 meters wide. The width of the buffer zones, set at the time the regulations were established, is based on cultivation practices in Japan, topography, and other factors that would influence the natural or artificial spread of citrus canker. These 400-meter-wide buffer zones are part of a system of safeguards that has proven to be effective in keeping Unshu oranges in the export areas free of citrus canker.

The proposed changes would affect neither the size of the export-growing area nor the number of Unshu oranges exported to the United States. We would continue to prohibit importation of citrus from buffer zones into U.S. markets. The stringent security precautions on which the canker-free Unshu orange export program depends would not change.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule would have an annual effect on the econmy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposal would allow additional varieties of citrus to be grown in buffer zones surrounding Unshu orange export areas. This would affect citrus supply and demand within Japan, but not within the United States. Because citrus grown in buffer zones cannot be imported into the United States, the volume of oranges imported from Japan would be unaffected by this proposed regulatory change.

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

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

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

List of Subjects in 7 CFR Part 319

Agricultural commodities, Citrus canker, Fruit, Imports, Plant diseases, Plant pests, Plants (agriculture), Quarantine, Transportation.

Accordingly, we are proposing to amend 7 CFR Part 319 as follows:

PART 319—[AMENDED]

1. The authority citation for Part 319 would continue to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 319.28, paragraph (b) introductory text and (b)(1) would be revised to read as follows:

§ 319.28 Notice of quarantine

* * * * *

(b) The prohibition does not apply to Unshu oranges (*Citrus reticulata* Blanco var. *unshu*, Swingle [*Citrus unshiu* Marcovitch, Tanaka]), also known as Satsuma, grown in Japan and imported under permit into any area of the United States except for Alabama, American Samoa, Arizona, California, Florida, Georgia, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, the Northern Mariana Islands, Puerto Rico, South Carolina, Texas, and the Virgin Islands of the United States: *Provided*, that each of the following safeguards is fully carried out:

(1) The Unshu oranges must be grown and packed in insolated, canker-free export areas established by the Japanese Plant Protection Service. Only Unshu orange trees may be grown in these areas, which must be kept free of all citrus other than the propagative material of Unshu oranges. The export areas must be inspected and found free of citrus canker and prohibited plant material by qualified plant pathologists of both Japan and the United States. The export areas must be surrounded by 400-meter-wide buffer zones. The buffer zones must be kept free of all citrus other than the following 10 varieties: Buntan Hirado (*Citrus grandis*); Buntan Vietnam (*C. grandis*); Hassaku (*C. hassaku*); Hyuganastu (*C. tamurana*); Kinkan (*Fortunella* spp. non *Fortunella hindsii*); Kiyomi tangor (hybrid); Orange Hyuga (*C. tamurana*); Ponkan (*C. reticulata*); Unshu (*C.* unshiu Marcovitch, Tankana [*Citrus reticulata* Blanco var. *unshu*, Swingle]); and Yuzu (*C. junos*). The buffer zones must be inspected and found free of citrus canker and prohibited plant material by qualified plant pathologists of both Japan and the United States.

* * * * *

Done in Washington, DC., this 10th day of June, 1988.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 88–13506 Filed 6–14–88; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Ch. I

[Summary Notice No. PR–88–5]

Petition for Rulemaking; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for rulemaking received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for ruelmaking (14 CFR Part 11), this notice contains a summary of certain petitions requesting the initiation of rulemaking procedures for the amendment of specified provisions of the Federal Aviation Regulations and of denials or withdrawals of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before August 15, 1988.

ADDRESS: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-10), Petition Docket No.——, 800 Independence Avenue SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-10), Room 916, FAA Headquarters Building (FOB 10A), 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-3132.

This notice is published pursuant to paragraphs (b) and (f) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC, on June 8, 1988.

Deborah E. Swank,

Acting Manager, Program Management Staff.

PETITIONS FOR RULEMAKING

Docket No.	Petitioner	Regulations affected	Descriptions of petition
25571	Aerospace Industries Association of America, Inc.	14 CFR Part 21	To add a new regulation to make it illegal to sell an unapproved modification or replacement part for use on a certificated aircraft, or falsify or intentionally make false entry in any record that is used to show compliance with any requirement contained in this chapter.

[FR Doc. 88-13451 Filed 6-14-88; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-NM-59-AD]

Airworthiness Directives; Boeing Model 737-100 and -200 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes a new airworthiness directive (AD), applicable to Boeing Model 737-100 and 737-200 series airplanes, which would require modification of the Air/Gound Sensing System to allow the thrust reverser activation to be enabled by a second means in addition to the existing logic. This proposal is prompted by reports of pilot inability to obtain effective braking while landing at above normal speeds during adverse weather and runway conditions. Without this modification, a condition would develop which would delay the time a pilot has to obtain reverse thrust when abnormal landings are made during adverse weather and runway conditions. This delay may result in overrun of the departure end of the runway.

DATES: Comments must be received no later than September 12, 1988.

ADDRESSES: Send comments on the proposal in duplicate to Federal Aviation Administration, Northwest Mountain region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 88-NM-59-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. Service information may be obtained from the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth J. Schroer, Aerospace Engineer, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1943. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel (Attn: ANM-103), Attention: Airworthiness Rules Docket No. 88-NM-59-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington, 98168.

Discussion

The Airplane Pilot Association (ALPA) has provided the FAA with several reports of pilots having difficulty in obtaining effective braking after landing, including instances where damage has occurred due to airplane overrun of the runway. Several devices are involved in airplane braking after landing, including engine thrust reversers, ground and flight spoilers, as well as normal wheel braking. The Boeing Model 737 airplane is equipped with several logic systems designed to

prevent deployment of engine thrust reversers and ground spoilers in flight, touchdown with wheel brakes applied, and wheel skid during braking. These logic systems use a discrete signal indicates that the airplane is on the ground when the right main wheel strut is compressed 5 inches or more, or that it is in the air when the strut is within ½-inch of full extension.

The signal is supplied from an air/ground safety sensor which is mounted in the right main landing gear wheel well. It is activated by a push/pull cable connected to the oloe strut which also actuates a hydraulic system interconnect valve for the gound spoiler system. At a strut compression between 1½ inches and 3 inches, the hydraulic system interconnect valve provides hydraulic pressure to the ground spoiler actuators.

Prior to ground spoiler deployment, the flight spoilers (speedbrakes) must have been deployed either manually or automatically. Automatic deployment of the speedbrakes will occur when the speed brake lever is placed in the ARM position prior to touchdown, the engine thrust levers are near idle, and various combinations of main wheels have spun up to a specific speed. If the main wheel spin up should fail to occur, compression of the right main wheel strut of 5 inches or more will provide a discrete signal to allow for speedbrake deployment. Landing with the speedbrakes armed, i.e., automatic speedbrakes deployment mode, is normal operation for the Model 737.

It has been shown that without automatic activation of the flight spoilers (speedbrakes), and at high speeds, the force on the main gear can be such that the air/ground senor will continue to indicate that the airplane is in the "air mode," thereby preventing reverse thrust activation. To activate automatic deployment of the flight spoilers, one of the required logic conditions is wheel spin up. If the runway should be flooded with water or is icy, and landing is made at above normal touchdown speed, wheel spin up may not occur immediately, thus delaying autospoiler deployment and air to ground logic transition which is needed for thrust reverser activation. Under these conditions, instructions in the Airplane Flight Manual (AFM) require the crew to: "Check that the auto speedbrakes deploy immediately after the main gear contacts the runway. If the speedbrakes deploy immediately after the main gear contacts the runway. If the speedbrake lever fails to actuate automatically, immediately actuate it manually. Speedbrakes will reduce lift, increase drag and increase main gear loading. Quick extension of the speedbrakes is important because the effects of reduced lift and increased drag are additive in shortening landing roll."

A Boeing Technical Bulletin was issued on February 18, 1988, which reiterated that prompt activation of the speedbrakes is mandatory, should auto-deployment not occur, in order to put weight on the landing gear, thus ensuring timely activation of the air/ground safety sensor and the enabling of thrust reversers. The present Operations Manual states that the pilot not flying ensure that the speedbrake handle is full up. However, the information provided by ALPA indicates that in the rare instances in which automatic deployments of the speedbrakes does not occur, there have been cases where manual deployment of the speedbrake lever has not been accomplished.

In addition to the above thrust reverser logic, a few older Model 737 airplanes still retain the originally certified nose landing gear logic for the thrust reverser to reduce exposure to thrust reverser contact with the runway during reverser translation with a nose high attitude. After monitoring service experience with this reverser, the reverser control system was revised to delete the nose gear logic and use the main gear ground logic to enable quicker reverser ground operation. The majority of the Model 737 fleet has been so modified.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require modification of the thrust reverser arming logic to allow additional means of arming the thrust reversers by use of nose gear compression logic.

The Boeing Commercial Airplane Company has notified FAA that it can develop a modification of the thrust reverser, allowing logic to be enabled by nose gear strut compression in addition to the existing logic of the right main gear compression. The FAA would review the modification when designed and, if it is found to be acceptable, may consider revising the final rule to include the installation of that modification as a means of compliance.

It is estimated that 750 airplanes of U.S. registry would be affected by this AD, that it would take approximately 16 manhours per airplane to accomplish the required actions, and that the average labor cost would be $40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $480,000.

The regulations set forth in this notice would be promulgated pursuant to the authority in the Federal Aviation Act of 1958, as amended [49 U.S.C. 1301, *et seq.*], which statute is construed to preempt state law regulating the same subject. Thus, in accordance with Executive Order 12612, it is determined that such regulations do not have federalism implications warranting the preparation of a Federalism Assessment.

For these reasons, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Development of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities because few, if any, Boeing Model 737 series airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

Boeing: Applies to Model 737-100 and 737-200 series airplanes, certificated in any category, which presently do not use nose gear compression logic to enable thrust reversers. Compliance required as indicated, unless previously accomplished.

To ensure timely deployment of reverse thrust, ground spoilers, and effective wheel braking when landing under adverse weather and runway conditions, accomplish the following:

A. Within 12 months from the effective date of this AD, install an FAA approved modification to the Air/Ground Sensing

System which causes the thrust reverser logic to be enabled by nose gear strut compression in addition to the present logic of the right main gear oleo compression.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may add any comments and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the modification required by this AD.

Issued in Seattle, Washington, on June 8, 1988.

Frederick M. Isaac,

Acting Director, Northwest Mountain Region.

[FR Doc. 88-13449 Filed 6-14-88; 8:45 am]

BILLING CODE 4910-13-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW FRL-3398-4]

Hazardous Waste Management System; Identification And Listing of Hazardous Waste; Correction and Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction and extension of comment period.

SUMMARY: EPA is correcting a proposed delisting decision for U.S. Nameplate Company, Inc., Mount Vernon, Iowa, which appeared in the **Federal Register** on May 3, 1988 (53 FR 15704). In that notice, some of the preamble discussion was inadvertently omitted or was repeated; today's notice corrects the preamble of that notice. Today's notice also extends the public comment period for the proposed notice. This extension is provided to allow an adequate opportunity for comments on the proposed notice as corrected by today's publication.

DATES: EPA will accept public comments on the previously proposed decision until July 29, 1988. This date reflects an extension of the original comment period as cited in the proposed rule. Comments postmarked after the close of the extended comment period will be stamped "late".

ADDRESSES: Send three copies of your comments to EPA. Two copies should be sent to the Docket Clerk, Office of Solid Waste (WH-562), 401 M Street SW., Washington, DC 20460. A third copy should be sent to Jim Kent, Variances Section, Assistance Branch, PSPD/OSW (WH-563), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. All comments must be identified at the top with docket number "F-88-USEP-FFFFF".

The public docket where the information can be viewed for the proposed rule is located in the sub-basement of the U.S. Environmental Protection Agency, 401 M Street SW., Washington DC 20460. The docket is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. Call (202) 475-9327 for appointments. The public may copy material from any regulatory docket at a cost of $0.15 per page.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free at (800) 424-9436, or at (202) 382-3000. For technical information, contact Robert Kayser, Office of Solid Waste (WH-563), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 382-4536.

SUPPLEMENTARY INFORMATION: On May 3, 1988, EPA proposed to exclude retreated waste generated by U.S. Nameplate Co., Inc., located in Mount Vernon, Iowa, from the lists of hazardous wastes published in 40 CFR 261.31 and 261.32, pursuant to 40 CFR 260.20 and 260.22. See 53 FR 15704-15709. That notice also proposed to deny exclusion for Nameplate's wastes generated prior to retreatment, and should have specifically stated that the waste management unit containing the wastes generated prior to retreatment would remain regulated under Subtitle C of RCRA. The proposed notice inadvertently omitted some of the preamble discussion of the regulatory status of the waste unit which handled the petitioned waste prior to retreatment and also, repeated some of the narrative text in the preamble. These misprints appeared in the subsection entitled "Residual Waste at Nameplate's Surface Impoundment". Today's notice corrects the preamble discussion in that subsection.

The public comment period for the proposed rule was originally scheduled to end on June 17, 1988. Today's notice extends the public comment period for the proposed rule to allow the public an opportunity to review the corrected information presented in today's notice. The Agency will now accept public comments on the proposed rule until July 29, 1988.

Date: June 9, 1988.

J.W. McGraw,

Acting Assistant Administrator, Office of Solid Waste and Emergency Response.

The following correction is made to SW-FRL-3373-8, the Hazardous Waste Management System: Identification and Listing of Hazardous Waste, proposed rule published in the **Federal Register** on May 3, 1988 (53 FR 154704). The subsection entitled "Residual Waste at Nameplate's Surface Impoundment" found on page 15709 should be corrected to read as follows:

B. Residual Waste at Nameplate's Surface Impoundment

EPA's decisions to exclude a waste from Subtitle C control are typically retrospective and typically deregulate, from Subtitle C control, those waste management units holding the petitioned waste, because such units would not be considered to have received a hazardous waste. See 40 CFR Part 260.10(a) for the definition of a hazardous waste unit. However, in cases where the original petitioned wastestream has been retreated (through aeration, chemical stabilization, reprocessing, etc.), the Agency may distinguish between the original petitioned waste and the newly retreated waste. That is, the delisting decision on the retreated waste may be prospective (effective from the date of retreatment forward) and may apply only to the retreated waste.

When treated wastes are hazardous, remaining residues (*e.g.*, sludge and soil/sludge mixtures) containing or derived from the treated waste prior to retreatment are hazardous by definition, continue to be hazardous until excluded, and continue to constitute part of the waste management unit. See 40 CFR 261.3 (c)(2)(i) and (d)(2). A delisting decision for the retreated waste, therefore, does not affect the regulatory status of the unit which held the treated hazardous waste, if there is reason to believe that the treated waste was hazardous, and if waste residues containing or derived from the treated waste may still be present or if the waste already contaminated or is likely to contaminate the ground water in the future. Such units, therefore, continue to be classified as hazardous waste units subject to all Subtitle C requirements, including closure requirements.

Nameplate's originally petitioned waste (prior to retreatment) contained TCE. As discussed in the July 23, 1986, proposal, EPA's Region VII Office had determined that TCE was present in the ground water beneath Nameplate's

facility. The Agency's spot-check visit confirmed the presence of TCE in ground water, identifying a concentration of 0.012 mg/l in the downgradient monitoring well. The concentration of TCE detected in the downgradient well exceeds the current regulatory limit of 0.005 mg/l for TCE in drinking water. Since Nameplate's original waste contained TCE at sufficient levels to contaminate ground water, the ground-water contamination with TCE is present, the Agency is concerned that Nameplate's original waste may be responsible.

The Agency, therefore, proposes to limit the scope of today's decision to grant an exclusion only to Nameplate's retreated waste, and not to exclude residual wastes containing or derived from the treated waste still present at Nameplate's surface impoundment. The effect of this exclusion (if finally promulgated) is that the retreated wastes would no longer be subject to or regulated under Subtitle C control and may be removed from Nameplate's surface impoundment and managed as non-hazardous wastes. Nameplate's unlined surface impoundment, having at one time held a listed hazardous waste which appears to have caused ground-water contamination, would still, however, be defined as a hazardous waste management unit and would continue to be regulated as such under 40 CFR Parts 260 through 268 and the permitting standards of 40 CFR 270.

[FR Doc. 88-13455 Filed 6-14-88; 8:45 am]
BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 411, and 489

[BERC-302-P]

Medicare as Secondary Payer and Medicare Recovery Against Third Parties

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposal would—

1. Update and revise policies dealing with Medicare as secondary payer;
2. Revise policy on the exclusion of services of immediate relatives of the beneficiary or members of the beneficiary's household;
3. Revise policy on the exclusion of services furnished outside the United States; and
4. Clarify policy on the "no legal obligation to pay" exclusion as it applies to services furnished to prisoners.
5. Reflect a recent statutory amendment that provides an additional exception to the exclusion of services that are "not reasonable and necessary".

The changes in the Medicare secondary payer provisions are necessary to reflect amendments made to section 1862(b) of the Social Security Act (the Act) by section 2344 of the Deficit Reduction Act of 1984 (Pub. L. 98-369), section 9201 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272), and section 4036(a) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203). Separate regulations will be issued to implement section 9319 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), which made Medicare secondary payer for certain disabled Medicare beneficiaries under age 65 who are covered under a large group health plan.

DATES: Consideration will be given to comments received by August 15, 1988.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-302-P, P.O. Box 26676, Baltimore, Maryland 21207

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC,

or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland

In commenting, please refer to file code BERC-302-P. Comments will be available for public inspection as they are received, beginning approximately three weeks from today, in Room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT:

Herbert Shankroff 301 (966-7171) Identification and billing of other primary payers by providers; prompt reimbursement to Medicare when providers or suppliers receive payment from other primary payers.

Herbert Pollock (301) 966-4474 All other provisions.

SUPPLEMENTARY INFORMATION:

Background

During the first 15 years of the Medicare program, Medicare was primary payer for all services to Medicare beneficiaries, with the sole exception of services covered under workers' compensation. It was not until 1980 that Congress began to amend section 1862 of the Act to make Medicare secondary, first to no-fault and liability insurance, and later to employer group health plans that cover end-stage renal disease (ESRD) patients and that cover employed aged and aged spouses of employed individuals. Despite regulations and instructions, implementation has fallen short of expectations. It is hospitals that are most directly affected by these changes because it is primarily hospital services that are covered by private insurance.

Experience has been that many "Medicare secondary payer" (MSP) claims are not identified for MSP processing and that hospitals do not have procedures to identify other insurance that the beneficiary may have. This situation has been documented by—

- A Bureau of Quality Control study (summer of 1984), which found that up to 90 percent of all working aged claims were billed to Medicare rather than the other insurer because the hospital did not ask the beneficiary for information on other insurance or did not follow through on that information.
- Bureau of Program Operations (BPO) on-site review of hospitals, which revealed that hospitals did not have procedures to use at the time of admission to identify other insurers.
- BPO investigation of hospital software vendors, which revealed that the standard software packages for hospital admission routines do not include sufficient questions about insurers other than Medicare.

As a result, the claims that would properly be billed to another payer are sometimes mistakenly billed to Medicare. In some instances, the intermediary is able to identify the claim as an MSP claim and, at considerable expense, follow through to achieve the MSP savings. In many other instances, there is no way for the intermediary to know that a particular beneficiary has other insurance. In those cases, the claim is paid incorrectly and MSP savings are lost.

This problem is particularly acute when the health insurance policyholder is not the Medicare patient, but his or her spouse. There is no way of identifying this person (who may be under 65 years of age) through HCFA/

SSA records. Only the hospital can identify this type of MSP case.

A second observation on program experience was made by the Office of the Inspector General in a memo dated March 18, 1985. The OIG review of hospitals indicates that some hospitals bill both Medicare and the other insurer (which is contrary to program instructions) and, instead of refunding Medicare's payment, retain it, unless Medicare requests that it be refunded. The hospital has no incentive to refund the money. Since it is unlikely that the intermediary will find the case and ask for the refund, the hospital keeps a credit balance on the patient account and holds the payment.

Incorrect payments must be recovered. Medicare conditional payments, made when a claim against the other insurer is contested or payment is otherwise delayed, are also subject to recovery. Recent legislation has a direct bearing on this aspect of the program, as explained below.

Statutory Changes

A. Section 2344 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) amended sections 1862(b)(1), 1862(b)(2)(B), and 1862(b)(3)(A)(ii) of the Act as follows:

1. Makes explicit the Federal Government's right to recover from—

- Third parties that are required to pay before Medicare; and
- Any entity (such as a beneficiary, provider, physician or State agency) that has received payment from a third party that is required to pay before Medicare.

2. Provides that the government—

- Is subrogated to the right of any individual or other entity to receive payments from a third party payer to the extent of Medicare payment; and
- May join or intervene in any action related to the events that gave rise to the need for the items or services for which Medicare paid.

3. Adds the word "promptly" to paragraph 1862(b)(1), thus providing that Medicare payments are limited to the extent that payment has been made or can reasonably be expected to be made "promptly" by workers' compensation, or automobile, liability, or no-fault insurance. Medicare makes conditional primary payments only if the other insurer will not pay promptly.

4. Adds the phrase "or could be" to sections 1862(b)(1), (b)(2)(B), and (b)(3)(A)(ii), thus providing that Medicare conditional payments are subject to recoupment when information is received that primary payment "could be" made by a workers' compensation plan, an automobile, liability, or no-fault insurer, or an employer group health plan, even though such payment has not yet been made. This change reinforces Medicare's position as secondary payer, i.e., expressly permits HCFA to pursue recovery of conditional or incorrect payments as soon as it learns that another insurer is liable for the payment.

The provisions of section 2344 were self-executing. A notice to that effect was published on July 17, 1985 at 50 FR 28988.

B. Section 9201 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272 enacted April 7, 1986) eliminated the age 70 upper limit for individuals subject to the working aged provision, effective May 1, 1986. This amendment makes Medicare secondary payer to employer group health plan coverage for employed individuals age 65 or over and spouses age 65 or over of employed individuals of any age. Previously, Medicare was secondary for such individuals only until they attained age 70.

C. Section 4036(a) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203), enacted December 22, 1987, provides that Medicare may not make conditional primary payments on behalf of an ESRD beneficiary who is covered by an employer group health plan if the plan "can reasonably be expected" to pay. Under previous law, Medicare could make conditional primary payments if the Secretary determined that the plan would not pay as promptly as Medicare. This change makes the conditional payment criteria for ESRD beneficiaries the same as for working aged beneficiaries who are covered by employer group health plans. This change is effective for services furnished on or after January 21, 1988. The section 4036(a) provision supersedes HCFA's implementation of a court order that was issued in 1984.

In *National Association of Patients on Hemodialysis v. Heckler*, (Civil Action No. 83–2210 (D.D.C.)), the district court for the District of Columbia held that HCFA's existing regulations, dealing with conditional primary Medicare payments when Medicare is secondary to employer group health plans for ESRD beneficiaries, are not consistent with the statute. The existing regulations provide that Medicare may pay conditional primary benefits only if the Medicare contractor knows from experience or ascertains that the employer plan payments in general are substantially less prompt than Medicare's. The court held that the regulations that were in effect at that time were not consistent with the statutory language which directed the Secretary to deny primary Medicare benefits only if

- The employer group health plan has paid; or
- The Secretary has determined that the employer plan will pay as promptly as Medicare.

Manual instructions implementing the court decision were issued in 1985. They stipulated that providers and suppliers were no longer required to bill the employer plan first in ESRD cases; they had the option to bill Medicare first. Contractors were instructed to pay conditional Medicare benefits if billed first and to attempt to recover later from the employer plan.

D. Section 4085(i)(15) of Pub. L. 100–203 provides a fourth exception to the exclusion of services that are not reasonable and necessary "for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". Under this amendment, Medicare payment is available for services that are reasonable and necessary to carry out the purpose of the patient outcome assessment program established under section 1875(c) of the Act.

Changes in the Regulations

I. To Implement Statutory Amendments

A. Prompt Payment

To implement the statutory amendment that added the word "promptly" to section 1862(b)(1) of the Act, we would make clear that Medicare makes conditional primary payments when the workers' compensation carrier or the no-fault insurer will not pay promptly, that is, within 120 days after receipt of the claim. Current rules already provide for Medicare conditional payments in liability cases, if the beneficiary has filed, or has a right to file, a liability claim.

The changes pertaining to ESRD beneficiaries covered by an employer group health plan would provide that Medicare makes conditional primary payments when a proper claim has been filed with the employer plan and the plan has denied the claim in whole or in part.

B. Authority To Recover as Soon as Liability is Known To Exist, Subrogation, and Right To Intervene

As discussed above under "Statutory Changes", the addition of the phrase "or could" means that HCFA can seek recovery of conditional primary payments when it learns that another party is primary payer, without waiting for the other party to actually pay (411.24(a)). If HCFA is unable to recover conditional Medicare payments from a beneficiary or other party that receives

payment from an entity that is primary to Medicare, HCFA has the right to recover its payment from that entity in spite of the fact that the entity has already reimbursed the beneficiary or other party (§ 411.24(h)). Therefore, entities that are primary to Medicare ought to make sure that Medicare has no claim against payments they plan to make to individuals who are entitled to Medicare benefits.

HCFA's clarified recovery rights, including subrogation and the right to intervene, apply to all payers that are primary to Medicare. These rights are set forth in § 411.24 and § 411.26.

In view of the clarified recovery rights, we propose to remove the requirement (in § 405.319(b) of the current rules) for obtaining a repayment agreement from the beneficiary as a prerequisite for Medicare conditional payment in workers' compensation cases.

C. Removal of Upper Age Limit For Working Aged

This change is reflected in § 411.70 of the regulations.

D. Coverage of Services That Are Reasonable and Necessary to Carry Out the Purposes of the Patient Outcome Evaluation Program

This change is reflected in § 411.15(k)(4).

II. To Implement Policy Changes

A. To Ensure Identification of Other Payers That Are Primary to Medicare and Prompt Reimbursement When the Beneficiary, Provider, or Supplier Receives Payment From These Payers

1. *Current rules.* a. Part 489 of the Medicare rules deals with provider agreements. Section 489.20, which sets forth the commitments that a provider must make when it executes a provider agreement, does not include any requirement that the provider identify other insurance, bill primary payers before billing Medicare or refund Medicare payments that duplicate payments by a payer that is primary to Medicare.

b. Current rules do not expressly address HCFA's right to obtain information from another payer with whom a claim has been or could have been filed.

2. *Discussion.* a. Although the changes in the law have clarified HCFA's ability to recover conditional payments, it is obvious that there can be no recovery without identification of other insurers that are primary to Medicare. We believe that this aspect of the problem must be dealt with in regulations to the maximum extent permitted under current law.

b. In order to determine Medicare's proper payment under the law, it may be necessary for HCFA to contact other payers that may be primary to Medicare with regard to benefit coordination. For instance, if a claim for Medicare primary benefits is received, but Medicare was secondary on a prior claim, HCFA intermediaries or carriers may have to contact the other payer to determine whether it is still primary to Medicare.

3. *Proposed changes.* a. We propose to amend § 489.20 to require providers to make four additional commitments, as follows:

(1) To maintain a system for identifying, during the admission process, other payers that are primary to Medicare.

(2) Except in the case of liability insurance, to bill the other insurer first.

(3) When it receives payment from both Medicare and another payer that is primary to Medicare, to reimburse Medicare within 30 days. (Section 411.24, which deals with HCFA's recovery rights, would also require beneficiaries and other parties that receive duplicate payments to reimburse HCFA within 30 days.)

(4) If it receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim with that payer—

- To bill Medicare only to the extent that secondary benefits would have been payable if the primary insurer had reimbursed the provider on the basis of a proper claim; and
- To charge the beneficiary no more than it would have been entitled to charge if it had filed a proper claim with the primary insurer. (This fourth commitment is discussed under section H of this preamble, which deals with Medicare Secondary Payments.)

b. We propose to stipulate, in § 411.24(a), that the filing of a Medicare claim, by or on behalf of the beneficiary, expressly authorizes the third party payer to release any information pertinent to the Medicare claim.

B. To Reflect Changed Interpretation of the "Immediate Relative" Exclusion

1. *Current rules.* The current rule at 42 CFR 405.315 implements the "immediate relative exclusion" provision of section 1862(a)(11) of the Act. This provision precludes payment for expenses that "constitute charges imposed by an immediate relative of the beneficiary or a member of the beneficiary's household". Section 405.315—

a. Refers only to Medicare Part B;

b. Bars payment for charges other than actual costs incurred by the physician or other person (hereafter referred to as "out-of-pocket expenses") for items furnished to relatives or household members;

c. Defines "immediate relative" and "member of household";

d. Notes that the person who imposes the charges may be a person other than the one who furnished the services;

e. Exempts from the exclusion

- Charges imposed by a partnership except when all the partners bear the excluded relationship to the patient; and
- Charges imposed by a corporation, regardless of the beneficiary's relationship to the directors, officers, and stockholders of the corporation; and

f. Makes the exclusion applicable to charges imposed by an individual proprietorship if the individual who owns and operates the business is an immediate relative or member of the beneficiary's household.

2. *Discussion.* Reexamination of these rules has led us to conclude that our previous interpretation of section 1862(a)(11) of the Act was inconsistent with the purpose of that provision, namely—

- To bar Medicare payment for items and services that would ordinarily be furnished gratis because of the relationship of the provider or physician to the beneficiary; and
- To avoid payment for medically unnecessary services.

Congress recognized that, in family situations, it is difficult to differentiate between medically necessary services and those that are furnished because of affection or concern. Thus, the exclusion was also intended to guard against potential program abuse.

The prohibition is unqualified. Neither the statutory language nor the legislative history support certain of our previous interpretations under which we—

- Limited the exclusion to services of physicians and suppliers, payable on a charge basis under Medicare Part B, while continuing to pay for services payable under Medicare Part A, and for actual out-of-pocket expenses incurred by physicians or suppliers to furnish their relatives items such as drugs or prosthetic devices; and
- Exempted from the exclusion physicians who are members of a partnership or corporation.

We have concluded that Congress intended to exclude the following:

a. Services furnished under Medicare Part A as well as under Medicare Part B.

b. All charges imposed by persons having an excluded relationship, including out-of-pocket expenses.

c. Services furnished by physicians who are immediate relatives or

household members, regardless of whether they work within a partnership or a professional corporation, or as individual practitioners.

It seems clear that a physician who joins a partnership or corporation does not, for that reason, become less likely to furnish free services to a relative or to bill the program for unnecessary services.

The current policy that excludes charges imposed by partnerships only when all partners are immediate relatives or members of the beneficiary's household is too limited an application of the exclusion as it was intended by Congress.

Current policy that exempts all corporations also permits circumvention of the law's intent and is inequitable. It allows Medicare payment for services furnished by incorporated physicians (even corporations consisting of single physicians), but bars payment in identical situations for services furnished by unincorporated physicians.

Generally, State laws provide that the professional corporation, while existing as a separate legal entity, does not shield the practitioner from liability for the professional acts performed by the practitioner or under his or her supervision. The professional corporation affords the stockholders certain advantages, such as favorable tax treatment, but does not permit the abdication of responsibilities assumed in the practice of the profession. We, therefore, propose to make a distinction between the traditional corporation and the professional corporation in applying the "immediate relative exclusion". (It is relatively easy to identify a professional corporation because State statutes provide that only duly licensed members of the profession may own shares.)

Under the amended rules, physicians who are members of a professional corporation would be subject to the exclusion, but the exclusion would not apply to other corporations, such as incorporated suppliers of medical equipment.

3. *Proposed changes.* We would revise § 405.315 (redesignated as § 411.12) to—

a. Remove the reference to Medicare Part B, so that the exclusion applies to both programs;

b. Remove the exemption of out-of-pocket expenses;

c. Amend the definition of "immediate relative" to include adoptive sibling and spouse of grandparent or grandchild, which were omitted inadvertently; and

d. Specify that the exclusion applies to the following:

- Physician services and services furnished incident to those services if the physician who furnished the services or who ordered or supervised services incident to his or her services has an excluded relationship to the beneficiary, even if the bill or claim is submitted by a nonrelated individual or by an entity such as a partnership or a professional corporation.
- Services other than physician services when charges are imposed by—

(1) An individually owned provider or supplier, if the owner has an excluded relationship to the beneficiary; or

(2) A partnership, if any of the partners has an excluded relationship to the beneficiary.

Charges imposed by a corporation other than a professional corporation would not be excluded.

C. To Reflect Changed Interpretation of the "No Legal Obligation to Pay" Exclusion as it Applies to Services Furnished to Prisoners

1. *Current rules.* Section 405.311 of the Medicare rules (which implements section 1862(a)(2) of the Act) precludes Medicare payment for services when—

- The individual who receives the services has no legal obligation to pay for them; and
- No other person has a legal obligation to provide or pay for those services.

2. *Discussion.* Prisoners generally have the status of public charges who, as such, have no obligation to pay for the medical care they receive. Under those circumstances, § 405.311 bars Medicare payment. However, § 405.311 does not state the converse, namely, that if a prisoner receives services and is legally obligated to pay for the services or to reimburse the State or other government entity the cost of the services, the exclusion does not apply. General instructions issued by HCFA do provide for payment in the latter circumstances. Under those instructions, the fact that State law or regulation provides that certain prisoners or groups of prisoners may be charged for medical care is not enough to establish legal obligation. It is necessary to show that the State regularly enforces the legal obligation by routinely billing and seeking collection from all such prisoners for medical care they receive. For those prisoners who are Medicare-eligible, this must include collection of applicable deductible and coinsurance amounts and the cost of services not covered under Medicare. The State is expected to pursue collection of these sums in the same way and with the same vigor that it pursues collection of other debts owed the State. This includes the filing of lawsuits to obtain liens against the prisoner's assets outside the prison and income derived from nonprison sources, when it is believed that such action would result in the recovery of all or part of the debt.

3. *Proposed changes.* We propose to specify in the pertinent rule (now § 411.4) that Medicare payment for services to prisoners may be made—

- Only if State law requires prisoners to repay the cost of the services; and
- Only if the State actually enforces the requirement by billing and pursuing collection of amounts owed in the same way and with the same vigor that it pursues the collection of other debts.

D. To Clarify the Rules on the Exclusion of Services Furnished Outside the United States

1. *Current rules.* Section 405.313 of the current rules (which implements section 1862(a)(4) of the Act)—

- Excludes services that are not furnished within the United States; and
- Defines the United States to include the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

General instructions issued by HCFA further specify that—

- United States territorial waters are part of the United States; and
- Shipboard services furnished in a United States port or on the same day the ship arrived at, or departed from, that port are considered as furnished in U.S. territorial waters.

2. *Discussion.* The definition of "United States" needs to be expanded to include the Northern Mariana Islands. Under the Covenant to establish the Commonwealth of the Northern Mariana Islands (Pub. L. 94-241), effective January 9, 1978, "* * *those laws which provide Federal services and financial assistance programs * * *" apply to the Marianas as they do to Guam.

The "same day" rule is too vague and too broad to be satisfactory. It could result in claims for services furnished in a foreign port (e.g., in the Bahamas) that is less than 24 hours sailing distance from a U.S. port.

Despite the specific language of the current definition of "United States", people tend to think that facilities owned and operated by the United States Government are part of the United States, no matter where in the world they are located. As a result of this misconception, we frequently receive claims for services furnished in U.S. Army hospitals in Europe, the Canal Zone, etc., and requests for hearings on the denial of benefits for those services.

3. *Proposed changes.* In accordance with the preceding discussion, we would, in § 411.9—

- Add the Northern Mariana Islands and U.S. territorial waters to the definition of the United States;
- Specify that shipboard services are considered furnished in U.S. territorial waters if they are furnished while a ship is in a U.S. port or within 6 hours before arrival at, or after departure from, a U.S. port; and
- Specify that a hospital that is not located within the United States as defined, is not part of the United States even though it is owned or operated by the United States Government.

E. To Update and Clarify Policies on Services Covered Under Workers' Compensation

1. *Current rules.* The workers' compensation rules need revision to remove outdated content and to make them consistent with the rules pertaining to other types of insurance that are primary to Medicare.

2. *Discussion.* Some of the rules have become obsolete because workers' compensation laws and plans and medical care delivery systems have changed. For example, the laws and plans have fewer limitations on number of days of care and amounts payable, and ward accommodations are no longer used.

The workers' compensation rules also need to be updated to make them consistent with the rules for other payers that are primary to Medicare.

3. *Proposed changes.* We would make the following changes:

- Delete obsolete provisions, including those that deal with limitations in workers' compensation laws regarding the number of days of care or the amount payable, and payment for ward accommodations.
- Delete the provision dealing with Medicare payment for ancillary services not payable by workers' compensation. These cases would be covered by §§ 411.32 and 411.33 which set forth the basis and amounts of Medicare secondary payments when a third party payer does not pay in full.
- Stipulate that the beneficiary must cooperate in any action HCFA takes against a workers' compensation carrier. Since this rule applies to all entities that are primary to Medicare, it would be set forth in § 411.23.
- Apply workers' compensation payments toward Medicare deductible amounts (§ 411.30).
- Specify different policies for lump sum workers compensation payments that are commutations of future benefits (§ 411.46), and those that are compromise settlements (§ 411.47).
- Make clear that Medicare does not pay for services for which payment would have been made under the Federal Black Lung Program administered by the Department of Labor (DOL) if the DOL fails to pay solely because the provider did not obtain a provider number that must be included with the claim for DOL payment (§ 411.40(b)).

F. To Incorporate Changed Policy on No-Fault Insurance

1. *Current rules.* With respect to no fault insurance, current rules—

a. Apply only to *automobile* no fault, not to other kinds of no-fault insurance such as homeowners;

b. Provide for Medicare conditional payment if the no-fault insurance payment will be delayed "for any reason";

c. Do not address the beneficiary's responsibility for obtaining payment under no fault insurance; and

d. Do not permit third party payments to be credited against the Medicare deductibles. (This limitation also applies to payments under workers compensation, automobile medical and liability insurance.)

2. Discussion. We believe that—

a. Medicare should be secondary payer to all types of no-fault insurance, not just automobile no-fault, since the law is not limited to automobile no fault.

b. Medicare should not make a conditional payment when a no fault insurer refuses to pay primary benefits on the grounds that it is secondary to Medicare.

c. Beneficiaries should be responsible for taking necessary action to obtain any payments that can reasonably be expected under no fault insurance as they are required to do in the case of workers' compensation.

d. All third party payments should be credited against the Medicare deductibles. Although title XVIII is silent as to whether payments under workers compensation, or automobile, liability, or no-fault insurance must be so credited, the more recent amendments do provide for employer plan payments to be used to reduce the deductible amount for which the beneficiary is responsible. We believe that supports the proposed uniform policies.

3. *Proposed changes.* a. In § 411.50(b), we would expand the definition of "no fault insurance" to include all other types of no fault insurance, in addition to automobile no-fault.

b. In § 411.53, we would provide that Medicare conditional payment will not be made if the no fault insurance payment will be delayed because the insurer claims that its benefits are secondary to Medicare benefits.

c. In § 411.51, we would require that beneficiaries take any necessary action to obtain payment under no fault insurance, and specify the circumstances under which Medicare does or does not pay.

d. In § 411.30, we would provide that all third party payments are credited towards the Medicare deductibles.

G. To Reflect Changed Policies on Liability Insurance

1. *Current rules.* With respect to liability insurance, current rules—

a. Leave the way open for an insured individual or other entity to avoid use of its liability coverage by paying out-of-pocket instead of reporting the incident to the liability insurer.

b. In defining terms, under § 405.322—

- Include self-insured plans within the definition of liability insurance;
- Include, within the definition of "self insured plan", a statement that it is a plan under which an entity is "authorized by State law to carry its own risk";
- Do not specify that payments under the Federal Tort Claims Act (FTCA) are a type of liability payment under a self-insured plan; and
- Do not specify that payments made by an insured party to cover deductibles imposed by the liability insurance policy are considered to be liability insurance payments.

c. Do not clearly state that a provider has no right to charge a liability insurer or a beneficiary who has received a liability insurance payment;

d. Provide that Medicare will make a conditional payment if the beneficiary has filed or has a right to file a liability claim; and

e. Do not specifically include underinsured motorist insurance (except as a type of uninsured motorist insurance) in the definition of liability insurance.

2. *Discussion.* a. In the first situation discussed above, HCFA pays for medical expenditures properly covered by liability insurance and has no opportunity to recover from the liability insurer. This needs to be corrected.

b. The definitions need to be revised to—

- Reflect the fact that section 1862(b)(1) of the Act, which specifically includes self-insured plans, applies to entities that choose to carry their own risk, not only to plans authorized by State law;

- Make clear that the FTCA is a type of self-insured plan, since it is a plan under which the Federal Government pays for losses caused by wrongful actions of its employees or agents; and
- Specify that payments made by an insured party to cover liability insurance deductibles are considered to be liability insurance payments.

c. A provider, or a supplier that has accepted assignment may not, under the law, bill the liability insurer or the beneficiary who has received a liability payment, or file a lien against a liability settlement. There are four reasons:

- With respect to Medicare covered services, sections 1866(a) and 1842(b)(3)(B)(ii) of the Act permit providers, and suppliers who have accepted assignment, to bill the beneficiary only for applicable deductible and coinsurance amounts.
- Services for which liability insurance payments have been made or can reasonably be expected do not lose their identity as covered services. Since the amounts a beneficiary receives or is due to receive from a liability insurer are his or her own funds, billing the liability insurer or the beneficiary or filing a lien against the settlement would violate the statutory prohibition.
- In the case of liability insurance, the provider or supplier has no standing to sue or send a bill to the insurer. Since only the beneficiary—not the provider or supplier—has a right to sue the liability insurer, a bill to the liability insurer or a lien against the settlement would, in effect, be a bill to the beneficiary.
- Bills to liability insurers or beneficiaries or liens against liability settlements, if effectuated, reduce the beneficiary's recovery from the insurer unduly, since liability payments include compensation for damages other than medical expenses.

d. We believe that, given HCFA's strengthened recovery rights, no conditions need be placed on making conditional payments in liability insurance cases.

e. We consider that underinsured motorist insurance is a form of liability insurance.

3. *Proposed changes.* a. In § 411.50(b), we would expand the definition of "liability insurance payment" to include out-of-pocket payments by entities that carry liability insurance. This includes payments by the insured party to cover deductibles required by the liability policy.

b. We would revise the definition of "self-insured plan" to include the FTCA and to remove the statement "authorized by State law".

c. Under § 411.54, providers and suppliers who have accepted assignment, would be precluded from billing liability insurers, from billing beneficiaries who have received liability insurance payments, and from filing liens against liability settlements.

d. In § 411.52, we would specify that a conditional payment may be made when Medicare benefits are claimed for treatment of an injury or illness allegedly caused by another party.

e. In § 411.50(b), we would clarify the definition of "liability insurance" by specifying that underinsured motorist insurance is an example of liability insurance.

H. To Provide Uniform Rules for Computing the Amount of Medicare Secondary Payment, and to Limit Charges When a Proper Claim Is Not Filed

1. *Current rules.* a. Under § 405.328 (for ESRD beneficiaries) and § 405.342 (for working aged), in the case of services paid on a reasonable charge basis, the method for computing the Medicare secondary payment is different if the claim is assigned.

b. Under § 405.342(b), when Medicare pays on a basis other than reasonable charge, the amount of the Medicare secondary payment is computed on the basis of the Medicare payment rate, which may be more than charges.

c. Under the above noted sections, the Medicare secondary payment is computed on the basis of the amount paid by the primary insurer. [Current rules do not speak to situations in which an insurer primary to Medicare reduces its payment because a proper claim was not filed.)

2. *Discussion.* a. As a result of the difference noted in a. above, the amount of secondary payment to a physician (or other supplier) who accepts assignment may be less than the amount paid to the beneficiary when the physician does not accept assignment, even though the reasonable charge is the same in both cases. This difference is unfair and could discourage acceptance of assignment, which is desirable for the beneficiary.

b. With respect to the situation noted under b. above, since the law provides for secondary payments only when the primary payer pays less than the charges, we believe that the intent of the law is for Medicare to supplement the amount paid by the primary payer only in an amount that, combined with the primary payment, equals the charges for the services, or the amount the provider or supplier is obligated to accept as full payment. (When a provider or supplier is obligated to accept as full payment an amount less than its charges, HCFA considers that lower amount to be the provider's or supplier's charges.)

c. With respect to item c. above, we believe that providers and suppliers, and beneficiaries who are not physically or mentally incapacitated, are responsible for filing proper claims and for any third party payment reduction that results from their failure to file proper claims. Therefore,

- Medicare should not have to increase its secondary payment when the primary insurer pays less because a proper claim was not filed; and
- The beneficiary should not be subject to higher charges because the provider or supplier fails to file a proper claim.

3. *Proposed changes.* a. With respect to services paid on a reasonable charge basis, we would remove the special provisions applicable to claims filed under assignment (§§ 405.328(a)(4) and 405.342(a)(4)). Because monthly capitation payments are now used for certain ESRD services we would make the rules for determining the secondary payment amount (now in § 411.33), applicable also to that method of payment.

b. With respect to services paid on other than a reasonable charge basis, we would revise the current formula for computing Medicare secondary payments to ensure that those payments are not greater than the excess of the charges over the primary payments (§ 411.33(e)).

c. In §§ 411.32(c) and 489.20(i), respectively, we would provide that, when a primary insurer pays less because a proper claim was not filed—

- The Medicare secondary payment will be no greater than it would have been if the primary insurer had paid on the basis of a proper claim; and
- A provider may charge Medicare and the beneficiary no more than it would be entitled to charge if it had filed a proper claim.

I. To Reflect Changed Interpretation of the Working Aged Provisions

1. *Current rules.* Current rules—

a. Do not specify what is meant by "employed";

b. Do not clearly interpret how the statutory language "by reason of such employment" applies in the case of reemployed retirees and annuitants;

c. Do not specify that employer group health plans include "employee-pay-all" plans.

d. Make Medicare primary for members of a multiemployer plan that the plan identifies as employees of employers of less than 20 employees (§ 405.340(b)(1)(ii));

e. Provide (in § 405.341(d)) that an individual who is receiving employer disability payments is not considered to be employed if that individual was, before attaining age 65, entitled to disability benefits under title II of the Act before attainment of age 65, or is not receiving remuneration subject to taxation under the Federal Insurance Contributions Act (FICA).

f. Specify (in § 405.341(c)(2)) that Medicare pays primary benefits for Medicare-covered services that are not covered under the employer plan; and provide that HCFA may make a Medicare conditional payment when employer plan payment is denied "for any reason" (§ 405.344(a)).

2. *Discussion.* a. For Social Security purposes generally, the term "employed" includes the self-employed. (For example, self-employment earnings help to qualify individuals for Medicare entitlement.) We concluded, therefore, that it is appropriate to make the working aged provisions applicable to all categories of employment, including self-employment. We have made this clear in HCFA general instructions.

b. In providing that the beneficiary must be covered "by reason of such employment", Congress clearly intended to ensure that other health insurance plans not specified in the law (such as privately purchased plans and retirement plans) were not considered primary to Medicare. However, it is necessary to clarify the rules with respect to reemployed retirees or annuitants. Some employers have rehired retirees, and continued secondary coverage under the retiree plan, on the grounds that the employee is covered "by reason of retirement" rather than "by reason of employment". This misinterpretation could lead to incorrect Medicare primary payments and to the costly and sometimes fruitless recovery efforts that they entail.

c. The law defines "group health plan" as "a plan of or contributed to by an employer". The phrase "plan of" encompasses a plan that is under the auspices of an employer who makes no financial contribution—a so-called "employee-pay-all" plan.

d. Section 1862(b)(3) of the Act makes employer group health plans primary to Medicare for the working aged. Section 1862(b)(4), added by section 9319 of the Omnibus Budget Reconciliation Act of October 21, 1986 (OBRA '86), makes "large" employer plans primary to Medicare for certain disabled beneficiaries. Neither paragraph (b)(3), nor paragraph (b)(4) defines employer plan. Instead, they cite two sections of the Internal Revenue Code:

- Section 162(i)(2) (later redesignated as (i)(3)) of the 1984 Code, for the working aged; and
- Section 5000(b) of the 1986 Code, for the disabled.

Section 162(i)(2) makes no reference to number of employees. However, the Committee Report that accompanied the amendment indicated that the limitation was not intended to apply to employers of less than 20 employees. That was the basis for our current rule under which Medicare is primary payer for—

- Employees of employers of less than 20 employees; and
- Employees who can be identified, among those covered under a multiemployer plan, as employed by employers of less than 20 employees.

Section 5000(b) defines "large group health plan" as a plan that covers employees of "at least one employer that normally employed at least 100 employees * * *"

Under this definition, there is no basis for exempting employees of employers of less than 100 employees when they are covered under a multiemployer plan that meets the section 5000(b) definition. On the basis of the more recent legislation that deals with the multiemployer plan situation, we believe that the exemption provided by our current working aged rules (as noted under 1.d. above) is no longer appropriate. Instead, we would make the rule for the working aged consistent with the rule for the disabled so that there will be no exemption for employees of employers of less than 20 when they are covered under a multiemployer plan.

e. Under section 1862(b)(4) of the Act, added by section 9319 of OBRA '86, Medicare is secondary for disabled "employees" under age 65 who are receiving social security disability benefits. By enacting this provision, Congress established the principle that an individual who is receiving disability benefits can be considered an employee for purposes of making Medicare secondary to an employer group health plan. This principle is contrary to the current working aged rule in § 405.341(d). Under that rule, an individual aged 65 or over, who received social security disability benefits before attaining age 65, is not considered employed even if he or she receives, from an employer, disability payments that are subject to FICA taxes. In order to make the working aged rules consistent with section 9319 of OBRA '86, we need to disregard receipt of social security disability benefits before age 65, and classify as "employed" all those who receive employee disability payments that are subject to FICA taxes.

Since the basis for entitlement to social security benefits changes automatically from "disability" to "age" at age 65, no member of the "working aged" group could be currently eligible for or receiving social security disability benefits. However, for consistency with the section 9319 provisions, we would disregard the fact that the individual had been entitled to social security disability benefits before attaining age 65.

f. We believe that the statement in two current sections are too broad. Section 405.341(c)(2) states that Medicare makes primary payments for services not covered under the employer plan. This may not always be so. For example, Medicare does not pay primary benefits for particular services that are covered under the employer plan for younger employees but not for aged employees. (Such a difference in scope of benefits violates the requirements of the Federal Age Discrimination in Employment Act.)

Section 405.344(a) provides that Medicare may make conditional primary payments if the employer plan claim is denied "for any reason". We believe that HCFA should not make conditional primary payments when—

- The employer plan refuses to furnish to HCFA the information necessary to determine whether the plan is primary to Medicare;
- The employer plan is primary payer, but claims that its benefits are secondary to Medicare; or
- The employer plan claim is denied because the beneficiary, provider, or supplier failed to meet a claim filing requirement of the plan.

(We would make an exception if the beneficiary failed to file a proper claim because of physical or mental incapacity.)

3. *Proposed changes.* We would—

a. Make clear that the Medicare working aged provisions apply not only to employees but also to the self-employed, such as owners of businesses or independent contractors, and to members of the clergy and of religious bodies (§ 411.70(d)).

b. Make clear that a reemployed annuitant or retiree who is covered by an employer group health plan is considered covered "by reason of employment", even if—

- The plan is the same plan that previously provided coverage to that individual when he was a retiree or annuitant; or

• The premiums for the plan are paid from a retirement pension or fund. (§ 411.72(c))

c. Modify the definition of "employer group health plan" to make clear that it includes plans under the auspices of employers that make no financial contribution, the so-called "employee-pay-all" plans.

d. Remove from the definition of "employer group health plan" (§ 411.70(d)), the statement that a multiemployer plan does not have to pay primary benefits for individuals whom it can identify as employed by employers of less than 20 employees. (This currently appears in § 405.340(b)(1).)

e. Specify that, effective July 17, 1987, individuals who receive employer disability payments that are subject to taxation under FICA are considered employed (for purposes of the working aged provisions), even if they received social security disability benefits before attaining age 65. (July 17, 1987 is the effective date of HCFA general instructions issued under OBRA section 9319.)

f. Make clear, in § 411.75, the circumstances under which HCFA does or does not make Medicare primary payments and conditional primary payments.

J. To Provide Uniform Rules for Determination of the Amount of Medicare Recovery From a Party That Has Incurred Costs To Obtain a Judgment or Settlement That Resulted in a Third Party Payment

1. *Current rules.* Under § 405.324(b), when a beneficiary has received a liability insurance payment as a result of a judgment or settlement, Medicare reduces its recovery to take account of the procurement costs, that is, costs such as attorney fees that the beneficiary incurred in order to obtain the judgment or settlement.

2. *Discussion.* Although procurement costs are generally incurred by a beneficiary and in connection with liability insurance, occasionally they may be incurred by another party or in connection with other types of insurance that are primary to Medicare.

We believe that, as a matter of equity, the current provision should be made applicable also when another party has incurred procurement costs and when the judgment or settlement is obtained under other types of insurance primary to Medicare.

However, there need to be some exceptions and limitations. HCFA should not take account of procurement costs that do not reduce the amount of a judgment or settlement payment that is actually available to the party. This is the case, for instance, under the many workers' compensation laws that provide separate awards for attorney fees.

Furthermore, there should be a special rule for a situation in which HCFA itself incurs procurement costs, i.e., must file suit because the party that received payment opposes HCFA's recovery.

3. *Proposed change.* We would broaden the current rules, as noted under the above discussion and include it in Subpart B, which is of general applicability, as § 411.37. Section 411.37 would specify the amounts of Medicare recovery under different circumstances:

(a) If the Medicare payment is less than the judgment or settlement payment, HCFA would share proportionately in the party's procurement costs.

(b) If Medicare payment equals or exceeds the judgment or settlement payments, HCFA recovers only the amount that remains after subtracting the party's total procurement costs.

(c) If HCFA incurs procurement costs of its own because the party that received payment opposes HCFA's recovery, the recovery amount would be the lower of the following:

• The Medicare payment.

• The total judgment or settlement amount, minus the party's total procurement costs.

K. Clarifying Changes

1. In § 411.6 (which excludes from Medicare payment services furnished by a Federal provider) we would include a paragraph (b)(4) to make clear that services of a Federal provider (for example a VA hospital) are not excluded if they are furnished under arrangements made by a participating hospital. This ensures that a participating hospital can secure for its patients necessary services that it cannot itself provide.

2. Consistent with Departmental rules (45 CFR 30.15) and other HCFA rules (42 CFR 401.607), § 411.24(c) would make clear that HCFA may recover by offset against any monies it owes to the entity responsible for refunding the Medicare conditional primary payment.

3. In § 411.35, we would clarify the limits on the amounts that a provider or supplier may charge the beneficiary (or someone on his or her behalf) when workers' compensation, no-fault insurance, or an employer plan is primary to Medicare.

L. Organization Change

In order to eliminate needless repetition, Subpart B of the new Part 411 would set forth those definitions and rules that apply equally to all or most of the types of insurance that are primary to Medicare.

These include definitions of "conditional payment", "secondary payment", "third party payment", and "proper claim", the rules on recovery of conditional payments, and the effect of third party payment on benefit periods, benefit utilization, and deductibles.

Redesignation

As part of the overall plan to reorganize the Medicare rules and provide adequate room for expansion, most of Subpart C of Part 405 would be redesignated under a new Part 411—Exclusions from Medicare, with a separate subpart for each type of third party payer. A redesignation table presented at the end of this preamble will enable the reader to locate specific content under the new numbers.

Response to Comments

Because of the large number of pieces of correspondence we normally receive on proposed regulations, we cannot acknowledge or respond to them individually. However, we will consider all comments that are received by the end of the comment period and, if we proceed with a final rule, we will respond to those comments in the preamble to that rule.

Regulatory Impact Statement

Executive Order (E.O.) 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities. For the purposes of the RFA, we treat all providers and third party insurers as small entities. Also, section 1102(b) of the Social Security Act requires the Secretary to prepare a

regulatory impact analysis if this proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must also conform to provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside a metropolitan statistical area.

Many provisions of this proposed rule either conform to recent statutory changes or reflect current HCFA operating policies as expressed in program instructions and manuals. These regulatory provisions, of themselves, would not affect Medicare program expenditures. The other provisions of this proposed rule would either correct overly narrow interpretations of existent statutory authority, extend statutory precedents applying to some third party payers to additional categories of payers, or clarify and increase the consistency of our Medicare secondary payer rules. Of these proposed rule changes, we anticipate that all but one would have a negligible impact upon program expenditures.

The proposed change at § 411.50(b), under which the definition of "no fault insurance" would be extended to include all types of no fault insurance, would bring our regulations into line with the intended scope of section 1862(b)(1) of the Act. The enacting legislation (section 953 of the Omnibus Reconciliation Act of 1980) clearly does not limit Medicare's secondary status to automobile no fault situations. However, our current regulations at § 405.322 (published as a final rule at 48 FR 14810) only partially implements the statute by making Medicare the secondary payer to automobile no fault medical coverage only. We did not consider other forms of no fault liability insurance in the development of our current regulations. Because of this regulatory oversight, our intermediaries and carriers have been precluded from pursuing Trust Fund savings that would otherwise be available. This proposed rule change would then allow us to maximize Trust Fund savings to the extent permitted by law. While we cannot at this time produce a precise estimate of the savings that would be achieved by this change, we expect that the maximum available savings would fall significantly short of the E.O. 12291 thresholds specified above.

We expect that implementation of these rule changes would not have a significant economic impact on a substantial number of small entities. For example, our proposal to amend § 489.20 to require certain additional commitments in all provider agreements would largely serve to highlight the importance of identifying Medicare secondary payer claims. Our intermediary and provider instructions already require hospitals and other providers to systematically identify and, where appropriate, bill payers that are primary to Medicare first.

Subsequent to the OIG study, discussed under "Background" above, we instituted a computerized cross reference system (insurance companies, ESRD programs, etc.) to identify claims that should have been billed to payers primary to Medicare. Once these payers are identified by the computer tracking system, the claims are referred back to the provider responsible for initial billing. Under this system, Medicare no longer pays such bills automatically.

This computerized cross reference system may eventually bring about some administrative cost savings, to the extent that intermediaries may not be required to process claims that providers properly charge to third party payers. Providers may also reap several benefits once they take advantage of the fact that, in many circumstances, Medicare is the secondary payer. Current manuals instruct hospitals and other providers on how to identify payers that are primary to Medicare. The marginal advantages for providers would be savings on the administrative costs of billing Medicare, and additional income when the third party payer pays a higher rate than Medicare would normally pay as primary payer. These benefits are already available to providers under current instructions, and would not be altered by these proposed rules.

The proposed rule change at § 411.70(d) would remove from the definition of "employer group health plan" the statement that a multiemployer plan does not have to pay primary benefits for individuals whom it can identify as employees of employers of less than 20 employees. We had used our administrative discretion (at 50 FR 14510) to grant this exception in light of then applicable statutory precedents. However, for the reasons set forth elsewhere in this preamble, we no longer believe this exception is appropriate. This regulatory change may have an economic impact on some small entities, primarily those multiemployer plans (and the corresponding small employers with fewer than 20 employees) which have routinely taken advantage of the current provision at § 405.340(b)(1)(ii). Such insurers may initially face the possibility of increased outlays; however, employers with fewer than 20 employees may react to this rule change by setting up a single employer plan or by joining multiemployer plans composed entirely of employers with less than 20 employees. In the long run, then, we anticipate that this proposed provision would have little economic effect. Furthermore, we do not believe that this provision would affect a substantial number of small entities, as (to the best of our knowledge) few plan administrators have taken advantage of the current exception in the past.

For these reasons, we have determined that a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that this proposed rule would not have significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. We have therefore not prepared a regulatory flexibility analysis.

Paperwork Reduction Act

These regulations contain no new information collection requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X rays.

42 CFR Part 411

Medicare, Recovery against third parties, Secondary payments.

42 CFR Part 489

Health facilities, Medicare.

REDESIGNATION TABLE FOR 42 CFR PART 405, SUBPART C

Old section	New section
405.308(a)	Removed as duplicative of § 412.42.
405.308(b)	489.34.
405.310	411.15.
405.310–1	411.2.
405.311	411.4.
405.311a	411.6.
405.311b	411.7.
405.312	411.8.
405.313	411.9.
405.314	411.10.
405.315	411.12.
405.316	411.40.

REDESIGNATION TABLE FOR 42 CFR PART 405, SUBPART C—Continued

Old section	New section
405.317(a)–(c)	411.30.
405.317(d)–(f)	Removed as inconsistent with current policy.
405.318	411.43.
405.319(a)	Removed for inclusion in instructions.
405.319(b)	411.45.
405.320 and 321(a)	411.46.
405.321(b)	411.47.
405.322(a)–(d)	411.50.
405.322(e)	411.28.
405.323(a)	Removed as outdated.
405.323(b)	411.50.
405.323(c)(1)	411.53.
405.323(c)(2)	411.23.
405.323(c) (3) and (4)	411.24.
405.323(c)(5)	Removed as meaningless.
405.324(a)	411.52.
405.324(b)	411.37.
405.325	411.30.
405.326	411.60.
405.327	411.62.
405.328(a)–(d)	411.33.
405.328 (e) and (f)	411.30.
405.329	411.65.
405.330	411.200.
405.332	411.202.
405.334	411.204.
405.336	411.206.
405.340	411.70.
405.341	411.72.
405.342 (a) and (b)	411.33.
405.342 (c) and (d)	411.30.
405.343	411.35.
405.344(a)	411.75.
405.344(b)	411.24.

I. 42 CFR Chapter IV would be amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Subpart C of Part 405 is amended as follows:

Subpart C—Exclusions, Recovery of Overpayments, Liability of a Certifying Officer and Suspension of Payment

1. The subpart title, the table of contents, and the authority citation are revised to read as follows:

Subpart C—Recovery of Overpayments and Suspension of Payment

Sec.
405.301 Scope of subpart.

Liability for Payments to Providers and Suppliers, and Handling of Incorrect Payments

405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.
405.351 Incorrect payments for which the individual is not liable.
405.352 Adjustment of title XVIII incorrect payments.
405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.
405.354 Procedures for adjustment or recovery—title II beneficiary.
405.355 Waiver of adjustment or recovery.
405.356 Principles applied in waiver of adjustment or recovery.
405.359 Liability of certifying or disbursing officer.

Suspension of Payment to Providers and Suppliers and Collection and Compromise of Overpayments

405.370 Suspension of payments to providers of services and other suppliers of services.
405.371 Proceeding for suspension.
405.372 Submission of evidence and notification of administrative determination to suspend.
405.373 Subsequent action by intermediary or carrier.
405.374 Collection and compromise of claims for overpayments.
405.375 Withholding Medicare payments to recover Medicaid overpayments.
405.376 Interest charges on overpayments and underpayments to providers and suppliers.

Authority: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, and 1879 of the Social Security Act; 42 U.S.C. 1302, 1395g, 1395(1) 1395u, 1395cc, 1395gg, 1395hh, and 1395pp, and 31 U.S.C. 3711.

2. Section 405.301 is revised to read as follows:

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

§§ 405.308 through 405.344 [Removal]

3. Sections 405.308 through 405.344 are removed.

II. A New Part 411 is added, to redesignate, revise, and amplify the content removed from Part 405, Subpart C of this chapter, to read as follows:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

Subpart A—General Exclusions and Exclusion of Particular Services

Sec.
411.1 Basis and scope.
411.2 Conclusive effect of PRO determination on payment of claims.
411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.
411.6 Services furnished by a Federal provider of services or other Federal agency.
411.7 Services that must be furnished at public expense under a Federal law or Federal Government contract.
411.8 Services paid for by a Government entity.
411.9 Services furnished outside the United States.
411.10 Services required as a result of war.
411.12 Charges imposed by an immediate relative or member of the beneficiary's household.
411.15 Particular services excluded from coverage.

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

411.20 Basis and scope.
411.21 Definitions.
411.23 Beneficiary's cooperation.
411.24 Recovery of conditional payments.
411.26 Subrogation and right to intervene.
411.28 Waiver of recovery and compromise of claims.
411.30 Effect of third party payment on benefit period, benefit utilization, and deductibles.
411.32 Basis for Medicare secondary payment.
411.33 Amount of Medicare secondary payment.
411.35 Limitations on charges to a beneficiary or other party when a worker's compensation plan, a no-fault insurer, or an employer group health plan is primary payer.
411.37 Amount of Medicare recovery when a third party payment is made as a result of a judgment or settlement.

Subpart C—Limitations on Medicare Payment for Services Covered Under Workers' Compensation

411.40 General provisions.
411.43 Beneficiary's responsibility with respect to workers' compensation.
411.45 Basis for conditional Medicare payment in workers' compensation cases.
411.46 Lump-sum payments.
411.47 Apportionment of a lump-sum compromise settlement of a workers' compensation claims.

Subpart D—Limitations on Medicare Payment for Services Covered Under Liability or No-Fault Insurance

411.50 General provisions.
411.51 Beneficiary's responsibility with respect to no-fault insurance.
411.52 Basis for conditional Medicare payment in liability cases.
411.53 Basis for conditional Medicare payment in no-fault cases.
411.54 Limitation on charges when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer.

Subpart E—Limitations on Payment for Services Furnished to End-Stage Renal Disease Beneficiaries Who Are Also Covered Under an Employer Group Health Plan

411.60 Scope and definitions.

Authority: Secs. 1102, 1862(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1395hh).

Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by Federal providers or agencies (sections 1814(c) and 1835(d)), by hospitals and physicians outside the United States (sections 1814(f) and 1862(a)(4)), and by hospitals and SNFs of the Indian Health Service (section 1880).

(b) *Scope.* This subpart identifies:

(1) The particular types of services that are always excluded;

(2) The circumstances under which certain services, usually paid for by Medicare, will not be reimbursed; and

(3) The circumstances under which Medicare will pay for services usually excluded from payment.

§ 411.2 Conclusive effect of PRO determinations on payment of claims.

If a utilization and quality control peer review organization (PRO) has assumed review responsibility, in accordance with Part 466 of this chapter, for services furnished to Medicare beneficiaries, Medicare payment is not made for those services unless the conditions of Subpart C of Part 466 of this chapter are met.

§ 411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *Basic provision.* Except as provided in paragraph (b) of this section, Medicare does not pay for a service if—

(1) The beneficiary has no legal obligation to pay for that service; and

(2) No other person or organization (such as a prepayment plan of which the beneficiary is a member) has a legal obligation to provide or pay for that service.

(b) *Exception.* This exclusion does not apply to services that constitute exceptions under § 411.8.

(c) *Special conditions for services furnished to individuals in custody of penal authorities.* Payment may be made for services furnished to individuals or groups of individuals who are in the custody of the police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met:

(1) State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody.

(2) The State or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

§ 411.6 Services furnished by a Federal provider of services or other Federal agency.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency.

(b) *Exceptions.* Payment may be made—

(1) For emergency hospital services, if the conditions of §§ 405.152 and 410.168 of this chapter are met;

(2) For services furnished by a participating Federal provider which HCFA has determined is providing services to the public generally as a community institution or agency;

(3) For services furnished by participating hospitals and SNFs of the Indian Health Service; and

(4) For services furnished under arrangements (as defined in § 409.3 of this chapter) made by a participating hospital.

§ 411.7 Services that must be furnished at public expense under a Federal law or Federal Government contract.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, payment may not be made for services that any provider or supplier is obligated to furnish at public expense, in accordance with a law of, or a contract with, the United States.

(b) *Exception.* Payment may be made for services that a hospital or SNF of the Indian Health Service is obligated to furnish at public expense.

§ 411.8 Services paid for by a Government entity.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services that are paid for directly or indirectly by a government entity.

(b) *Exceptions.* Payment may be made for the following:

(1) Services furnished under a health insurance plan established for employees of the government entity.

(2) Services furnished under a title of the Social Security Act other than title XVIII.

(3) Services furnished in or by a participating general or special hospital that—

(i) Is operated by a State or local government agency; and

(ii) Serves the general community.

(4) Services furnished in a hospital or elsewhere, as a means of controlling infectious diseases or because the individual is medically indigent.

(5) Services furnished by a participating hospital or SNF of the Indian Health Service.

(6) Services furnished by a public or private health facility that receives government funds under a health support program that requires the facility to seek reimbursement, for services not covered under Medicare, from all available sources such as private insurance, patients' cash resources, etc.

(7) Rural health clinic services that meet the requirements set forth in Part 491 of this chapter.

§ 411.9 Services furnished outside the United States.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare does not pay for services furnished outside the United States. For purposes of this paragraph (a), the following rules apply:

(1) The United States includes the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana

Islands, and, for purposes of services rendered on board ship, the territorial waters adjoining the land areas of the United States.

(2) Services furnished on board ship are considered to have been furnished in United States territorial waters if they were furnished while the ship was in a port of one of the jurisdictions listed in paragraph (a)(1) of this section, or within 6 hours before arrival at, or 6 hours after departure from, such a port.

(3) A hospital that is not physically situated in one of the jurisdictions listed in paragraph (a)(1) of this section is considered to be outside the United States, even if it is owned or operated by the United States Government.

(b) *Exception.* Under the circumstances specified in § 405.153 of this chapter, payment may be made for covered inpatient services furnished in a foreign hospital and, on the basis of an itemized bill, for covered physicians' services and ambulance service furnished in connection with those inpatient services, but only for the period during which the inpatient hospital services are furnished.

§ 411.10 Services required as a result of war.

Medicare does not pay for services that are required as a result of war, or an act of war, that occurs after the effective date of a beneficiary's current coverage for hospital insurance benefits or supplementary medical insurance benefits.

§ 411.12 Charges imposed by an immediate relative or member of the beneficiary's household.

(a) *Basic rule.* Medicare does not pay for services usually covered under Medicare if the charges for those services are imposed by—

(1) An immediate relative of the beneficiary; or

(2) A member of the beneficiary's household.

(b) *Definitions.* As used in this section—"*Immediate relative*" means any of the following:

(1) Husband or wife.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of grandparent or grandchild.

"*Member of the household*" means any person sharing a common abode as part of a single family unit, including domestic employees and others who live together as part of a family unit, but not including a mere roomer or boarder.

"*Professional corporation*" means a corporation that is completely owned by one or more physicians and is operated for the purpose of conducting the practice of medicine, osteopathy, dentistry, podiatry, optometry, or chiropractic, or is owned by other health care professionals as authorized by State law.

(c) *Applicability of the exclusion.* The exclusion applies to the following charges in the specified circumstances:

(1) *Physicians' services.*

(i) Charges for physicians' services furnished by an immediate relative of the beneficiary or member of the beneficiary's household, even if the bill or claim is submitted by another individual or by an entity such as a partnership or a professional corporation.

(ii) Charges for services furnished incident to a physician's professional services (for example by the physician's nurse or technician), only if the physician who ordered or supervised the services has an excluded relationship to the beneficiary.

(2) *Services other than physicians' services.*

(i) Charges imposed by an individually owned provider or supplier if the owner has an excluded relationship to the beneficiary; and

(ii) Charges imposed by a partnership if any of the partners has an excluded relationship to the beneficiary.

(d) *Exception to the exclusion.* The exclusion does not apply to charges imposed by a corporation other than a professional corporation.

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage.

(a) *Routine physical checkups such as*—

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptom, complaint, or injury; or

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Eyeglasses or contact lenses, except for* post-surgical lenses customarily used during convalescence from eye surgery in which the lens of the eye was removed (e.g., cataract surgery); or prosthetic lenses for patients who lack the lens of the eye because of congential absence or surgical removal.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examination for the purpose of prescribing, fitting, or changing hearing aids.

(e) *Immunizations, except for*—

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin, or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin; and

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in Part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as posthospital SNF care as set forth in §§ 409.30 through 409.35 of the chapter.)

(h) Cosmetic Surgery and related services, except as required for the prompt repair of accidential injury or to improve the functioning of a malformed body member.

(i) *Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, *except for* inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(1) The individual's underlying medical condition and clinical status; or

(2) The severity of the dental procedures.[1]

(j) *Personal confort services, except* as necessary for the palliation or management of terminal illness as provided in Part 418 of this chapter. The use of a television set or a telephone are examples of personal confort services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

[1] Paragraph (i)(2) is effective for service furnished after June 30, 1981.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in Part 418 of this chapter.

(3) In the case of pneumococcal vaccine for the prevention of illness.

(4) In the case of the patient outcome assessment program established under section 1875(c) of the Act, for carrying out the purpose of that section.

(l) *Foot care.*—(1) *Basic rule.* Except as provided in paragraph (1)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care,* such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any service performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) *The evaluation or treatment of subluxations of the feet,* regardless of underlying pathology. Z(Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.

(iii) *The evaluation or treatment of flattened arches* (including the prescription of supportive devices) regardless of the underlying pathology.

(2) *Exceptions.* (i) Treatment of warts in not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (l)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital inpatients*(1) *Basic rule.* Except as provided in paragraph (m)(2) of this section, any service furnished to an inpatient of a hospital by an entity other than the hospital, unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's inpatients.[2]

(2) *Exceptions.* (i) Physicians' services that meet the criteria of § 405.550(b) of this chapter for payment on a reasonable charge basis, and services of an asthetist employed by a phsyician that meet the conditions of § 405.553(b)(4) of this chapter, are not excluded.

(ii) The exclusion may be waived temporarily by HCFA, in accordance with § 489.23 of this chapter.

(Services subject to exclusion under this paragraph include, but are not limited to, clinical laboratory services, pacemakers, artificial limbs, knees, and hips, intraocular lenses, total parenteral nutrition, and services incident to physicians' services.)

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

§ 411.20 Basis and scope.

(a) *Statutory basis.* Section 1862(b) of the Act precludes Medicare payments for services to the extent that payment has been made or can reasonably be expected to be made promptly under any of the following:

(1)Workers' compensation.

(2) Liability insurance.

(3) No fault insurance.

(4) An employer group health plan, with respect to a beneficiary who is under age 65 and entitled to Medicare solely on the basis of ESRD or who is age 65 or over and either employed, or the spouse of an employed individual of any age.

(b) *Scope.* This subpart sets forth the rules that are applicable to all or several of the types of insurance coverage that are the subject of Subparts C through F of this part.

§ 411.21 Definitions.

As used in this subpart and Subparts C through F of this part—"*Conditional payment*" means a Medicare payment for services for which another insurer is primary payer, made either on the bases set forth in Subparts C through F of this part, or because the intermediary or carrier did not known that the other coverage existed.

"Prompt" or *"promptly"*, when used in connection with third party payments, means payment within 120 days after receipt of the claim.

"Proper claim" means a claim that if filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

"Secondary", when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other insurance that is primary to Medicare.

"Secondary payments" means payments made for Medicare covered services or portions of services that are not payable under other insurance that is primary to Medicare.

Third party payer" means an insurance policy, plan, or program that is primary to Medicare.

Third party payment" means payment by a third party payer for services that are also covered under Medicare.

§ 411.23 Beneficiary's cooperation.

(a) If HCFA takes action to recover conditional payments, the beneficiary must cooperate in the action.

(b) If HCFA's recovery action is unsuccessful because the beneficiary does not cooperate, HCFA may recover from the beneficiary.

§ 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) The filing of a Medicare claim by or on behalf of the beneficiary constitutes an express authorization for the third party to release to Medicare and information pertinent to the Medicare claim.

(b) HCFA may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) HCFA may recover and amount equal ot the Medicare payment ot the amount payable by the third party, whichever is less. (The "amount payable by the third party" does not include the doubled portion of damages the third party may have paid under section 1862(b)(5) of the Act or any other punitive damages.)

(d) HCFA may recover by direct collection or by offset against any monies HCFA owes the entity responsible for refunding the conditional payment.

(e) HCFA has a direct right of action to recover its payments from any employer, insurance carrier, plan or program responsible to pay primary benefits for the services. In the case of employer group health plans, HCFA may recover from either the employer or the employer's insurance carrier.

(f) HCFA may recover without regard to any claims filing requirements imposed by the insurance program or plan, and applicable to the beneficiary, such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for, or receipt of, services.

(g) HCFA has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State

agency or private insurer that has received a third party payment.

(h) If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 30 days.

(i) If the beneficiary or other party that received payment does not reimburse Medicare, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party. (In situations that involve procurement costs, the rule of § 411.37(a)(2) applies.)

(j) If a third party payment is made to a State Medicaid agency and that agency does not reimburse Medicare, HCFA may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the third party payment, whichever is less.

(k) If a Medicare intermediary or carrier also administers a program or plan that is primary to Medicare, and does not reimburse Medicare, HCFA may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act.

(l) If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim, and Medicare is unable to recover from the third party payer, Medicare may recover from the beneficiary or provider or supplier that was responsible for filing a proper claim. (This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.)

§ 411.26 Subrogation and right to intervene.

(a) *Subrogation.* With respect to services for which Medicare paid, HCFA is subrogated to any individual, provider, supplier, physician, private insurer, State agency, attorney, or any other entity entitled to payment by a third party payer.

(b) *Right to intervene.* HCFA may join or intervene in any action related to the events that gave rise to the need for services for which Medicare paid.

§ 411.28 Waiver of recovery and compromise of claims.

(a) HCFA may waive recovery, in whole or in part, if the probability of recovery, or the amount involved, does not warrant pursuit of the claim.

(b) General rules applicable to compromise of claims are set forth in Subpart F of Part 401 and § 405.374 of this chapter.

(c) Other rules pertinent to recovery are contained in Subpart C of Part 405 of this chapter.

§ 411.30 Effect of third party payment on benefit period, benefit utilization, and deductibles.

(a) *Benefit period.* Inpatient hospital or SNF care, regardless of whether it is paid for by Medicare or by a third party payer, is considered in determining whether a new benefit period, as described in § 409.60 of this chapter, has begun.

(b) *Benefit utilization.* Inpatient hospital and SNF care that is paid for by a third party payer is not counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

(c) *Deductibles.* Expenses for Medicare covered services that are paid for by third party payers are credited toward the Medicare Part A and Part B deductibles.

§ 411.32 Basis for Medicare secondary payment.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare makes secondary payments, within the limits specified in paragraph (c) of this section and in § 411.33, to supplement the third party payment if that payment is less than the charges for the services and, in the case of services paid on other than a reasonable charge basis, less than the gross amount payable by Medicare under § 411.33(e).

(b) *Exception.* Medicare does not make a secondary payment if the provider or supplier is either obligated to accept, or voluntarily accepts, as full payment, a third party payment that is less than its charges.

(c) *General limitation: Failure to file a proper claim.* When a provider or supplier, or a beneficiary who is not physically or mentally incapacitated, receives a reduced third party payment because of failure to file a proper claim, the Medicare secondary payment may not exceed the amount that would have been payable under § 411.33 if the third party payer had paid on the basis of a proper claim.

§ 411.33 Amount of Medicare secondary payment.

(a) *Services reimbursed by Medicare on a reasonable charge basis.* Except as specified in paragraph (c) of this section, the Medicare secondary payment will be the lowest of the following:

(1) The actual charge by the supplier minus the amount paid by the third party payer.

(2) The amount that Medicare would pay if the services were not covered by a third party payer.

(3) The higher of the Medicare reasonable charge or other amount which would be payable under Medicare (without regard to any applicable Medicare deductible or co-insurance amounts) or the third party payer's allowable charge (without regard to any deductible or co-insurance imposed by the policy or plan) minus the amount actually paid by the third party payer.

(b) *Example:* An individual received treatment from a physician for which the physician charged $175. The third party payer allowed $150 of the charge and paid 80 percent of this amount or $120. The Medicare reasonable charge for this treatment is $125. The individual's Part B deductible had been met. As secondary payer, Medicare pays the lowest of the following amounts:

(1) Excess of actual charge minus the third party payment: $175−120=$55.

(2) Amount Medicare would pay if the services were not covered by a third party payer: .80×$125=$100.

(3) Third party payer's allowable charge without regard to its coinsurance (since that amount is higher than the Medicare reasonable charge in this case) minus amount paid by the third party payer: $150−120=$30.

The Medicare payment is $30.

(c) *Exception.* When an employer plan is primary to Medicare for ESRD beneficiaries, for services paid on a reasonable charge or monthly capitation rate basis, the Medicare secondary payment amount is the lowest of the following:

(1) The actual charge by the supplier, minus the amount paid by the employer plan.

(2) The amount that Medicare would pay if the services were not covered by the employer plan.

(3) The sum of the amounts that would have been paid by Medicare as primary payer and the employer plan as secondary payer, minus the amount actually paid by the employer plan as primary payer.

(d) Example: Using the amounts spcified in paragraph (b) of this section, the Medicare secondary payment for services furnished to an ESRD beneficiary is the lowest of the following:

(1) Excess of actual charge over the employer plan's payment: $175−$120=$55.

(2) Amount Medicare would pay if the services were not covered by employer plan: .80×$125=$100.

(3) The sum of the amounts that would have been paid by Medicare as primary payer and the employer plan as secondary payer; minus the amount

actually paid by the employer plan as primary payer ($100+75=$175−$120=$55. The Medicare payment is $55.

(e) *Services reimbursed on a basis other than reasonable charge or monthly capitation rate.* The Medicare secondary payment is the lowest of the following:

(1) The gross amount payable by Medicare (that is, the amount payable without considering the effect of the Medicare deductible and coinsurance or the payment by the third party payer), minus the applicable Medicare deductible and coinsurance amounts.

(2) The gross amount payable by Medicare, minus the amount paid by the third party payer.

(3) The provider's charges (or the amount the provider is obligated to accept as payment in full, if that is less than the charges), minus the amount payable by the third party payer.

(4) The provider's charges (or the amount the provider is obligated to accept as payment in full if that is less than the charges), minus the applicable Medicare deductible and coinsurance amounts.

(f) *Examples:*

(1) A hospital furnished 7 days of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totalled $2,800. The third party payer paid $2,360. No part of the Medicare inpatient hospital deductible of $520 had been met. If the gross amount payable by Medicare in this case is $2,700, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare inpatient hospital deductible: $2,700−$520=$2,180.

(ii) The gross amount payable by Medicare minus the third party payment: $2,700−$2,360=$340.

(iii) The provider's charges minus the third party payment: $2,800−$2,360=$440.

(iv) The provider's charges minus the Medicare deductible: $2,800−$520=$2,280. Medicare's secondary payment is $340 and the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $2,700. The $520 deductible was satisfied by the third party payment so that the beneficiary incurred no out-of-pocket expenses.

(2) A hospital furnished 1 day of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totalled $750. The third party payer paid $450. No part of the Medicare inpatient hospital deductible had been met previously. The third party payment is credited toward that deductible. If the gross amount payable by Medicare in this case is $850, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare deductible: $850−$520=$330.

(ii) The gross amount payable by Medicare minus the third party payment: $850−$450=$400.

(iii) The provider's charges minus the third party payment: $750−$450=$300.

(iv) The provider's charges minus the Medicare deductible: $750−$520=$230. Medicare's secondary payment is $230, and the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $680. The hospital may bill the beneficiary $70 (the $520 deductible minus the $450 third party payment). This fully discharges the beneficiary's deductible obligation.

(3) An ESRD beneficiary received 8 dialysis treatments for which a facility charged $160 per treatment for a total of $1,280. No part of the beneficiary's $75 Part B deductible had been met. The third party payer paid $1,024 for Medicare-covered services. The composite rate per dialysis treatment at this facility is $131 or $1,048 for 8 treatments. As secondary payer, Medicare pays the lowest of the following:

(i) The gross amount payable by Medicare minus the applicable Medicare deductible and coinsurance: $1,048−$75−$194.60=$778.40. (The coinsurance is calculated as follows: $1,048 composite rate −$75 deductible =$973×.20=$194.60.)

(ii) The gross amount payable by Medicare minus the third party payment: $1,048−$1,024=$24.

(iii) The provider's charges minus the third party payment: $1,280−$1,024=$256.

(iv) The provider's charges minus the Medicare deductible: $1,280−$75=$1,205. Medicare pays $24. The beneficiary's Medicare deductible and coinsurance were met by the third party payment.

(4) A hospital furnished 5 days of inpatient care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services were $4,000 and the gross amount payable was $3,500. The provider agreed to accept $3,000 from the third party as payment in full. The third party payer paid $2,900 due to a deductible requirement under the third party plan. Medicare considers the amount the provider is obligated to accept as full payment ($3,000) to be the provider charges. The Medicare secondary payment is the lowest of the following:

(i) The gross amount payable by Medicare minus the Medicare inpatient deductible: $3,500−$520=$2,980.

(ii) The gross amount payable by Medicare minus the third party payment: $3,500−$2,900=$600.

(iii) The provider's charges minus the third party payment: $3,000−$2,900=$100.

(iv) The provider's charges minus the Medicare inpatient deductible: $3,000−$520=$2480. The Medicare secondary payment is $100. When Medicare is the secondary payer, the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $3,000. The beneficiary has no liability for Medicare-covered services since the third party payment satisfied the $520 deductible.

§ 411.35 Limitations on charges to a beneficiary or other party when a worker's compensation plan, a no-fault insurer, or an employer group health plan is primary payer.

(a) *Definition.* As used in this section, "Medicare-covered services" means services for which Medicare benefits are payable or would be payable except for the Medicare deductible and coinsurance provisions and the amounts payable by the third party payer.

(b) *Applicability.* This section applies when a worker's compensation plan, a no-fault insurer or an employer group health plan is primary to Medicare.

(c) *Basic rule.* Except as provided in paragraph (d) of this section, the amounts the provider or supplier may collect or seek to collect, for the Medicare-covered services, from the beneficiary or any entity other than the workers' compensation plan, the no-fault insurer, or the employer plan and Medicare, are limited to the following:

(1) The amount paid or payable by the third party payer to the beneficiary.

(2) The amount, if any, by which the applicable Medicare deductible and coinsurance amounts exceed any third party payment made or due to the beneficiary or to the provider or supplier for the medical services.

(3) The amount of any charges that may be made to a beneficiary under § 413.35 of this chapter when cost limits are applied to the services, or under § 489.32 of this chapter when the services are partially covered, but only to the extent that the third party payer is not responsible for those charges.

(d) *Exception.* The limitations of paragraph (c) of this section do not apply if the services were furnished by a supplier that is not a participating

supplier and has not accepted assignment for the services or claimed payment under § 405.1684 of this chapter.

§ 411.37 Amount of Medicare recovery when a third party payment is made as a result of a judgment or settlement.

(a) *Recovery against the party that received payment.*—(1) *General rule.* Medicare reduces its recovery to take account of the cost of procuring the judgment or settlement, as provided in this section, if—

(i) Procurement costs are incurred because the claim is disputed; and

(ii) Those costs are borne by the party against which HCFA seeks to recover.

(2) *Special rule.* If HCFA must file suit because the party that received payment opposes HCFA's recovery, the recovery amount is as set forth in paragraph (e) of this section.

(b) *Recovery against the third party payer.* If HCFA seeks recovery from the third party payer, in accordance with § 411.24(i), the recovery amount will be no greater than the amount determined under paragraph (c) or (d) or (e) of this section.

(c) *Medicare payments are less than the judgment or settlement amount.* If Medicare payments are less than the judgment or settlement amount, the recovery is computed as follows:

(1) Determine the ratio of the procurement costs to the total judgment or settlement payment.

(2) Apply the ratio to the Medicare payment. The product is the Medicare share of procurement costs.

(3) Subtract the Medicare share of procurement costs from the Medicare payments. The remainder is the Medicare recovery amount.

(d) *Medicare payments equal or exceed the judgment or settlement amount.* If Medicare payments equal or exceed the judgment or settlement amount, the recovery amount is the total judgment or settlement payment minus the total procurement costs.

(e) *HCFA incurs procurement costs because of opposition to its recovery.* If HCFA must bring suit against the party that received payment because that party opposes HCFA's recovery, the recovery amount is the lower of the following:

(1) Medicare payment.

(2) The total judgment or settlement amount, minus the party's total procurement cost.

Subpart C—Limitations on Medicare Payment for Services Covered under Workers' Compensation

§ 411.40 General provisions.

(a) *Definition. "Workers' compensation plan of the United States"* includes the workers' compensation plans of the 50 States, the District of Columbia, American Samoa, Guam, Puerto Rico, and the Virgin Islands, as well as the systems provided under the Federal Employees' Compensation Act and the Longshoremen's and Harbor Workers' Compensation Act.

(b) *Limitations on Medicare payment.* (1) Medicare does not pay for any services for which—

(i) Payment has been made, or can reasonably be expected to be made promptly under a workers' compensation law or plan of the United States or a State; or

(ii) Payment could be made under the Federal Black Lung Program, but is precluded solely because the provider of the services has failed to secure, from the Department of Labor, a provider number to include in the claim.

(2) If the payment for a service may not be made under workers' compensation because the service is furnished by a source not authorized to provide that service under the particular workers compensation program, Medicare pays for the service if it is a covered service.

(3) Medicare makes secondary payments in accordance with § 411.32 and 411.33.

§ 411.43 Beneficiary's responsibility with respect to workers' compensation.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under workers' compensation.

(b) Except as specified in § 411.45(a), Medicare does not pay until the beneficiary has exhausted his or her remedies under workers' compensation.

(c) Except as specified in § 411.45(b), Medicare does not pay for services that would have been covered under workers' compensation if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.45 Basis for conditional Medicare payment in workers' compensation cases.

A conditional Medicare payment may be made under either of the following circumstances:

(a) The beneficiary has filed a proper claim for workers' compensation benefits, but the intermediary or carrier determines that the workers' compensation carrier will not pay promptly. This includes cases in which a workers' compensation carrier has denied a claim.

(b) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

§ 411.46 Lump-sum payments.

(a) *Lump-sum commutation of future benefits.* If a lump-sum compensation award stipulates that the amount paid is intended to compensate the individual for all future medical expenses required because of the work-related injury or disease, Medicare payments for such services are excluded until medical expenses related to the injury or disease equal the amount of the lump-sum payment.

(b) *Lump-sum compromise settlement.* (1) A lump-sum compromise settlement is deemed to be a workers' compensation payment for Medicare purposes, even if the settlement agreement stipulates that there is no liability under the workers' compensation law or plan.

(2) If a settlement appears to represent an attempt to shift to Medicare the responsibility for payment of medical expenses for the treatment of a work-related condition, the settlement will not be recognized. For example, if the parties to a settlement attempt to maximize the amount of disability benefits paid under workers' compensation by releasing the workers' compensation carrier from liability for medical expenses for a particular condition even though the facts show that the condition is work-related, Medicare will not pay for treatment of that condition.

(c) *Lump-sum compromise settlement: Effect on services furnished before the date of settlement.* Medicare pays for medical expenses incurred before the lump-sum compromise settlement only to the extent specified in § 411.47.

(d) *Lump-sum compromise settlement: Effect on payment for services furnished after the date of settlement.*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, if a lump-sum compromise settlement forecloses the possibility of future payment of workers' compensation benefits, medical expenses incurred after the date of the settlement are payable under Medicare.

(2) *Exception.* If the settlement agreement allocates certain amounts for specific future medical services, Medicare does not pay for those services until medical expenses related to the injury or disease equal the

amount of the lump-sum settlement allocated to future medical expenses.

§ 411.47 Apportionment of a lump-sum compromise settlement of a workers' compensation claim.

(a) *Determining amount of compromise settlement considered as a payment for medical expenses.* (1) If a compromise settlement allocates a portion of the payment for medical expenses and also gives reasonable recognition to the income replacement element, that apportionment may be accepted as a basis for determining Medicare payments.

(2) If the settlement does not give reasonable recognition to both elements of a workers' compensation award or does not apportion the sum granted, the portion to be considered as payment for medical expenses is computed as follows:

(i) Determine the ratio of the amount awarded (less the reasonable and necessary costs incurred in procuring the settlement) to the total amount that would have been payable under workers' compensation if the claim had not been compromised.

(ii) Multiply that ratio by the total medical expenses incurred as a result of the injury or disease up to the date of the settlement. The product is the amount of the workers' compensation settlement to be considered as payment for medical expenses.

Example: As the result of a work injury, an individual suffered loss of income and incurred medical expenses for which the total workers' compensation payment would have been $24,000 if the case had not been compromised. The medical expenses amounted to $18,000. The workers' compensation carrier made a settlement with the beneficiary under which it paid $8,000 in total. A separate award was made for legal fees. Since the workers' compensation compromise settlement was for one-third of the amount which would have been payable under workers' compensation had the case not been compromised ($8,000/$24,000 = ⅓), the workers' compensation compromise settlement is considered to have paid for one-third of the total medical expenses (⅓ × $18,000 = $6,000).

(b) *Determining the amount of the Medicare overpayment.* When conditional Medicare payments have been made, and the beneficiary receives a compromise settlement payment, the Medicare overpayment is determined as set forth in this paragraph (b). The amount of the workers' compensation payment that is considered to be for medical expenses (as determined under paragraph (a) of this section) is applied, at the workers' compensation rate of payment prevailing in the particular jurisdiction, in the following order:

(1) First to any beneficiary payments for services payable under workers' compensation but not covered under Medicare.

(2) Then to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part B. (These include deductible and coinsurance amounts and, in unassigned cases, the charge in excess of the reasonable charge.)

(3) Last to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part A. (These include Part A deductible and coinsurance amounts and charges for services furnished after benefits are exhausted.

The difference between the amount of the workers' compensation payment for medical expenses and any beneficiary payments constitutes the Medicare overpayment. The beneficiary is liable for that amount.

Example: In the example in paragraph (a) of this section, it was determined that the workers' compensation settlement paid for $8000 of the total medical expenses. The $18,000 in medical expenses included $1,500 in charges for services not covered under Medicare, $7,500 in charges for services covered under Medicare Part B, and $9,000 in hospital charges for services covered under Medicare Part A. All charges were at the workers' compensation payment rate, that is, in amounts the provider or supplier must accept as payment in full.

The Medicare reasonable charge for physicians' services was $7,000 and Medicare paid $5,600 (80 percent of the reasonable charge). The Part B deductible had been met. The Medicare payment rate for the hospital services was $9,000. Medicare paid the hospital $7,480 ($8,000—the Part A deductible of $520).

In this situation, the beneficiary's payments totalled $3,920:

Services not covered under Medicare	$1,500
Excess of physicians' charges over reasonable charges	500
Medicare Part B coinsurance	1,400
Part A deductible	520
Total	3,920

The Medicare overpayment, for which the beneficiary is liable, would be $2,080 ($6,000–$3,920).

Subpart D—Limitations on Medicare Payment for Services Covered under Liability or No-Fault Insurance

§ 411.50 General provisions.

(a) *Limits on applicability.* The provisions of this Subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) *Definitions.*

"Automobile" means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

"Liability insurance" means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

"Liability insurance payment" means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

"No-fault insurance" means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called "medical payments coverage", "personal injury protection", or "medical expense coverage".

"Self-insured plan" means a plan under which an individual or other entity engaged in a business, trade, or profession, or a Federal, State, or local government agency, carries its own risk instead of taking out insurance with a carrier. This includes the self-insured plan established for the Federal government under the Federal Tort Claims Act.

"Underinsured motorist insurance" means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

"Uninsured motorist insurance" means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) *Limitation on payment for services covered under no-fault insurance.* (1) Except as provided under §§ 411.52 and 411.53 with respect to conditional payments, Medicare does not pay for the following:

(i) Services for which payment has been made or can reasonably be expected to be made promptly under automobile no-fault insurance.

(ii) Services furnished on or after [effective date of final regulations] for which payment has been made or can reasonably be expected to be made promptly under any no-fault insurance other than automobile no-fault.

(2) In the case of no-fault insurance, the limitations apply even if State law or the insurance policy or plan states that its benefits are secondary to Medicare benefits, or otherwise excludes or limits its payments to an injured party that is also entitled to Medicare benefits.

§ 411.51 Beneficiary's responsibility with respect to no-fault insurance.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under no-fault insurance.

(b) Except as specified in § 411.53, Medicare does not pay until the beneficiary has exhausted his or her remedies under no-fault insurance.

(c) Except as specified in § 411.53, Medicare does not pay for services that would have been covered by the no-fault insurance if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.52 Basis for conditional Medicare payment in liability cases.

If HCFA has information that services for which Medicare benefits have been claimed are for treatment of an injury or illness that was allegedly caused by another party, a conditional Medicare payment may be made.

§ 411.53 Basis for conditional Medicare payment in no-fault cases.

A conditional Medicare payment may be made in no-fault cases under either of the following circumstances:

(a) The beneficiary, or the provider or supplier, has filed a proper claim for no-fault insurance benefits but the intermediary or carrier determines that the no-fault insurer will not pay promptly for any reason other than the circumstances described in § 411.50(c)(2). This includes cases in which the no-fault insurance carrier has denied the claim.

(b) The beneficiary, because of physical or mental incapacity, failed to meet a claim-filing requirement stipulated in the policy.

§ 411.54 Limitation on charges when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer.

(a) *Definition.* As used in this section, *"Medicare-covered services"* means services for which Medicare benefits are payable or would be payable except for applicable Medicare deductible and coinsurance provisions. Medicare benefits are payable notwithstanding potential liability insurance payments, but are recoverable in accordance with § 411.24.

(b) *Applicability.* This section applies when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer for injuries or illness allegedly caused by another party.

(c) *Basic rules.* Except as provided in paragraph (d) of this section, the provider or supplier—

(1) May not bill the liability insurer nor place a lien against the beneficiary's liability insurance settlement;

(2) May bill Medicare for Medicare-covered services; and

(3) May bill the beneficiary only for applicable Medicare deductible and coinsurance amounts plus the amount of any charges that may be made to a beneficiary under § 413.35 of this chapter (when cost limits are applied to the services) or under § 489.32 of this chapter (when services are partially covered).

(d) *Exception.* The limitations of paragraph (c) of this section do not apply if the services were furnished by a supplier that is not a participating supplier and has not accepted assignment for the services or has not claimed payment for them under § 405.1684 of this chapter.

Subpart E—Limitations on Payment for Services Furnished to End-Stage Renal Disease Beneficiaries Who Are Also Covered Under an Employer Group Health Plan

§ 411.60 Scope and definitions.

(a) *Scope.* This Subpart E sets forth the policies and procedures for payment for services furnished to beneficiaries who are entitled to Medicare solely on the basis of end-stage renal disease (ESRD) and who are also covered under an employer group health plan.

(b) *Definitions.* As used in this Subpart E—

"Employer" means, in addition to individuals and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the District of Columbia, and the agencies, instrumentalities, and political subdivisions of these governments.

"Employer group health plan" or *"employer plan"* means a group health plan that—

(1) Is of, or contributed to by, an employer; and

(2) Provides medical care directly or through other methods such as insurance or reimbursement, to current or former employees, or to current or former employees and their families.

It includes a plan that is under the auspices of an employer who makes no financial contribution, a so-called "employee-pay-all" plan.

"Monthly capitation payment" means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyzes at home or as an outpatient in an approved ESRD facility.

§ 411.62 Medicare benefits secondary to employer group health plan benefits.

(a) *General rules.* (1) Medicare benefits are secondary to benefits payable under an employer plan, for services furnished to an ESRD beneficiary during a period of up to 12 consecutive months as specified in paragraphs (b) and (c) of this section.

(2) If the individual becomes entitled to Medicare after the 12-month period has begun, as set forth in paragraph (c) of this section, Medicare benefits are secondary only for that portion of the 12-month period that begins with the month of entitlement.

(3) During the period in which Medicare benefits are secondary, the following rules apply:

(i) Medicare makes primary payments only for Medicare covered services that are—

(A) Furnished to Medicare beneficiaries who are not enrolled in the employer plan;

(B) Not covered under the employer plan; or

(C) Covered under the employer plan but not available to particular enrollees because they have exhausted their benefits.

(ii) Medicare makes secondary payments, within the limits specified in §§ 411.32 and 411.33, to supplement the amount paid by the employer plan if that plan pays only a portion of the charge for the services.

(4) During the period of up to 12 months, Medicare benefits are secondary to employer plan benefits

even though the employer policy or plan states that its benefits are secondary to Medicare's or otherwise excludes or limits its payments to Medicare beneficiaries.

(b) *Beginning of 12-month period.* The period of 12 consecutive months specified by law begins with the earlier of the following months:

(1) The month in which the individual initates a regular course of renal dialysis.

(2) In the case of an individual who receives a kidney transplant, the first month in which the individual could become entitled to Medicare if he or she filed a timely application, that is, the earliest of the following:

(i) The month in which the transplant is performed.

(ii) The month in which the individual is admitted to the hospital in preparation for, or anticipation of, a transplant that is performed within the next two months.

(iii) The second month before the month the transplant is performed, if performed more than 2 months after admission.

(c) *Beginning of period in which Medicare is secondary payer.* The period in which Medicare is secondary payer begins later than the beginning of the 12-month period (and therefore lasts less than 12 months) if the individual—

(1) Is subject to the 3-month waiting period for individuals who initiate renal dialysis but do not begin training for self-dialysis during the first 3 months of dialysis; or

(2) Files the application for Medicare entitlement more than 12 months after the month in which a 12-month period begins. (Under the Act, an application may not be retroactive for more than 12 months.)

(d) *Examples.* The following examples illustrate how to determine, in different situations, the number of months during which Medicare is secondary payer.

(1) *Individual filed a timely application and became entitled without a waiting period.* In October 1981, John began a regular course of dialysis and filed an application for Medicare. In December 1981, John began training for self-dialysis. Since John initiated self-dialysis training during the first 3 months of dialysis, he is exempt from the waiting period and becomes entitled as of October 1981, the first month of dialysis. In this situation, the month of entitlement coincides with the beginning of the 12-month period and Medicare is secondary payer during the entire period.

(2) *Individual filed a timely application and became entitled to Medicare after a waiting period.* (i) Janice started a regular course of renal dialysis in October 1981 and filed an application in the same month. The 12-month period begins with October 1981, but the 3-month waiting period doesn't end until December 1981. The month of entitlement for Janice is January 1982. Medicare is secondary payer from January through September 1982.

(ii) Peter started a regular course of dialysis in January 1982, and was hospitalized and received a kidney transplant in March 1982. The 12-month period begins with January 1982. The kidney transplant cuts short the dialysis waiting period so that Peter becomes entitled in March 1982. Medicare is secondary payer from March through December 1982.

(3) *Individual did not file a timely application.* In January 1982, Katherine suffered kidney failure and received a kidney transplant but did not apply for Medicare until July, 1983. Since the application is retroactive for only 12 months, Katherine becomes entitled to Medicare in July 1982. The 12-month period begins in January 1982, the month in which Katherine could have been entitled if she had filed a timely application. Medicare is secondary payer from July through December 1982.

(e) *Effect of changed basis for Medicare entitlement.* If the basis for an individual's entitlement to Medicare changes from ESRD to age 65 or disability, the 12-month period terminates with the month before the month in which the change is effective.

(f) *Determinations for subsequent periods of ESRD entitlement.* If an individual has more than one period of entitlement based solely on ESRD, a period during which Medicare may be secondary payer will be determined for each period of entitlement, in accordance with this section.

§ 411.65 Basis for conditional Medicare payments.

(a) *General rule.*[1] Except as specified in paragraph (b) of this section, the Medicare intermediary or carrier may make a conditional payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment files a proper claim under the employer plan and the plan denies the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, fails to file a proper claim.

(b) *Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the employer plan is secondary to Medicare.

(ii) The employer plan limits its payments when the individual is entitled to Medicare.

(iii) The beneficiary fails to file a proper claim for any reason other than physical or mental incapacity.

(2) The employer plan fails to furnish information requested by HCFA and necessary to determine whether the employer plan is primary to Medicare.

[1] For services furnished before January 21, 1988, conditional Medicare payments were made unless HCFA determined that the employer plan would pay the particular claims as promptly as Medicare.

Subpart F—Limitations on Payment for Services Furnished to Employed Aged and Aged Spouses of Employed Individuals Who Are Also Covered Under an Employer Group Health Plan

§ 411.70 General provisions.

(a) *Basis and scope.* This Subpart F implements section 1862(b)(3) of the Act. It sets forth the limitations that apply to Medicare payment for services furnished to employed aged and to aged spouses of employed individuals who are covered under an employer group health plan of an employer who employs at least 20 employees.

(b) *Applicability.* The rules of this subpart apply only to services furnished after December 1982.

(c) *Determination of "aged".* (1) An individual attains a particular age on the day preceding the anniversary of his or her birth.

(2) The period during which an individual is considered to be "aged" begins on the first day of the month in which that individual attains age 65.

(3) For services furnished before May 1986, the period during which an individual is considered "aged" ends as follows:

(i) For services furnished before July 18, 1984, it ends on the last day of the month in which the individual attains age 70.

(ii) For services furnished between July 18, 1984 and April 30, 1986, it ends on the last day of the month *before* the month the individual attains age 70.

(4) For services furnished on or after May 1, 1986, the period has no upper age limit.

(d) *Definitions.* As used in this subpart—

"*Employed*" encompasses not only employees but also self-employed persons such as consultants, owners of businesses, and directors of corporations, and members of the clergy and religious orders who are paid for

their services by a religious body or other entity.

"Employer" means, in addition to individuals and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the District of Columbia, and the agencies, instrumentalities and political subdivisions of these governments.

"*Employer group health plan*" or "*employer plan*" means a group health plan that provides medical care, directly or through other methods such as insurance or reimbursement, to current or former employees or to employees and their families, and meets one of the following conditions:

(1) Is of, or contributed to by, a single employer of at least 20 employees.

(2) Is a multiemployer group health plan that includes at least one employer of 20 or more employees.

It includes a plan that is under the auspices of an employer who makes no financial contribution, a so-called "employee-pay-all" plan.

(e) *Referral of cases to the Equal Employment Opportunity Commission (EEOC).* HCFA refers to the EEOC cases of apparent noncompliance with the Age Discrimination in Employment Act (29 U.S.C. 623). That Act requires employers to provide the same health benefits under the same conditions, to aged employees and their spouses as they provide to younger employees and their spouses.

§ 411.72 Medicare benefits secondary to employer group health plan benefits.

(a) *Conditions the individual must meet.* Medicare Part A and Part B benefits are secondary to benefits payable by an employer plan for services furnished during any month in which the individual—

(1) Is aged;

(2) Is entitled to Medicare Part A benefits under § 406.10 of this chapter;

(3) Is not entitled, and could not upon filing an application become entitled, to Medicare on the basis of end-stage renal disease as provided in § 406.13 of this chapter; and

(4) Meets one of the following conditions:

(i) Is employed and covered, by reason of that employment, under an employer plan.

(ii) Is the aged spouse [1] of an employed individual who—

(A) For services furnished before January 1985 was, at the time the services were furnished, age 65 through 69;

(B) For services furnished from January 1, 1985 through April 30, 1986 was, at the time the services were furnished, any age through 69; or

(C) For services furnished after April 30, 1986 was, at the time the services were furnished, any age.

(b) *Refusal to accept employer plan coverage.* An employee or spouse may refuse the health plan offered by the employer. If the employee or spouse refuses the plan—

(1) Medicare is primary payer for that individual; and

(2) The plan may not offer that individual coverage complementary to Medicare.

(c) *Coverage of reemployed retiree or annuitant.* A reemployed retiree or annuitant who is covered by an employer group health plan is considered covered "by reason of employment", even if—

(1) The plan is the same plan that previously provided coverage to that individual when he was a retiree or annuitant; or

(2) The premiums for the plan are paid from a retirement pension or fund.

(d) *Secondary payments.* Medicare pays secondary benefits, within the limitations specified in §§ 411.32 and 411.33, to supplement the primary benefits paid by the employer plan if that plan pays only a portion of the charge for the services.

(e) *Disabled aged individuals who are considered employed.* (1) For services furnished on or after November 12, 1985, and before July 17, 1987, a disabled, nonworking individual age 65 or older was considered employed if he or she—

(i) Was receiving, from an employer, disability payments that were subject to tax under the Federal Insurance Contributions Act (FICA); and

(ii) For the month before the month of attainment of age 65, was not entitled to disability benefits under title II of the Act and 20 CFR 404.315 of teh SSA regulations.

(2) For services furnished on or after July 17, 1987, an individual is considered employed if he or she receives, from an employer, disability benefits that are subject to tax under FICA, even if he or she was entitled to Social Security disability benefits before attaining age 65.

§ 411.75 Basis for Medicare primary payments.

(a) *General rule.* Medicare makes primary payments only for Medicare covered services that are—

(1) Furnished to employed individuals or spouses who are not enrolled in the employer plan;

(2) Not covered for any of the employed individuals or spouses who are enrolled in that plan; or

(3) Covered under the plan but not available to particular employed individuals or spouses because they have exhausted their benefits.

(b) *Conditional primary payments: Basic rule.* Except as provided in paragraph (c) of this section, Medicare may make a conditional primary payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim under the employer plan and the plan has denied the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, failed to file proper claim.

(c) *Conditional primary payments: Exceptions.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the employer plan is secondary to Medicare.

(ii) The plan limits its payments when the individual is entitled to Medicare.

(iii) The services are covered by the employer plan for younger employees and spouses but not for employees and spouses age 65 or over.

(iv) Failure to file a proper claim if that failure is for any reason other than physical or mental incapacity of the beneficiary.

(2) The employer plan fails to furnish information requested by HCFA and necessary to determine whether the employer plan is primary to Medicare.

Subparts G–J—[Reserved]

Subpart K—Payment for Certain Excluded Services

§ 411.200 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k), Medicare pays for "custodial care" and "services not reasonable and necessary" if the following conditions are met:

[1] A spouse may be entitled to Medicare Part A benefits on the basis of the employed individual's earnings record or the spouse's own earnings record.

(1) The services were furnished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under § 411.15 (g) or (k).

(b) *Time limits on payment.*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for impatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under § 411.204, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(ii) The day on which the provider has been determined, under § 411.206, to have knowledge, actual or imputed, that the services are excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the PRO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. If the PRO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§ 411.202 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of § 411.200(a)(2) are not met, Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the end of the sixth month after whichever of the following is later:

(i) The month in which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.* The amount of indemnification is the amount the beneficiary paid the provider, practitioner, or supplier, less any deductible and co-insurance amounts that would have been applied if the services had been covered.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider, practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

§ 411.204 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* Written notice has been given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines. A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion. For example, program payment may not be made for the treatment of obesity, no matter what form the treatment may take. After the beneficiary who is treated for obesity with dietary control is informed in writing that Medicare will not pay for treatment of obesity, he or she will be presumed to know that there will be no Medicare payment for any form of subsequent treatment of this condition, including use of a combination of exercise, machine treatment, diet, and medication.

(c) *Source of notice.* The notice was given by one of the following:

(1) The PRO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

§ 411.206 Criteria for determining that a provider, practioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) *Notice from the PRO, intermediary or carrier.* The PRO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending phyician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of—

(1) Its receipt of HCFA notices, including manual issuances, bulletins or other written guides or directives from intermediaries, carriers or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by the PRO; or

(2) Its knowledge of what are considered acceptable standards of practice by the local medical community.

III. Part 489 is amended as follows:

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1864, 1866 and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc and 1395hh), unless otherwise noted.

2. Section 489.20 is amended as set forth below:

§ 489.20 [Amended]

a. The undesignated introductory statement is revised to read:

"The provider agrees to the following:"

b. Periods are substituted for the semicolons at the end of paragraphs (a) through (c) and for the "; and" at the end of paragraph (d).

c. New paragraphs (f) through (i) are added to read as follows:

(f) To maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented.

(g) To bill other primary payers before billing Medicare except when the primary payer is a liability insurer.

(h) If the provider receives payment for the same services from Medicare and another payer that is primary to Medicare, to reimburse Medicare any overpaid amount within 30 days.

(i) If the provider receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim—

(1) To bill Medicare for an amount no greater than would have been payable as secondary payment if the primary insurer's payment had been based on a proper claim; and

(2) To charge the beneficiary no more than it would have been entitled to charge it if had filed a proper claim and received payment based on such a claim.

3. A new § 489.34 is added, and the table of contents is amended to reflect the addition:

§ 489.34 Allowable charges: Hospitals participating in State reimbursement control systems or demonstration projects.

A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Pub. L. 92–603 (42 U.S.C. 1395b–1 (note)) and that would otherwise be subject to the prospective payment system set forth in Part 412 of this chapter may charge a beneficiary for noncovered services as follows:

(a) For the custodial care and medically unnecessary services described in § 412.42 (c) of this chapter, after the conditions of § 412.42(c)(1) through (c)(4) are met; and

(b) For all other services in accordance with the applicable rules of this Subpart C.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; and No. 13.773, Medicare—Hospital Insurance)

Dated: March 14, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: April 21, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 88–13226 Filed 6–14–88; 8:45 am]

BILLING CODE 4120–01–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 61 ,65, and 69

[CC Docket 87–313, FCC 88–172]

Policy and Rules Concerning Rates for Dominant Carriers

AGENCY: Federal Communications Commission.

ACTION: Further notice of proposed rulemaking.

SUMMARY: The Commission has issued a specific plan for implementing a proposed change in regulation of the rates of dominant carriers which would replace the current rate-of-return regulatory model with one that directly limits rates by means of price caps. The plan applies to dominant carriers other than Comsat and Alascom. The Commission reaffirms its tentative finding that the price cap method of regulation will promote efficiency and innovation and benefit consumers more effectively than rate of return regulation. The Commission seeks comment on this conclusion, on the details of the plan it proposes and on the implementation issues which the plan raises.

DATES: Comments must be submitted on or before July 26, 1988 and reply coments on or before August 26, 1988.

ADDRESS: Secretary, Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Mary Brown, Common Carrier Bureau, (202) 632–6917.

SUPPLEMENTARY INFORMATION: The collection of information requirements contained in these proposed rules have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act. Persons wishing to comment on this collection of information requirement should direct their coments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer for Federal Communications Commission.

Number of copies. In addition to the number of copies required by 47 CFR § 1.419, interested parties are requested to file an additional ten copies of their pleadings, addressed to the Price Cap Task Force, Federal Communications Commission, 1919 M Street, Room 518, Washington, DC 20554.

Background. Notice of Proposed Rulemaking, In the Matter of Policy and Rules Concerning Rates for Dominant Carriers, CC Docket No. 87–313. *Adopted:* August 4, 1987. *Released:* August 21, 1987. 52 FR 33962 (Sept. 9, 1987). By the Commission.

Summary of Further Notice of Proposed Rulemaking

This is a summary of the Commission's *Further Notice of Proposed Rulemaking* in *In the Matter of Policy and Rules Concerning Rates for Dominant Carriers,* CC Docket No. 87–313, FCC 88–172, Adopted May 12, 1988 and Released May 23, 1988. By the Commission.

The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street, Suite 140, Washington, DC 20037.

I. In General

1. The price cap proposal we adopt for regulating dominant carriers [1] is designed to replicate better than traditional rate-of-return regulation the incentives to efficiency that characterize a competitive market. The essential premise underlying the proposal is that by limiting the rates carriers may charge, rather than their rates of return, price caps will drive carriers to avoid unnecessary costs, invest in efficiency enhancing technology, and employ innovative service approaches in order to earn the greatest levels of return within the applicable rate limitations. At the same time, the plan guarantees that ratepayers obtain their share of expected productivity gains first, with carriers retaining any additional profits

[1] The proposed price cap plan would be applicable to American Telephone and Telegraph Company (AT&T) and the local exchange carriers (LECs). We tentatively conclude that extending the price cap plan to Comsat or to Alascom is not warranted at this time. If, however, AT&T elects price caps, the plan would apply to Alascom to the extent that Alascom concurred in AT&T tariffs.

they may generate. Thus, the plan promises that both ratepayers and carriers will be better off than under traditional regulation. In arriving at our proposal, we have considered alternative regulatory approaches adopted by other jurisdictions, in particular, in Great Britain and the State of New York.

2. During an initial period of four years, the price cap plan will operate in concert with existing regulation and will be available on an elective basis to AT&T and to any LECs not electing to participate in either the common line or traffic sensitive pools administered by the National Exchange Carrier Association (NECA). At the end of the third year, we will conduct a comprehensive performance review of the plan's operation. In view of our long-standing policy of structuring regulation to harmonize with developing or existing competition, we seek coment on our tentative decision to rely on competitive distinctions between the interstate interexchange and interstate access markets as a means of differentiating price cap implementation for AT&T and the LECs, and on whether such competitive differences merit providing AT&T with greater flexibility.

3. Because of the importance we attach to safeguarding the integrity of jurisdictional allocations, we seek comment on what, if any, unique effect price caps may have on this process, and what, if any, specific changes in existing monitoring procedures might be required to offset such an effect.

II. Legal Authority

4. We reiterate our initial tentative conclusion that we are not legally required to continue rate-of-return regulation of dominant carriers. Furthermore, we tentatively conclude that the Communications Act and relevant judicial precedent empower this Commission to address the demonstrated limitations of rate-of-return regulation with the modest, but important, reforms that we propose in this Further Notice.

5. Rather than insisting on a single regulatory method for determining whether rates are just and reasonable, courts evaluate whether the end results of particlar regulatory schemes produce rates that fall within a "zone of reasonableness" bounded at the one end by investor interest in maintaining financial integrity and access to capital markets, and at the other end of the consumer interest in being charged non-exploitative rates.[2] The substantive mandate under which we operate requires only that we select a reasonable ratemaking approach that is capable of driving rates into the zone of reasonableness, or of detecting and correcting for the failure of market forces to do so.[3] We tentatively conclude that our price cap proposal, and the manner, detailed below, in which it takes account of carrier costs and profits, satisfies the Act's substantive requirement of ensuring just and reasonable rates.

6. Moreover, our proposals represent to a large extent, simply the considered exercise of our discretionary power regarding suspension of tariffs under section 204 of the Act, 47 U.S.C. 204, and of our authority to modify tariff filing procedures under section 203 of the statute, 47 U.S.C. 203. Our price cap plan establishes a "no-suspension zone" for tariffs that propose rate level changes falling within applicable cap and band limits, and subjects such tariffs to streamlined filing and review procedures. Above-cap or above-band filings, on the other hand, would generally be suspended and, therefore, subject to full tariff scrutiny. In this respect the plan is similar to the Civil Aeronautics Board (CAB) tariff rules that were upheld in the 1984 District of Columbia Circuit decision in *Advanced Micro Devices.*[4]

7. Although we believe that the proposed reforms will ensure just and reasonable rates and advance the objectives of the Communications Act more effectively than rate-of-return regulation, we do not propose an affirmative prescription of just and reasonable rates in implementing price cap regulation. We tentatively conclude that such a course could delay implementation without any countervailing benefits. We seek comment regarding why the benefits of price cap regulation cannot be achieved though our proposed no-suspension zone policy.

III. Scope of Price Cap Regulation

A. Services Covered

8. The proposed regulatory model will regulate rates through a system of aggregate caps on specified service groups ("baskets"), and rate element-specific bands. It wil cap all of AT&T's existing services, except the carrier's Tariff 5 Special Construction services, Tariff 12 services (including Special Routing Arrangement Service, Defense Commercial Telecommunications Network, Digital Tandem Switched Network and Arrangements, and Virtual Telecommunications Network Service), and services subject to separate, "below-the-line" accounting requirements (such as Accunet Packet Switching and Skynet KU). For participating LECs, the proposal will cap all existing services, except the common line element, and services contained in special construction and individual case basis (ICB) tariffs. The excepted service categories will remain subject to conventional 45-day tariff notice and existing tariff review requirements. Revenues and costs associated with such services will be segregated from those of capped services for carrier performance review purposes.

9. We tentatively propose to include the carrier common line (CCL) element in price cap regulation as part of the annual access tariff filing that takes effect in 1990; we do not propose to include this rate element in price cap regulation from the outset, because at the time price caps begin, on April 1, 1989, there will be no tested depooled CCL rates. At the time that common line is brought into the cap, we propose to use a total common line rate per minute in the price cap formula (computed as if there were no end user charges) rather than using the CCL charge, and to cap the CCL charge at the difference between the common line charge per minute and the end user charge per minute (i.e., total end user revenues divided by the same demand number used to compute common line revenues per minute). Alternatively, we propose to use an index of the price per line, rather than the price per minute, as the common line component of the PCI. We also propose to require that CCL price reductions associated with demand stimulation caused by exogenous revenue changes be treated as exogenous. We seek comment on whether we need to adjust the productivity factor we propose to apply to the LECs because of our proposed exclusion of common line from April 1989 through July 1990 and on whether we need to adjust the productivity factor after common line is brought into price cap regulation at the conclusion of that period.

10. Our proposal provides that new services, which by definition include only those services offering users an additional measure of choice, will initially be offered outside of the price cap structure. Subsequently, such services will be brought under caps based upon the historical price and revenue figures that were established

[2] *Jersey Cent. Power & Light v. FERC*, 810 F.2d 168, 1177–78 (D.C. Cir. 1987) (en banc).

[3] *Farmers Unions Cent. Exch. v. FERC*, 734 F.2d 1486, 1509 (D.C. Cir.), *cert denied*, 469 U.S. 1034 (1984).

[4] *Advanced Micro Devices v. CAB*, 742 F.2d 1520, 1531 (D.C. Cir. 1984).

during the period outside the cap. On the other hand, restructured services, defined as those involving the modification of a method of charging or provisioning for an existing service, or the introduction of a new method of charging or provisioning, will remain subject to price cap regulation from the outset. As is the case under existing procedures, the degree of rate structure flexibility accorded AT&T and the LECs under price cap regulation differs. The LECs must maintain the rate structure established in Part 69 of this Commission's Rules, or petition for a waiver of the prescribed rate structure.

B. Initiation of Price Cap Regulation

11. We tentatively conclude that existing prices are the most appropriate starting point for the beginning price cap regulation. Alternatively, however, we seek comment on whether we should capture consumer benefits from price caps by means of a higher short-term productivity factor, in lieu of our current proposal to ensure benefits to ratepayers by including an additional increment in the productivity adjustment on an on-going basis.

C. Baskets and Bands

12. We tentatively decide that a combination of "baskets" (aggregate caps) and "bands" (maximum and minimum limits on individual service prices) would best satisfy the objectives which guide our determination of what a "price cap" is. The weighted average of the prices of services within a basket must remain below the Price Cap Index (PCI). For AT&T, the proposal contemplates creation of two baskets—one for private line services, and one for services, such as MTS, international MTS, and WATS, that use the switched network. Similarly, capped LEC services will be separated into a switched access basket, and another basket for all other services, consisting primarily of special access services, but also including LEC interexchange services.

13. We also propose to add individual rate element bands as additional protections for consumers. By band we refer to the range within which a carrier may raise or lower any individual rate element in any year and still be entitled to streamlined review. All rate changes within or above a band are "credited" or counted in the Actual Price Index (API) for purposes of measuring compliance with the PCI. Rate reductions below the band, however, would not be credited. The bands, after applying the PCI, would permit a 5 percent fluctuation above and below existing rates. We also solicit comment on an alternative proposal to apply more focused pricing rules to MTS services used by residential and small business customers.

IV. Tariff Filing Procedures

A. In General

14. The plan established new tariff filing and review procedures for participating carriers. For each basket of services, the plan proposes a ceiling on the aggregate revenue-weighted rates that may be charged if a carrier is to receive streamlined filing and review treatment for its tariff. Under this approach, carriers are given flexibility in setting rate levels for individual services within the baskets, although, through rate element-specific bands, we propose to restrain the maximum annual change in the rates for each service to protect ratepayers and to discourage potentially anticompetitive practices. As described below, the applicable cap for each basket of services will be expressed through the mechanisms of a price cap index (PCI), which measures changes in inflation, productivity, and certain specific costs beyond a carrier's control. Compliance with the cap will be measured through the mechanism of an actual price index (API), an index or aggregate revenue-weighted proposed rates within a basket, and a base price index (BPI), and index of that basket's aggregate revenue-weighted average rates during the "base year"—the 12-month period ending six months prior to the effective date of each annual price cap tariff.

15. Within the aggregate ceilings established for each basket of services, the plan provides for bands (described in more detail in Section V.B, *infra*) that limit the degree to which individual rate element prices may fluctuate during any given year while retaining streamlined tariff filing and review treatment. Rate decreases below a band's lower boundary may be permitted upon a demonstration that the proposed rate covers the cost of providing the service. However, as explained below, the carrier receives no credit for the below-band rates in calculating compliance with the basket's aggregate rate ceiling.

B. Annual Filings

16. The proposal provides that initial price cap tariffs must be filed by the LECs on December 30, 1988, with an effective date of April 1, 1989. AT&T's initial price cap tariff must be filed on February 16, 1989, with an April 1 effective date. Thereafter, the effective date of annual price cap tariffs would be July 1, and LECs must continue to file annual price cap tariffs on 90 days' notice, while AT&T would continue to file on 45 days' notice. The notice period for AT&T reflects the fact that (as under current practice) the AT&T filing must incorporate proposed access rate changes filed by the LECs. As part of the annual filing, carriers must demonstrate that they have made appropriate adjustments to their PCIs and BPIs according to the required procedures. In order to receive streamlined treatment and to avoid likely tariff suspension, they must also demonstrate that their APIs do not exceed applicable PCIs. Carriers electing price cap regulation are not otherwise required to comply with traditional cost support filing requirements.

C. Streamlined Review

17. The plan provides that once the annual PCI adjustments have become effective, rate level changes within applicable cap and band limits will be subject to streamlined tariff filing and review treatment. Such tariffs may be filed on 14 days' notice, shall be *prima facie* lawful, and need be accompanied only by a showing that the proposed prices are at or below the PCI ceiling and are within the price band. Such rates normally will not be subject to suspension, unless this Commission determines on our own or upon challenge by a petitioner (1) that there is a high probability that the tariff would be found unlawful under section 201 or section 202 of the Communications Act (or under any other provision of the Act or any other statutory or other legal requirements) after investigation; (2) that suspension would not substantially harm other parties; (3) that irreparable injury would be suffered if suspension does not issue; and (4) that the suspension would not otherwise harm the public interest. Current complaint procedures under section 208 of the Communications Act would not be altered by the price cap plan. And, upon suspension or investigation of a tariff, current procedures under section 204 of the Act would remain unchanged.

D. Above-Cap or Out-of-Band Rate Filings

18. Tariffs containing above-cap or above-band rates must be filed on 90 days' notice and will be subject to full regulatory scrutiny under the price cap proposal. Tariffs proposing above-cap rates must be accompanied by cost support data covering each rate in the basket for the entire period under price caps, and a detailed explanation of the carrier's cost allocation methodology. The carrier must demonstrate that the proposed above-cap rates are just and reasonable by showing, for example,

that such rates are essential to attract capital sufficient to conduct its business. In the case of above-band filings, carriers must demonstrate "substantial cause" for the rate increase. Since applicable cap and band limits reflect this Commission's tentative view of the dividing line between reasonable and unreasonable rates, above-cap or above-band filings presumptively will be subject to suspension and investigation. Tariffs containing below-band rates must be filed on 45 days' notice and must be accompanied by a showing that the rates are sufficient to cover the cost of providing the service.

E. Review of New and Restructured Services

19. New service offerings outside the cap must be filed on 45 days' notice and must be accompanied by a demonstration that they meet the "net revenue" test. Thus, the carrier must establish that the service, and each unbundled element thereof, will generate a net revenue increase—measured against revenues generated from services in the same basket, and calculated based on present value—within a 24-month period after an annual price cap tariff including the new service takes effect, or within 36 months from the date the new service becomes effective, whichever occurs first. Capped services that have been restructured shall remain under price cap regulation. However, rate restructuring will be subject to 45 days' notice and, in order to avoid likely suspension, must be accompanied by a showing that the proposed restructuring will not drive the affected API above its respective PCI. Minor text changes will continue to be subject to existing tariff review procedures.

F. Review

20. At the end of the third year under price cap regulation, this Commission will commence a comprehensive examination of the price cap plan. This review will consider all available measures of market and carrier performance, including the level of actual prices, achieved rates of return, quality of service, and technological progressiveness. While the plan proposes that no retroactive payments will be exacted from carriers for high profit levels achieved under price caps, the review may lead to adjustments to the overall level of price caps in future years, if such changes are found to be appropriate.

V. Operation of Price Cap Adjustment Mechanisms

21. As noted above, the plan contemplates creation of a price cap index, a base price index, and an actual price index for each basket of services. The PCI is an index of change in the cost of factors of production (*i.e.*, inflation), carrier productivity, and certain carrier-specific cost factors that are beyond the carrier's control. The PCI is adjusted annually to account for changes in its component cost factors, and it acts as a ceiling above which he index of proposed prices within the basket, the API, cannot go without full regulatory scrutiny. Similarly, the BPI is adjusted annually to reflet the basket's aggregate revenue-weighted average rates during the base year, and is used as a benchmark against which proposed rates are measured in calculating the API.

A. Basic Formulas and Calculations

1. *PCI Adjustments.* 22. Broadly speaking, the PCI is adjusted according to the following formula:

Proportion change to the price cap index = $w(I-X)/100+\Delta Y/R+\Delta Z/R$

where I = the percentage change in the GNP-PI,[8]

X = productivity factor of 3.0%,

w = the fraction of base period gross revenues represented by non-access costs net of ΔZ (as defined below) divided by base period gross revenues,

ΔY = the dollar magnitude of any change in access charges for the upcoming tariff year, evaluated at base period demand,

ΔZ = the dollar magnitude of any other exogenous cost changes, and

R = base period gross revenues.

The productivity factor "X" reflects the conclusion that the telecommunications industry's productivity gains have in the recent past exceeded those of the economy as a whole by approximately 2.5 percent annually. In order to share the benefits of price caps with ratepayers and to induce carriers to achieve greater productivity gains, the Further Notice assigns "X" a value of 3 percent. Carrier-specific exogenous cost changes which are represented by the term "ΔZ," include those caused by (1) changes in tax laws; (2) the completion of the amortization of depreciation reserve deficiencies and inside wiring costs; (3) changes in the Uniform System of Accounts (USOA); and (4) changes in the Separations Manual.[9]

23. The actual mechanics of adjusting the PCI are slightly more complex than the formula described above. The initial base year PCI for each basket will be assigned a value of 100. However, the PCI must be adjusted at the time of the initial price cap filing, and at every annual filing thereafter, to reflect changes in costs. Adjustments to the PCI would be made pursuant to the following formula:

$$PCI\ (new) = PCI\ (base)\ [1.0 + w\ (I - X) / 100 + \Delta Y/R + \Delta Z/R].$$

2. *API and BPI Adjustments.* 24. Under the plan, the initial BPI for each basket of services is established using the revenue-weighted average rates of the basket's services in effect during the first base year (the 12-month period ending September 30, 1988). Like the initial base year PCIs, the initial BPIs will be assigned a value of 100. Beginning with the initial price cap tariff filing, the carrier will propose prices for the services in each basket. For each such service, the ratio of its proposed new price to its average price in the base year is calculated. Thus, for each service, the ratio is calculated as the proposed price for the coming year, denoted as p2, divided by its average price during the base year, p1. This term (p2/p1) will be multiplied by the corresponding weight that should be attached to that price. The sum of all such terms (representing weights multiplied by price ratios) is multiplied by the BPI value to determine the API value. The weights applied to the price ratios described above are the ratios of revenues generated by each corresponding service to total basket revenues during the base year. Denoting these weights as "v" and the services by the index "i," the API is derived according to the following formula:

$$API = BPI\ [\Sigma i^{v}i\ (p2/p1)_i]$$

25. The BPIs are adjusted in each annual price cap filing following the inaugural filing to reflect the change in revenue-weighted average rates in a basket one base period to the next. Each adjustment is made pursuant to the following formula:

$$BPI = BPI\ (previous\ year)\ [\Sigma i^{v}i\ (p2/p1)_i]$$

where

[8] The GNP-Price Index (GNP-PI) (a fixed-weight price index produced by the U.S. Department of Commerce) is employed instead of the better known Consumer Price Index or Producer Price Index, because it exhibits less volatility over time, and is more broadly based to better reflect carriers' actual cost experience. The GNP-PI is published in the *Survey of Current Business* at Table 7.1 and in the *Economic Report of the President* at Table B-4.

[9] We seek additional comment on whether changes in international accounting rates should be included as a "Y" factor under the PCI adjustment formula.

BPI (previous year) = the BPI from the base year preceding the most recently completed base year,
p2 = the average price (revenue divided by quantity) of a ratable element during the most recently completed base year,
p1 = the average price (revenue divided by quantity) of a ratable element during the base year preceding the most recently completed base year,
v = the ratio of revenues generated by a ratable element during the base year preceding the most recently completed base year to the basket's total revenues during that base year, and
i = the ratable elements in the basket.

B. Reductions Below Price Floors

26. Excepted from the basic API adjustment formula described above are price reductions beneath the plan's lower band boundaries. Rate bands for a rate element define a zone within five percentage points above or below an amount equal to the rate that prevailed on the last day of the base year, increased or decreased (as appropriate) by the percentage change in the current PCI compared to the previous PCI. The portion of a proposed rate reduction that falls below the band will be disregarded for the purpose of calculating the API.

C. Calculations for News Services

27. The plan provides that new services introduced during any base year are to be brought into the API, and consequently made subject to the pricing limitations imposed by the PCI and bands, at the first annual price cap tariff filing following the close of the base year in which the new service was introduced. Since BPI calculations require a comparison of rates in two completed base years, new services cannot be brought into the BPI calculations until the second annual tariff filing following the close of the base year in which they are introduced.

28. To introduce a new service into price cap regulation, the revenue weights and average rates used in calculating the API must be calculated with the new service included in the price cap basket for the base year that is used as a basis for the upcoming annual filing. The percentage change between the base year average prices (including that of the new service), at these revenue weights, and the proposed prices (including that of the new service), at these same revenue weights, is multiplied by the value of the BPI to produce the appropriate API value. This API value will then be compared to the PCI for compliance with price cap requirements.

D. Calculations for Restructured Services

29. The plan contemplates that restructured services must remain subject to the cap and band limitations applicable to the basket(s) that contained those services prior to restructuring. Thus, unlike the introduction of new services (which are brought into the various index calculations after an initial period outside price caps), restructuring requires a simultaneous recalculation of the API. The plan provides that the API should measure the change that would result in the total cost of purchasing the bundle of services for which restructuring is proposed. This calculation may require use of carrier data and estimation techniques to assign customers of the original service to those services (including the restructured service) that will remain or become available in the cap.

VI. Effect on Current Commission Rules and Procedures

30. Price cap regulation will result in little change to many of this Commission's applicable current rules and policies. This Commission's current policy favoring geographic toll rate averaging will remain intact, and we will retain the Interim Cost Allocation Manual (ICAM) unless AT&T opts for price cap regulation. If AT&T elects price caps, we propose to require AT&T to adhere to the cost allocation requirements we have proffered for the LECs for all of its exogenous adjustments, including access costs. The plan does not disturb current quality of service monitoring procedures, including requirements that AT&T and the Bell Operating Companies file semi-annual quality of service reports, and the routine scrutiny given to all dominant carriers pursuant to the facilities authorization process conducted under section 214 of the Communications Act. The plan also preserves the Separations Manual, the USOA, and the joint cost procedures codified in Part 32 and Part 64 of this Commission's Rules. In addition, price cap regulation leaves undisturbed current market rules designed to foster competition and prevent discrimination. These rules include open entry, equal access, resale and shared use, interconnection, unbundling of tariff services, non-structural safeguards for joint provision of regulated and nonregulated activities, and the Open Network Architecture and Comparably Efficient Interconnection protections against discrimination. With respect to ONA and CEI, although we are open to the use of pricing rules to implement these policies, we believe that concerns as to discriminatory or anticompetitive pricing of Basic Service Elements will continue to be addressed in the tariff review process. We also propose to retain our existing section 208 complaint procedures. Our proposed revisions to our Part 2, Part 61, Part 65 and Part 69 Rules follow.

VII. Ex Parte Requirements, Regulatory Flexibility Act Initial Analysis, Paperwork Reduction Analysis

31. This is a non-restricted notice and comment rulemaking proceeding. *See* § 1.1206 of the Commission's Rules, 47 CFR 1.1206, for rules governing permissible *ex parte* contacts. It is certified that the Regulatory Flexibility Act of 1980, 5 U.S.C. 605, to the rule changes we are proposing in this proceeding. The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to decrease the information collection burden on the public.

VIII. Ordering Clauses

32. Accordingly, IT IS ORDERED that, pursuant to sections 4(i), 4(j), 201–205, 303(r), and 403 of the Communications Act of 1934, 47 U.S.C. 154(i), 154(j), 201–205, 303(r), 403, and section 553 of Title 5, United States Code, notice is hereby given of proposed amendments to Part 61, Part 69, and §§ 1.773, 61.32, 61.33, 61.38, 61.39, 61.58, 65.1, 65.200, 65.701, 65.703, 69.1, 69.3, 69.111, 69.113, 69.205, and 69.206 of this Commission's Rules, 47 CFR Part 61, Part 69, §§ 1.773, 61.32, 61.33, 61.38, 61.39, 61.58, 65.1, 65.200, 65.701, 65.703, 69.1, 69.3, 69.111, 69.113, 69.205, 69.206, in accordance with the proposals, discussion, and statement of issues in this Further Notice of Proposed Rulemaking, and that comment is sought regarding such proposals, discussion, and statement of issues.

33. We hereby give notice that in reaching our decisions in this proceeding we will not necessarily be limited to comments, reply comments, and responses that may be filed, and that we may utilize other information, analyses, and reports, provided that in each such case a copy of the material relied upon will be associated with the record in this proceeding.

34. It is further ordered that, in accordance the provisions of § 1.419(b) of this Commission's Rules, 47 CFR 1.419(b), an original and five copies of all comments, replies, pleadings, briefs, and the other documents filed in the proceeding shall be furnished to this Commission. In addition, parties should file ten copies of any such pleadings with the Price Cap Task Force, Common

Carrier Bureau, Room 518, 1919 M Street NW., Washington, DC. Members of the public who wish to express their views by participating informally may do so by submitting one or more copies of their comments without regard to form (so long as the docket number is clearly stated in the heading). Copies of all filings will be available for public inspection during regular business hours in this Commission's Docket Reference Room (Room 239) at our headquarters at 1919 M Street NW., Washington, DC.

35. It is further ordered that the motion to accept late-filed comments submitted by the Computer and Communications Industry Association is granted.

36. It is further ordered that the motion to accept late-filed comments submitted by the Oklahoma Corporation Commission is granted.

37. It is further ordered that the motion to accept late-filed reply comments submitted by the United States Department of Justice is granted.

38. It is further ordered that the late-filed pleadings submitted by the Arkansas Public Service Commission, the Communications Satellite Corporation, the Contel Corporation, the District of Columbia Office of the People's Counsel, the Indiana Office of Utility Consumer Counselor, the Kentucky Public Service Commission, the Michigan Public Service Commission, the New Hampshire Public Utilities Commission, the Office of Telecommunications, UK, Rollins, Inc., and the State Commissioners on the CC Docket No. 80-286 Joint Board are accepted and made part of the record in this proceeding.

39. It is further ordered that the motion filed by Southwestern Bell Telephone Company on February 17, 1988, to strike certain comments filed on February 10, 1988, with respect to certain draft rule revisions filed on January 27, 1988, is dismissed.

40. It is further ordered that the waiver of § 1.49(c) of this Commission's Rules, 47 CFR 1.49(c), requested by the Ad Hoc Telecommunications Users Committee in connection with its filing of proposed rules on January 27, 1988, is granted.

41. It is further ordered that comments on this Further Notice of Proposed Rulemaking shall be due not later than July 26, 1988, and that reply comments shall be due not later than August 26, 1988.

List of Subjects

47 CFR Part 1

Administrative practice and procedure.

47 CFR Part 61

Communications common carriers, Reporting and recordkeeping requirements, Telephone, Price cap tariff filing and review procedures.

47 CFR Part 65

Administrative practice and procedure, Communications common cariers, Reporting and recordkeeping requirements.

47 CFR Part 69

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Proposed Amendments to Code of Federal Regulations

For the reasons set forth in the preamble, Title 47, Chapter 1, Part 1 of the Code of Federal Regulations is proposed to be amended as follows.

PART 1—PRACTICE AND PROCEDURE

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

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended 47 U.S.C. 154, 303; Implement, 5 U.S.C. 552, unless otherwise noted.

2. Section 1.773 is amended by adding paragraph (a)(1)(iv) as follows:

§ 1.773 Petitions for suspension or rejection of new tariff filings.

(a) * * *

(1) * * *

(iv) For the purposes of this section, tariff filings made pursuant to § 61.47(b) by dominant carriers will be considered *prima facie* lawful, and will not be suspended by the Commission unless the petition shows that the support information required in § 61.47(b) was not provided. If such a showing is not made, then the filing will be considered *prima facie* lawful and will not be suspended by the Commission unless the petition requesting suspension shows each of the following:

(A) That there is a high probability the tariff would be found unlawful pursuant to section 201 or section 202 of the Communications Act (or pursuant to any other provision of the Communications Act or any other statutory or other legal requirement) after investigation;

(B) That the suspension would not substantially harm other interested parties;

(C) That irreparable injury will result if the tariff filing is not suspended; and

(D) That the suspension would not otherwise be harmful to the public interest.

PART 61—[AMENDED]

1. The authority citation for Part 61 continues to read as follows:

Authority: Sec. 4, 48 Stat. 1066, as amended; 47 U.S.C. 154. Interpret or apply sec. 203, 48 Stat. 1070; 47 U.S.C. 203.

2. Section 61.3 is added as follows:

§ 61.3 Definitions.

(a) *Act.* The Communications Act of 1934 (48 Stat. 1004; 47 U.S.C. Chapter 5), as amended.

(b) *Actual Price Index* (API). A base period-weighted index of the proposed rates in a service group offered by carriers electing price cap regulation.

(c) *Association.* This term has the meaning given it in § 69.2(c).

(d) *Band.* An annual zone of flexibility for individual rate elements of services offered under price cap regulation ranging from 5 percent above to 5 percent below the level that prevailed on the last day of the base year, as adjusted by the most recent percentage change in the Price Cap Index.

(e) *Base Price Index* (BPI). An index of the aggregate revenue-weighted average rates in effect for a service group offered by a carrier electing price cap regulation.

(f) *Base year.* The 12-month period ending six months prior to the effective date of annual price cap tariffs.

(g) *Change in rate structure.* A restructuring or other alteration of the rate components for an existing service.

(h) *Charges.* The price for service based on tariffed rates.

(i) *Commercial contractor.* The commercial firm to whom the Commission annually awards a contract to make copies of Commission records for sale to the public.

(j) *Commission.* The Federal Communications Commission.

(k) *Concurring carrier.* A carrier (other than a connecting carrier) subject to the Act which concurs in and assents to schedules of rates and regulations filed on its behalf by an issuing carrier or carriers.

(l) *Connecting carrier.* A carrier engaged in interstate or foreign communication solely through physical connection with the facilities of another carrier not directly or indirectly controlling or controlled by, or under direct or indirect common control with, such carrier.

(m) *Corrections.* The remedy of errors in typing, spelling, or punctuation.

(n) *Dominant carrier.* A carrier found by the Commission to have market power (i.e., power to control prices).

(o) *GNP Price Index* (GNP-PI). The 75-day estimate of the "Fixed-Weighted

Price Index for Gross National Product, 1982 Weights" published by the United States Department of Commerce.

(p) *Issuing carrier.* A carrier subject to the Act that publishes and files a tariff or tariffs with the Commission.

(q) *Local Exchange Carrier.* A telephone company that provides telephone exchange service as defined in section 3(r) of the Act.

(r) *New service offering.* A tariff filing that provides for a class or sub-class of service not previously offered by the carrier involved and that enlarges the range of service options available to ratepayers.

(s) *Non-dominant carrier.* A carrier not found to be dominant.

(t) *Other participating carrier.* A carrier subject to the Act that publishes a tariff containing rates and regulations applicable to the portion of through service it furnishes in conjunction with another subject carrier.

(u) *Price Cap Index* (PCI). An index of costs facing carrier electing price cap regulation, which index is calculated for each service group.

(v) *Price cap regulation.* An alternative method of rate regulation that may be elected by eligible dominant carrier pursuant to § 6141 through § 61.47.

(w) *Price cap tariff.* Any tariff filing that involves a calculation pursuant to § 61.44 or § 61.45.

(x) *Productivity factor.* An adjustment factor (3.0 percent) used to make adjustments to the Price Cap Index, which adjustments represent increased output from constant factors of production or constant output from decreased levels of production factor utilization.

(y) *Rate.* The tariff price per unit of service.

(z) *Rate increase.* Any change in a tariff which results in an increased rate or charge to any of the filing carrier's customers.

(aa) *Rate level change.* A tariff change that only affects the actual rate associated with a rate element, and does not affect any tariff regulations or any other wording of tariff language.

(bb) *Regulations.* The body of carrier prescribed rules in a tariff governing the offering of service in that tariff, including rules, practices, classifications, and definitions.

(cc) *Restructured service.* An offering which represents the modification of a method of charging or provisioning a service and/or the introduction of a new method of charging or provisioning.

(dd) *Service group.* Any class or category of tariffed services (1) which is established by the Commission pursuant to price cap regulation; (2) the rates of which are used to calculate an Actual Price Index and Base Price Index; and (3) the related costs of which are used in calculating adjustments to a Price Cap Index.

(ee) *Supplement.* A publication filed as part of a tariff for the purpose of suspending or cancelling that tariff, or tariff publication and numbered independently from the tariff page series.

(ff) *Tariff.* Schedules of rates and regulations filed by common carriers.

(gg) *Tariff publication, or publication.* A tariff, supplement, revised page, additional page, concurrence, notice of revocation, adoption notice, or any other schedule of rates or regulations.

(hh) *Text change.* A change in the text of a tariff which does not result in a change in any rate or regulation.

(ii) *United States.* The several States and Territories, and the District of Columbia, and the possessions of the United States.

3. The center heading preceding § 61.11 is removed, and §§ 61.11, 61.12, 61.13, 61.14, 61.15, 61.16, 61.17, 61.18, 61.19, 61.20, 61.21, 61.22, 61.23, 61.24, 61.25, and 61.26 are removed and reserved.

4. The fifth sentence of § 61.32 is revised as follows:

§ 61.32 Method of filing publications.

* * * Simultaneously with the filing of the publications and by the same means, the issuing carrier must send a copy of the publication, supporting information specified in § 61.38, or, as appropriate, § 61.47, and transmittal letter to the commercial contractor (at its office on Commission premises) and the Chief, Tariff Review Branch. * * *

5. Section 61.33 is amended to redesignate paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), to revise the redesignated paragraph (d), and to add a new paragraph (c) as follows:

§ 61.33 Letters of transmittal.

* * * * *

(c) In addition to the requirements set forth in paragraph (a) of this section, any carrier choosing to file a price cap tariff must include in the letter of transmittal a statement that the filing is made pursuant to § 61.47.

(d) In addition to the requirements set forth in paragraphs (a), (b), and (c) of this section, the letter of transmittal must specifically reference by number any special permission necessary to implement the tariff publication. Special permission must be granted prior to the filing of the tariff publication, and may not be requested in the transmittal letter.

6. Section 61.38(a) is amended by adding a new sentence at the end thereof as follows:

§ 61.38 Supporting information to be submitted with letters of transmittal.

(a) * * * This section (other than the preceding sentence of this paragraph) shall not apply to tariff filings proposing rates for services identified in § 61.42 (a), (b), and (d), which filings are submitted by carriers that have elected price cap regulation pursuant to § 61.43(a).

7. Section 61.39(a) is amended by revising the section heading and adding a new sentence at the end thereof as follows:

§ 61.39 Optional supporting information to be submitted with letters of transmittal for Access Tariff filings effective on or after January 1, 1989, by local exchange carriers serving 50,000 or fewer access lines that are described as subset 3 carriers in § 69.602.

(a) * * * This section (other than the preceding sentence of this paragraph) shall not apply to tariff filings proposing rates for services identified in §§ 61.42(a), (b), and (d), which filings are submitted by carriers that have elected price cap regulation pursuant to § 61.43(a).

8. Sections 61.41 through 61.47 are added as follows:

§ 61.41 Price cap requirements generally.

(a) Sections 61.42 through 61.47 apply to eligible dominant carriers that elect price cap regulation pursuant to § 61.43.

(b) Any dominant carrier that is not an Association tariff participant for tariffed access service as of April 1, 1989, and has notified the Association, in accordance with § 69.3(e)(9), that it no longer will be a participant in the Association Carrier Common Line tariff effective April 1, 1989, is eligible to elect price cap regulation. If a telephone company, or any one of a group of affiliated telephone companies, files a price cap tariff in any study area, that telephone company and it affiliated companies must file price cap tariffs in all of their study areas.

§ 61.42 Price cap service groups.

(a) Subject to the limitations established in paragraphs (c) and (d) of this section, each dominant interexchange carrier electing price cap regulation must establish two service groups containing, respectively:

(1) Private line services; and

(2) Message services.

(b) Subject to the limitations established in paragraphs (c) and (d) of this section, each dominant local

exchange carrier electing price cap regulation must establish two service groups containing, respectively:

(1) Switched access services; and

(2) All other tariffed interstate services.

(c) The following services must be excluded from service groups subject to price cap regulation:

(1) For dominant interexchange carriers:

(i) Special construction services;

(ii) American Telephone and Telegraph Company Tariff F.C.C. No. 12 services; and

(iii) Other services subject to below-the-line accounting requirements.

(2) For dominant exchange carriers:

(i) The Carrier Common Line element, until July 1, 1990;

(ii) special construction services; and

(iii) Individual case basis services.

(d) New services, other than those covered by paragraph (c) of this section, must be included in the appropriate service group at the first annual price cap tariff filing following completion of the base year in which they are introduced.

§ 61.43 Initial price cap tariffs; annual filings.

(a) Eligible dominant carriers may elect price cap regulation as follows:

(1) Dominant local exchange carriers may elect price cap regulation by filing initial price cap tariffs December 30, 1988, to be effective April 1, 1989.

(2) Dominant interexchange carriers may elect price cap regulation by filing initial price cap tariffs February 16, 1989, to be effective April 1, 1989.

(b) The initial price cap tariff filing described in paragraph (a) of this section shall include:

(1) A list of each ratable element for each service contained in a service group;

(2) The proposed rate for each ratable element identified in paragraph (b)(1) of this section;

(3) The total revenues generated during the base year by each ratable element identified in paragraph (b)(1) of this section;

(4) The quantity of each ratable element identified in paragraph (b)(1) sold during the base year;

(5) For each service group, the access costs and the other exogenous cost changes identified in § 61.44(c) during the base year;

(6) For each service group, a Price Cap Index (PCI) value, calculated pursuant to the methodology provided in § 61.44(b), and premised upon an initial value of 100 for the variable designated as "PCI(base)" in the formula contained in § 61.44(b);

(7) For each service group, an Actual Price Index (API) value, calculated pursuant to the methodology provided in § 61.45(a), and premised upon a Base Price Index (BPI) value of 100.

(c) Carriers electing price cap regulation must submit annual price cap tariff filings that make appropriate adjustments to their PCI and BPI values pursuant to §§ 61.44 and 61.45(b), that incorporate new services into the API or BPI calculations values pursuant to § 61.45(c), and that propose rates for the upcoming year. Carriers may propose rate or other tariff changes more often than annually, consistent with the requirements of § 61.59.

§ 61.44 Adjustments to the PCI.

(a) Except as otherwise provided, each carrier electing price cap regulation must annually adjust the PCI for each service group as part of the annual price cap tariff filing.

(b) Adjustments to each PCI must be made pursuant to the following formula:

$$PCI(new) = PCI(base)[1.0 + w(I - X)/100 + \Delta Y/R + \Delta Z/R]$$

where

I = the percent change in the GNP–PI during the base year,

X = a productivity factor of 3.0%,

w = base year gross revenues, minus base year access costs and net of ΔZ, all divided by base year gross revenues,

ΔY = the dollar magnitude, at base year demand levels, of any change in access charges for the upcoming tariff year,

ΔZ = the dollar magnitude, at base period levels of operations, of exogenous cost changes identified in paragraph (c) of this section, and

R = base year gross revenues.

(c) The exogenous cost changes represented by the term "ΔZ" in the formula detailed in paragraph (b), include those caused by:

(1) Changes in tax laws;

(2) The completion of the amortization of depreciation reserve deficiencies and inside wiring costs;

(3) Changes in the Uniform System of Accounts; and

(4) Changes in the Separations Manual.

(d) The costs and revenues of new services subject to price cap regulation must be included in the appropriate PCI calculations under paragraph (a) of this section beginning at the first annual price cap tariff filing following completion of the base year in which they are introduced.

(e) In the event that a price cap tariff becomes effective, which tariff results in an API value (calculated pursuant to § 61.45(a)) that exceeds the currently applicable PCI value, the PCI value shall be adjusted upward to equal the API value.

§ 61.45 Adjustments to the API and BPI.

(a) In connection with any price cap tariff filing proposing rate changes, the carrier must calculate an API for each affected service group pursuant to the following methodology:

$$API = BPI[\Sigma_i v_i(p2/p1)_i]$$

where

BPI = the most recent BPI calculated pursuant to paragraph (b) of this section,

v = the ratio of revenues generated by a ratable element during the base year to the service group's total revenues during the base year,

p2 = the proposed price of a ratable element, subject to any banding limitations described in § 61.46,

p1 = the average price of a ratable element offered during the base year, determined by dividing the revenue generated by the element during the base year by the quantity of units sold, and

i = the ratable elements in the service group.

(b) Each carrier electing price cap regulation must calculate a BPI for each service group for the most recently completed base year as part of the annual price cap tariff filing. This calculation must be made pursuant to the following methodology.

$$BPI = BPI(previous\ year)[\Sigma_i v_i(p2/p1)_i]$$

where

BPI (previous year) = the BPI from the base year preceding the most recently completed base year,

p2 = the average price (revenue divided by quantity) of a ratable element during the most recently completed base year,

p1 = the average price (revenue divided by quantity) of a ratable element during the base year preceding the most recently completed base year,

v = the ration of revenues generated by a ratable element during the base year preceding the most recently completed base year to the service group's total revenues during that base year, and

i = the ratable elements in the service group.

(c) New services subject to price cap regulation must be included in the appropriate API calculations under paragraph (a) of this section beginning at the first annual price cap tariff filing following completion of the base year in which they are introduced. New services subject to price cap regulation must be included in the appropriate BPI calculations under paragraph (b) of this section at the second annual price cap filing following completion of the base year in which they are introduced.

(d) Any price cap tariff filing proposing rate restructuring shall require an adjustment to the API pursuant to the general methodology described in paragraph (a) of this section. This adjustment shall measure the change that would result in the total cost of purchasing the bundle of services for which restructuring is proposed. This

calculation may require use of estimation techniques to assign customers of the withdrawn service to those services (including the substitute service) that will remain or become available in the service group.

(e) In calculating adjustments to the API pursuant to paragraph (a) of this section, any portion of a proposed rate reduction for a ratable element that falls below the applicable band limit established pursuant to § 61.46 shall be disregarded.

§ 61.46 Pricing bands.

Pricing bands shall be established each tariff year for each ratable element contained in a service group. Each band shall define a zone within 5 percentage points above or below an equal to the rate that prevailed on the last day of the base year, increased or decreased (as appropriate) by the percent change in the current PCI compared to the immediately preceding PCI.

§ 61.47 Supporting information to be submitted with letters of transmittal for tariffs of carriers electing price cap regulation.

(a) Each price cap tariff filing must be accompanied by supporting materials sufficient to calculate required adjustments to each API pursuant to the methodology provided in § 61.45(a), and each annual price cap filing must be accompanied by supporting materials sufficient to calculate new PCI and BPI values pursuant to the methodologies provided in §§ 61.44 and 61.45(b), respectively.

(b) Each price cap tariff filing that proposes rates that are within applicable bands established pursuant to § 61.46, and that results in an API value that is equal to or less than the applicable PCI value, must be accompanied by supporting materials sufficient to establish compliance with the applicable bands and to calculate the necessary adjustment to the API pursuant to § 61.45(a).

(c) Each price cap tariff filing that proposes a rate that is above applicable band limit must be accompanied by supporting materials establishing substantial cause for the proposed above-band rate.

(d) Each price cap tariff filing that proposes a rate below an applicable band limit must be accompanied by supporting materials sufficient to demonstrate that the proposed rate will cover the cost of providing the corresponding service.

(e) Each price cap tariff filing that proposes rates that will result in an API value that exceeds the applicable PCI value must be accompanied by cost data for each ratable element in the service group for each of the previous four years under price cap regulation, and a detailed explanation of the carrier's cost allocation methodology for each ratable element for each year.

(f) Each price cap tariff filing that proposes restructuring of existing rates must be accompanied by supporting materials sufficient to make the adjustments to each affected API required by § 61.45(d).

(g) Each tariff filing that introduces a new service that will later be included in an appropriate service group and reflected in the service group's API pursuant to § 61.45(c) and PCI pursuant to § 61.44(d) must be accompanied by cost data sufficient to establish that the new service, and each unbundled element thereof, will generate a net revenue increase—measured against revenues generated from services in the applicable service group, and calculated based upon present value—within the lesser of a 24-month period after an annual price cap tariff including the new service takes effect, or 36 months from the date the new service becomes effective.

9. Section 61.58 is amended to redesignate paragraph (c) as paragraph (d), to revise the first sentence of redesignated paragraph (d)(1) introductory text, and to add a new paragraph (c) as follows:

§ 61.58 Notice requirements.

* * * * *

(c) *Carriers electing price cap regulation.* This paragraph applies only to carriers electing price cap regulation. Such carriers must file tariffs according to the following notice periods.

(1) For annual adjustments to the PCI values under § 61.44 and the BPI values under § 61.45(b), local exchange carrier tariffs must be filed on not less than 90 days' notice, and interexchange carrier tariffs must be filed on at least 45 days' notice.

(2) Tariff filings that alter rate levels only, and that (i) do not cause any API to exceed any applicable PCI pursuant to calculations provided for in § 61.45(a); and (ii) do not cause the price of any ratable element to exceed its banding limitations established in § 61.46, must be filed on at least 14 days' notice.

(3) Tariff filings that would cause any API to exceed any applicable PCI pursuant to calculations provided for in § 61.45(a), or that would cause a price for a ratable element to exceed its banding limitations established in § 61.46, must be filed on at least 90 days' notice.

(4) Tariff filings that would cause a price for a ratable element to fall below its banding limitations established in § 61.46 must be filed on at least 45 days' notice.

(5) Tariff filings involving a change in rate structure of a service covered by § 61.42 (a) or (b), or the introduction of a new service covered by § 61.42(d), must be made on at least 45 days' notice.

(6) The required notice for tariff filings made by dominant carriers involving services covered by § 61.42(c), or involving changes to tariff regulations, shall be that required in connection with such filings by dominant carriers that have not elected price cap regulation.

(d) *Other carriers.* (1) Tariff filings in the instances specified in paragraphs (d)(1) (i), (ii) and (iii) of this section must be made on at least 15 days' notice.

* * *

PART 65—INTERSTATE RATE OF RETURN PRESCRIPTION PROCEDURES AND METHODOLOGIES

1. The authority citation for Part 65 continues to read as follows:

Authority: Secs. 4, 201, 202, 203, 205, 218, 403, 48 Stat. 1066, 1072, 1077, 1094, as amended, 47 U.S.C. 154, 201, 202, 203, 205, 218, 403.

2. Section 65.1 is revised as follows:

§ 65.1 Application of Part 65.

This part establishes procedures and methodologies for Commission prescription of interstate rates of return. This part shall apply to those interstate services and carriers as the Commission shall designate by Order. This part and the existing rate of return prescription shall not apply to carriers subject to §§ 61.41 through 61.47, except as set forth in §§ 65.600 (b), (d) and (e), 65.701(c), and 65.703(g).

3. Section 65.200 is amended to revise paragraph (b) introductory text as follows:

§ 65.200 State authorized returns for exchange carriers.

* * * * *

(b) Notwithstanding any other provision of this section, paragraph (a) of this section shall only apply (except as hereafter provided) to those exchange carriers and exchange carrier holding companies that are not subject to §§ 61.41 through 61.47 and that:

* * * * *

4. Section 65.600 is amended to revise paragraph (b), and to add new paragraphs (d) and (e) as follows:

§ 65.600 Rate of return reports.

* * * * *

(b) Each local exchange carrier or group of affiliated carriers which is not

subject to §§ 61.41 through 61.47 and which has filed individual access tariffs during the preceding enforcement period shall file with the Commission within three (3) months after the end of each calendar quarter, a quarterly rate of return monitoring report. Each report shall contain two parts. The first part shall contain rate of return information on a cumulative basis from the start of the enforcement period through the end of the quarter being reported. The second part shall contain similar information for the most recent quarter. The final quarterly monitoring report for the entire enforcement period shall be considered the enforcement period report. Reports shall be filed on the appropriate report form prescribed by the Commission (see § 1.795 of this chapter) and shall provide full and specific answers to all questions propounded and information requested in the currently effective report form. The number of copies to be filed shall be specified in the applicable report form. At least one copy of the report shall be signed on the signature page by the responsible officer. A copy of each report shall be retained in the principal office of the respondent and shall be filed in such manner as to be readily available for reference and inspection. Final adjustments to the enforcement period report shall be made by September 30 of the year following the enforcement period to ensure that any refunds can be properly reflected in an annual access filing. For carriers subject to §§ 61.41 through 61.47, final adjustments to the final enforcement period report covering the period from January 1, 1987, through March 31, 1989, shall be made no later than December 29, 1989.

* * * * *

(d) Each interexchange carrier subject to §§ 61.41 through 61.47 shall file with the Commission, within three (3) months after the end of each calendar year, the total interstate rate of return for that year for all interstate services subject to regulation by the Commission. Each such filing shall include a report of the total revenues, total expenses and taxes, operating income, and the rate base, as calculated according to § 65.800. A copy of the filing shall be retained in the principal office of the respondent and shall be filed in such manner as to be readily available for reference and inspection.

(e) Each local exchange carrier or group of affiliated carriers subject to §§ 61.41 through 61.47 shall file with the Commission within three (3) months after the end of each calendar year a report of its total interstate access rate of return for that year. Such filings shall include a report of the total revenues, total expenses and taxes, operating income, and the rate base, as calculated according to § 65.800. Until October 1, 1990, such carriers shall also file a second report within three (3) months after the end of each calendar quarter to include the total interstate rate of return for the common line element of access for each jurisdiction for which separate tariffs were in effect. Carriers filing this second report shall proceed as required in paragraph (b) of this section. Copies of both filings shall be retained in the principal office of the respondent and shall be filed in such manner as to be readily available for reference and inspection.

5. Section 65.701 is amended to add a new paragraph (c) as follows:

§ 65.701 Period of review.

* * * * *

(c) Notwithstanding other provisions in this subpart, the final period of review for any local exchange carrier electing price cap regulation (as defined in § 61.3(v)) shall conclude the day preceding implementation of price caps for that carrier. For exchange carriers subject to price cap regulation effective April 1, 1989, the final review period shall begin January 1, 1987, and shall end on March 31, 1989.

6. Section 65.703 is amended to revise paragraphs (a), (e), and (f), and to add a new paragraph (g) as follows:

§ 65.703 Refunds.

(a) For carriers not subject to §§ 61.41 through 61.47, refunds shall be effected automatically if a carrier's earnings for any category of services, as set forth in § 65.702, exceed the maximum allowable rate of return. In determining whether a carrier's earnings exceed the maximum allowable rate of return, the reports filed by a carrier shall be deemed conclusively binding on the carrier.

* * * * *

(e) For exchange carriers not subject to §§ 61.41 through 61.47, tariffs reflecting the revenue requirements reductions effectuating the refund shall be filed by the carrier to become effective no later than January 1 of the year following the submission of the final report for the earning review period.

(f) For interexchange carriers subject to this part but not subject to §§ 61.41 through 61.47, tariffs reflecting the revenue requirement reductions effectuating the refund shall be filed on 45 days' notice no later than 60 days after submission of the final report for the earnings review period.

(g) For all exchange carriers and interchange carriers subject to §§ 61.41 through 61.47, refund obligations incurrred prior to the effective date of §§ 61.41 through 61.47 shall be effectuated by an adjustment to the applicable Base Price Index, Actual Price Index, and Price Cap Index (as defined in § 61.3). Carriers making an adjustment to effectuate any outstanding refund requirements from the final enforcement period shall make such adjustments no later than during the next scheduled annual price cap adjustment tariff filing following the submission of the final enforcement report. The adjustment shall be designed to complete the required refund within 12 months, following which the Actual Price Index or the Price Cap Index shall be adjusted to remove the effect of the adjustment.

PART 69—ACCESS CHARGES

1. The authority citation for Part 69 continues to read as follows:

Authority: Secs. 4, 201, 202, 203, 205, 218, 403, 48 Stat. 1066, 1070, 1072, 1077, 1094, as amended, 47 U.S.C. 154, 201, 202, 203, 205, 218, 403.

2. Section 69.1 is amended to revise paragraph (b) as follows:

§ 69.1 Application of access charges.

* * * * *

(b) Charges for such access services shall be computed, assessed, and collected and revenues from such charges shall be distributed as provided in this part, except that the following provisions of this part shall apply only to telephone companies that have not elected to be subject to price cap regulation pursuant to § 61.43 or, to the extent companies have elected price cap regulation, the following sections, if applicable, shall apply to these companies' carrier common line charge: Sections 69.3(f), 69.103(b), 69.106(b), 69.109(b), 69.111(c), 69.112(c), 69.112(b)(2), 69.112(b)(3), 69.112(d)(2), 69.112(d)(3), 69.113(b), 69.113(d), 69.205(d)(1), 69.205(f), 69.301 through 69.310, and 69.401 through 69.414.

3. Section 69.3 is amended to revise paragraphs (a) and (e) (4) and to add a new paragrarph (g) as follows:

§ 69.3 Filing of access service tariffs.

(a) Except as provided in § 69.3(f) and (g), a tariff for access service shall be filed with this Commission for an annual period. Such tariffs shall be filed so as to provide a minimum of 90 days' notice with a scheduled effective date of

January 1. Such tariff filings shall be limited to rate level changes.

* * * * *

(e) * * *

(4) (i) Except for charges subject to price cap regulation under Part 61 of this chapter, any charge in such a tariff that is not an association charge must be computed to reflect the combined investment and expenses of all companies that participate in such a charge;

(ii) Carriers subject to price cap regulation shall be required to adhere to the requirements of paragraph (4) (i) of this section only in filing carrier common line charges;

* * * * *

(g) Telephone companies electing price cap regulation shall file with this Commission a price cap tariff for access service for an annual period. Such tariffs shall be filed so as to provide a minimum of 90 days' notice with a scheduled effective date corresponding to the effective date of all other annual access services tariffs. Such tariff filings shall be limited to changes in the Price Cap Indices and Base Price Indices, rate level changes (with corresponding adjustments to the appropriate Actual Price Indices), and the incorporation of new services into the affected indices.

4. Section 69.111(a) is revised as follows:

§ 69.111 Common transport.

(a) A charge that is expressed in dollars and cents per access minute shall be assessed upon all interexchange carriers that use switching or transmission facilities that are apportioned to the Common Transport element for purposes of apportioning net investment, or that are equivalent to those facilities for companies subject to price cap regulation under Part 61 of this chapter.

* * * * *

5. Section 69.113(a) is revised as follows:

§ 69.113 Special access.

(a) Appropriate subelements shall be established for the use of equipment or facilities that are assigned to the Special Access element for purposes of apportioning net investment, or that are equivalent to such equipment or facilities for companies subject to price cap regulation under Part 61 of this chapter.

* * * * *

6. Section 69.205(d) is revised as follows:

§ 69.205 Transitional premium charges.

* * * * *

(d)(1) Except for telephone companies electing price caps pursuant to § 61.43, the charge for an LS2 premium access minute shall be computed by dividing the premium Local Switching revenue requirements by the sum of the projected LS2 premium access minutes and a number that is computed by multiplying the projected LS1 premium access minutes by the applicable LS1 transition factor. The charge for an LS1 premium access minute shall be computed by multiplying the charge for an LS2 premium access minute by the applicable LS1 transition factor. The premium Local Switching revenue requirement shall be computed by subtracting the projected revenues from non-premium charges attributable to the Local Switching element from the revenue requirement for each element.

(2) For telephone companies electing price caps, the charge for an LS1 premium access minute shall be computed by multiplying the charge for an LS2 premium access minutes by the applicable LS1 transition factor.

7. Section 69.206(c) is revised as follows:

§ 69.206 Transitional non-premium charges for MTS-WATS equivalent services.

* * * * *

(c) The transitional non-premium charge for the Local Switching element shall be computed by multiplying a hypothetical premium charge for such element by .45. Except as noted below, the hypothetical premium charge for such element shall be computed by dividing the annual revenue requirement for such element by the sum of the projected premium access minutes for such element for such period and a number that is computed by multiplying the projected non-premium minutes for such elements for such period by .45. For telephone companies that elect price cap regulation pursuant to § 61.43, the hypothetical premium charge for such element shall be computed by setting a premium LS2 rate that assumes the LS1 transition factor is 1.00.

* * * * *

8. Section 69.415 is added as follows:

§ 69.415 Apportionment of certain exogenous costs for companies regulated under price caps.

Companies that elect price cap regulation shall apportion the exogenous costs identified in § 61.44(c) between price cap service groups, as defined in § 61.3(dd), on a cost causation basis, or where cost causation is not practicable, pursuant to a fully distributed cost methodology.

Federal Communications Commission.

H. Walker Feaster III,

Secretary.

[FR Doc. 88-13054 Filed 6-14-88; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 663

[Docket No. 80459-8059]

Pacific Coast Groundfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: NOAA proposes an amendment to the regulations implementing the Pacific Coast Groundfish Fishery Management Plan (FMP). The amendment would make it a Federal requirement that all landings of groundfish be reported to the appropriate State in compliance with State laws. The intended effect of this action would be to improve the ability of the NMFS and the States of California, Oregon, and Washington to accurately monitor landing receipts for individual fishing trips and account for all landings of groundfish, without imposing any new data collection requirements. Furthermore, it would enhance enforcement, and could provide more reliable and timely information to improve fisheries management, particularly in-season actions.

DATE: Comments on the proposed rule are invited until July 11, 1988.

ADDRESS: Comments should be addressed to E.C. Fullerton, Regional Director, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, CA 90731, or Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE., BIN C15700, Seattle, WA 98115.

FOR FURTHER INFORMATION CONTACT: Svein Fougner, Fisheries Management Division, Southwest Region, Terminal Island, California (213-514-6660), or Bill Robinson, Fisheries Management Division, Northwest Region, Seattle, Washington (206-526-6142).

SUPPLEMENTARY INFORMATION: No Federal reports are required of domestic fishermen, processors, or dealers as long as the date collection systems of the States provide the Secretary with the statistical information adequate for management. State requirements are

found in the Washington Administrative Code 220–69, Oregon Administrative Rules 635–06, and California Fish and Game Code Articles 6 and 7. Information such as boat name, gear type, days fished, catch area, value by species, and weight of catch by species is to be provided to the appropriate State within specified time limits.

The State data collection systems still are providing the necessary information for monitoring the overall groundfish fishery. There is no Federal requirement, however, that fishermen, processors, or dealers comply with State fishery data reporting laws. When NMFS enforcement agents monitor the unloading of a fishing vessel, they have no Federal authority to review landings receipts or other records to ensure that the unloading is properly reported. The submission of a landing receipt for each landing in a timely manner with the above information has become increasingly important in the groundfish fishery because in-season management actions are frequent and need to be based on the best information available. The proposed rule will enable the States to increase the effectiveness of existing data collection efforts by augmenting State enforcement efforts, without imposing any additional State or Federal reporting requirements.

There are no environmental or economic effects from implementing the proposed regulatory change, because it will not affect the amount of groundfish harvested, the species harvested, or the time and location of fishing activity. This is an administrative action, which will have no effect on marine resources, ocean and coastal habitats, or public health and safety. No new reporting requirements are being proposed.

Classification

The proposed rule is published under authority of section 305(c) of the Magnuson Act and was prepared at the request of the Pacific Fishery Management Council. The Assistant Administrator for Fisheries, NOAA has determined that this proposed rule is necessary for the conservation and management of the groundfish fisheries of the Pacific coast and that it is consistent with the Magnuson Act and other applicable law.

The Acting Under Secretary, NOAA, has determined that the proposed rule falls within a categorical exclusion from the requirements of the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, by NOAA Directive 02–10, because it would not result in any significant change from the status quo and because the reportings of landing data is routine with limited potential for effect on the human environment.

The Acting Under Secretary also had determined that it is not a major rule requiring a regulatory impact analysis under Executive Order 12291.

The proposed action will not have a cumulative effect on the economy of $100 million or more nor will it result in a major increase in costs to consumers, industries, government agencies, or geographical regions. No significant adverse impacts are anticipated on competition, employment, investments, productivity, innovation, or competitiveness of U.S.-based enterprises.

The General Counsel of the Department of Commerce has certified to the Small Business Administration that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 603 *et seq.*, because it does not create any new burdens. As a result, a regulatory flexibility analysis was not prepared.

This proposed rule does not contain new collection-of-information requirements subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

The Acting Under Secretary has determined that these rules will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of California, Oregon, and Washington. This determination has been submitted for review to the responsible state agencies under section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

List of Subjects in 50 CFR Part 663

Fisheries, Fishing.

Dated: June 10, 1988.

James E. Douglas, Jr.,

Deputy Assistant Administrator For Fisheries, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR Part 663 is proposed to be amended as follows:

PART 663—[AMENDED]

1. The authority citation for Part 663 continues to read as follows:

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

2. In § 663.4 the existing text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 663.4 Reports.

* * * * *

(b) Any person who is required to do so by the applicable State law must make and/or file any and all reports of groundfish landings containing all data, and in the exact manner, required by the applicable State law.

3. In § 663.7, the period following paragraph (q) is changed to a semicolon and a new paragraph (r) is added to read as follows:

§ 663.7 General prohibitions.

* * * * *

(r) To falsify or fail to make and/or file, any and all reports of groundfish landings, containing all data, and in the exact manner, required by the applicable State law, as specified in § 663.4, provided that person is required to do so by the applicable State law.

[FR Doc. 88–13475 Filed 6–10–88; 3:52 pm]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 53, No. 115
Wednesday, June 15, 1988

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

National Advisory Council on Rural Development; Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463, 86 Stat. 770–776), the Office of the Secretary schedules the fourth meeting of the National Advisory Council on Rural Development:

Name: National Advisory Council on Rural Development, USDA.

Date: July 27–28, 1988.

Time and Place: July 27–28, 1988; Radisson Hotel, 60 Battery Street, Burlington, Vermont. July 27, 7:30 a.m.-5:00 p.m.; July 28, 8:00 a.m.-2:00 p.m.

Type of Meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person below.

Purpose: To advise the Secertary on the rural development needs, goals, objectives, plans, and recommendations of multistate, state, substate and local organizations and jurisdictions. The Council will provide the Secretary with assistance in identifying rural problems and supporting efforts and initiatives in rural development.

Contact Person: Leslie Schuchart, Confidential Assistant, Office of the Under Secretary for Small Community and Rural Development, U.S. Department of Agriculture, Room 219–A, Administration Building, Washington, DC 20250, telephone (202) 447–5371.

Done at Washington, DC, this 9th day of June, 1988.

Roland R. Vautour,

Under Secretary for Small Community and Rural Development.

[FR Doc. 88–13442 Filed 6–14–88; 8:45 am]

BILLING CODE 3410–01–M

Animal and Plant Health Inspection Service

[Docket No. 88–080]

National Animal Damage Control Advisory Committee; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the National Animal Damage Control Advisory Committee.

PLACE, DATES, AND TIME OF MEETING: The meeting will be held in the Madison Room of the National Clarion Hotel, 300 Army/Navy Drive, Arlington, Virginia, 22202, July 12–14, 1988, from 9 a.m. to 5:30 p.m. each day.

FOR FURTHER INFORMATION CONTACT: Gerald J. Fichtner, Deputy Administrator, ADC, APHIS, USDA, Room 1624, South Building, 14th and Independence Avenue SW., Washington, DC 20090–6464, (202) 447–2054.

SUPPLEMENTARY INFORMATION: The purpose of the Committee is to advise the Secretary of Agriculture concerning policies, program issues, and research needed to conduct the Animal Damage Control Program. Committee members will discuss these matters during the meeting, which will be open to the public. Written statements concerning the Animal Damage Control Program can be sent to Gerald J. Fichtner at the address listed in this document. Please refer to Docket Number 88–080 when submitting your comments.

This notice is given in compliance with the Federal Advisory Committee Act (Pub. L. 92–463).

Done in Washington, DC, this 10th day of June, 1988.

Larry B. Slagle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 88–13505 Filed 6–14–88; 8:45 am]

BILLING CODE 3410–34–M

Soil Conservation Service

South Fork of Little River Watershed KY

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is being prepared for the South Fork Little River Watershed, Christian and Todd Counties, Kentucky.

FOR FURTHER INFORMATION CONTACT: Randall W. Giessler, State Conservationist, Soil Conservation Service, 333 Waller Avenue, Lexington, KY 40504, telephone: 606–233–2749.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project may cause significant local, regional, or national impacts on the environment. As a result of these findings, Randall W. Giessler, State Conservationist, has determined that the preparation and review of an environmental impact statement are needed for this project.

The plan calls for a dam to reduce floodwater and sediment damages occurring to about 1,700 acres of cropland and pastureland and to 127 of 137 residential, commercial, and industrial properties. It will also store 5,234 acre feet of muncipal and industrial water for Hopkinsville, Kentucky and sorrounding agricultural and urban areas. The structure will require 640 acres for storing permanent water, 272 added acres for temporary floodwater storage, and 21 acres for the dam and emergency spillway.

Alternatives include a single purpose floodwater retarding structure, a multiple purpose structure with floodwater and municipal and industrial water storage, channel modification, three floodwater retarding structures, a non structural (land treatment) plan, and no action.

A draft Watershed Plan and Environmental Impact Statement is being prepared and circulated for review by agencies and the public. The Soil Conservation Service invites participation and consultation of the agencies and individuals that have special expertise, legal jurisdiction, or

interest in the preparation of the draft Watershed Plan and Environmental Impact Statement.

A scoping meeting was held on June 17, 1981, in Hopkinsville, Kentucky to determine the scope of the proposed action. Public and agency inputs were solicited, and have been taken into account in plan development. However, proper filing of this notice was overlooked. On May 3, 1988, a public meeting was held in Hopkinsville, Kentucky to review a draft of the Watershed Plan and Environmental Impact Statement. Further information on the scoping meeting, public meeting, or proposed actions may be obtained from Randall W. Giessler, State Conservationist, at the above address or telephone 606–233–2749.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials)

Randall W. Giessler,

State Conservationist.

Date: June 7, 1988.

[FR Doc. 88–13479 Filed 6–14–88; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

International Trade Administration

[CA–475–701), (C–475–702]

Postponement of Final Antidumping and Countervailing Duty Determinations; Certain Granite Products from Italy

AGENCY: International Trade Administration, Import Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: This notice informs the public that we have received a request from the respondents in the antidumping duty investigation to postpone the final determination, as permitted under section 735(a)(2)(A) of the Tariff Act of 1930, as amended (the Act), (19 U.S.C. 1673d(a)(2)(A)).

Based on this request, we are postponing our final determinations as to whether sales of certain granite products from Italy have occurred at less than fair value, and whether producers or exporters receive subsidies within the meaning of the countervailing duty law, until not later than July 13, 1988.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Charles E. Wilson, (AD) (202–377–5288), or Barbara Tillman (CVD) (202–377–2438), Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On February 29, 1988, we published a preliminary determination of sales of less than fair value with respect to this merchandise (53 FR 6021). This notice stated that if the investigation proceeded normally, we would make our final detemination by May 9, 1988.

On March 2, 1988, the respondents requested a postponement of the final detemination in the antidumping duty investigation until not later than June 20, 1988, the 112th day after publication of our preliminary detemination, pursuant to section 735(a)(2)(A) of the Act, (19 U.S.C. 1673d(a)(2)(A)). These repondents account for a significant proportion of exports of the merchandise to the United States. If exporters who account for a significant proportion of exports of the merchandise under investigation request an extension after an affirmative preliminary determination, we are required, absent compelling reasons to the contrary, to grant the request. Accordingly, we postponed the date of the final antidumping duty determination until not later than June 20, 1988. In addition on January 28, 1988, we granted the request of petitioner, the Ad Hoc Granite Trade Group, to extend the deadline date for the final countervailing duty detemination to correspondent to the date of the final antidumping duty determination of the product, pursuant to section 705(a)(1) of the Act, (19 U.S.C. 1671(a)(1)) (53 FR 2521). Accordingly, we also postpond the date of the final countervailing duty determination until not later than June 20, 1988. We published notice of these postponements on March 15, 1988 (53 FR 8479).

On June 2, 1988, the respondents requested another postponement of the final determination in the antidumping duty investigation until not later than the 135th day after the date upon which the Department published notice of its preliminary determination in this case, pursuant to section 735(a)(2)(A) of the Act, (19 U.S.C. 1673d(a)(2)(A)). Accordingly, we are postponing the date of the final antidumping duty detemination and final countervailing duty determination until not later than July 13, 1988.

The U.S. International Trade Commission is being advised of these postponements, in accordance with sections 705(d) and 735(d) of the Act. This notice is published pursuant to sections 705(d) and 735(d) of the Act.

Dated: June 9, 1988.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 88–13495 Filed 6–14–88; 8:45 am]

BILLING CODE 3510–DS–M

[A–588–404]

Fabric Expanded Neoprene Laminate From Japan; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: International Trade Administration/Import Administration Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review.

SUMMARY: In response to requests by one respondent and the petitioner, the Department of Commerce has conducted an administrative review of the antidumping duty order on fabric expanded neopreme laminate from Japan. The review covers two manufacturers of this merchandise exported to the United States, and the period July 1, 1986 through June 30, 1987. The review indicates the existence of dumping margins during the period.

Where company-supplied information was inadequate, the Department used the best information available. As a result of the review, the Department has preliminarily determined to assess antidumping duties equal to the calculated differences between United States price and foreign market value. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: June 15, 1988.

FOR FURTHER INFORMATION CONTACT: Marquita Steadman or Phyllis Derrick, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377–2923.

SUPPLEMENTARY INFORMATION:

Background

On September 28, 1987, the Department of Commerce ("the Department") published in the **Federal Register** (52 FR 36295) the final results of its last administrative review of the antidumping duty order on fabric expanded neopreme laminate ("FENL") from Japan (50 FR 29466, July 19, 1985). In accordance with § 353.53a(a) of the Commerce Regulations, we received requests for review from the petitioner and one respondent. We published a

notice of initiation on August 19, 1987 (52 FR 31056). The Department has now conducted that administrative review in accordance with section 751 of the Tariff Act of 1930 ("the Tariff Act").

Scope of the Review

Imports covered by the review are shipments of FENL currently classifiable under item numbers 355.81, 355.82, 359.50 and 359.60 of the Tairff Schedules of the United States Annotated and under item numbers 5906.91.20, 5906.99.20, 5911.10.20, 5906.91.25, 5906.99.25 and 5602.10.00 of the Harmonized System.

The review covers two manufacturers of Japanese FENL, and the period July 1, 1986 through June 30, 1987.

Yamamoto provided an untimely and inadequate response to the Department's questionnaire for this review period. Yamamoto did not submit its response in accordance with the format outlined in the Department's questionnaire. The firm failed to submit home market data or computer tapes. Furthermore, invoice numbers, dates of sale, payment terms, and customer information were missing. The Department consequently used the best information available for assessment and deposit purposes which is the margin from the fair value investigation.

United States Price

In calculating United States price, the Department used purchase price as defined in section 772 of the Tariff Act. Purchase price was based on the packed f.o.b. or c&f price to unrelated purchasers in the United States. Where applicable, we made adjustments for brokerage expenses and foreign inland freight. No other adjustments were claimed or allowed.

Foreign Market Value

In calculating foreign market value the Department used home market price, as defined in section 773 of the Tariff Act. Sufficient quantities of such or similar merchandise were sold in the home market to provide a basis for comparison.

Home market price was based on the packed, delivered and ex-factory price to unrelated purchasers in the home market, with adjustments, where applicable, for inland freight, brokerage/handling charges, differences in the physical characteristics of the merchandise, and differences in the cost of credit and packing. No other adjustments were claimed or allowed.

Preliminary Results of Review

As a result of our comparison of United States price to foreign market value, we preliminarily determine that the following margins exist:

Manufacturer	Time period	Margin (percent)
Heiwa Rubber Industries.	7/1/86-6/30/87	1.57
Yamamoto Corporation.	7/1/86-6/30/87	3.09

Interested parties may request disclosure and/or an administrative protective order within 5 days of the date of publication and may request a hearing within 8 days of the date of publication. Any hearing, if requested, will be held 35 days after the date of publication, or the first workday thereafter. Prehearing briefs and/or written comments from interested parties may be submitted not later than 25 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues in those comments, may be filed not later than 32 days after the date of publication. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

Further, as provided for by section 751(a)(1) of the Tariff Act, a cash deposit of estimated antidumping duties based on the above margins shall be required for these firms. For any future entries of this merchandise from a new exporter, not covered in this or prior reviews, whose first shipments occured after June 30, 1987, and who is unrelated to any reviewed firm, a cash deposit of 1.57 percent shall be required. These deposit requirements are effective for all shipments of fabric expanded neoprene laminate entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 353.53a of the Commerce Regulations (19 CFR 353.53a).

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

Dated: June 8, 1988.

[FR Doc. 88-13498 Filed 6-14-88; 8:45 am]

BILLING CODE 3510-05-M

Short-Supply Review on Certain Silicon Steel; Request for Comments

AGENCY: Import Administration/International Trade Administration, Commerce.

ACTION: Notice and request for comments.

SUMMARY: The Department of Commerce hereby announces its review of a request for a short-supply determination under Paragraph 8 of the U.S.-Japan Arrangement Concerning Trade in Certain Steel Products, with respect to certain silicon steel.

DATE: Comments must be submitted on or before June 27, 1988.

ADDRESS: Send all comments to Nicholas C. Tolerico, Director, Office of Agreements Compliance, Import Administration, U.S. Department of Commerce, Room 7866, 14th Street and Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Richard O. Weible, Office of Agreements Compliance, Import Administration, U.S. Department of Commerce, Room 7866, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone (202) 377-0159 or telefax (202) 377-1388.

SUPPLEMENTARY INFORMATION: Paragraph 8 of the U.S.-Japan Arrangement Concerning Trade in Certain Steel Products provides that if the U.S. "* * * determines that because of abnormal supply or demand factors, the United States steel industry will be unable to meet demand in the United States of America for a particular category or sub-category (including substantial objective evidence such as allocation, extended delivery periods, or other relevant factors), an additional tonnage shall be allowed for such category or sub-category * * *"

We have received a short-supply request for cold-rolled grain-oriented electrical silicon steel, high permeability, domain refined, in coils, 0.009 inch in thickness and 31 to 40 inches in width.

Any party interested in commenting on this request should send written comments as soon as possible, and no later than June 27, 1988. Comments should focus on the economic factors involved in granting or denying this request.

Commerce will maintain this request and all comments in a public file. Anyone submitting business proprietary information should clearly so label the business proprietary portion of the submission and also provide a non-

proprietary submission which can be placed in the public file. The public file will be maintained in the Central Records Unit, Room B–099, Import Administration, U.S. Department of Commerce at the above address.

Joseph A. Spetrini,
Acting Assistant Secretary for Import Administration.

[FR Doc. 88–13497 Filed 6–14–88; 8:45 am]
BILLING CODE 3510–05–M

National Oceanic and Atmospheric Administration

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The North Pacific Fishery Management Council will meet June 21–24, 1988 at the Sheraton Hotel in Anchorage, AK. The Council will review proposed amendments to the groundfish FMPs for the Gulf of Alaska and Bering Sea and Aleutian Islands, submitting those they approve to the Secretary of Commerce. The Council will review revised plans for crab and salmon and its joint venture policy. The Council's Future of Groundfish committee will report their recommendations, as will the Maritime Support Group that has been studying ways to encourage the development of the U.S. service support industry.

The Council is scheduled to review a report on alternative approaches, including limited access, to manage the longline sablefish fishery. They will adopt a preferred management alternative for further analysis and public review. The Council also will consider alternative means to determine the extent to which various participants may accrue credit in the groundfish fisheries should access limitation be implemented in the future. The Council will hear recommendations on how pollock bycatch should be treated in the joint venture fisheries for other target species, and the standard reports on NMFS management, Coast Guard, ADF&G, and joint ventures.

In addition a special session has been scheduled at 1:00 p.m., Sunday, June 19, 1988, at the Sheraton Hotel in Anchorage. The Council will hear the report and recommendations of their Future of Groundfish Fisheries Committee regarding future management of Alaska's groundfish fisheries. The Council will not take formal action until later in the meeting week.

The Council's Scientific and Statistical Committee and Advisory Panel will convene at 10:00 a.m., June 20, at the Sheraton and reconvene at 1:00 p.m. on June 21, and continue through June 24.

Other plan team and workgroup meetings may be held on short notice during the week. The Council will meet in executive session at least once to review ongoing litigation, personnel, and foreign affairs. All other meetings are open to the public.

Date: June 10, 1988.

Richard H. Schaefer,
Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 88–13463 Filed 6–14–88; 8:45 am]
BILLING CODE 3510–22–M

Permits; Pacific Coast Groundfish Fishery; Experimental Fishing

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of receipt of an experimental fishing permit application and request for comments.

SUMMARY: This notice acknowledges receipt of an application for an experimental fishing permit (EFP) to harvest soupfin sharks and other shark species with gill nets north of 38° N. latitude in the exclusive economic zone (EEZ) off the coasts of Oregon and Washington. If granted, this permit would allow no more than 90 domestic vessels to harvest groundfish species with fishing gear which otherwise would be prohibited by Federal regulations.

DATE: Comments on this application must be received by July 1, 1988.

ADDRESS: Send comments to Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NW., Seattle, WA 98115.

FOR FURTHER INFORMATION CONTACT: William Robinson, 206–526–6140.

SUPPLEMENTARY INFORMATION: The Pacific Coast Groundfish Fishery Management Plan (FMP) and implementing regulations at 50 CFR Part 663 specify that EFPs may be issued to authorize fishing which is otherwise prohibited by the FMP and regulations. The procedures for issuing EFPs appear in § 663.10.

An EFP application from the States of Oregon and Washington for the harvest of groundfish using gill nets in the EEZ off their coasts was received on May 16, 1988. Current groundfish regulations at § 663.26 do not authorize the use of gill nets north of 38° N. latitude to harvest groundfish. Oregon and Washington will be conducting an experimental fishery in 1988 on thresher shark, a species that is not managed under the FMP, and request that the vessels issued permits by the States also be issued a Federal EFP to authorize the retention and marketing of Federally-managed sharks (soupfin, leopard, and spiny dogfish sharks) taken incidentially in the State experimental drift gill net fishery for thresher sharks.

Washington, Oregon, and California are developing an interstate fishery management plan for thresher shark under the Inter-jurisdictional Fisheries Act of 1986 (IJFA). In addition to obtaining information on thresher shark for development of this plan, the States need information on incidental catch of other marine species in the thresher shark fishery. To obtain such information on groundfish, a Federal EFP is necessary. The EFP allows for retention and marketing of an undertermined number of Federally-managed shark, especially soupfin shark (*Galeorhinus galeus*), taken incidentially in the thresher shark fishery so that information can be collected on the size, sex, occurrence, and marketability of these incidentially-taken sharks. This information will be used to evaluate the regulations which have the effect of prohibiting the use of drift gill nets to harvest groundfish species.

The States anticipate that 20 to no more than 90 domestic vessels will participate in the State experimental drift gill net fishery. In past years, no more than 30 to 37 vessels actually participated, although over 90 vessels expressed an interest each year. The States anticipate that no more than the 20 vessels that participated in the fishery last year will be involved again this year. The States request that an EFP be issued to each vessel that obtains and validates an Oregon or Washington experimental permit in 1988. The State permits restrict each vessel to use of one drift gill net having a total length of not more than 1000 fathoms with mesh sizes of 16 inches or greater. The experimental fishery will be restricted to the EEZ off Washington and Oregon in waters west of 20 nautical miles from shore from July 15 to October 31, 1988. The States have established these

offshore and seasonal restrictions to alleviate concerns for potential marine mammal or seabird involvement with the nets. The States will require the vessels to carry observers if requested, and have received funding under the IJFA for approximately 12 work-months of observer coverage.

Federal EFPs for this purpose have been issued in the past, but none of the permittees actually conducted any experimental fishing until 1987. Eighty-five vessels were issued EFPs for this fishery in 1987. However, only 29 of the vessels actually participated in the fishery, making 84 landings from July 1 to October 15, 1987. Logbook records show that 987 thresher shark and 253 soupfin shark were taken. No leopard or spiny dogfish shark were harvested.

Copies of the EFP application are being forwarded to the Pacific Fishery Management Council, the U.S. Coast Guard, and the fishery management agencies of Washington, Oregon, California and Idaho along with information concerning the current utilization of the species, the citation of regulations which would prohibit the proposed fishery, and relevant biological information.

The application will be discussed at the July 12–14, 1988, public meeting of the Pacific Fishery Management Council in Portland, Oregon. The NMFS Regional Director's decision to approve or deny issuance of an EFP will be based on a number of considerations including recommendations made by the Council and comments received from the public. A copy of the application is available for review at the address above.

(16 U.S.C. 1801 *et seq.*)

Dated: June 9, 1988.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 88-13462 Filed 6-14-88; 8:45 am]

BILLING CODE 3510-22-M

National Technical Information Service

Intent To Grant Exclusive Patent License; Bristol-Meyers/Integra Institute

The National Technical Information Service (NTIS), U.S. Department of Commerce, intends to grant to Bristol-Meyers/Integra Institue, having a place of business in New York, NY, an exclusive right in the United States and foreign countries to practice the invention embodied in U.S. Patent Application Serial Number 7-048, 148, "Small Peptides Which Inhibit Binding to T-4 Receptors and Act as Immunogens", to develop peptide T as a retroviral vaccine. The patent rights in this invention will be assigned to the United States of America, as represented by the Secretary of Commerce.

The intended exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The intended license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the intended license would not serve the public interest.

Inquiries, comments and other materials relating to the proposed license must be submitted to Papan Devnani, Office of Federal Patent Licensing, NTIS, Box 1423, Springfield, VA 22151.

Douglas J. Campion,

Office of Federal Patent Licensing, National Technical Information Service, U.S. Department of Commerce.

[FR Doc. 88-13480 Filed 6-14-88; 8:45 am]

BILLING CODE 3510-04-M

Intent To Grant Exclusive Patent License; Cetus Corp.

The National Technical Information Service (NTIS), U.S. Department of Commerce, intends to grant to Cetus Corporation, having a place of business in Emeryville, CA, an exclusive right in the United States and foreign countries to practice the invention embodied in U.S. Patent Application Serial Number 7-094,618, "rCSF-1 Facilitated Detection Isolation and Propagation of Monocyte-Tropic HIV in Human Monocytes". The patent rights in this invention have been assigned to the United States of America, as represented by the Secretary of Commerce.

The intended exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The intended license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the intended license would not serve the public interest.

Inquiries, comments and other materials relating to the proposed license must be submitted to Papan Devnani, Office of Federal Patent Licensing, NTIS, Box 1423, Springfield, VA 22151.

Douglas J. Campion,

Office of Federal Patent Licensing, National Technical Information Service, U.S. Department of Commerce.

[FR Doc. 88-13481 Filed 6-14-88; 8:45 am]

BILLING CODE 3510-04-M

DEPARTMENT OF DEFENSE

Office of the Secretary

DOD Advisory Group of Electron Devices; Advisory Committee Meeting; Closed

SUMMARY: The DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATE: The meeting will be held at 0900, Thursday, 7 July 1988.

ADDRESS: The meeting will be held at Palisades Institute for Research Services, Inc., 2011 Crystal Drive, Suite 307, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: David Slater, AGED Secretariat, 201 Varick Street, New York, 10014.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Acquisition, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs 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 § 10(d) of Pub. L. No. 92-463, as amended, (5 U.S.C. App. II 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

June 9, 1988.

[FR Doc. 88-13446 Filed 6-14-88; 8:45 am]

BILLING CODE 3810-01-M

DOD Advisory Group On Electron Devices; Advisory Committee Meeting; Closed

SUMMARY: Working Group B (Microelectronics) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATE: The meeting will be held at 0900, Thursday and Friday, 23–24 June 1988.

ADDRESS: The meeting will be held at the National Bureau of Standards, 325 Broadway, Room 1107, Boulder, Colorado 80303.

FOR FURTHER INFORMATION CONTACT: Becky Terry, AGED Secretariat, 2011 Crystal Drive, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Acquisition, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The Microelectronics area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with § 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App. II 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer Department of Defense.

June 9, 1988.

[FR Doc. 88–13447 Filed 6–14–88; 8:45 am]

BILLING CODE 3810–01–M

Joint Staff; National Defense University Board of Visitors Meeting

AGENCY: National Defense University, Department of Defense.

ACTION: Notice of meeting.

SUMMARY: The President, National Defense University has scheduled a meeting of the Board of Visitors.

DATE: The meeting will be held between 0830–1200 and 1330–1600, July 8, 1988.

ADDRESS: The meeting will be held in the Hill Conference Center of Theodore Roosevelt Hall (Building 61), Fort Lesley J. McNair, Washington, DC 20319–6000.

FOR FURTHER INFORMATION CONTACT: The Director, University Plans and Programs, National Defense University, Fort Lesley J. McNair, Washington, DC 20319–6000, phone 475–1145, to reserve space.

SUPPLEMENTARY INFORMATION: The agenda will include present and future educational and research plans for the National Defense University and its components. The meeting is open to the public, but the limited space available for observers will be allocated on a first-come, first-served basis.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

June 9, 1988.

[FR Doc. 88–13448 Filed 6–14–88; 8:45 am]

BILLING CODE 3810–01–M

Department of the Army

Board of Visitors, United States Military Academy; Open Meeting

In accordance with section 10(a)(20) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following meeting.

Name of Committee: Board of Visitors, United States Military Academy.

Dates of Meeting: 14–15 July 1988.

Place of Meeting: West Point, New York.

Start Time of Meeting: 9:00 a.m., 14 July 1988.

PROPOSED AGENDA: Briefings on the Standards of Admissions; Fourth Class System and Disciplinary System; and Changes in the Military Development Program. The Board will also receive updates on the following: the Academy Schedule; Fellowship in Leader Development; Career Impact of USMA Assignment; DA Report on the West Point Child Care Center and Cadet Pay.

All proceedings are open. For further information, contact Colonel Larry Donnithorne, United States Military Academy, West Point, New York 10996–5000, (914) 938–4723.

For the Board of Visitors.

Larry R. Donnithorne,

COL, EN, Executive Secretary, USMA Board of Visitors.

[FR Doc. 88–13484 Filed 6–14–88; 8:45 am]

BILLING CODE 3710–08–M

Corps of Engineers, Department of the Army

Availability of a Public Domain Data Base of Waterborne Commodity Movement Data

AGENCY: Corps of Engineers, Department of the Army, DOD.

ACTION: Notice.

SUMMARY: This notice announces the U.S. Army Corps of Engineers' Water Resource Support Center, Waterborne Commerce Statistics Center release of a public domain data base of waterborne commodity movement data.

EFFECTIVE DATE: June 15, 1988.

ADDRESS: U.S. Army Corps of Engineers, Waterborne Commerce Statistics Center, P.O. Box 61280, New Orleans, LA 70161–1280. (For further information, Contact: David Penick, 504–862–1470).

SUPPLEMENTARY INFORMATION: The U.S. Army Corps of Engineers' Water Resource Support Center, Waterborne Commerce Statistics Center, will release a public domain data base of waterborne commodity movement data. The Corps receives detailed waterborne commodity movement information as required by the 1922 Rivers and Harbors Act from vessel operating companies but is prohibited from releasing the data to the public unless the data are aggregated such that the individual company moves cannot be identified. The Corps will continue to protect the confidentiality of the data provided by individual companies and will simultaneously provide the general public with useful origin/destination (O/D) commodity flow data which heretofore have not been available. The geographical entities used in this data base are shown below:

PUBLIC DOMAIN DATA BASE REACH DEFINITIONS

Reach Name	Description	Included
1. Upper Mississippi River.	Minneapolis, MN, to mouth of Illinois River.	. . . Upper Mississippi River.
2. Lower Upper Mississippi River.	Mouth of Illinois River to mouth of Ohio River (Cairo, IL).	. . . Lower Upper Mississippi River (Illinois River to Missouri River). . . . Middle Mississippi River (Missouri River to Ohio River including Kaskaskia River).

PUBLIC DOMAIN DATA BASE REACH DEFINITIONS—Continued

Reach Name	Description	Included
3. Lower Mississippi River: Cairo to Baton Rouge.	Mouth of Ohio River (Cairo, IL), to Baton Rouge, LA.	. . . Lower Middle Mississippi River (Ohio River to White River) including Yazoo River. . . . Upper Lower Mississippi River (White River to Old River). . . . Lower Mississippi River (Old River to Baton Rouge).
4. Lower Mississippi River: Baton Rouge to Gulf.	Baton Rouge, LA (including port) to Gulf and other channels and rivers.	. . . Mississippi River (Baton Rouge to New Orleans). . . . Mississippi River (New Orleans to Gulf). . . . Ouachita—Black and Red Rivers. . . . Old and Atchafalaya Rivers (from Mississippi River to Gulf). . . . Baton Rouge to Morgan City, LA, Bypass.
5. Illinois Waterway.	Chicago, IL (Chicago River Lock) to mouth of Illinois River.	. . . Illinois Waterway.
6. Missouri River.	Sioux City, IA to mouth at Mississippi River.	. . . Missouri River.
7. Ohio River System.	Heads of navigation to mouth.	. . . Upper Ohio River (confluence of Monongahela and Allegheny at Pittsburgh to Kanawha River). . . . Middle Ohio River (Kanawha River to Kentucky River). . . . Lower Ohio River—Three (Kentucky River to Green River). . . . Lower Ohio River—Two (Green River to Tennessee River). . . . Lower Ohio River—One (Tennessee River to mouth). . . . Monongahela River. . . . Allegheny River. . . . Kanawha River. . . . Kentucky River. . . . Green and Barren Rivers. . . . Cumberland River.

PUBLIC DOMAIN DATA BASE REACH DEFINITIONS—Continued

Reach Name	Description	Included
8. Tennessee River.	Head of navigation above Knoxville, TN to mouth.	. . . Upper Tennessee River and Clinch River (head of navigation to junction with Tennessee-Tombigbee Waterway). . . . Lower Tennessee River (from junction with Tennessee-Tombigbee Waterway to Ohio River).
9. Arkansas River.	Catoosa, OK (near Tulsa) to mouth.	. . . Arkansas River (including Verdigris, White and Black Rivers).
10. Gulf Coast-West.	New Orleans to Brownsville, TX.	. . . GIWW West—One (from New Orleans, LA to Calcasieu River). . . . GIWW West—Two (Calcasieu River to Corpus Christi, TX). . . . GIWW West—Three (Corpus Christi, TX to Brownsville, TX). . . . Houston Ship Channel.
11. Gulf Coast-East.	New Orleans to Key West, FL.	. . . GIWW East—One (from New Orleans, LA to Mobile Bay including Mississippi River Gulf Outlet and Pearl River). . . . GIWW East—Two (Mobile Bay to St. Marks, FL). . . . Florida Gulf Coast (St. Marks, and Flint Rivers. . . . Apalachicola, Chattahoochee, and Flint Rivers.
12. Mobile River and Tributaries.	Head of navigation to mouth.	. . . Black Warrior-Mobile Harbor (Black Warrior River—head of navigation to mouth, Tombigbee River—mouth of Black Warrior River to confluence with Alabama River, Mobile River to Mobile Bay, Mobile Harbor). . . . Alabama-Coosa Rivers. . . . Tennessee-Tombigbee Waterway.
13. South Atlantic Coast.	Key West, FL, to North Carolina/ Virginia border.	. . . Florida-Georgia coast. . . . Carolinas coast.

PUBLIC DOMAIN DATA BASE REACH DEFINITIONS—Continued

Reach Name	Description	Included
14. Middle Atlantic Coast.	North Carolina/ Virginia border to New York/ Connecticut border (includes Hudson River from Waterford, NY to mouth).	. . . Chesapeake and Delaware Bays. . . . New Jersey/ New York coasts (includes Hudson River to Waterford, NY).
15. North Atlantic Coast.	New York/ Connecticut border to Canadian border.	. . . North Atlantic Coast.
16. Great Lakes System (U.S.).	Great Lakes, St. Lawrence Seaway, New York State waterways, and connecting channels.	. . . New York State waterways. . . . Lake Ontario and St. Lawrence Seaway. . . . Lake Erie. . . . Lake Huron. . . . Lake Michigan. . . . Lake Superior.
17. Washington/ Oregon Coast.	Puget Sound to California/ Oregon border.	. . . Puget Sound. . . . Oregon/ Washington coast.
18. Columbia-Snake Waterway/ Willamette River.	Lewiston, ID, to mouth.	. . . Upper Columbia-Snake Waterway (Lewiston, ID to Bonneville Lock and Dam). . . . Lower Columbia-Snake Waterway (from Bonneville Lock to mouth)/Willamette River.
19. California Coast.	California/ Oregon border to Mexican border.	. . . Northern California (Oregon/California border to San Francisco Bay). . . . San Francisco Bay area, Sacramento River, and San Joaquin River. . . . Central/South California (from San Francisco Bay to Mexican border).
20. Alaska		. . . Southeast Alaska (panhandle). . . . South Central Alaska coast. . . . West and north coasts of Alaska (including Aleutians).
21. Hawaii and Pacific Territories.		. . . Hawaii and Pacific Territories (includes Hawaii, American Samoa, Guam, and Commonwealth of Northern Mariana Islands).

PUBLIC DOMAIN DATA BASE REACH DEFINITIONS—Continued

Reach Name	Description	Included
22. Caribbean.	Puerto Rico and Virgin Islands.	. . . Caribbean (Puerto Rico and Virgin Islands). . . . Rest of World (not included as a Reach).
23. Great Lakes (Canada).		. . . Lake Ontario and St. Lawrence Seaway (Canada). . . . Lake Erie (Canada) including Welland Canal. . . . Lake Huron (Canada). . . . Lake Superior (Canada).
24. Rest of world (overseas).		
25. Trans-Shipment Area.		
26. Other		

The confidentiality of individual company data will be protected by first aggregating commodities to higher level generic commodity groups. These commodity groups are defined below:

PDDB comm groups	Description
0100	Farm and Tobacco Products.
0900	Fresh Fish and Other Marine Products.
1000	Metallic Ores.
1100	Coal and Lignite.
1300	Crude Petroleum.
1400	Non-Metallic Minerals, except Fuels.
2000	Food and Kindred Products.
2400	Lumber, Wood and Forest Products, Including Furniture.
2600	Pulp, Paper and Allied Products.
2800	Chemicals and Fertilizers.
2900	Petroleum Products.
3200	Stone Clay, Glass and Concrete Products.
3300	Metal Products and Scrap.
4000	Other Waste and Scrap.
4100	Other.

Secondly, it will be required that there exist three or more vessel operating companies moving the commodity group from the area of origin to the area of destination.

Thirdly, the data base will be analyzed to determine if there exists any one operator carrying more than 80% of any one commodity group between an area of origin and an area of destination. Should this occur the data for that particular O/D pair and commodity group will be changed to the commodity group 4100–Other.

The public domain data base will be provided in three distinct presentations. The first will group all commodity movements by unique reach-to-reach combinations sorted by origin reach.

EXAMPLE: ILLINOIS WATERWAY TO MISSOURI RIVER

Year	[1] Origin reach	Dest reach	Comm	Tons (1000)	
85	5	6	2000	7,000	Food & Kindred Products.
85	5	6	2800	1,300	Chemicals & Fertilizers.
85	5	6	2900	17,000	Petroleum Products.
85	5	6	3330	1,000	Metal Products & Scrap.

[1] sort key.

The second presentation will be similar to the first except that the data will be sorted by destination reach. This will simplify a search for information on the receiving side.

The third presentation will group all unique reach-to-reach combinations by commodity group sorted by origin reach within commodity group.

EXAMPLE: FARM AND TOBACCO PRODUCTS

Year	[1] Origin reach	Dest reach	Comm	Tons (1000)	
85	1	4	0100	75,000	Upper Miss. to Lower Miss.
85	1	7	0100	14,000	Upper Miss. to Ohio River System.
85	4	8	0100	10,000	Lower Miss. to Tenn. River.

[1] sort key.

As shown in these examples each data record will contain the calendar year that the movement occurred, the origin reach, the destination reach, commodity code and tonnage. This same data will be made available on magnetic tape or floppy disk.

Availability: This public domain O/D data for calendar year 1985 is available in printed form in all three presentations at a cost of $15.00. The cost of the data in ASCII text on floppy disk is an additional $35.00.

Calendar year 1986 public domain O/D data will be available in February 1988.

Requests should be mailed to: Waterborne Commerce Statistics Center, P.O. Box 61280, New Orleans, LA 70161–1280.

Checks or money orders should accompany the requests and be made payable to FAO, USAED, New Orleans.

Richard A. Rothblum,

Colonel, CE Commander/Director, Water Resources Support Center.

[FR Doc. 88–13483 Filed 6–14–88; 8:45 am]

BILLING CODE 3710–08–M

DELAWARE RIVER BASIN COMMISSION

Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, June 22, 1988 beginning at 1:00 p.m. in Anita's Room of the White Beauty View Resort on Lake Wallenpaupack in Greentown, Pennsylvania. The hearing will be part of the Commission's regular business meeting which is open to the public.

An informal pre-meeting conference among the Commissioners and staff will be open for public observation at about 11:00 a.m. at the same location and is scheduled to include a presentation on the water management Task Force recommendations of the Economic Development Council of Northeastern Pennsylvania.

The subjects of the hearing will be as follows:

Applications for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact

1. *Longwood Gardens D–87–53.* An application to modify a 0.1 million gallons per day (mgd) sewage treatment plant that serves Longwood Gardens and several homes in East Marlborough Township, Chester County, Pennsylvania. The applicant proposes to improve existing secondary treatment effluent by the spray irrigation process on 40 acres of land west of Conservatory Road. Only during prolonged or heavy rainfall and extremely cold weather will effluent be discharged through the existing outfall to an unnamed tributary of the East Branch Red Clay Creek. No expansion of treatment plant capacity is required.

2. *East Marlborough Township D–87–82 CP.* An application to construct a sewage treatment plant to serve some existing and proposed homes in Kennett and East Marlborough Townships, Chester County, Pennsylvania. The proposed sequencing batch reactor facility is designed to provide high quality secondary treatment of an average flow of 0.15 mgd and a peak flow of 0.375 mgd. Treatment plant effluent will be discharged to an unnamed tributary of the East Branch Red Clay Creek.

3. *County of Bucks D–87–99 CP.* An application for approval of a ground water withdrawal project to supply up to 3.0 million gallons (mg)/30 days of water to Neshaminy Manor Complex from new Well No. 5, and to retain the existing withdrawal limit from all wells (Nos. 1–5) of 4.5 mg/30 days. Well No. 5 is located about 310 feet north northwest of the intersection of Kelly Road and Route 611, in Doyletownship, Bucks County, and is located in the Southeastern Pennsylvania Ground Water Protected Area.

4. *American Olean Tile Company D–88–16.* An application to upgrade an industrial process wastewater treatment plant located in Lansdale Borough, Montgomery County, Pennsylvania. The existing tertiary treatment plant processes an average flow of 0.08 mgd. The proposed upgrade is designed to treat up to 0.2 mgd which will accommodate future process expansion. Treatment plant effluent will be discharged to an unnamed tributary of West Branch Neshaminy Creek.

5. *City of Harrington D–88–27 CP.* An application for approval of a ground water withdrawal project to supply up to 17 mg/30 days of water to the applicant's distribution system from existing Well Nos. 1, 2 and 3, which have not previously been included in the Comprehensive Plan. The project is located in the City of Harrington, Kent County, Delaware.

6. *Shohol Falls Trails End Property Owners Association D–88–32.* An application to construct a new sewage treatment plant (STP) designed to provide tertiary treatment of an average flow of 0.205 mgd from 1,850 campground lots located in Shohola Township, Pike County, Pennsylvania. The existing 0.075 mgd plant will be abandoned upon completion of the proposed STP. The existing physical/chemical process will be replaced by an innovative process that features biological treatment via the Intermittent Cycle Extended Aeration System. Plant effluent will be discharged to an unnamed tributary of Shohola Creek, approximately 100 feet downstream from the existing outfall.

Documents relating to these items may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact David B. Everett concerning docket-related questions. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing.

Susan M. Weisman,

Secretary.

June 7, 1988.

[FR Doc. 88–13482 Filed 6–14–88; 8:45 am]

BILLING CODE 6360–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP88–416–000 et al.]

Southern Natural Gas Company et al.; Natural Gas Certificate Filings

June 10, 1988.

Take notice that the following filings have been made with the Commission:

1. Southern Natural Gas Company

[Docket No. CP88–416–000]

Take notice that on May 26, 1988, Southern Natural Gas Company (Southern), Post Office Box 2563, Birmingham, Alabama 35202–2563, filed in Docket No. CP88–416–000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to construct and operate a delivery point under the authorization issued to Southern in Docket No. CP82–406–000 for a new point of delivery to the city of Dublin, Georgia (Dublin), all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Southern states that it provides natural gas service to Dublin at two points of delivery in Baldwin and Laurens County, Georgia, as specified in the Service Agreement between Southern and Dublin dated September 23, 1987. Southern proposes to install and operate an additional point of delivery (Dublin No. 3) in Laurens County. Southern states that Dublin has informed Southern that the additional point of delivery would be used to provide a natural gas service to the Southeast Paper Company.

In order to implement the new point of delivery, Southern states that it plans to construct, install and operate a regulatory station, a meter station and all appurtenant facilities. The total estimated cost of the proposed facilities is $184,580.00. Dublin has agreed to reimburse Southern for the total actual cost of the proposed construction and installation, it is stated.

Southern states that the total contract demand to be delivered to Dublin after the proposed installation would not exceed the total contract demand authorized prior to the implementation of the new point of delivery. In addition, Southern indicates that the activities are not prohibited by any existing tariff of Southern. Southern proposes to provide Dublin No. 3 with a contract delivery pressure of 400 psig.

Southern also states that it has sufficient capacity to accomplish the deliveries proposed by the installation and operation of the new delivery point without detriment to Southern's other customers, and that construction and operation of the facilities would not result in any termination of service and would have a de minimus impact on Southern's peak day and annual deliveries.

Comment date: July 25, 1988, in accordance with Standard Paragraph G at the end of this notice.

2. CNG Transmission Corporation

[Docket No. CP88-422-000]

Take notice that on May 27, 1988, CNG Transmission Corporation (formerly, Consolidated Gas Transmission Corporation), 445 West Main Street, Clarksburg, West Virginia 26301 (referred to herein as "CNG"), filed in Docket No. CP88-422-000 a request pursuant to § 157.205 and 157.212(a) of the Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212(a)) to add one additional delivery point to deliver sales volumes for the account of Rochester Gas & Electric Corporation ("RG&E"), its existing jurisdictional customer, under CNG's "blanket certificate" issued in Docket No. CP82-537-000 pursuant to section 7 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.

CNG proposes to add the new delivery point for RG&E's account, to be known as the Caledonia-Barks Road Connection, at the existing interconnection between CNG and National Fuel Gas Supply Corporation (National Fuel) in the Town of Caledonia, Livingston County, New York. National Fuel states it would then transport the volumes for RG&E's account to an existing interconnection between National Fuel and RG&E in the Village of Avon, Monroe County, New York. The gas to be delivered at this point would be from CNG's own system supply, with estimated deliveries of approximately 100,000 dekatherms of natural gas per year.

CNG states that the proposed delivery point would provide RG&E with additional supplies needed for new residential and commercial demand in or near Avon, New York, which cannot be delivered at existing delivery points due to capacity constraints. Thus, the new delivery point would enable CNG to maintain a continuing, dependable supply of gas to RG&E, it is stated. In addition, CNG states that the addition of this delivery point is not prohibited by its tariff, and that RG&E has advised CNG that the volumes to be purchased at this point are for its system supply.

Comment date: July 25, 1988, in accordance with Standard Paragraph G at the end of this notice.

3. Distrigas of Massachusetts Corporation

[Docket Nos. CP88-160-003 and CP88-161-003]

Distrigas of Massachusetts Corporation ("DOMAC") on June 6, 1988,[1] filed a section 7(c) request for an amendment extending the term of the certificates issued on March 21, 1988 in the above-referenced dockets to permit DOMAC to provide the certificated interruptible terminalling service and interruptible sales for resale service our LNG imported by Distrigas Corporation ("Distrigas") beyond May 15, 1988. Specifically, DOMAC requests an extension of the terms of the certificates until the expiration of authority granted by the Economic Regulatory Administration ("ERA") related to imports under Amendment No. 2 to the 1976 Agreement between Distrigas and Sonatrach.

It is stated that on March 21, 1988, DOMAC was granted authority to render Interruptible Resale Service ("IRS") and Interruptible Terminalling Service ("ITS"). It is explained that this authority was directly linked to ERA Order No. 228, issued March 4, 1988, in Docket No. 88-05-LNG, which authorized LNG imports by Distrigas under Amendment No. 2 to its 1976 Agreement with Sonatrach. It is stated that the Order allowed LNG to be imported through May 15, 1988. In the order, the Commission determined that the interruptible resales and interruptible terminalling service authority granted to DOMAC should be coextensive with the ERA import authority granted in ERA Order No. 228.

Comment date: July 1, 1988, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

4. Trunkline Gas Company

[Docket No. CP88-431-000]

Take notice that on May 31, 1988, Trunkline Gas Company (Trunkline), P.O. Box 1642, Houston, Texas, 77001, filed in Docket No. CP88-431-000 an application pursuant to section 7(b) of the Natural Gas Act and the regulations thereunder for authorization permitting and approving abandonment of a certificate of public convenience and necessity which authorized the receipt, transportation and redelivery of natural gas on behalf of Columbia Gas Transmission Corporation (Columbia), all as more fully set forth in the application which is on file with the Federal Energy Regulatory Commission (Commission) and open for public inspection.

By this application, Trunkline specifically requests Commission authorization to abandon service provided to Columbia under Rate Schedule T-63 of its FERC Gas Tariff, Original Volume No. 2. Trunkline states that Trunkline and Columbia entered into a letter agreement dated March 17, 1988 which provides for the termination of the transportation agreement. Upon grant of the abandonment, Trunkline would cancel Rate Schedule T-63.

Comment date: July 1, 1988, in accordance with Standard Paragraph F at the end of this notice.

5. High Island Offshore System

[Docket No. CP88-426-000]

Take notice that on May 27, 1988, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP88-426-000 an application pursuant to section 7(c) of the Natural Gas Act requesting authorization to transport natural gas, on an interruptible basis, for ANR Gathering Company (ANR Gathering), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

HIOS states that it has entered into two gas transportation agreements dated May 1, 1988, to provide, on an interruptible basis, transportation of up to a maximum daily quantity of 103,900 Mcf as long-haul gas and a maximum daily quantity of 127,000 Mcf as short-haul gas for ANR Gathering for a primary term of five years for each transportation agreement and continuing year to year thereafter. HIOS states that the gas for the long-haul transportation would be received at twenty-three (23) receipt points located along HIOS system in the High Island Area, offshore Texas and that the gas for the short-haul transportation would be received at three (3) receipt points located along HIOS in the West Cameron Area, offshore Louisiana and one (1) receipt point in High Island Area, offshore Texas. HIOS proposes to transport the long-haul gas to an existing interconnection of ANR Pipeline Company (ANR) or U-T Offshore

[1] The petition to amend was tendered for filing on May 16, 1988, however, the fee required by § 381.207 of the Commission's Rules (18 CFR 381.207) was not paid until June 6, 1988. Section 381.103 of the Commission's Rules provides that the filing date is the date on which the fee is paid.

System (U–TOS) in Block 167, West Cameron Area, offshore Louisiana or Stingray Pipeline Company in Block A–330, High Island Area, offshore Texas and to transport the short-haul gas to an existing interconnection of ANR or UTOS in Block 167, West Cameron Area, offshore Louisiana.

HIOS proposes to charge ANR Gathering 9.69 cents per Mcf for the long-haul transportation and 4.90 cents per Mcf for the short-haul transportation under its Rate Schedule IT for long-haul and short-haul transportation service.

Comment date: July 1, 1988, in accordance with Standard Paragraph F at the end of this notice.

6. High Island Offshore System

[Docket No. CP88–427–000]

Take notice that on May 27, 1988, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP88–427–000 an application pursuant to section 7(c) of the Natural Gas Act requesting authorization to transport natural gas, on an interruptible basis, for ANR Supply Company (ANR Supply), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

HIOS states that it has entered into a gas transportation agreement dated May 18, 1988, to provide, on an interruptible basis, transportation of up to a maximum daily quantity of 168,000 Mcf of gas for ANR Supply for a primary term of five years and continuing year to year thereafter. HIOS states that the gas would be received at eighteen (18) receipt points located along HIOS system in the High Island Area, offshore Texas and transported to an existing interconnection of ANR Pipeline Company (ANR) or U–T Offshore System (U–TOS) in Block 167, West Cameron Area, offshore Louisiana or Stringray Pipeline Company in Block A–330, High Island Area, offshore Texas.

HIOS proposes to charge ANR Supply 9.69 cents per Mcf under its Rate Schedule IT for long-haul transportation service.

Comment date: July 1, 1988, in accordance with Standard Paragraph F at the end of this notice.

7. Northwest Pipeline Corporation

[Docket No. CP88–418–000]

Take notice that on May 26, 1988, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP88–418–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon certain leasehold properties, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Northwest proposes to abandon by transfer to Arco Oil and Gas Company, Division of Atlantic Richfield (ARCO) its interest in certain leasehold properties located in La Plata County, Colorado and San Juan County, New Mexico. It is stated that the assignment of such properties would be effectuated pursuant to a Settlement Agreement dated May 4, 1988, between Northwest and ARCO which serves as a final settlement of all litigation and claims concerning Northwest's special overriding royalty obligations under its PLA–2 Agreement with ARCO. It is further stated that under the terms of the Settlement Agreement Northwest has agreed to convey to ARCO 100 percent of Northwest's interest in the PLA–2 leasehold properties and to make a one time payment to ARCO of $2 million.

Northwest states that the PLA–2 Agreement covers approximately 1,620 gross acres and that there are approximately 55 gas wells in which Northwest has an interest. Northwest indicates that production from these wells for the 12-month period ending December 31, 1987, was approximately 1,100,000 MMBtu and the maximum daily stabilized producing capacity of Northwest's interest in these wells is approximately 3.1 MMCf. It is indicated that as of April 30, 1988, Northwest's net investment in the PLA–2 properties was $925,505.

Northwest states that the subject properties are not included in Northwest's rate base and the production therefrom has been deemed to be sold to the transmission division of the company at the wellhead. It is further stated that each of the wells has received final Commission approval for a maximum lawful price under sections 103 and 108 of the NGPA or is subject to a ceiling price under Section 104 of the NGPA.

It is stated that Northwest and ARCO have entered into a Gas Purchase Contract (GPK) dated May 4, 1988, to provide for the continued purchase by Northwest of volumes of gas to be produced from the subject leasehold properties. It is also stated that the price to be paid by Northwest for gas purchased under the GPK would be the lower of the applicable NGPA maximum lawful price or the current alternate fuel price.

Northwest states the Settlement Agreement resolves the disputed royalty claims and associated liability and eliminates any future exposure which Northwest would otherwise have with respect to gas price increases resulting from escalating PLA–2 royalties. Northwest also states that it would not attempt to recover in its jurisdictional rates either the undepreciated investment which it has in the PLA–2 properties or the two million settlement payment.

Comment date: July 1, 1988, in accordance with Standard Paragraph F at the end of this notice.

8. Tennessee Gas Pipeline Company

[Docket No. CP88–432–000]

Take notice that on May 31, 1988, Tennessee Gas Pipeline Company (Applicant), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP88–432–000 a request, pursuant to § 284.223 of the Commission's Regulations, for authorization to provide a transportation service for Bienville Gas Marketing, Inc. (Bienville), a marketer, under Applicant's blanket certificate issued in Docket No. CP87–115–000 on June 18, 1987, pursuant to section 7(c) of the Natural Gas Act, all as more fully set out in the request on file with the Commission and open to public inspection.

Applicant states that pursuant to a transportation agreement dated April 15, 1988, it proposed to transport natural gas for Bienville from a point located in West Monroe, Ouchita Parish, Louisiana, to a delivery point on Tennessee's system located in Chicot County, Arkansas. The end-user of the gas is a catfish farmer and right-of-way grantor.

The Applicant further states that the peak day quantities would be 200 dekatherms, the average daily quantities would be 40 dekatherms, and that the annual quantities would be 14,600 dekatherms. Service under § 284.223(a) commenced April 27, 1988, as reported in Docket No. ST88–3582 (filed May 9, 1988).

Comment date: July 25, 1988, in accordance with Standard Paragraph G at the end of this notice.

9. Pacific Gas Transmission Company

[Docket No. CP83–32–001]

Take notice that on October 11, 1988, Pacific Gas Transmission Company (PGT), 245 Market Street, San Francisco, California 94106, filed in Docket No. CP83–32–001 a petition to amend the order issued May 13, 1983, in Docket No. CP83–32–000, pursuant to section 7 of the Natural Gas Act, so as to authorize an extension of the term of the authorized transportation service for J.R. Simplot Company, (Simplot), all as more fully set forth in the petition to amend which is currently on file with the

Commission and open to public inspection.

PGT requests that its authorized interruptible transportation service for Simplot be extended to expire October 27, 1985. PGT proposes no other changes to its original authority.

Comment date: July 1, 1988, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

10. Pacific Gas and Electric Company

[Docket No. CP83-35-002]

Take notice that on October 17, 1984, Pacific Gas and Electric Company (PG&E), P.O. Box 7442, San Francisco, California 94120, filed in Docket No. CP83-35-002 an application to amend the order issued May 13, 1983, in Docket No. CP83-35-000 pursuant to then-effective §§ 284.127 and 284.222 of the Commission's Regulations so as to authorize an extension of term of the authorized transportation service for J.R. Simplot Company (Simplot), all as more fully set forth in the application to amend which is on file with the Commission and open to public inspection.

PG&E requests that the term of its authorized interruptible transportation service be extended from October 27, 1984, to October 31, 1985. No other changes are proposed.

Comment date: July 1, 1988, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

11. El Paso Natural Gas Company

[Docket No. CP82-556-005]

Take notice that on September 21, 1984, El Paso Natural Gas Company (El Paso), P.O. Box 1492, El Paso, Texas 79978, filed a petition to amend the order issued May 13, 1983, in Docket No. CP82-556-000 pursuant to section 7 of the Natural Gas Act so as to extend the term of the transportation service it provides for Beker Industries Corporation (Beker), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

El Paso requests that the term of its authorized interruptible transportation service for Beker be extended from October 27, 1984, to April 1, 1986. No other changes are proposed.

Comment date: July 1, 1988, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). 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 a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the 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 § 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.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88-13515 Filed 6-14-88; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. RP88-188-000 and TM88-3-20-000]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

June 10, 1988.

Take notice that Algonquin Gas Tranmission Company ("Algonquin") on June 3, 1988, tendered for filing to its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Proposed to be Effective March 1, 1988

Original Sheet No. 203-A
Second Revised Sheet No. 362
Third Revised Sheet No. 363
Fifth Revised Sheet No. 364
Fourth Revised Sheet No. 365
Fourth Revised Sheet No. 366
Fifth Revised Sheet No. 600
Original Sheet No. 661
Original Sheet No. 662
Original Sheets No. 663-699

Proposed to be effective May 1, 1988

Alternate Eighteenth Revised Sheet No. 204
Fifth Revised Sheet No. 373
Fourth Revised Sheet No. 374
Fourth Revised Sheet No. 375

Proposed to be effective June 1, 1988

Nineteenth Revised Sheet No. 204

Algonquin states that these tariff sheets are being filed to incorporate the flow through of certain charges by its suppliers, CNG Transmission Corporation ("CNGT") and Transcontinental Gas Pipeline Corporation ("Transco") in the services underlying Rate Schedule F-2 and F-3, respectively. Algonquin states that the revised tariff sheets, are proposed to be effective on March 1, 1988, May 1, 1988, and June 1, 1988 as set forth above.

Algonquin states that on March 14, 1988, in Docket No. CP83-75-000, CNGT filed to make effective a charge to begin collection of the costs associated with the abandonment of Consolidated System LNG Company's Cove Point facilities as approved by Commission "Order Approving Contested Settlement" issued on January 28, 1988. Algonquin states that it is filing Original Sheet No. 203-A, Second Revised Sheet No. 362, Third Revised Sheet No. 363, Fifth Revised Sheet No. 364, Fourth Revised Sheet No. 365, Fourth Revised Sheet No. 366, Fifth Revised Sheet No. 600, Original Sheet No. 661, Original Sheet No. 662 and Original Sheets No. 663-699 to revise its tariff to incorporate language and charges to reflect the flow through of the above mentioned charge.

Algonquin states that on April 29, 1988, in Docket No. RP88-68 *et. al.*,

Transco made a filing in compliance with the Commission's "Order Accepting Filing Subject to Refund and Conditions, Establishing Technical Conference, Remanding Limited Issues, And Consolidating Proceedings" ("Order"), issued March 31, 1988 to incorporate the conditions of Commission's Order into its tariff that will allow Transco to recover 75% of its producer contract buydown/buyout costs. Based upon Transco's fulfillment of the Commission's Order, the effective date for Transco's filing is May 1, 1988.

Algonquin further states that under its transportation arrangement with Transco in the service underlying Rate Schedule F-3, it will be assessed a Commodity Producer Settlement Payment ("PSP") Charge on every MMBtu transported on Transco's system. Algonquin states that it is filing Alternate Eighteenth Revised Sheet No. 204, Fifth Revised Sheet No. 373, Fourth Revised Sheet No. 374 and Fourth Revised Sheet No. 375 to reflect the flow through of Transco's Commodity PSP Charge to Algonquin's F-3 customers. Algonquin also states that Nineteenth Revised Sheet No. 204 is filed for the sole purpose of bringing forward Transco's change into the proposed effective rates for June 1, 1988 filed for, by Algonquin, on May 17, 1988 in Docket No. TM88-2-20-000 (tracker of National Fuel Gas Supply Corporation's Purchased Gas Adjustment filing, dated April 29, 1988).

Algonquin states that, based upon actual sales for the 12 month period ended April 30, 1988, revenues and expenses will increase $126,000 under Rate Schedule F-2 and $517,000 under Rate Schedule F-3.

Algonquin notes that a copy of this filing is being served upon each affected party and interested state commissions.

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, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before June 17, 1988. 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 this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois Cashell,

Acting Secretary.

[FR Doc. 88-13516 Filed 6-14-88; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP63-272-000 et al.]

CNG Transmission Corp.; Redesignation

June 13, 1988.

On April 26, 1988, CNG Transmission Corporation filed in Docket No. CP63-272-000, *et al.*, a petition requesting that it be designated as holder of all certificate, rate, tariff and other proceedings relating to Consolidated Gas Transmission Corporation.

Accordingly, the authorizations issued by this Commission and by the Federal Power Commission, the proceedings currently pending before the Commission, the FERC Gas Tariff on file and any other records or proceedings relating to Consolidated Gas Transmission Corporation are hereby redesignated as those of CNG Transmission Corporation.

A listing of authorizations and pending proceedings is set forth in the appendix.

This action is taken pursuant to 18 CFR 375.302(s) of the Commission's rules.

Lois D. Cashell,

Acting Secretary.

Appendix

CP63-272, CP63-285, CP63-302, CP63-311, CP64-35, CP64-56, CP65-394, CP66-45, CP66-225, CP66-250, CP66-290, CP66-343, CP67-6, CP67-40, CP67-212, CP67-254, CP67-307, CP67-328, CP67-372, CP68-9, CP68-113, CP68-280, CP68-281, CP68-298, CP68-315, CP69-17, CP69-78, CP69-87, CP69-92, CP69-120, CP69-207, CP69-235, CP69-242, CP69-253, CP69-264, CP69-274, CP69-286, CP69-292, CP69-308, CP70-31, CP70-170, CP70-215, CP70-227, CP70-250, CP70-263, CP71-17, CP71-46, CP71-100, CP71-101, CP71-102, CP71-103, CP71-104, CP71-105, CP71-212, CP71-251, CP72-40, CP72-173, CP72-183, CP72-203, CP72-213, CP72-249, CP72-250, CP72-300, CP72-303, CP73-148, CP73-206, CP73-242, CP73-280, CP73-313, CP74-9, CP74-34, CP74-113, CP74-168, CP74-229, CP74-249, CP74-288, CP74-312, CP75-4, CP75-5, CP75-8, CP75-22, CP75-72, CP75-158, CP75-233, CP75-245, CP75-259, CP75-260, CP75-317, CP75-318, CP75-319, CP75-320, CP76-5, CP76-180, CP76-194, CP76-280, CP76-285, CP76-294, CP76-295, CP76-390, CP77-144, CP77-189, CP77-201, CP77-205, CP77-211, CP77-257, CP77-325, CP77-336, CP77-355, CP77-372, CP77-444, CP77-538, CP77-585, CP78-22, CP78-55, CP78-141, CP78-143, CP78-161, CP78-225, CP78-269, CP78-288, CP78-289, CP78-394, CP78-479, CP78-506, CP78-529, CP79-14, CP79-25, CP79-92, CP79-132, CP79-190, CP79-193, CP79-272, CP79-319, CP79-333, CP79-419, CP79-441, CP80-44, CP80-121, CP80-208, CP80-223, CP80-260, CP80-268, CP80-292, CP80-293, CP80-296, CP80-299, CP80-307, CP80-330, CP80-375, CP80-385, CP80-410, CP80-442, CP80-445, CP80-486, CP81-31, CP81-69, CP81-179, CP81-187, CP81-188, CP81-244, CP81-268, CP81-277, CP81-284, CP81-285, CP81-289, CP81-395, CP81-407, CP81-441, CP81-447, CP81-452, CP81-484, CP81-490, CP81-519, CP81-528, CP82-10, CP82-11, CP82-61, CP82-113, CP82-135, CP82-162, CP82-187, CP82-191, CP82-195, CP82-277, CP82-353, CP82-381, CP82-400, CP82-415, CP82-531, CP82-537, CP82-557, CP83-3, CP83-52, CP83-82, CP83-87, CP83-176, CP83-177, CP83-338, CP83-382, CP83-386, CP83-403, CP83-416, CP84-52, CP84-126, CP84-127, CP84-274, CP84-280, CP84-298, CP84-300, CP84-306, CP84-520, CP84-526, CP84-575, CP85-52, CP85-85, CP85-87, CP85-110, CP85-248, CP85-354, CP85-355, CP85-480, CP85-564, CP85-651, CP85-693, CP85-756, CP86-3, CP86-42, CP86-45, CP86-146, CP86-208, CP86-227, CP86-277, CP86-311, CP86-312, CP86-319, CP86-320, CP86-344, CP86-625, CP86-626, CP86-694, CP86-729, CP87-5, CP87-32, CP87-195, CP87-203, CP87-285, CP87-313, CP87-314, CP87-371, CP87-428, CP87-447, CP88-69, CP86-96, CP86-126, CI87-401, GP86-9, RP85-169, RP85-179, TA87-2-22, *et al.*, CI87-416, RP88-118, RP88-10, TA87-3-22, *et al.*

[FR Doc. 88-13517 Filed 6-14-88; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ88-2-4-000]

Granite State Gas Transmission, Inc.; Proposed Changes in Rates and Tariff Provisions

June 10, 1988.

Take notice that on June 3, 1988, Granite State Gas Transmission, Inc. (Granite State), 120 Royall Street, Canton, Massachusetts 02021, tendered for filing with the Commission the following revised tariff sheets in its FERC Gas Tariff, First Revised Volume No. 1, containing changes in rates and tariff provisions for effectiveness on the dates shown below:

Revised Tariff Sheet	Proposed Effective Date
Eighth Substitute Twenty-First Revised Sheet No. 7.	July 1, 1988.
Third Substitute Second Revised Sheet No. 70-A.	June 1, 1988.

According to Granite State, Eighth Substitute Twenty-First Revised Sheet No. 7 is a quarterly adjustment in rates pursuant to the purchased gas cost adjustment procedures in Section XIX of the General Terms and Conditions of its tariff as revised in Docket No. PR88-

165–000 to conform to the Commission's Revisions to the Purchased Gas Cost Adjustment Regulations, Docket No. RM86–14–000 (Order Nos. 483 and 483–A) Granite State further states that Third Substitute Second Revised Sheet No. 70–A corrects a typographical error in one of the revised sheets filed in Docket No. RP88–165–000.

Granite State further states that copies of its filing were served upon its customers, Bay State Gas Company and Northern Utilities, Inc., and the regulatory commissions of the States of Maine and Massachusetts and New Hampshire.

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, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before June 17, 1988. 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 this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88–13518 Filed 6–14–88; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP88–47–003]

Northwest Pipeline Corp.

June 9, 1988.

Take notice that on June 6, 1988, Northwest Pipeline Corporation (Northwest) tendered for filing changes to its FERC Gas Tariff to be effective on July 3, 1988. The filing reflects changes to four alternate sets of tariff sheets originally filed as part of Northwest's general rate filing of January 4, 1988 in the above-captioned proceeding. Northwest's January 4, 1988 filing proposed to increase jurisdictional revenues by $56,802,000 based on the test period consisting of the twelve-month period ended September 30, 1987, adjusted for known and measurable changes through April 30, 1988. The January 4, 1988 filing consisted of Primary Tariff Sheets and three sets of alternate tariff sheets.

Northwest requests that the Commission accept the Third Alternate Tariff Sheets or First Alternate Tariff Sheets and grant any waivers necessary to make such tariff sheets effective at the expiration of the rate suspension period on July 3, 1988. In the event that the Commission does not accept such tariff sheets, Northwest requests that the Commission accept the instant revisions to Second Alternate Tarriff Sheets or Primary Tariff Sheets, which were accepted by the Commission subject to suspension and conditions in its order of May 18, 1988.

Northwest states that the Third Alternate Tariff Sheets and the First Alternate Tariff Sheets both reflect revisions to Northwest's sales and service rate schedules, including elimination of the minimum annual commodity charge in Northwest's PL–1 Rate Schedule. These sets of tariff sheets differ in that the Third Alternate Tariff Sheets reflect the circumstance where Northwest has not yet accepted an open-access certificate in Northwest's Docket No. CP86–578, while the First Alternate Tariff Sheets are based on Northwest's acceptance of an open-access certificate. The Primary Tariff Sheets reflected retention of Northwest's PL–1 minimum annual commodity charge, and also contemplated acceptance by Northwest of an open-access certificate in Docket No. CP86–578. The Second Alternate Tariff Sheets reflected retention of the PL–1 minimum annual commodity charge, but assumed Northwest had not yet accepted an open-access certificate.

Northwest states that it has requested that the Commission accept the Third Alternate Tariff Sheets or First Alternate Tariff Sheets so that Northwest's rates as placed into effect on July 3, 1988 will currently reflect the Commission's present minimum bill policy.

Northwest states that the tariff sheets contained in the instant filing differ from the tariff sheets originally filed on January 4, 1988, in the following respects. First, in accordance with the Commission's orders issued in this proceeding on February 3, 1988 and May 18, 1988, Northwest has eliminated the proposed tariff sheets which would have established two new tariff provisions, namely, a "Federal Income Tax Adjustment Provision" and a "Normalization Compliance Adjustment Provision." Second, Northwest has revised the tariff sheets to reflect changes in the cost of purchased gas, in accordance with the changes contained in Northwest's latest purchased gas adjustment filing of June 1, 1988, in Docket No. TQ88–2–37, which is proposed to become effective on July 1, 1988. Northwest states that these changes based upon Northwest's PGA filing include changes to D–1 and D–2 billing determinants for the purpose of projecting the gas cost component of rates only (and, it asserts, not for purposes of nongas cost rate design) to reflect the anticipated conversion of 15% of firm sales contract demand to firm transportation contract demand by Northwest Natural Gas Company, Southwest Gas Corporation, and Intermountain Gas Company, pursuant to 18 CFR 284.10. Third, Northwest's fuel reimbursement percentage has been revised to reflect Northwest's latest annual fuel reimbursement revision filed on April 1, 1988, and to reflect the refunctionalization of certain facilities from gathering to transportation as reflected in Northwest's January 4, 1988 filing. Finally, as approved by the Commission by order issued on June 1, 1988 in Docket Nos. RP88–154 and TA88–1–37, Northwest has stated its sales rates in MMBtu's rather than in therms.

Northwest states that a copy of this filing is available for public inspection during regular business hours in a convenient form and place at Northwest's offices at 295 Chipeta Way, Salt Lake City, Utah, and that copies of this filing have been mailed to all affected customers and the regulatory commission of each state in which any customer distributes gas.

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, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before June 16, 1988. 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 fule a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88–13519 Filed 6–14–88; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP88–177–001]

Texas Gas Transmission Corp.; Filing

June 10, 1988.

Take notice that on June 1, 1988, Texas Gas Transmission Corporation (Texas Gas) filed Substitute Seventh

Revised Sheet No. 14 and Original Sheet No. 124 as part of its FERC Gas Tariff, Original Volume No. 1.

Texas Gas states that Substitute Seventh Revised Sheet No. 14 reflects a numbering revision, and Original Sheet No. 124 was omitted from the original filing, both relate to its filing of May 24, 1988.

Texas Gas requests the Commission to waive any and all provisions of Part 154 in order to permit these tariff sheets to become effective subject to refund June 1, 1988.

Copies of this filing are being mailed to all of Texas Gas' jurisdictional and non-jurisdictional sales customers affected by the filing and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Emergy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211 (1987)). All such motions or protests should be filed on or before June 17, 1988. 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 this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88-13520 Filed 6-14-88; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA88-5-29-000]

Transcontinmental Gas Pipe Line Corp.; Proposed Changes in FERC Gas Tariff

June 10, 1988.

Take notice that Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing on June 3, 1988 the following tariff sheets to its FERC Gas Tariff Second Revised Volumes No. 1. Such sheets are proposed to be effective August 1, 1988.

Revised Fifty-Second Revised Sheet No. 12

Forth-Ninth Revised Sheet No. 15

Ninth Revised Sheet No. 15-A

Transco states that the proposed tariff sheets reflect on overall rate increase as compared to the currently effective rates of 11.6 cents per dt in the commodity charge under the CD, G, OG, E, PS, ACQ and S-2 Rate Schedules.

Tranaco states that the increase of 11.6 cents relates solely to the current gas cost portion of the commodity rates. The Deferred Adjustment and the Special transition Gas Cost Surcharge remain unchanged.

Transco states that the instant FGA filing reflects a projected average cost of purchased gas of $2.3498/dt for the quarterly period August through October 1988. System Sales are projected to be 400 Mdt per day based on Transco's status as an open access pipeline.

Transco further states that it has filed the necessary schedules in order to comply with § 154.305 and FERC Form 542. Transco has also filed a 9-track magnetic tape as required by FERC Form 542.

Transco states that copies of the instant filing are being mailed ot its judisdictional customers and interested state commissions. In accordance with the provisions of § 154.16 of the Commission's Regulations, copies of this filing are available for public inspection during regular business hours, in a convenient form and place at Transco's main office at 2800 Post Oak Boulevard in Houston, Texas.

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, 825 North Capitol Street, NE., Washington DC 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before June 30, 1988. Protests will be considered by the Commission in determining the approrpriate 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 this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88-13521 Filed 6-14-88; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

Agency Information Collection Activities Under OMB Review

[FRC-3398-2]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and is available to the public for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

FOR FURTHER INFORMATION CONTACT: Carla Levesque at EPA, (202) 382-2740).

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: Request for Contractor Access to TSCA Confidential Business Information. (EPA ICR # 1250). Renewal of an existing collection.

Abstract: The EPA uses the information from this collection to determine whether contractors are eligible for access to Agency Confidential Business Information (CBI). Contractors must establish on Form 7740-6A (entitled "Federal TSCA CBI Access Request, Agreement, and Approval—Contractor/Subcontractor Employee") that access is needed to satisfactorily perform their contracts with EPA.

Respondents: EPA Contractors.

Estimated Burden: 75 hours.

Frequency of Collection: One time only.

Comments on the ICR should be sent to:

Carla Levesque, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M St., SW., Washington, DC 20460

and

Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, (Telephone (202) 395-3084).

Date: June 6, 1988.

Paul Lapsley,

Acting Director, Information and Regulatory Systems Division.

[FR Doc. 88-13458 Filed 6-14-88; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3398-3]

Agency Paperwork Reduction Act Requests Completed by OMB

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces Office of Management and Budget (OMB) action on the Information Collection Request (ICR) submitted by EPA.

Approved

Office of Pesticides and Toxic Substances

EPA ICR #0575; Health and Safety Data Reporting, Submissions of Lists, and Copies of Health and Safety Studies; OMB action date: 5/13/88; OMB #2070-0004; expires 5/31/91. Renewal of an existing collection.

EPA #1198; Section 8 (A) Chemical Specific Rule; OMB action date: 5/13/88; OMB #2070-0067; expires 5/31/88. Renewal of an existing collection.

Office of Research and Development

EPA #0866; Quality Assurance Specifications and Requirements; OMB action date: 5/25/88; OMB #2080-0033; expires: 5/31/88. Reinstatement.

FOR FURTHER INFORMATION CONTACT:

Carla Levesque, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M St., SW., Washington, D.C. 20460, Telephone No. (202) 382-2740

or

Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, Telephone No. (202) 395-3084.

Dated: June 6, 1988.

Paul Lapsley,

Acting Director, Information and Regulatory Systems Division.

[FR Doc. 88-13457 Filed 6-14-88; 8:45 am]

BILLING CODE 6560-50-M

[PP 7G3468/T563; FRL-3398-1]

Avermectin; Extension of Temporary Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has extended temporary tolerances for residues of the pesticide avermectin and its delta 8,9-geometric isomer of avermectin B_1a in or on certain raw agricultural commodities.

DATE: These temporary tolerances expire May 1, 1989.

FOR FURTHER INFORMATION CONTACT:

By mail:

George LaRocca, Product Manager (PM) 15, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460

Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson David Highway, Arlington, VA, (703) 557-2400.

SUPPLEMENTARY INFORMATION: EPA issued a notice, which was published in the Federal Register of July 15, 1987 (52 FR 26561), announcing the establishment of temporary tolerances for residues of the pesticide avermectin and its delta 8,9-geometric isomer of avermectin B_1a in or on the following raw agricultural commodities citrus fruits at 0.005 part per million (ppm); meat, fat, and meat byproducts of cattle at 0.01 ppm; milk at 0.001 ppm; citrus oil at 0.10 ppm and citrus pulp at 0.10 ppm. A related food and feed additive regulation FAP 7H5518, in or on the raw agricultural commodities citrus fruits at 0.005 part per million (ppm); meat, fat, and meat byproducts of cattle at 0.01 ppm; milk at 0.001 ppm, citrus oil at 0.10 ppm and citrus pulp at 0.10 ppm has also been extended. These tolerances were issued in response to pesticide petition (PP) 7G3468, submitted by Merck and Co., Inc., Merck Sharp and Dohme Research Lab., Hillsborough Rd., Three Bridges, NJ 08887.

These temporary tolerances have been extended to permit the continued marketing of the raw agricultural commodities named above when treated in accordance with the provisions of experimental use permit 618-EUP-12, which is being extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that the extension of these temporary tolerances will protect the public health. Therefore, the temporary tolerances have been extended on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active insecticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Merck and Co., Inc., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

These tolerances expire May 1, 1989. Residues not in excess of this amount remaining in or on the raw agricultural commodities after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisioins of the experimental use permit and temporary tolerances. These tolerances may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: June 1, 1988.

Edwin F. Tinsworth,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 88-13458 Filed 6-14-88; 8:45 am]

BILLING CODE 6560-50-M

[PP 6G3339/T565; FRL-3397-9]

E.I. du Point De Nemours and Co., Inc.; Establishment of Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established a temporary tolerance for residues of the pesticide *trans*-5-(4-chlorophenyl-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide in or on the raw agricultural commodity pears at 0.5 part per million (ppm).

DATE: This temporary tolerance expires May 13, 1989.

FOR FURTHER INFORMATION CONTACT:

By mail:

George LaRocca, Product Manager (PM) 15, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Rm. 204, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703–557–2400).

SUPPLEMENTARY INFORMATION: E.I. du Pont de Nemours and Co., Inc., Agricultural Products Dept., Walker's Mill Building, Barley Mill Plaza, Wilmington, DE 19898, has requested in pesticide petition PP 6G3339 the establishment of a temporary tolerance for residues of the pesticide *trans* -5-[4-chlorophenyl-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide in or on the raw agricultural commodity pears at 0.5 part per million (ppm).

This temporary tolerance will permit the marketing of the above raw agicultural commodity when treated in accordance with the provisions of experimental use permit 352-EUP-131, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that establishment of the temporary tolerance will protect the public health. Therefore, the temporary tolerance has been established on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. E.I. du Pont de Nemours and Co., Inc., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This tolerance expires May 13, 1989. Residues not in excess of this amount remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 610–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerances requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: June 1, 1988.

Edwin F. Tinsworth,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 88–13459 Filed 6–14–88; 8:45 am]

BILLING CODE 6560-50-M

EXECUTIVE OFFICE OF THE PRESIDENT

Office of Science and Technology Policy

Biotechnology Science Coordinating Committee; Meeting

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Open meeting.

Name: Federal Coordinating Council for Science, Engineering and Technology, Biotechnology Science Coordinating Committee (BSCC).

Date and Time: July 29, 1988, from 1:30 to 3:30 p.m.

Place: Federal Home Loan Bank Board Amphi-Theatre on 2nd Floor, 1700 G. Street, NW., Washington, DC.

Contact: Dr. Janet Dorigan, Executive Secretary, Biotechnology Science Coordinating Committee, Office of Science and Technology Policy, New Executive Office Building, Room 5026, Washington, DC 20506

Purpose of the Committee: The BSCC serves as an interagency coordinating forum for addressing scientific biotechnology issues.

Tentative Agenda: The BSCC, after over two years in existence, is particularly interested in hearing comments from all sectors of the public on the effectiveness of the BSCC in handling scientific issues under the Coordinated Framework. Other scientific issues on the agenda include: report on the OECD biotechnology meeting of April 1988, report on the hearings before the House Subcommittee on Natural Resources, Agricultural Research and Environment, and overviews of the Environmental Protection Agency proposed rules and the U.S. Department of Agriculture guidelines for research outside the laboratory.

Public Participation: The meeting is open to the public. Members of the public who wish to make oral presentations pertaining to agenda items should send a 2–3 page summary of their topic to Dr. Dorigan at the address listed above. Presentations on the Coordinated Framework are encouraged. Requests must be received 14 days in writing prior to the meeting; reasonable provisions will be made to include the presentation of the agenda. All presentations from members of the public will be limited to 5 minutes. Copy for the public record must be submitted at the time of presentation. The Chairman of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Jonathan F. Thompson,

Executive Director, Office of Science and Technology Policy.

June 8, 1988.

[FR. Doc. 88–13466 Filed 6–14–88; 8:45 am]

BILLING CODE 3115-01-M

FEDERAL HOME LOAN BANK BOARD

[No. AC–720]

The Columbian Building Association of Harford County, Havre De Grace, MD, Final Action, Approval of Conversion Application

Date: June 2, 1988.

Notice is hereby given that on June 2, 1988, the Federal Home Loan Bank Board, as operating head of the Federal Savings and Loan Insurance Corporation, pursuant to section 5(i) of the Home Owners' Loan Act of 1933, as amended, approved the application of The Columbian Building Association of Harford County, Havre de Grace, Maryland (the "Association"), for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of the Secretariat at the Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, and at the Office of the Supervisory Agent at the Federal Home Loan Bank of Atlanta, 147 Peachtree Street NE., Atlanta, Georgia, 30348.

By the Federal Home Loan Bank Board.

Nadine Y. Washington,

Assistant Secretary.

[FR Doc. 88–13512 Filed 6–14–88; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202–006190–051.
Title: United States Atlantic and Gulf-Venezuela Freight Association.
Parties:
Compania Anonima Venezolana De Navigacion
American Transport Lines, Inc.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–006200–030.
Title: U.S. Atlantic & Gulf/Australia-New Zealand Conference.
Parties:
Columbus Line
PACE Line
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202088900–041.
Title: The "8900" Lines Agreement.
Parties:
The National Shipping Company of Saudi Arabia
United Arab Shipping Company (S.A.G.)
Waterman Steamship Corporation
A.P. Moller-Maersk Line
Sea-Land Service, Inc.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–010848–003.
Title: North Europe-Virgin Islands Rate Agreement.
Parties:
Trans Freight Lines
Tropical Shipping and Construction Co., Ltd.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–010982–009.
Title: Bahamas Shipowners and Operators Association.
Parties:
Tropical Shipping & Construction Co., Ltd.
Universal Alco Ltd.
Pioneer Shipping, Ltd.
Seaxpress, Inc.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–010987–006.
Title: United States/Central America Liner Association.
Parties:
Crowley Caribbean Transport, Inc.
Sea-Land Service, Inc.
Seaboard Marine Ltd.
Crowley Trailer Marine Transport, Corp.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–010717–002.
Title: United States Atlantic and Gulf/Central America Freight Association.
Parties:
Crowley Caribbean Transport, Inc.
Seaboard Marine Line, Ltd.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

Agreement No.: 202–010776–030.
Title: Asia North America Eastbound Rate Agreement.
Parties:
American President Lines, Ltd.
Barber Blue Sea.
Japan Line, Ltd.
Kawasaki Kisen Kaisha, Ltd.
A.P. Moller-Maersk Lines
Mitsui O.S.K. Lines, Ltd.
Neptune Orient Lines, Ltd.
Nippon Yusen Kaisha Line
Orient Overseas Container Line, Inc.
Sea-Land Service, Inc.
Showa Line, Ltd.
Yamashita-Shinnihon Steamship Co., Ltd.
Synopsis: The proposed amendment would conform the agreement to the Commission's requirements concerning service contract provisions.

By Order of the Federal Maritime Commission.
Tony P. Kominoth,
Assistant Secretary.
Dated: June 10, 1988.

[FR Doc. 88–13504 Filed 6–14–88; 8:45 am]
BILLING CODE 6730–01–M

Fact Finding Investigation No. 16; Possible Malpractices in the Trans-Atlantic Trades; Order Extending Investigation

June 10, 1988.

By Order issued April 9, 1987, (52 FR 12064, April 14, 1987) the Federal Maritime Commission instituted this nonadjudicatory investigation into the practices of rebates, concessions, absorptions and allowances in excess of those set forth in applicable tariffs, and any other devices or means of obtaining, providing, or allowing other persons to obtain transportation of property at less, or different compensation than the rates and charges shown in applicable tariffs or service contracts, in the United States foreign commerce, between ports and points in the Trans-Atlantic Trades. The Investigative Officer has now advised that in order to complete ongoing fact finding activities it is necessary to extend this investigation an additional year.

Therefore, it is ordered, that the Investigative Officer shall issue a final report of findings and recommendations to the Commission on or before April 14, 1989, such report to remain confidential unless and until the Commission rules otherwise.

By the Commission.
Tony P. Kominoth,
Assistant Secretary.
[FR Doc. 88–13503 Filed 6–14–88; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Chesthill Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than July 7, 1988.

A. **Federal Reserve Bank of Boston** (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. *Chesthill Bancorp, Inc.*, Chestnut Hill, Massachusetts; to become a bank holding company by acquiring 100 percent of the voting shares of Chestnut Hill Bank and Trust Company, Chestnut Hill, Massachusetts.

2. *NBB Bancorp, Inc.*, New Bedford, Massachusetts; to become a bank holding company by acquiring 100 percent of the voting shares of New Bedford Institution for Savings, New Bedford, Massachusetts, which engages in Massachusetts Savings Bank Life Insuance activities.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *NSB Bancshares, Inc.*, La Crosse, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of The Nekoma State Bank, La Crosse, Kansas.

Board of Governors of the Federal Reserve System, June 9, 1988.

William W. Wiles,

Secretary of the Board.

[FR Doc. 88-13422 Filed 6-14-88; 8:45 am]

BILLING CODE 6210-01-M

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Mutual Series Fund, Inc., et al.

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may expressed their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 30, 1988.

A. **Federal Reserve Bank of Boston** (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston Massachusetts 02106:

1. Mutual Series Fund, Inc. and Heine Securities Corporation, Short Hills, New Jersey; to acquire 15 percent of the voting shares of The Boston Bancorp, South Boston, Massachusetts, and thereby indirectly acquire South Boston Savings Bank, South Boston, Massachusetts.

B. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Winton Jones Trust, Wayzata, Minnesota, c/o Anchor Bancorp, Inc.; to acquire 61.66 percent of the voting shares of Anchor Bancorp, Inc., Wayzata, Minnesota.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Charles Travis Henderson, Oklahoma City, Oklahoma; to acquire an additional 96.65 percent of the voting shares of Allied Oklahoma Bancorporation, Inc., Oklahoma City, Oklahoma, and thereby indirectly acquire Allied Oklahoma Bank, N.A., Oklahoma City, Oklahoma.

Board of Governors of the Federal Reserve System, June 9, 1988.

William W. Wiles,

Secretary of the Board.

[FR Doc. 88-13423 Filed 6-14-88; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Establishment; AIDS Advisory Committee

Pursuant to the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 Stat. 770-776) the Secretary, Health and Human Services, announces the establishment of the Alcohol, Drug Abuse, and Mental Health Administration AIDS Advisory Committee on June 2, 1988.

Date: June 9, 1988.

Donald Ian Macdonald.

Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 88-13429 Filed 6-14-88; 8:45 am]

BILLING CODE 4160-20-M

Food and Drug Administration

[Docket No. 88N-0201]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Certain Benzodiazepine Drugs; Certain Controlled Substances Analog Drugs and Certain Cannabinoid Drugs

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit data or comments concerning abuse potential, actual abuse, and medical usefulness, and trafficking of 14 various drug substances. This information will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding abuse liability, acutal abuse, and trafficking of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting information is required by the Controlled Substances ACT (CSA) (21 U.S.C. 811 et seq.).

DATE: Comments by July 15, 1988.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The United States is a party to the 1971 Convention on Psychotropic Substances (the Convention). Article 2 of the Convention provides that if a party to the Convention or WHO has information about a substance which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations and provide the

Secretary-General with information in support of its opinion.

The CSA (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Convention on Psychotropic Substances that it has information that may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (HHS). The Secretary of HHS must then publish the notice in the Federal Register and provide opportunity for interested persons to submit comments to assist HHS in preparing scientific and medical evaluations about the drug or substance. The Secretary of HHS received the following notice from the Director-General, WHO:

I. WHO Notification

Reference: NAR/CL. 9/1988.

WHO QUESTIONNAIR FOR COLLECTION OF INFORMATION FOR REVIEW OF DEPENDENCE PRODUCING PYSCHOACTIVE SUBSTANCES

The Director-General of the World Health Organization presents his compliments and has the pleasure to inform Member States that the Fifth Programme Planning Working Group for review of dependence producing psychoactive substances for international control met from 29 February to 4 March 1988. It recommended that the Twenty-sixth Expert Committee on Drug Dependence, which will meet 17–22 April 1989, will review the following substances:

1. BENZODIAZEPINES

1.1 Brotizolam
1.2 Etizolam
1.3 Midazolam
1.4 Quazepam
1.5 Diazepam (this substance will be used as standard of reference)

2. CONTROLLED SUBSTANCES ANALOGUES ("DESIGNER DRUGS")

Analogues of fentanyl

2.1 Alfa-methylthiofentanyl
2.2 Para-fluorofentanyl
2.3 Beta-hydroxyfentanyl
2.4 Beta-hydroxy-3-methylfentanyl
2.5 Thiofentanyl
2.6 3-methylthiofentanyl

Analogues of MDA (methylenedioxyamphetamine)

2.7 N-hydroxy MDA
2.8 N-ethyl MDA (MDE)
2.9 4-methyl aminorex

3. CANNABINOIDS

3.1 Delta-9-tetrahydrocannabinol

The Executive Board at its seventy-third session adopted resolution EB73.R11 establishing guidelines for review by WHO of dependence producing psychoactive substances for international control. One of the essential elements of this process is for WHO to collect and review information, and subsequently to prepare a Critical Review document for submission to the Expert Committee on Drug Dependence.

The Director-General invites Member States to collaborate in this process by providing all pertinent information available. In particular he would appreciate receiving any such information under the six headings mentioned in the attached questionnaire. For each individual substance, a separate questionnaire form should be filled.

Further clarification on any of the above items can be obtained from the Division of Mental Health (WHO/HQ), Geneva, to which responses should be sent not later than 31 July 1988.

Geneva, 25 April 1988

INSTRUCTIONS FOR FILLING THE QUESTIONNAIRE ON DEPENDENCE PRODUCING PSYCHOACTIVE SUBSTANCES:

i. *Please fill a separate questionnaire for each substance using the enclosed forms.*

ii. Answer to each heading with the available information or reply "*YES*" or "*NO*" if applicable.

iii. Attach additional sheets, reports, documents etc. with complementary information if required, with reference to specific questionnaire heading.

iv. The questionnaire has to be sent *directly* to the Division of Mental Health, WHO/HQ, Geneva, *not later than 31 July 1988.* (Please use the enclosed pre-addressed label).

This copy of the questionnaire refers to the following substance:

1. Availability of the Substance in the Country

Please indicate "YES" or "NO" to the following questions:

1.1 Is the substance presently registered?
1.2 Was the substance previously registered?
1.3 Is the substance presently marketed?
1.4 Is the substance also marketed in combinations?
1.5 Is the substance also available in generic preparations?
1.6 Is the substance supplied on medical prescription?
1.7 Is the substance available without prescription?
1.8 Is the substance a "controlled drug?"
1.9 If the answer to 1.8 is "YES" please specify the National Schedule (class or Regulation) to which this substance has been allocated:
1.10 Indicate trade names of the products and their manufacturers (or distributors) from whom the same substance is available for medical use:
1.11 Any additional information on this heading

2. Production, Consumption and International Trade Data

2.1 Date of introduction in your country
2.2 Yearly quantity manufactured in your country
2.3 Yearly quantity imported in your country
2.4 Yearly quantity purchased by health institutions
2.5 Yearly quantity exported from your country
2.6 Other relevant statistical data recorded through the years available, e.g. from wholesalers, distributing agents, purchasing establishments:
2.7 Any additional information available on this heading.

3. Data on Drug Utilization

3.1 Therapeutic indications for the product:
3.2 Recommended dosage for the above mentioned indications:
3.3 Any report (published or unpublished, please attach a copy if available) on the medical usefulness as well as the known warnings and adverse reactions of this substance. Available reports, studies or any other kind of information on prescription and/or drug consumption statistics of this substance are also desirable. If there are data on the combined use and on interaction(s) of this substance with other substances, they should be specified.
3,4 Any additional available information on this heading.

4. Illicit Manufacture and Illicit Traffic

4.1 Data under this heading are being collected by the Secretary-General of the United Nations and Interpol. It would be appreciated if additional data could also be included on cases of clandestine manufacture, diversion, prescription

forgery, seizure, theft, loss and other related information recorded through the years (please attach copy of reports if available):

4.2 Any additional available information on this heading

5. Extent and Nature of Public Health and Social Problems

5.1 Data on mortality: published or unpublished reports on deaths, when this substance has been involved:

5.2 Data on morbidity: published or unpublished reports on the effects of use of this substance and particularly: actual or potential dependence (physical and/or psychological) and withdrawal phenomena as recorded through the years by drug dependence treatment centres, mental hospitals, prisons, poisoning centres, emergency departments in hospitals, etc.:

5.3 Any additional available information on this heading

6. Extent of Drug Abuse

6.1 Any report (published or unpublished) or other information on the epidemiology of the misuse of abuse pattern of this substance (alone or combined with other substances) including number of addicts cases recorded through the years and other data available; e.g, from interviews, analytical laboratory controls, etc:

6.2 Any additional data on the above heading.

Date:

This questionnaire has been filled by:

Name of the responsible officer:

Position title:

Name of the institution (e.g. Ministry of Health, Department, etc.):

Address: (telephone, telex, telefax):

II. Background

A. Benzodiazepines

WHO reviewed benzodiazepines as a class in 1983 and 1984. As a result of that review, the United Nations Commission on Narcotic Drugs voted to add 33 benzodiazepine substances to Schedule IV of the Psychotropic Convention. This included diazepam which is listed in this notice, and will be used as a standard of reference. The remaining four substances listed in this notice, brotizolam, etizolam, midazolam, and quazepam, were not commercially available at the time of the previous benzodiazepine review. Midazolam and quazepam are marketed in the United States and controlled in Schedule IV of the CSA.

B. Controlled Substance Analogs

The six fentanyl analogs listed in the notification, *alpha*-methylthiofentanyl, para-fluorofentanyl, *beta*-hydroxyfentanyl, *beta*-hydroxy-3-methylfentanyl, thiofentanyl, and 3-methylthiofentanyl are all controlled as narcotic substances in Schedule I of the CSA (52 FR 20070; May 29, 1987 and 53 FR 500; January 8, 1988). None of the substances are commercially available in the United States.

C. Analogues of MDA.

The three substances listed under this heading in the Director-General's notification, *N*-hydroxy MDA, *N*-ethyl MDA (MDE), and 4-methyl aminorex are temporarily controlled under Schedule I of the CSA pursuant to the emergency scheduling provisions of section 811(h) of the CSA.

D. Cannabinoids

Delta-9-tetrahydrocannabinol (▲-9-THC) is currently controlled in Schedule I of the Psychotropic Convention. In December 1987, the U.S. Government filed a petition with the United Nations that requested the transfer of ▲-9-THC from Schedule I to Schedule II of the Psychotropic Convention. The U.S. Government request was acknowledged by a notification from the Secretary-General of the United Nations dated January 28, 1988. The January 28, 1988, notification was the subject of a **Federal Register** notice (53 FR 10155; March 29, 1988) that also requested information to aid the international review of ▲-9-THC. However, information on ▲-9-THC submitted in accordance with section III of the current notice will be forwarded to the Director-General.

Synthetic ▲-9-THC (dronabinol) is the active ingredient in Marinol®, an approved antiemetic product available in the United States since 1986. Marinol® (synthetic ▲-9-THC in sesame oil formulated in a soft gelatin capsule and approved by FDA) is controlled in Schedule II of the CSA.

III. Opportunity to Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA (21 U.S.C. 811(c)(2)(A)), FDA on behalf of HHS invites interested persons to submit data or comments regarding the above-named 14 drugs. Data and information received in response to this notice will be used to prepare scientific and medical information on these drugs, with a particular focus on each drug's abuse liability. HHS will forward that information to WHO, through the Secretary of State, for WHO's consideration in preparing a report for presentation to a WHO review group, which will evaluate the need for international control or modification of the existing international control of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs, and could impose certain recordkeeping requirements on them.

HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in the second half of 1989. Any HHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comment as required by 21 U.S.C. 811(d)(2)(B).

Interested persons may, on or before July 15, 1988, submit to the Dockets Management Branch (address above) written comments regarding this action. This abbreviated acceptance period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO.

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.

This notice contains information collection requirements that were submitted for review and approval to the Director, Office of Management and Budget (OMB). The requirements were approved and assigned OMB control number 0910-0226.

Dated: June 8, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-13469 Filed 6-14-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-88-1813]

Submission of Proposed Information Collections to the Office of Management and Budget

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comments regarding these proposals. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755–6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Date: June 8, 1988.

David S. Cristy,

Deputy Director, Information Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Recertification and Housing Unit Evaluation Forms for the Housing Allowance Supply Experiment (EHAP) in South Bend, Indiana and Green Bay, Wisconsin.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: Section 504 of the Housing and Urban Development Act of 1970 authorizes HUD to conduct an experiment in housing allowances, the Experimental Housing Allowance Program (EHAP). The information is used to recertify participating families' eligibility for the EHAP program. The information is needed to make a determination of continuing eligibility so that families would be able to receive housing assistance.

Form Number: Form 10.05–1, 11.04–2, A–140, and HUD No. H–3–9.

Respondents: Individuals or Households.

Frequency of Respondents: Annually.

Estimated Burden Hours: 1,500.

Status: Extension.

Contact: Myra E. Newbill, HUD, (202) 755–6887, John Allison, OMB, (202) 395–6880.

Date: June 8, 1988.

Proposal: Prepayment of a HUD-Insured Mortgage by an Owner of Low-Income Housing.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: This information is needed to assure that affordable multifamily housing units are preserved for low-income families and that displacement of such families is minimized while public and private sectors find long term remedies to the potential loss of affordable housing. The information will be used to offset prepayment of a HUD-insured multifamily housing unit without prior approval by HUD.

Form Number: None.

Respondents: Individuals or Households, State or Local Governments, Businesses or Other For-Profit, and Federal Agencies or Employees.

Frequency of Submission: On Occasion.

Estimated Burden Hours: 11,800.

Status: New.

Contact: James J. Tahash, HUD, (202) 426–3970, John Allison, OMB, (202) 395–6880.

Date: June 6, 1988.

Proposal: Section 202 Application Submission Requirements.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: This information is necessary to assist HUD in determining applicant eligibility and capacity to develop housing for the elderly or handicapped within statutory and program criteria. A thorough evaluation of an applicant's qualifications and capabilities is critical to protect the Government's financial interst and to mitigate any possibility of fraud, waste, or mismanagement of public funds.

Form Number: HUD–92013.

Respondents: Non-Profit Institutions.

Frequency of Respondents: Annually.

Estimated Burden Hours: 73,190

Status: Revision.

Contact: Aretha M. Williams, HUD, (202) 755–5866, John Allison, OMB, (202) 395–6880.

Date: June 7, 1988.

[FR Doc. 88–13507 Filed 6–14–88; 8:45 am]
BILLING CODE 4210–01–M

Office of the Regional Administrator—Regional Housing Commissioner

[Docket No. D–88–979]

Acting Manager, Region IV (Atlanta); Designation for Columbia Office

AGENCY: Department of Housing and Urban Development.

ACTION: Designation.

SUMMARY: Updates the designation of officials who may serve as Acting Manager for the Columbia Office.

EFFECTIVE DATE: May 13, 1988.

FOR FURTHER INFORMATION CONTACT: Henry E. Rollins, Director, Management Systems Division, Office of Administration, Atlanta Regional Office, Department of Housing and Urban Development, Room 634, Richard B. Russell Federal Building, 75 Spring Street SW., Atlanta, Georgia 30303–3388, 404–331–5199.

Designation of Acting Manager for Columbia Office

Each of the officials appointed to the following positions is designated to serves as Acting Manager during the absence of, or vacancy in the position of, the Manager, with all the powers, functions, and duties redelegated or assigned to the Manager: Provided, That no official is authorized to serve as Acting Manager unless all other employees whose titles precede his/hers in this designation are unable to serve by reason of absence:

1. Deputy Manager
2. Director, Housing Development Division
3. Director, Housing Management Division

4. Director, Community Planning and Development Division
5. Chief Counsel
6. Director, Fair Housing and Equal Opportunity Division

This designation supersedes the designation effective October 2, 1987 (52 FR 44491, November 19, 1987).

(Delegation of Authority by the Secretary effective October 1, 1970 (36 FR 5390, February 23, 1971)).

This designation shall be effective as of May 13, 1988.

Ted B. Freeman,

Manager, Columbia Office.

Richard W. Compton,

Acting Regional Administrator, Regional Housing Commissioner, Office of the Regional Administrator.

[FR Doc. 88-13508 Filed 6-14-88; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-150-08-4830-11]

National Public Lands Advisory Council—Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of the National Public Lands Advisory Council.

SUMMARY: Notice is hereby given that the National Public Lands Advisory Council will meet July 13–15, 1988, at the Red Lion Inn, 2065 Idaho Street, Elko, Nevada. The meeting hours will be 8:00 a.m. to 4:30 p.m. on Wednesday, the 13th, 3:30 p.m. to 5:00 p.m. on Thursday, the 14th, and 8:00 a.m. to 12:00 p.m. on Friday, the 15th. The Council will also participate in a field tour highlighting gold mining and geothermal development in Nevada on July 14. The proposed agenda for the meeting is:

Wednesday, July 13: Morning: The State view of public land management in Nevada; Presentation on issues surrounding gold mining and multiple use management; Council old and new business, to include Department responses to previous Council resolutions and status reports on BLM's recreation policy and wild horse and burro program.

Afternoon: Public statement period; Meeting of Council Subcommittees (Energy and Minerals, Lands, and Renewable Resources).

Thursday, July 14: Afternoon: Meeting of Council Subcommittees.

Friday, July 15: Discussion of agendas for future Council sessions; Meetings of Council Subcommittees; Reports from Subcommittees to full Council and consideration of Council resolutions.

All meetings of the Council are open to the public. Opportunity will be given for members of the public to make oral statements to the Council, beginning at 1:00 p.m. on Wednesday, July 13. Speakers should address specific national public lands issues on the meeting agenda and are encouraged to submit a copy of their written comments by July 6 to the Bureau of Land Management's Nevada State Office at the address listed below. Depending on the number of people who wish to address the Council, it may be necessary to limit the length of oral presentations.

DATES: July 13–15—Council Meeting. July 13—Public Statements.

ADDRESS: Copies of public statements should be mailed by July 6, to: Director, Nevada State Office (912), Bureau of Land Management, P.O. Box 12000, Reno Nevada 89520.

FOR FURTHER INFORMATION CONTACT: Karen Slater, Washington, DC Office, BLM, telephone (202) 343-5101; or Bob Stewart, Nevada State Office, BLM, telephone (702) 784-5311.

SUPPLEMENTARY INFORMATION: The Council advises the Secretary of the Interior through the Director, Bureau of Land Management, regarding policies and programs of a national scope related to public lands and resources under the jurisdiction of BLM.

June 10, 1988.

Robert F. Burford,

Director.

[FR Doc. 88-13522 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-84-M

[AZ-040-08-4333-12 SPCA]

Opening of Part of San Pedro Management Area to Limited Public Use; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Amendment to the San Pedro closure notice.

SUMMARY: The Safford District of the Bureau of Land Management issued a "notice of closure of public lands along the upper San Pedro River to public use" in the March 13, 1986 **Federal Register** (Vol. 51, No. 49). The Safford District is now amending that notice by announcing the opening on July 1, 1988 of a portion of the San Pedro Management Area to a limited amount of public recreational use. The portions to be opened are described as the San Rafael del Valle land grant (the north boundary of which is about 2 miles north of Highway 90 and the south boundary is at Hereford) and those public lands south of the land grant (south of Hereford) in T. 23 S., R. 22 E.

In addition, the recently acquired Palominas property (south of Highway 92 along the San Pedro River) has been added to the San Pedro Management Area and will also be available for public recreational use.

The remainder of the lands in the San Pedro Management Area will still be under the closure notice.

This limited opening will not affect the management alternatives or future decisions to be made in the San Pedro Management Area's Plan and Environmental Impact Statement (EIS), expected to be completed in September 1988.

FOR FURTHER INFORMATION CONTACT: Vernon L. Saline, Acting Area Manager, Safford District, 425 E. 4th St., Safford, AZ 85546, telephone (602) 428-4040 or Erick Campbell, Project Manager, San Pedro Project Office, Box 9853, RR 1, Huachuca City, AZ 85616, telephone (602) 457-3395.

SUPPLEMENTARY INFORMATION: The following rules apply to the newly-opened lands:

1. No motorized or mechanized devices are allowed. Parking is available at two designated entry points at: (a) the San Pedro Ranch House (south side of Highway 90 about 0.25 mile west of the San Pedro River), and (b) at Hereford (south side of the Hereford Road about 0.1 mile east of the San Pedro River). On the Palominas property, no motorized or mechanized devices are allowed except on the main north-south access road starting about 0.5 mile east of the San Pedro River and ending at the Mexican border.

2. Public use is limited to day-use only (sunrise to sunset), with no overnight camping or campfires and no pets allowed.

3. Equestrian use will be allowed. Horses are restricted to entering at the San Pedro Ranch House entry point/parking area and along the north-south access road on the Palominas property. Such use is limited to groups of 10 horses or less.

4. No firearms will be allowed at any time. The area will remain closed to all firearms until the San Pedro Management Plan is completed and BLM, in consultation with concerned publics, can establish long term rules and regulations about the use of firearms.

Copies of the rules, as well as a map, will be posted at each of the designated entry points/parking areas and on the

Palominas property. They will also be available at the Safford District Office and the San Pedro Project Office (at the old town of Fairbank on Highway 82). Additional amendments to the original closure notice will appear in the future in the Federal Register as other portions of the San Pedro Management Area are opened to public use. Notice will also be made through the local media.

Date: June 7, 1988.

Ray A. Brady,

District Manager.

[FR Doc. 88-13485 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-32-M

[NM-030-4212-12; NM NM 63095]

Issuance of Land Exchange Conveyance Document; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States issued an exchange conveyance document to the State of New Mexico, on May 3, 1988, for the surface and mineral estate in the following described lands in Eddy County, New Mexico, pursuant to section 206 of the Act of October 21, 1976 (43 U.S.C. 1716):

New Mexico Principal Meridian

T. 21 S., R. 31 E.,
Sec. 23, SE¼;
Sec. 24, SW¼;
Sec. 25, E½NW¼;
Sec. 26;
Sec. 27, E½;
Sec. 34, NE¼; N½SE¼; SE¼SE¼;
Sec. 35.
T. 22 S., R. 31 E.,
Sec. 1, lots 3, 4, S½NW¼;
Sec. 5, S½S½S½;
The areas described aggregate 2,519.43 acres.

In exchange for these lands, the surface and mineral estate in the following described lands in Eddy County, New Mexico, were reconveyed to the United States:

New Mexico Prinicipal Meridian

T. 22 S., R. 31 E.,
Sec. 16;
Sec. 32.

The areas described aggregate 1,280.00 acres

The purpose of this exchange was to acquire the State lands and minerals to accommodate the United States Department of Energy with their full implementation of the Waste Isolation Pilot Plant (WIPP). The project's design is the safe disposal of low level nuclear waste.

The values of Federal public land and non-Federal land in the exchange were equal.

Larry L. Woodard,

State Director.

Dated: May 31, 1988.

[FR Doc. 88-13487 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-FB-M

[NM-010-3110-10-7201; NM NM 65032/GP8-0111]

Issuance of Mineral Exchange Conveyance Document; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States issued an exchange conveyance document to New Mexico and Arizona Land Company on September 25, 1987, for all minerals existing upon, in or under the following described lands in Cibola, Valencia, and McKinley Counties, New Mexico, pursuant to section 206(a) of the Act of October 21, 1976 (43 U.S.C. 1716):

New Mexico Principal Meridian

T. 4 N., R. 2 W.,
Sec. 8, All.
T. 6 N., R. 3 W.,
Sec. 26, NW¼ and S½;
Sec. 28, All.
T. 5 N., R. 4 W.,
Sec. 24, NW¼ and S½.
T. 4 N., R. 5 W.,
Sec. 10, All.
T. 5 N., R. 5 W.,
Sec. 10, All.
T. 8 N., R. 13 W.,
Sec. 4, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 6, lots 1 to 7, inclusive, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 8, All;
Sec. 10, All;
Sec. 18, lots 1 to 4, inclusive, E½, and E½W½.
T. 9 N., R. 13 W.,
Sec. 6, lots 1 to 7, inclusive, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 8, All;
Sec. 10, All;
Sec. 14, All;
Sec. 18, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 20, All;
Sec. 24, All;
Sec. 30, lots 1 to 4, inclusive, E½, and E½W½.
T. 9 N., R. 14 W.,
Sec. 10, All;
Sec. 12, All;
Sec. 14, N½;
Sec. 24, All;
Sec. 26, E½E½ and W½;
Sec. 28, N½ and SE¼;
Sec. 34, E½.
T. 10 N., R. 14 W.,
Sec. 22, All;
Sec. 28, All;
Sec. 34, All.
T. 11 N., R. 20 W.,
Sec. 24, W½.
Aggregating 17,564.87 acres.

In exchange for the minerals in the lands described above, all minerals existing upon, in, or under the following described lands in Cibola County, New Mexico, were reconveyed to the United States.

New Mexico Principal Meridian

T. 8 N., R. 10 W.,
Sec. 1, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 3, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 5, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 7, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 9, NE¼SE¼, S½SE¼;
Sec. 17, NE¼NE¼, S½NE¼, and SE¼;
Sec. 19, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 21, All;
Sec. 27, All;
Sec. 29, All;
Sec. 31, lots 1 to 4, inclusive, E½, and E½W½.
T. 8 N., R.11 W.,
Sec. 1, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 3, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 5, lots 1 to 4, inclusive, S½N½, and S½;
Sec. 7, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 9, All;
Sec. 11, All;
Sec. 13, All;
Sec. 15, All;
Sec. 17, All;
Sec. 19, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 21, All;
Sec. 23, All;
Sec. 25, All;
Sec. 27, All;
Sec. 29, All;
Sec. 31, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 33, All;
Sec. 35, All.
Aggregating 17,547.11 acres, more or less.

The purpose of the exchange was to consolidate the Federal mineral ownership, where the Bureau also owned the surface estate, in the El Malpais Special Management Area consistent with the approved Rio Puerco Resource Management Plan approved January 16, 1986. The value of the mineral estates exchanged was equal.

Larry L. Woodard,

State Director.

Dated: June 1, 1988.

[FR Doc. 88-13488 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-FB-M

[(MT-930-08-4212-12; M-73159)]

Montana; Realty Action; Exchange

AGENCY: Bureau of Land Management, Butte District Office, Interior.

ACTION: Exchange of public lands for lands owned by the State of Montana in Beaverhead and Madison Counties.

SUMMARY: The following described lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716.

PRINCIPAL MERIDIAN, MONTANA

Parcel No.	Legal description	Acreage
Beaverhead County:		
US 1	T. 11 S., R. 10 W., Sec. 35, SE¼SW¼, SW¼ SE¼.	201.74
	T. 12 S., R. 10 W., Sec. 2, Lots 2, 3, SE¼ NW¼.	
US 2	T. 12 S., R. 6 W., Sec. 10, NE¼NW¼.	40.00
US 3	T. 12 S., R. 6 W., Sec. 24, NE¼NE¼.	40.00
US 4	T. 12 S., R. 10 W., Sec. 26, SW¼.	160.00
US 5	T. 13 S., R. 1 W., Sec. 18, All.	1,640.47
	Sec. 19, E½	
	T. 13 S., R. 2 W., Sec. 12, Lot 9, SE¼.	
	Sec. 13, Lots 1, 2, 3, 4, 5, 6, NE¼, E½NW¼.	
US 6	T. 13 S., R. 5 W., Sec. 5, SE¼SE¼.	280.00
	Sec. 8, E½NE¼,SE¼	
US 7	T. 13 S., R. 5 W., Sec. 1, Lots 6,7, W½SE¼.	3,011.91
	Sec. 10, SW¼SW¼, E½SW¼, SE¼.	
	Sec. 11, S½	
	Sec. 12, All	
	Sec. 13, N½	
	Sec. 14, All	
	Sec. 15, All	
US 8	T. 13 S., R. 5 W., Sec. 21, N½NE¼.	80.00
Total		5,454.12
Madison County:		
US 9	T. 1 S., R. 3 W., Sec. 28, NE¼SW¼.	40.00
US 10	T. 13 S., R. 1 W., Sec. 1, Lots 1,2,3,4, S½ N½, SE¼.	1,369.95
	Sec. 2, Lots 1,2,3,4, S½ N½.	
	Sec. 3, Lots 1,2,3,4, S½ N½.	
	Sec. 4, Lots 1,2,3, S½ NE¼, SE¼NW¼.	
US 11	T. 13 S., R. 1 W., (Adjacent to Parcel US 5) Section 7, Lots 1,2,7,8,9,10,11, E½ SW¼.	351.94
Total		1761.89

Containing a total of 7216.01 acres of public lands.

In exchange for these lands, the United States will acquire the following lands owned by the State of Montana:

Beaverhead County:		
MT 1	T. 7 S., R. 11 W., Sec. 7, SE¼SE¼.	40.00
MT 2	T. 7 S., R. 11 W., Sec. 18, NW¼NE¼.	40.00
MT 3	T. 12 S., R. 11 W., Sec. 36, All.	640.00
MT 4	T. 13 S., R. 2 W., Sec. 6, Lots 4, 5, 6.	121.66
MT 5	T. 13 S., R. 10 W., Sec. 16, All.	640.00
MT 6	T. 13 S., R. 11 W., Sec. 2, SW¼, W½SE¼.	1,520.00
	Sec. 11, All	
	Sec. 12, SW¼SW¼	
	Sec. 13, NW¼	
	Sec. 14, N½, N½SW¼, NW¼SE¼.	
MT 7	T. 13 S., R. 12 W., Sec. 16, NE¼.	160.00
MT 8	T. 13 S., R. 12 W., Sec. 36, All.	640.00
MT 9	T. 14 S., R. 1 E., Sec. 36, All.	639.60
MT 10	T. 14 S., R. 3 W., Sec. 36, All.	640.00
MT 11	T. 14 S., R. 11 W., Sec. 6, Lots 4, 5.	72.40
MT 12	T. 14 S., R. 11 W., Sec. 6, S½SE¼.	80.00
MT 13	T. 14 S., R. 11 W., Sec. 8, NE¼NW¼.	40.00
MT 14	T. 14 S., R. 11 W., Sec. 9, SW¼NW¼.	40.00
MT 15	T. 14 S., R. 11 W., Sec. 16, NE¼NE¼.	40.00
MT 16	T. 14 S., R. 11 W., Sec. 16, W½W½.	160.00
MT 17	T. 14 S., R. 11 W., Sec. 25, E½.	1,320.03
	Section 36, All	
	T. 15 S., R. 11 W., Sec. 1, Lot 4, S½N½, N½S½.	
MT 18	T. 15 S., R. 2 W., Sec. 16, Lots 1, 2.	40.32

Containing 6,874.01 acres of State lands.

DATES: For a period up to and including August 1, 1988, interested parties may submit comments to the Bureau of Land Management, at the address shown below. Any adverse comments will be evaluated by the BLM, Montana State Director, who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of Interior.

FOR FURTHER INFORMATION CONTACT: Information to the exchange, including the environmental assessment/land report, is available for review at the Dillion Resource Area Office, Ibey Building, P.O. Box 1048, Dillon, Montana 59725.

SUPPLEMENTARY INFORMATION: The publication of this notice segregates the public lands described above from settlement, sale, location and entry under the public land laws, including the mining laws, but not from exchange pursuant to section 206 of the Federal Land Policy and Management Act of 1976 for a period of two years from the date of first publication. The exchange will be made subject to:

1. A reservation to the United States of a right-of-way for ditches or canals in accordance with 43 U.S.C. 945.

2. Both the surface and mineral estates will be exchanged on an equal value basis.

3. The lands will be exchanged subject to all valid, existing rights (e.g., rights-of-way, easements, and leases of record).

4. The exchange must meet the requirements of 43 CFR 4110.4-2.

This exchange is consistent with Bureau of Land Management policies and planning and has been discussed with State and local officials. The estimated completion date is September, 1988. The public interest will be served by this exchange because it will enable the Bureau of Land Management to acquire lands with high public values and will increase management efficiency of public lands in the area.

June 6, 1988.

J.A. Moorhouse,

District Manager.

[FR Doc. 88-13428 Filed 6-14-88, 8:45 am]

BILLING CODE 4310-DN-M

[UT-020-08-4212-14; U-53716]

Realty Action; Salt Lake District, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: This is a Notice of a direct sale of 140 acres of public land in Tooele county, in accordance with existing law.

DATE: the date of the sale is August 15, 1988.

SUPPLEMENTARY INFORMATION: The following described public land has been examined and identified as suitable for disposal by direct sale under Section (203) of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713) or FLPMA, to Mr. Lyle Bunker at the appraised fair market value of $12,600:

T. 6 S., R. 18 W., SLM:	
Sec. 4, W½E½SW¼;	40
Sec. 8, NE¼NE¼;	40
Sec. 9, W½NE¼NW¼, NW¼ NW¼.	60
	140

An amendment of the Tooele MFP has been completed and allows this action. The lands are being offered for sale to serve the public objective of economic development and the growing of cultivated crops. Authorizing the farming of these lands will enhance Mr. Bunker's adjoining farm operation. The objective could not be achieved on other public land such as a parcel that was noncontiguous. The parcel does not possess more important values than economic development since growing agricultural crops is the present and projected use of the land. The tract is no larger than necessary to support a family-sized farm.

A direct sale to Mr. Bunker will recognize a preference to him as a user with existing improvement and as an adjoining landowner, as set forth in FLPMA.

The sale is consistent with the Bureau of Land Management's planning system and with Tooele County planning and zoning.

The public lands will be sold on the 15th day of August, 1988.

Terms and conditions applicable to the sale are:

1. The sale of these lands will be subject to all valid existing rights.

2. A right-of-way is reserved for ditches and canals constructed by the authority of the United States Act of August 30, 1890 (26 Stat. 391; 43 U.S.C. 945).

3. All minerals will be reserved to the United States.

4. Federal law requires that the buyer be a U.S. citizen. Proof of this requirement shall be presented by Mr. Bunker on the date of the sale.

The designated purchaser, Mr. Bunker, will be required to pay for the cost to publish this notice in the **Federal Register** and in the local paper. He will also be required to submit a nonrefundable deposit of 20% of the full price of $12,600 on the sale date, August 15, 1988, by certified check, postal money order, bank draft or cashier's check. The remainder of the full price shall be paid within 180 days of the sale date. Failure to pay the full price within 180 days shall disqualify Mr. Bunker as the designated purchaser and the deposit shall be forfeited and disposed of as other receipts of sale. The lands may then be offered on a competitive bidding basis, with details of such a sale to be set forth in a subsequent notice.

Detailed information concerning the sale, including the planning documents and environmental assessment, is available for review at the Salt Lake District Office, 2370 South 2300 West, Salt Lake City, Utah 84119. Any adverse comments will be evaluated by the District Manager, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the District Manager, this realty action will become the final determination of the Department of the Interior. Comments concerning the sale will be accepted for a period of 45 days from the date of this notice by the District Manager at the above stated address. For further information contact Terry Catlin, Pony Express Realty Specialist, (801) 524–5348.

Deane H. Zeller,

District Manager.

[FR Doc. 88–13437 Filed 6–14–88; 8:45 am]

BILLING CODE 4310-DQ-M

Minerals Management Service

Outer Continental Shelf (OCS) Oil and Gas Information Program

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the Minerals Management Service has recently released a publication entitled "Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf," by its Offshore Rules and Operations Division. This 264-page report is a compilation of all blowouts, explosions and fires, pipeline breaks or leaks, significant pollution incidents, and major accidents that occurred on federal leased offshore lands from 1956 through 1986.

It lists accidents by five categories: detailing area, block, lease number, platform and well number, and operator. It describes the type of accident, corrective action taken, and the amount of pollution and provides figures on fatalities, injuries, and property and environmental damage.

EFFECTIVE DATE: June 15, 1988.

ADDRESSES: This OCS report, MMS 88–0011, is available for inspection at the Technical Publications Unit; Office of Offshore Information and Publications; Minerals Management Service, MS–642; 1951 Kidwell Drive, Room 536; Vienna, Virginia 22180; (703) 285–2604. Copies of this report can be obtained from the above mentioned address.

FOR FURTHER INFORMATION CONTACT: Lloyd M. Tracey; Branch of Oil and Gas Development; Minerals Management Service, MS–646; 12203 Sunrise Valley Drive; Reston, Virginia 22091; (703) 648–7836.

SUPPLEMENTARY INFORMATION: This report is published pursuant to 30 CFR 252—Outer Continental Shelf Information Program, 44 FR 46408, August 7, 1979. An outline of the contents of the report is set forth below.

Accidents Associated with oil and gas Operations on the Outer Continental Shelf

I. Introduction

II. Gulf of Mexico OCS Region

Table 1, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS—Gulf of Mexico.

Table 2–A, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Gulf of Mexico, Blowouts. Table 2–B, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Gulf of Mexico, Explosions and Fires.

Table 2–C, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Gulf of Mexico, Pipeline Breaks or Leaks.

Table 2–D, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Gulf of Mexico, Significant Pollution Incidents, 50 bbl (2,100 gal) or More.

Table 2–E, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Gulf of Mexico, Major Accidents.

III. Pacific OCS Region

Table 3, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS-Pacific.

Table 4–A, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Pacific, Blowouts.

Table 4–B, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Pacific, Explosions and Fires.

Table 4–C, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Pacific, Pipeline Breaks or Leaks.

Table 4–D, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Pacific, Significant Pollution Incidents 50 bbl (2,100 gal) or More.

Table 4–E, Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, Pacific, Major Accidents.

IV. Alaska OCS Region

V. Atlantic OCS Region

VI. Summary Tables for the Entire Outer Continental Shelf

Table 5, Summary of Crude Oil and Condensate Spill Incidents of 200 or More Barrels, Outer Continental Shelf.

Table 6, Summary of Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf, 1956–1986.

VII. Graphs of Data Pertaining to Accidents Associated with Oil and Gas Operations on the Outer Continental Shelf

Figure 1, Crude & Condensate Spills > 200 bbl, OCS—Gulf of Mexico.

Figure 2, Crude & Condensate Spills > 200 bbl, OCS—Pacific.

Figure 3, Volume of Crude & Condensate Spilled, OCS—Gulf of Mexico.

Figure 4, Volume of Crude & Condensate Spilled, OCS—Pacific.

Figure 5, Crude & Condensate Spills > 200 bbl, Outer Continental Shelf.

Figure 6, Volume of Crude & Condensate Spilled, Outer Continental Shelf.

Figure 7, Summary of Accidents Associated with Oil and Gas Operations on the OCS.

Date: June 3, 1988.

Price McDonald,

Acting Associate Director for Offshore Minerals Management.

[FR Doc. 88-13427 Filed 6-14-88; 8:45 am]

BILLING CODE 4310-MR-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-254]

Men's and Boys' Woven Manmade-Fiber Shirts from the People's Republic of China

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: June 7, 1988.

FOR FURTHER INFORMATION CONTACT: Dennis Rudy (202–252–1461) or Robert W. Wallace (202–252–1458), Textiles Division, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

Background and scope of investigation: Following receipt of a request from the United States Trade Representative (USTR), at the direction of the President, the Commission instituted the investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) for the purpose of determining the volume of imports of men's and boys' woven shirts of manmade fibers with two or more colors in the warp and/or filling, from the People's Republic of China (China) in 1987. The data requested by the USTR are for purposes of administering the new bilateral textile agreement with China. In his letter requesting the study, the USTR stated that "parties involved in the negotiation of the new agreement expressed concern about a possible inaccuracy of the reported statistics on imports of such shirts from China in 1987 that may make the statistics unsuitable for purposes of administering the agreement. The correct information is vital for us to determine the proper level for China's exports of this product to the United States."

The new agreement with China went into effect on January 1, 1988, and limits its exports of textiles and apparel to the United States through 1991. The shirts under investigation are reported for quota purposes under textile category 640, men's and boys' woven manmade-fiber shirts. The agreement provides that a sublimit be established under category 640 for shirts with two or more colors in the warp and/or filling, referred to as "yarn-dyed" shirts (category 640–Y), and that the sublimit be based on trade with China in 1987.

As requested by USTR, to determine the volume of imports of the yarn-dyed shirts from China in 1987, the Commission will survey the 90 or so importers known to have entered such shirts from China under category 640 that year. The data submitted in response to the questionnaire will, as requested by the USTR, be reported to him in aggregate form only and that, in accordance with past instructions, the Commission's report will be classified as confidential.

The USTR has asked that the Commission submit its report not later than 120 days after receipt of the request (i.e., by September 28, 1988).

Hearing-impaired individuals are advised that information about this investigation can be obtained by contacting our TDD terminal on (202) 252–1810.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: June 9, 1988.

[FR Doc. 88-13476 Filed 6-14-88; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-262]

Certain Venetian Blind Components; Change of Commission Investigative Attorney

Notice is hereby given that, as of this date, Juan Cockburn, Esq., of the Office of Unfair Import Investigations (500 E Street SW., Washington, DC 20436) will be the Commission investigative attorney in the above-cited investigation instead of Stephen L. Sulzer, Esq.

The Secretary is requested to publish this Notice in the **Federal Register.**

Respectfully submitted,

Lynn I. Levine,

Director, Office of Unfair Import Investigations.

Dated: June 6, 1988.

[FR Doc. 88-13477 Filed 6-14-88; 8:45 am]

BILLING CODE 7020-02-M

[Investigation No. 337-TA-262]

Certain Venetian Blind Conponents

Notice is hereby given that the preliminary conference in this matter is presently scheduled to commence at 1:00 p.m. on Tuesday June 28, 1988, in Hearing Room B Room 111 at the new International Trade Commission Building at 500 E Street SW., Washington, DC. This date is subject to change through order of the administrative law judge. Non-parties wishing to attend should contact Mr. McKie at 202–252–1701 as to whether there have been any changes made in this schedule.

The Secretary shall publish this notice in the **Federal Register.**

Paul J. Luckern,

Administrative Law Judge.

Issued: June 8, 1988.

[FR Doc. 88-13478 Filed 6-14-88; 8:45 am]

BILLING CODE 7020

INTERSTATE COMMERCE COMMISSION

[Volume No. OP3MCF-285 (A)]

Motor Carrier Applications To Consolidate, Merge, or Acquire Control

The following applications seek approval to consolidate, purchase, merge, lease operating rights and properties, or acquire control of motor carriers pursuant to 49 U.S.C. 11343 or 11344. Also, applications directly related to these motor finance applications (such as conversions, gateway

eliminations and securities issuances) may be involved.

The applications are governed by 49 CFR 1182.1.

Persons wishing to oppose an application must follow the rules under 49 CFR 1182.2. If the protest includes a request for oral hearing, the request shall meet the requirements of 49 CFR 1182.3 and shall include the required certification. Failure seasonably to oppose will be construed as a waiver of opposition and participation in the proceeding.

In the absence of legally sufficient protests as to the finance application or to any application directly related thereto filed within 45 days of publication (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (unless the application involves impediments) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice.

Application(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notification of effectiveness of this decision-notice or the application of a non-complying applicant shall stand denied.

Findings

The findings for these applications are set forth at 49 CFR 1182.6.

Noreta R. McGee,

Secretary.

MC–F–19167, filed June 1, 1988. Greyhound Lines, Inc. (Transferee) (Suite 2500, 901 Main Street, Dallas, TX 75202)—Purchase—S.B. & E. Transportation Company, d/b/a/ Pacific Trailways (Transferor) (3113 Airport Way, Boise, ID 83705). Representatives: Fritz R. Kahn and William C. Evans, Suite 1000, 1660 L Street, NW., Washington, DC 20036. Transferee, a motor common carrier of passengers pursuant to MC–1515 and related subs, to purchase the interstate and intrastate operating authorities of Transferor, a motor common carrier of passengers in interstate and intrastate commerce. The operating authority to be transferred is contained in Certificate No. MC–70947 (Sub–No. 27), which authorizes the transportation of passengers and package express over a series of regular routes in the States of Idaho, Oregon, and Utah, (a principal route of service is between Portland and Eugene, OR, Boise, ID, and Salt Lake City, UT), and nationwide charter and special operations. The intrastate authority to be transferred is contained in Utah Certificate No. 2123, Oregon Certificate No. 18418, and Idaho Permit 7226. Transfer of the intrastate authority is pursuant to 49 U.S.C. 11341(a). Temporary authority under 49 U.S.C. 11349 was granted to transferee on June 6, 1988. Transferee is an indirect wholly owned subsidiary of GLI Holding Company, which indirectly controls BusLease Contract Services, Inc. (MC–193190). GLI Holding Company also has exercised options to purchase Vermont Transit Co., Inc., (MC–45626) and Texas, New Mexico, Oklahoma Coaches, Inc. (MC–61120) but has not yet consummated the transactions. The foregoing control relationships of GLI Holding Company were approved by the Commission in Docket MC–F–18260.

[FR Doc. 88–13399 Filed 6–14–88; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–290 (Sub–No. 3X)]

Georgia Midland Railway Co. and Southern Railway Co., Abandonment and Discontinuance of Service Exemption; Spalding County, GA, etc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts the Georgia Midland Railway Company and the Southern Railway Company from the requirements of 49 U.S.C. 10903, *et seq.*, to abandon and discontinue service, respectively, over a 67.0-mile line of railroad in Spalding, Pike, Meriwether, Talbot, Harris, and Muscogee Counties, GA, subject to: (1) The standard employee protective conditions; and (2) the condition that applicants not engage in any salvage operations until the process under Section 7 of the Endangered Species Act is completed and until the Georgia Department of Historic Preservation determines if any structures (50 years or older) are eligible for listing in the *National Register of Historic Places*.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on July 15, 1988. Petitions to stay must be filed by June 30, 1988, and petitions for reconsideration must be filed by July 11, 1988. Formal expressions of an intent to file an offer of financial assistance under 49 CFR 1152.27(c)(2)[1] must be filed by June 27, 1988. Requests for a public use condition must be filed by June 27, 1988.

ADDRESSES: Send pleadings referring to Docket No. AB–290 (Sub–No. 3X) to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioner's representative: Angelica Lloyd, Norfolk Southern Corporation, 8 North Jefferson Street, Roanoke, VA 24042–0041.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 275–7245 (TDD for hearing impaired: (202) 275–1721).

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–4357/4359 (DC Metropolitan area), (assistance for the hearing impaired is available through TDD services (202) 275–1721 or by pickup from Dynamic Concepts, Inc., in room 2229 at Commission headquarters.

Decided: May 25, 1988.

By the Commission, Chairman Gradison, Vice Chairman Andre, Commissioners Sterrett, Simmons, and Lamboley. Commissioner Lamboley concurred in part and dissented in part with a separate expression.

Noreta R. McGee,

Secretary.

[FR Doc. 88–13438 Filed 6–4–88; 8:45 am]

BILLING CODE 7035–01–M

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[1] *See Exemption of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987), and final rules published in the **Federal Register** on December 22, 1987 (52 FR 48440–48446).

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant To the Clean Air Act

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on June 6, 1988, a proposed consent decree in *United States* v. *Sunflower Electric Cooperative, Inc.*, Civil Action No. 88–2293–S, was lodged with the United States District Court for the District of Kansas. The proposed consent decree resolves a judicial enforcement action brought by the United States against Sunflower Electric Cooperative, Inc. ("Sunflower") for violations of the Clean Air Act.

The proposed consent decree requires Sunflower to comply with the Standards of Performance for New Stationary Sources for Electric Utility Steam Generating Units for Which Construction is Commenced after September 18, 1987, at 40 CFR Part 60, Subpart Da. The consent decree requires Sunflower to adopt an operations and

maintenance plan for its computerized continuous emission monitoring system and to make specific modifications to its piping system. Finally, the consent decree requires Sunflower to pay a total civil penalty of $20,000 within thirty (30) days of entry of the decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States v. Sunflower Electric Cooperative, Inc.*, D.J. Ref. 90-5-2-1-1161.

The proposed consent decree may be examined at the office of the United States Attorney, 412 Federal Building, 812 North Seventh Street, Kansas City, Kansas 66101 and at the Region VII office of the United States Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas 66101. Copies of the consent decree may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1517, Ninth Street and Pennsylvania Avenue NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $1.10 (10 cents per page reproduction cost) payable to the Treasurer of the United States.

Roger J. Marzulla,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 88-13488 Filed 6-14-88; 8:45 am]

BILLING CODE 4410-01-M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-327/50-328]

Tennessee Valley Authority, Sequoyah Nuclear Plant, Units 1 and 2; Receipt of Petition for Director's Decision

Notice is hereby given that by Petition dated March 24, 1988, Albert Bates, on behalf of certain named individuals, requested that the Commission take immediate action with regard to the Sequoyah Nuclear Plant. The Petition requests that the Commission issue an order suspending full power operation of the facility until remedial action is taken. The Petition asserts as grounds for this request that the licensee has failed to meet the requirements of Regulatory Guides 1.9 and 1.108 with respect to the capacity margin and performance testing of the Emergency Diesel Generator (EDG) system.

The Petition has been referred to the Director, Office of Special Projects. By letter dated March 28, 1988, the Director, Office of Special Projects, responded to the Petitioner denying his request for emergency relief and informing the Petitioner that his request is being treated pursuant to 10 CFR 2.206 of the Commission's regulations. As provided by § 2.206, appropriate action will be taken on this request within a reasonable time.

A copy of the Petition is available for inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555, and at the Local Public Document Room for the Sequoyah Nuclear Plant located at the Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

Dated at Rockville, Maryland, this ninth day of June 1988.

For the Nuclear Regulatory Commission.

Stewart D. Ebneter,

Director, Office of Special Projects.

[FR Doc. 88-13453 Filed 6-14-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-413 and 50-414]

Duke Power Co. et al.; Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 47 to Facility Operating License No. NPF-35 and Amendment No. 40 to Facility Operating License No. NPF-52 issued to Duke Power Company, et al., (the licensee) which revised the Technical Specifications for operation of the Catawba Nuclear Station, Units 1 and 2, (the facility) located in York County, South Carolina. The amendments were effective as of the date of issuance.

The amendments modify Technical Specification 3/4.4.5 "Steam Generators" and its associated Bases for tube plugging criteria.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Ch. I, which are set forth in the license amendments.

Notice of Consideration of Issuance of Amendments and Opportunity for Prior Hearing in connection with this action was published in the Federal Register on October 27, 1987 (52 FR 41374). No request for a hearing or petition for leave to intervene was filed following this notice.

The Commission has prepared an Environmental Assessment and Finding of No Significant Impact (53) FR 19355) related to the action and has concluded that an enviromental impact statement is not warranted and that issuance of these amendments will not have a significant adverse effect on the quality of the human environment.

For further details with respect to the action see (1) the application for amendments dated October 8, 1987, as supplemented December 3, 1987, (2) Amendment No. 47 to License No. NPF-35 and Amendment No. 40 to License No. NPF-52 and (3) the Commission's related Safety Evaluation and Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., and at the York County Library, 138 East Black Street, Rock Hill, South Carolina 29730. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects I/II.

Dated at Rockville, Maryland, this 6th day of June 1988.

For the Nuclear Regulatory Commission.

Kahtan N. Jabbour,

Project Manager, Project Directorate II-3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 88-13454 Filed 6-14-88; 8:45 am]

BILLING CODE 7590-01-M

Biweekly Notice Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission (the Commission) is publishing this regular biweekly notice. P.L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that

such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from May 23, 1988 through June 3, 1988. The last biweekly notice was published on May 18, 1988 (53 FR 17776).

NOTICE OF CONSIDERATION OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND PROPOSED NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION AND OPPORTUNITY FOR HEARING

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Procedures Branch, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 4000, Maryland National Bank Building, 7735 Old Georgetown Road, Bethesda, Maryland from 8:15 a.m. to 5:00 p.m. Copies of written comments received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, DC. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By July 15, 1988, 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 petition for leave to intervene. Requests for a hearing and petitions 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. 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 a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (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 fifteen (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, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. 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 involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish 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.

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, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (*Project Director*): petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page

number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the 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 factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Alabama Power Company, Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Dates of amendments request: January 28, 1988 and May 20, 1988

Brief description of amendments request: The proposed amendment will delete the Surveillance Specimen Withdrawal Schedule Table 4.4-5 from the Technical Specifications. Also, the portion of paragraph 4.4.10.1.2 relating to the reactor vessel material irradiation surveillance withdrawal table shall be removed and relocated to the Final Safety Analysis Report (FSAR). The program for surveillance of reactor vessel material would continue to be governed by 10 CFR Part 50, Appendix H.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee's findings are summarized below:

1. The proposed change does not significantly increase the probability or consequences of an accident previously evaluated because the reactor vessel material surveillance program is not affected by this proposed change. Implementation of the proposed change will delete a license requirement that is redundant to the Code of Federal Regulations. Thus, this proposed Technical Specification is considered to be administrative in nature.

2. The proposed change will not create the possibility of a new or different kind of accident from any previously evaluated because implementation of this change will not alter plant configuration or mode of operation. Compliance with existing regulations will ensure continued confidence in reactor vessel material properties.

3. The proposed change will not involve a significant reduction in the margin of safety because the evaluation of reactor vessel material embrittlement is not altered by this change. Additionally, Surveillance Requirement 4.4.10.1.2 and Table 4.4-5 are not beneficial to the primary user of the Technical Specifications (i.e., the reactor operator). Thus, deletion of this material will actually enhance the useability of the Technical Specifications by plant operators resulting in an incremental benefit to plant safety.

Based on the above reasoning, the licensee has determined that the proposed changes involve no significant hazards considerations. The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. In addition, the table being removed from the Technical Specifications will be retained in the FSAR. Thus, any future table changes will require a licensee safety analysis per 10 CFR 50.59. Accordingly, the Commission proposes to determine that the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303

Attorney for licensee: Ernest L. Blake, Esquire, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: Elinor G. Adensam

Alabama Power Company, Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Dates of amendments request: May 10, 1988, superseded May 26, 1988

Description of amendments request: The proposed amendments revise the corporate management position of Senior Vice President in Section 6, Administrative Controls, of the Technical Specifications (TS) to be Vice President-Nuclear. The reference to Senior Vice President will be deleted from TS 6.5.1.8 and 6.5.3.1.d, and TS 6.5.2.2 will now define the NORB Chairman to be the Vice President-Nuclear.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a no significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee's findings are summarized below:

1. The proposed change will not increase the probability or consequences of an accident previously evaluated. The change is administrative in nature and involves no physical alteration of the plant or changes to setpoints or operating parameters. Since the change has no direct bearing on operation, maintenance, or testing of the plant, the response of the plant to previously evaluated accident (sic) will not be affected.

2. The proposed change does not create the possibility of a new or different kind of accident than any accident previously evaluated. Since no change is being made to design, operation, maintenance, or testing of the plant, a new mode of failure is not created. A new or different kind of accident could therefore not result.

3. The proposed change does not reduce a margin of safety. The level of management oversight over activities affecting nuclear safety remains unchanged. The Vice President-Nuclear is the designated executive position that has corporate responsibility for overall nuclear safety and has the authority to take such measures to ensure nuclear safety. Margins of safety are therefore not reduced.

Based on the above reasoning, the licensee has determined that the proposed changes involve no significant hazards considerations. The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that

the requested amendment does not involve a significant hazards consideration.

Local Public Document Room location: George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303

Attorney for licensee: Ernest L. Blake, Esquire, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: Elinor G. Adensam

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2 and 3, Maricopa County, Arizona

Date of amendment request: May 9, 1988

Description of amendment request: The proposed amendments consist of changes to the Technical Specifications (Appendix A to Facility Operating License Nos. NPF-41, NPF-51 and NPF-74 for PVNGS Units 1, 2, and 3 respectively).

The proposed amendments would change Technical Specification Table 3.6-1, to revise the maximum actuation times of four containment air radiation monitor isolation valves, HCB-UV 044, HCA-UV 045, HCA-UV 046, and HCB-UV 047. The maximum actuation time of these four containment isolation valves would be reduced from 12 seconds to 1 second. The proposed change does not alter the configuration of the isolation valves or their operation. During testing the valves have always passed the one second actuation time. The proposed change revises the Technical Specifications to reflect what the actuation time should be, to ensure the integrity of containment, and protect the radiation monitor.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

A discussion of the proposed changes as they relate to these standards is presented below.

Standard 1 - Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The changes proposed by this submittal would not increase the probability or consequences of a previously evaluated accident because the changes have been determined to be more conservative by lowering the required maximum actuation times of four containment air radiation monitor isolation valves. To preclude possible damage to the radiation monitor in the event of a LOCA, the valves will be required to close in 1 second instead of 12 seconds. The design limits of the radiation monitor would be maintained, as well as the assumptions made for the loss of containment integrity.

Standard 2 - Create the Possibility of a New or Different Kind of Accident from any Accident Previously Evaluated

The changes proposed by this submittal would not create the possibility of a new or different kind of accident from any previously evaluated because the proposed changes do not alter the configuration of the plant or the way in which it is operated. The revision of the maximum actuation time reflects what the actual acuation time is, and will ensure that the radiation monitor is protected from high pressure, and that containment integrity is maintained.

Standard 3 - Involve a Significant Reduction in a Margin of Safety

The proposed changes would not involve a significant reduction in a margin of safety because, by revising the maximum valve actuation time, the assumptions made in the safety analyses are maintained. Therefore the margin of safety remains the same.

The staff has reviewed the proposed amendments and agrees with the licensee's conclusion and proposes to determine that the above changes do not involve a significant hazards consideration.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Attorney for licensees: Mr. Arthur C. Gehr, Snell & Wilmer, 3100 Valley Center, Phoenix, Arizona 85007.

NRC Project Director: Mr. George W. Knighton

Commonwealth Edison Company, Docket Nos. 50-254 , Quad Cities Nuclear Power Station, Unit 1, Rock Island County, Illinois

Date of amendment request: May 10, 1988

Description of amendment request: To improve clarity of the Quad Cities Unit 1 Technical Specifications (TS), Commonwealth Edison Company (CECo, the licensee) has retyped them in their entirety as an amendment to Facility Operating License DPR-29. This retyped version of TS involves such changes as those made to improve grammar, correct typographical errors, and improve legibility. Additionally, the Unit 1 retype was able to benefit from today's improved Word Processor capability. Since no technical changes were proposed, this amendment is considered to be administrative in nature.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists in 10 CFR 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards consideration if 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; (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. Pursuant to 10 CFR 50.91(a), the licensee provided the following analysis of their amendment request which addresses these three standards.

CECo has evaluated the proposed amendment in accordance with the criteria of 10 CFR 50.92(c) and determined it does not involve significant hazards consideration. Consequently, the licensee maintains that operation of Quad Cities Nuclear Power Station in accordance with the proposed amendment would not:

(1) involve a significant increase in the probability or consequences of accidents previously evaluated because this amendment does not change the content of the current approved TS. It is administrative in nature and is merely sought to improve the clarity and legibility of the Unit 1 TS. Plant system and procedures would not be affected;

(2) create the possibility of a new or different kind of accident from any accident previously evaluated because the proposed amendment contains no technical content changes of the currently approved Unit 1 DPR-29 TS. There will be no change in plant system or component configurations, nor the way they are operated; and

(3) involve a significant reduction in the margin of safety because the proposed amendment is merely a retyped version of the current, NRC

approved Unit 1 DPR-29 TS. There are no technical changes associated with this amendment and it is considered to be administrative in nature. As such, the margin of safety is unaffected.

The NRC staff reviewed the licensee's amendment request and concurs with the significant hazards consideration analysis detailed above. Furthermore, correcting typographical and editorial errors in the TS is considered an administrative change. The Commission's guidance (51 FR 7751) clearly establishes that a purely administrative change to technical specification "is an example of an amendment not likely to involve significant hazards consideration." Therefore, the NRC staff proposes to determine that this application for amendment does not involve a significant hazards consideration.

Local Public Document Room location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021.

Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60603.

NRC Project Director: Leif J. Norrholm

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: May 6, 1988

Description of amendment request: The proposed amendments would modify the Technical Specifications for Catawba Units 1 and 2 to: (1) add penetration M-375 to Table 3.6-1, (2) add valve NM-438B to Tables 3.6-2a and 3.6-2b, and (3) delete information which is no longer applicable.

The additions to the Tables are required due to the scheduled implementation of a modification which will reroute a Post Accident Liquid Sample (PALS) drain line in each unit. The PALS equipment is a part of the Nuclear Sampling System at Catawba which has been designed in accordance with the recommendations contained in NUREG-0737, item II.B.3. Rerouting the drain line will ensure that residual samples collected from the PALS panel will be returned to the containment floor and equipment sump in lieu of discharging them in the evaporator feed tank sump. This would reduce radiation exposures from reactor coolant samples and is consistent with the guidance contained in NUREG-0737. The modification is scheduled to be implemented during the next refueling outage for each unit.

The information to be deleted from Tables 3.6-1, 3.6-2a and 3.6-2b is no longer applicable. As such, its deletion is purely administrative.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of its standards set forth in 10 CFR 50.92(c) for no significant hazards consideration determinations by providing certain examples (51 FR 7744). The changes for the proposed amendments (except for the deletion of the information which is no longer applicable) do not match those examples. However, the staff has reviewed the licensee's request for the above amendments and determined that should the additions of a penetration and a valve per unit to the Tables be implemented, it would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated because the additions are the result of rerouting the PALS drain line back into the containment. The rerouting is to be done in accordance with the guidance contained in NUREG-0737, item II.B.3, to reduce radiation exposures from reactor coolant samples. Also, the additions of a penetration and a valve per unit would not (2) create the possibility of a new or different kind of accident from any accident previously evaluated because no new modes of reactor operation are introduced and the design of the reactor coolant system and its support systems are not significantly affected. Finally, the addition of a penetration and a valve per unit would not (3) involve a significant reduction in a margin of safety because of the reasons stated above in items (1) and (2).

The deletion of the information which is no longer applicable matches example (i) of the Commission's examples in 51 FR 7744 of actions likely to involve no significant hazards considerations, "a purely administrative change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature."

Accordingly, the Commission proposes to determine that the requested changes do not involve a significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: May 6, 1988

Description of amendment request: The proposed amendments would delete a footnote "NOTE 1" from Technical Specification (TS) 4.4.5.4 associated with steam generator tube plugging acceptance criteria, which states that "The application of F* expires at the end of the fifth fuel cycle for each respective unit." Removal of the footnote would authorize the application of F* for the life of the units. Also, the schedule for submittal of a report on the results of inspections of F* tubes, presently required by TS 4.4.5.5c to be submitted prior to the restart of the unit following the inspection, would be changed to require submittal within 15 days following the completion of the inspection. The NRC addressee for the report would be deleted.

Basis for proposed no significant hazards consideration determination: On August 19, 1986, by previous Amendments 59 (Unit 1) and 40 (Unit 2), the Commission revised the McGuire TSs to incorporate a distance, designated F* and identified as the F-star criterion, below the top of the steam generator tubesheet below which tube degradation of any extent does not necessitate plugging. In the SER for Amendments 59 and 40, the Commission concluded that tubes can safely be left in-service with degradation located below the F* distance. This represented the initial approval by the Commission for a plant to operate using F* criterion. Accordingly, the Commission concluded at that time that until behavior of F* tubes had been confirmed by actual operation, approval of these amendments should be limited to about two cycles of operation for each McGuire unit. The Commission has subsequently approved use of F* criteria on other nuclear plants which, like McGuire, use Westinghouse Model D steam generators (e.g., Catawba 1 and 2, V. C. Summer).

By application dated May 6, 1988, the licensee provided results of operating experience (328 tubes left in service) at McGuire 1 and 2 using F* criterion. The McGuire results demonstrate that the use of the F* criterion has had no adverse impact on any aspect of steam generator operability; no significant change in primary-to-secondary coolant leak rates and no degradation of tubesheet material have occurred. The experiences at other nuclear plants

using F* criterion have been similar. The F* criterion is also noted to have had a positive impact on the reduction of personnel radiation exposure. The favorable operating experience at McGuire and elsewhere, also eliminates the Commission's need for a separate reporting schedule for F* tube inspection results (i.e., F* tube inspection results may be reported consistent with the existing schedule for reporting results for non-F* tube inspections).

The Commission has provided guidance concerning the application of the standards for determining whether a significant hazards consideration exists by providing certain examples (51 FR 7744). One of the examples of actions involving no significant hazards considerations is example (iv) "a relief granted upon demonstration of acceptable operation from an operating restriction that was imposed because acceptable operation was not yet demonstrated." Because the subsequent operating experience at McGuire and elsewhere has met all criteria for continued operation and has demonstrated that potential concerns in the Commission's previous safety evaluation will not occur, relief from the limitation of F* to the end of the fifth fuel cycle and from separate reporting requirements matches this example.

Another example from 51 FR 7744 is example (i), "a purely administrative change to technical specifications." Because instructions for mailings to the NRC are specified by regulation (10 CFR 50.4), removal of the specified NRC addressee for receipt of the report provides for submittal consistent with the regulation. Therefore, this part of the proposed amendments is purely administrative and matches example (i).

Accordingly, the Commission proposes to determine that the proposed amendments would involve no significant hazards consideration.

Local Public Document Room location: Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: David B. Matthews

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendments request: January 16, 1987, as revised April 5, 1988

Description of amendments request: The purpose of the amendments is to change the refueling shutdown margin from 10 percent to 5 percent (delta k)/k in the Technical Specifications (TS) for Turkey Point Units 3 and 4, and to make some clarification changes to the respective TS.

Due to the large amount of excess reactivity currently installed at the beginning of a cycle, as a result of the recent increase in the length of fuel cycles, the refueling boron concentration to maintain a 10 percent (delta k)/k shutdown margin is now well over the required refueling boron concentration of greater than or equal to 1950 ppm. The proposed change in the shutdown margin would raise the associated effective multiplication factor (k_{eff}) from less than or equal to 0.90 to less than or equal to 0.95 and leave the refueling boron concentration requirement of greater-than-or-equal to 1950 ppm unchanged. The proposed change would require modifying Table 1.1, Section 3.10.8 and Bases B3.10.8 of the TS for Units 3 and 4.

The amendments also propose another change to Table 1.1 and changes to Table 4.18-1. The other change to Table 1.1 is to correct a typographical error. The changes in Table 4.18-1 would bring it into conformance with Table 1.1, i.e., for each unit, the designations for the operational modes as defined in Table 1.1 would be used in Table 4.18-1.

Basis for proposed no significant hazards consideration determination: As stated in 10 CFR 50.92, the Commission has provided guidelines and standards for determining whether a significant hazards consideration exists. According to 10 CFR 50.92(c), the Commission may make a proposed determination that a proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has evaluated the proposed change to the maximum effective multiplication factor during refueling in the plant Technical Specifications in accordance with the standards of 10 CFR 50.92(c) and has determined that operation of Turkey Point Units 3 and 4 in accordance with these changes would not:

(1) involve a significant increase in the probability or consequences of an accident previously evaluated. The effect of the proposed change would be to decrease the time to criticality in the event of a chemical and volume control system malfunction (i.e., a boron dilution during refueling accident). Since the operation and design of the chemical and volume control system remain as described in the FSAR, and an operator would still have at least 30 minutes to terminate a dilution event before a return to criticality occurs, the probability of an inadvertent dilution occurring would not be increased significantly, and the consequences would be the same.

(2) create the possibility of a new or different kind of accident from any accident previously evaluated. Since there is no significant change in the configuration or operation of the facility due to the proposed amendments, adopting a maximum k_{eff} of 0.95 for the refueling mode would not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) involve a significant reduction in a margin of safety. For example, comparative analyses for Unit 4 Cycle 11 show that the proposed change in the maximum k_{eff} from 0.90 to 0.95 would reduce the time to criticality after the worst dilution event from 58 to 44 minutes, leaving the operator with ample time to terminate the event.

In addition, the Commission has provided guidance for application of the criteria in 10 CFR 50.92 specified above by providing examples of amendments that are not likely to involve significant hazards considerations (51 FR 7751). The licensee proposes that of these the following example is applicable to the additional changes to Tables 1.1 and 4.18-1 identified in the amendment description, since they are administrative changes for consistency and to correct a typographical error:

Example (i) - a purely administrative change to the technical specifications, for example, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature.

The NRC staff believes that the proposed changes to the Technical Specifications meet the criteria specified in 10 CFR 50.92(c) and, as stated above, the guidance presented in 51 FR 7751 and, hence, proposes to determine that they involve no significant hazards considerations.

Local Public Document Room location: Environmental and Urban Affairs Library, Florida International University, Miami, Florida 33199

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzer, P.C., 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Herbert N. Berkow

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: January 28, 1988 and May 20, 1988

Description of amendment request: The proposed amendment would revise the Technical Specifications to correct the requirement for not testing the Log Power Level Chennels (used for startup and criticality) during Modes 1 and 2.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with a proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

The proposed amendment would correct the current requirement for and test of the Log Power Level Channels during modes where the trip function is not necessary. The test or operation of the full trip above 1.OE-4% of rated thermal power would trip the reactor therefore the trip is placed in bypass. The amendment would require the trip in the proper modes and provide operation when called upon to detect unplanned criticality from a shutdown condition. The proposed changes, therefore, do not involve a significant increase in the probability or consequences of an accident previously evaluated since the trip will be required to perform its intended function. Operation of the trip as required will not create the possibility of a new or different kind of accident from any previously evaluated. Since there is no change in the required operation of the trip, there is no significant reduction in a margin of safety. Based on the above considerations, the staff proposes to determine that the changes do not involve a no significant hazards consideration.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122

Attorney for licensee: Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N St., NW., Washington, DC 20037

NRC Project Director: Jose A. Calvo

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: May 20, 1988

Description of amendment request: The amendment would delete Figure 6.2.1; "Organization for Management and Technical Support," and Figure 6.2-2, "Plant Operation Organization," from the Technical Specifications. This action supersedes the licensee's request dated December 23, 1987 and as noticed on April 6, 1988 (53 FR 11373).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards in 10 CFR 50.92(c) for determining whether a significant hazards consideration exists. A proposed amendment to an Operating License for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability of consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The Louisiana Power & Light Company (LP&L) reviewed the proposed change and determined, and the NRC staff agrees, that:

(1) The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because deletion of the organization charts from the Technical Specifications does not affect plant operation. As in the past, the NRC will continue to be informed of organizational changes through other required controls. In accordance with 10 CFR 50.34(b)(6)(i) the applicant's organizational structure is required to be included in the Final Safety Analysis Report. Chapter 13 of the Final Safety Analysis Report provides a description of the organization and detailed organization charts. As required by 10 CFR 50.71(e), LP&L submits annual updates to the FSAR. Appendix B to 10 CFR Part 50 and 10 CFR 50.54(a)(3) govern changes to organization described in the Quality Assurance Program. Some of these organizational changes require prior NRC approval. Also, it is LP&L's practice to inform the NRC of organizational changes affecting the nuclear facilities prior to implementation.

(2) The proposed amendment does not create the possibility of a new or different kind of accident than previously evaluated because the proposed change is administrative in nature, and no physical alterations of plant configuration or changes to setpoints or operating parameters are proposed.

(3) The proposed amendment does not involve a significant reduction in a margin of safety because LP&L, through its Quality Assurance programs, its commitment to maintain only qualified personnel in positions of responsibility, and other required controls, assures that safety functions will be performed at a high level of competence. Therefore, removal of the organization chart from the Technical Specifications will not affect the margin of safety.

Accordingly, the Commission proposes to determine that this change does not involve a significant hazards consideration.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122

Attorney for licensee: Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N St., NW., Washington, DC 20037

NRC Project Director: Jose A. Calvo

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit No. 2, Scriba, New York

Date of amendment request: April 21, 1988

Description of amendment request: The proposed amendment would revise Technical Specification 4.8.1.1.2.a.4 to reduce the minimum allowable pressure for the Division 3 (EDG * 2) emergency standby diesel generator air start receivers from 225 psig to 190 psig.

The proposed amendment is in accordance with the licensee's application of April 21 1988.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3)

involve a significant reduction in a margin of safety.

The proposed changes will not involve a significant increase in the probability or consequences of an accident for the following reasons.

The proposed amendment involves lowering the minimum allowable pressure for the Division 3 emergency standby diesel generator (DG) air start receivers from 225 psig to 190 psig. The Division 3 DG has been tested by the licensee to demonstrated that it is capable of five consecutive starts within 10 seconds without recharging the air receivers with the initial air receiver pressure at 150 psig. Therefore, the Division 3 DG will still be capable of starting when required with the reduced pressure in the air receivers. Thus, the reduction in the minimum allowable air pressure will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated for the following reasons.

With the reduction in the air pressure to less than the specified 225 psig the Division 3 DG has been demonstrated by test to be able to start and be available when required. Furthermore, the licensee has stated that all safety-related systems and components will remain within their applicable design limits. In addition, the environmental qualification of plant equipment will not be adversely affected by the proposed change. Thus, system and component performance will not be adversely affected by this change, thereby assuring that the design capabilities of those systems and components will not be challenged in a manner not previously assessed. Therefore, the proposed changes will not create the possibility of a new or different accident from any accident previously evaluated.

The proposed changes will not involve a significant reduction in a margin of safety for the following reasons.

The proposed change would reduce the minimum required pressure for the Division 3 DG air start receivers but the system will still be able to meet the design criteria of starting five times consecutively within 10 seconds without recharging the air start receivers. The Division 3 DG has been tested and shown capable of performing these starts from a minimum pressure of 150 psig. The proposed minimum pressure is 190 psig, thereby allowing a 40 psig margin beyond the 150 psig minimum start test pressure. Therefore, the proposed change will not involve a significant reduction in a margin of safety.

Based on the above, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark Wetterhahn, Esq., Conner & Wetterhahn, Suite 1050, 1747 Pennsylvania Avenue, NW., Washington, DC 20006.

NRC Project Director: Robert A. Capra, Director

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit No. 2, Scriba, New York

Date of amendment request: April 28, 1988

Description of amendment request: The proposed amendment would revise Technical Specification Table 3.3.9-2 to reduce the allowable value for the Feedwater System/Main Turbine Trip System Reactor Water Level - High Level 8 from less than or equal to 209.3 in. to less than or equal to 203.8 in. The proposed amendment is in accordance with the licensee's application dated April 28, 1988.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

The proposed change will not involve a significant increase in the probability or consequences of an accident for the following reasons.

The proposed amendment involves correcting the narrow range level 8 allowable value for the feedwater system/main turbine trip system from 209.3 in. to 203.8 in. This lower value is conservative with respect to the transient analysis in Section 15 of the FSAR. The proposed value is also consistent with the existing design basis. Therefore, the proposed change will not result in an increase in the probability or consequences of an accident.

The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated for the following reasons.

This proposed change corrects an error in the Technical Specifications and does not change the design basis for Nine Mile Point Unit 2. Therefore, the fuel, pressure vessel and containment response to previously evaluated accidents remains within previously assessed limits of pressure and temperature. Further, all safety-related systems and components remain within their applicable design limits.

In addition, the environmental qualification of plant equipment is not adversely affected by this proposed amendment, further assuring that components are not challenged in a manner not previously assessed. In summary, the proposed amendment does not create the possibility of a new or different kind of accident from any previously assessed.

The proposed change will not involve a significant reduction in a margin of safety for the following reasons.

The proposed change will revise the allowable value to a more conservative value. In addition, the proposed change will correct the value in the Technical Specifications so that the revised value will agree with the existing design basis analysis. Therefore, the proposed change will not involve a significant reduction in a margin of safety.

Based on the above, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark Wetterhahn, Esq., Conner & Wetterhahn, Suite 1050, 1747 Pennsylvania Avenue, NW., Washington, DC 20006.

NRC Project Director: Robert A. Capra, Director

Philadelphia Electric Company, Docket No. 50-352, Limerick Generating Station, Unit 1, Montgomery County, Pennsylvania

Date of amendment request: December 1, 1986 and December 7, 1987

Description of amendment request: In accordance with the requirements of 10 CFR 73.55, the licensees submitted an amendment to the Physical Security Plan for the Limerick Generating Station to reflect recent changes to that

regulation. The proposed amendment would modify paragraph 2.E of Facility Operating License No. NPF-58 to require compliance with the revised Plan.

Basis for proposed no significant hazards consideration determination: On August 4, 1986 (51 FR 27817 and 27822), the Nuclear Regulatory Commission amended Part 73 of its regulations, "Physical Protection of Plants and Materials," to clarify plant security requirements to afford an increased assurance of plant safety. The amended regulations required that each nuclear power reactor licensee submit proposed amendments to its security plan to implement the revised provisions of 10 CFR 73.55. The licensee submitted its revised plan on December 1, 1986, and December 7, 1987, to satisfy the requirements of the amended regulations. The Commission proposes to amend the license to reference the revised plan.

In the Supplementary Materials accompanying the amended regulations, the Commission indicated that it was amending its regulations "to provide a more safety conscious safeguards system while maintaining the current levels of protection" and that the "Commission believes that the clarification and refinement of requirements as reflected in these amendments is appropriate because they afford an increased assurance of plant safety."

The Commission has provided guidance concerning the application of the criteria for determining whether a significant hazards consideration exists by providing certain examples of actions involving no significant hazards considerations and examples of actions involving significant hazards considerations (51 FR 7750). One of these examples of actions involving no significant hazards considerations is example (vii) "a change to conform a license to changes in the regulations, where the license change results in very minor changes to facility operations clearly in keeping with the regulations." The changes in this case fall within the scope of the example. For the foregoing reasons, the Commission proposes to determine that the proposed amendment involves no significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Attorney for licensee: Conner and Wetterhahn, 1747 Pennsylvania Avenue, NW., Washington, DC 20006

NRC Project Director: Walter R. Butler

Philadelphia Electric Company, Public Service Electric and Gas Company, Delmarva Power and Light Company, and Atlantic City Electric Company, Dockets Nos. 50-277 and 50-278, Peach Bottom Atomic Power Station, Units Nos. 2 and 3, York County, Pennsylvania

Date of application for amendments: March 21, 1988

Description of amendment request: The Licensee proposes to (1) revise the Section 1.2 BASES with regards to the description of the values and codes utilized in establishing the pressure safety limit of the reactor recirculation system, and revise the design pressure of the suction piping resulting from the installation of recirculation system piping which has been analyzed to a later version of the ASME Code (Units 2 and 3); (2) revise Tables 3.7.1, 3.7.4, and 4.2.A to reflect the removal of the Reactor Vessel Head Spray Primary containment isolation valves MO-10-32 and 33 (Unit 3); and (3) revise the Surveillance Requirements of Section 4.6.E to reflect the removal of the recirculation system cross-tie piping and equalizer valves (Units 2 and 3). These changes are identified as Category A, B and C changes in the following discussion.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards considerations if 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; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee addressed the above three standards for each of the three categories of changes in the amendment application as provided in the following analysis:

Category A: Operation of the plant under the proposed Technical Specification would not:

(i) Involve a significant increase in the probability or consequences of an accident previously evaluated.

This change reflects the use of ASME Section III as the design code for the new recirculation and Residual Heat Removal System piping. The increased design pressures are consistent with currently accepted criteria for nuclear piping. No change in the reactor system "over pressure set point" is required as a result of this change; the reactor vessel and the recirculation suction piping remain the limiting components in the system. Consequently, the probability or consequences of any accident previously evaluated in Chapter 14 of the Final Safety Analysis Report have not been increased. Additionally, removal of the references to the ANSI B31.1.0 Code in the Section 1.2 Bases is appropriate because the new recirculation system piping pressure limits have been established in accordance with the ASME Section III Code recognized in the Commission's regulations. Removal of the references to the discharge piping is appropriate because the pressure safety limit is based upon the suction piping and not the discharge piping. The removal of the reference to the discharge piping provides greater clarification to the Section 1.2 Bases. Consequently, the probability of consequences of any accident previously evaluated in Chapter 14 of the Final Safety Analysis Report have not been increased.

(ii) Create the possibility of a new or different kind of accident from any previously evaluated.

The revised design pressure of the recirculation system suction piping is in the conservative direction and will not create a new or different accident then previously evaluated in Chapter 14 of the Final Safety Analysis Report. Additionally, removal of the references to the ANSI B31.1.0 Code and discharge piping will not create a new or different accident than previously evaluated in Chapter 14 of the Final Safety Analysis Report.

(iii) Involve a significant reduction in a margin of safety.

The use of Type-316NG stainless steel recirculation system suction piping has resulted in a design pressure which allows greater margin of safety above normal operating pressure. Additionally, removal of the references to the ANSI B31.1.0 Code and discharge piping will not affect the margin of safety, nor affect any previous accident analysis evaluated in Chapter 14 of the Final Safety Analysis Report since the current design of the recirculation system reflects current requirements specified in the Commission's regulations.

Category B: Operation of the plant under the proposed Technical Specification would not:

(i) Involve a significant increase in the probability or consequences of an accident previously evaluated.

This change eliminates direct supply of cooling water to the vessel head region during shutdown. Additionally, the associated containment isolation valves will be removed and the containment penetration capped. The Residual Heat Removal System, independent of the head spray feature, is capable of reducing the reactor vessel to temperatures below 125 degrees F. within approximately 20 hours after inserting the control rods. The Reactor Vessel Head Spray System is merely an additional feature which was intended to expedite the shutdown cooling process and routine refueling. However, experience at Peach Bottom has shown that this capability has not been utilized because rapid head cooling is not

needed to expedite the start of refueling activities. Because Reactor Vessel Head Spray is not required for achieving or maintaining shutdown cooling, no credit is taken for this capability in any of the Final Safety Analysis Report Chapter 14 analyses. The containment isolation valves will be removed and the penetration will be capped on the inboard and outboard side of the containment maintaining the pressure boundary. Therefore, the removal of the Reactor Vessel Head Spray System and the associated containment isolation valves does not increase the probability or consequences of any accident previously evaluated in Chapter 14 of the Final Safety Analysis Report.

(ii) Create the possibility of a new or different kind of accident from any previously evaluated.

The removal of Reactor Vessel Head Spray System and the associated containment isolation valves would neither increase or decrease Residual Heat removal system reliability or impact on any other operating mode of the Residual Heat Removal System. As discussed previously, the Head Spray System does not perform a safety function. Removal of the containment isolation valves and capping the penetration establishes a passive primary containment boundary not subject to the effects of isolation valve degradation and malfunction. Elimination of a nonsafety function and the replacement of the containment isolation valves with a passive containment boundary provides protection at least equivalent to the present level and does not create the possibility of a new or different kind of accident.

(iii) Involve a significant reduction in a margin of safety.

The plant safety design basis is not affected by removal of the Reactor Vessel Head Spray piping and the associated containment isolation valves. The Reactor Vessel Head Spray System has no safety function and no credit is taken for its presence in Chapter 14 of the Final Safety Analysis Report analyses. However, the Technical Specifications must be amended to reflect the deletion of the Head Spray isolation valves. Since the system function is being removed and the associated pipe which contains these valves is being removed, there is no longer a surveillance requirement for these valves. Removal of the Head Spray piping and associated valves eliminates a portion of the primary coolant system that is susceptible to IGSCC degradation; therefore, a potential location for a primary system pipe break. Additionally, removal of the valves eliminates the potential for degradation of containment integrity due to valve malfunction. The containment penetration will be capped and the pressure boundary maintained. Consequently, the margin of safety is enhanced.

Category C: Operation of the plant under the proposed Technical Specifications would not:

(i) Involve a significant increase in the probability or consequences of an accident previously evaluated.

This proposed change reflects the elimination of the cross-tie piping and equalizer valves which provide a function previously identified as not being required for the safe operation of Peach Bottom Units 2 and 3. The two equalizer valves in the line are maintained in the locked-closed position during power operations. The cross-tie line was intended to provide the capability to promote equal flow distribution through Loops A and B during single loop operation (SLO). The Nuclear Steam System Supplier previously concluded that adequate core flow can be obtained during SLO with one recirculation pump operating and the cross-tie line closed. The Peach Bottom Units 2 and 3 safety analyses for SLO was performed assuming the valves are closed and not used. No credit has been taken for use of the cross-tie piping and equalizer valves in any Chapter 14 analysis. Therefore, the removal of the recirculation cross-tie piping and valves does not increase the probability or consequences of an accident previously evaluated in Chapter 14 of the Final Safety Analysis Report.

(ii) Create the possibility of a new or different kind of accident from any previously evaluated.

The equalizer valves have never been used during reactor power operations. As mentioned above, the safety analysis for SLO assumed that the valves are close and not used. Elimination of the cross-tie line, previously deemed not to be required for the safe operation of the plant, does not create a new or different kind of accident.

(iii) Involve a significant reduction in a margin of safety.

The cross-tie line has no safety function and no credit for its use has ever been taken in any accident or transient analysis or the emergency operating procedures. Removal of the cross-tie line would neither increase or decrease recirculation reliability since it has no impact on the recirculation system. Removal of the cross-tie line is beneficial in that it removes a potential location for a primary system pipe break and consequently maintains or enhances the margin of safety. The purpose of Surveillance Requirement 4.6.E.2 is to establish additional surveillance and operability requirement when operating with only one recirculation pump with the equalizer valves closed. Removing the equalizer valves does not impact the ability to comply with this Surveillance Requirements since the removal of the cross-tie piping and equalizer valves is equivalent to the equalizer valves being in the closed position.

The staff reviewed the licensee's no significant hazards determination analysis. The use of later versions of the ASME Code represent enhancements in the design criteria for the piping being replaced. The removal of the reactor vessel head spray piping and the recirculation piping cross-tie lines and valves involve deletion of design features that do not have a safety related function and have not been actively employed. Removal of these features will eliminate potential sites for intergranular stress corrosion cracking.

Based upon the above discussions, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126

Attorney for Licensee: Troy B. Conner, Jr., 1747 Pennsylvania Avenue, NW., Washington, DC 20006

NRC Project Director: Walter R. Butler

Public Service Company of Colorado, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Platteville, Colorado

Date of amendment request: April 29, 1988

Description of amendment request: The amendment would make certain changes to the Technical Specifications for the plant's DC power systems. It also allows for future changes to the station batteries.

Basis for proposed no significant hazards consideration determination: The licensee has analyzed the proposed amendment request for significant hazards consideration using the standards in Title 10, Code of Federal Regulation, Part 50.92. The licensee has concluded that the proposed amendment request involves no significant hazards consideration, based on the following analysis:

1. Does the amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Either one of the two station batteries is adequate to supply the required shutdown D.C. loads for four hours of allowing the loss of all A.C. power (FSAR 8.2.3.4). In the event all A.C. power is lost, the inoperable battery being charged can readily be reconnected to the system to perform its design function. For other possible accidents that could occur, the associated DC bus is supplied by the backup battery charger while maintaining D.C. bus independence such that both D.C. buses are available. Therefore, this change does not increase the probability or consequences of an accident.

2. Does the amendment create the possibility of a new or different kind of accident from any previously evaluated?

This change extends the period of time that a station battery and associated battery charger can be disconnected from its D.C. bus by allowing up to 5 consecutive days to perform an equalizing charge. This is required for proper maintenance of the batteries. Ensuring D.C. bus independence is maintained and the disconnect switch for the PPS battery is open when a station battery and/or associated battery charger is inoperable eliminates the possibility of a common mode failure. Therefore, it does not

create the possibility of a new or different kind of accident.

3. Does the amendment involve a significant reduction in a margin of safety?

The D.C. loads normally supplied by the station battery and associated battery charger are being supplied by the backup battery charger during the performance of an equalizing charge while maintaining D.C. bus independence. The allowance of up to 5 consecutive days to perform an equalizing charge will assure the station battery is capable of satisfying its design requirements. The disconnecting of a station battery and battery charger for up to 5 consecutive days does not reduce the margin of safety of the Auxiliary Electric Power System to provide adequate electric power since the required power source still exists. The station battery can be reconnected to supply the required electrical loads to effect a safe shutdown of the plant. Ensuring DC bus independence eliminates the possibility of a common mode failure. Therefore, continued operation under this configuration will not reduce significantly a margin of safety.

Based on the above evaluation, the licensee has concluded that operation of Fort St. Vrain in accordance with the proposed changes will involve no significant hazards consideration.

The staff has reviewed this analysis and finds it acceptable. Therefore, the staff proposes to determine that this amendment does not involve a significant hazards consideration.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado

Attorney for licensee: Byrant O'Donnell, Public Service Company of Colorado, P.O. Box 840, Denver, Colorado 80201-0840

NRC Project Director: Jose A. Calvo

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: April 28, 1988

Description of amendment request: The proposed change would revise the Applicability of Limiting Conditions for Operation (LCO) as specified by Technical Specification 3.0.4 and the Applicability of Surveillance Requirements as specified by Technical Specifications 4.0.3 and 4.0.4. The revisions are based on recommendations in Generic Letter 87-09 entitled "Sections 3.0 and 4.0 of the Standard Technical Specifications (STS) on the Applicability of Limiting Conditions for Operation and Surveillance Requirements." The proposed change to Technical Specification 3.0.4 would allow entry into an Operational Condition or other specified condition in accordance with Action Requirements when conformance to them would permit continued operation for an unlimited period of time. It would also delete noted exceptions to current Specification 3.0.4 from individual specifications where Operational Condition changes would not be precluded by the revised Specification 3.0.4. It would revise Surveillance Requirement 4.0.3 to allow a delay for up to 24 hours to permit the completion of the surveillance when the allowable outage time limits of some applicable Action Requirements are less than 24 hours. It would also revise Surveillance Requirement 4.0.4 to state that the provision on Specification 4.0.4 shall not prevent passage through or to operational conditions as required to comply with Action Requirements. The proposed revision to the Bases for all specifications in Sections 3.0 and 4.0 would provide a better justification supporting their applicability.

Basis for proposed no significant hazards consideration determination: The NRC staff proposes to determine that the proposed amendment does not involve a significant hazards consideration because, as required by the criteria of 10 CFR 50.92(c), 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; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The changes proposed by this amendment have been reviewed by the staff and are documented in Generic Letter 87-09. Current Technical Specification 3.0.4 states that entry into an Operational Condition or other specified condition shall not be made unless the LCO is met without reliance on the provisions of the Action Requirements. Its intent is to ensure that a higher Operational Condition is not entered when equipment is inoperable or when parameters exceed their specified limits. This precludes a plant startup when actions are being taken to satisfy an LCO, which — if not completed within the time limits of the Action Requirements — would result in a plant shutdown to comply with the Action Requirements. Current Technical Specification 3.0.4 also precludes entering an Operational Condition if an LCO is not met, even if the Action Requirements would permit continued operation of the facility for an unlimited period of time. Most, but not all of Hope Creek specifications that have Action Requirements which allow continued operation have a note that states that Specification 3.0.4 does not apply.

The staff stated in Generic Letter 87-09 that current Technical Specification 3.0.4 unduly restricts facility operation when conformance to the Action Requirements provides an acceptable level of safety for continued operation. For an LCO that has Action Requirements permitting continued operation for an unlimited period of time, entry into an Operational Condition or other specified condition should be permitted in accordance with those Action Requirements. Deletion of the notes taking exception to the current Specification 3.0.4 requirements and modification of the specification, as proposed to conform with Generic Letter 87-09, eliminates unnecessary restrictions on those few specifications that did not have notes of exception to Specification 3.0.4 and clarifies those that did have such notes of exceptions. The change may reduce the current margins slightly in those individual specifications that did not previously have notes of exception to Specification 3.0.4 and may increase the margin of safety slightly in those individual specifications that did have notes taking exception to Specification 3.0.4. The overall effect is that the margin has not been significantly changed. The proposed change to Technical Specification 4.0.3 would allow time to complete a missed surveillance test prior to commencing a power reduction. Since the majority of surveillances are completed successfully, this would avoid a potentially unnecessary transient and would therefore reduce the potential for plant upset and challenges to safety systems. The proposed change to Technical Specification 4.0.4 would resolve potential conflicts between Specifications 4.0.3 and 4.0.4 relating to Operational Condition changes; it would not change the intent of the specification in any way. For these reasons, the staff proposes to determine that the requested amendment would not involve a significant hazards consideration.

Local Public Document Room location: Pennsville Public library, 190 S. Broadway, Pennsville, New Jersey 08070

Attorney for licensee: Troy B. Conner, Jr., Esquire, Conner and Wetterhahn, 1747 Pennsylvania Avenue, NW., Washington, DC 20006

NRC Project Director: Walter R. Butler

Southern California Edison Company, et al., Docket Nos. 50-206, 50-361 and 50-362, San Onofre Nuclear Generating Station, Unit Nos. 1, 2 and 3, San Diego County, California

Date of amendment requests: December 14, 1987

Description of amendment requests: The proposed amendments involve a minor change in the location of a vital area boundary which slightly increases the size of a vital area.

Basis for proposed no significant hazards consideration determination: Based on the three criteria in 10 CFR 50.92, the proposed change for the San Onofre Nuclear Generating Station does not involve a significant hazards consideration based upon the following:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change affects only the Physical Security Plan which provides a basis for having assurance that acts of radiological sabotage will not significantly impact public health and safety. No FSAR accident analysis takes credit for the security provisions contained in the Physical Security Plan. Therefore, this change does not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed change to the Physical Security Plan does not alter any safety-related design basis of the facility or its operation. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in margin of safety?

The proposed change to the Physical Security Plan does not involve a significant reduction in a margin of safety since no change is made to the plant design or operating procedures. Therefore, margins of safety are not significantly reduced.

Based on the foregoing, the NRC staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: General Library, University of California, P.O. Box 19557, Irvine, California 92713.

Attorney for licensee: Charles R. Kocher, Assistant General Counsel, and James Beoletto, Esquire, Southern California Edison Company, P.O. Box 800, Rosemead, California 91770

NRC Project Director: George W. Knighton

Tennessee Valley Authority, Dockets Nos. 50-259, 50-260 and 50-296, Browns Ferry Nuclear Plant, Units 1, 2 and 3, Limestone County, Alabama

Date of amendment requests: June 1, 1988 (TS 245-T)

Description of amendment requests: The proposed amendment to the Browns Ferry Nuclear Plant (BFN) Units 1, 2 and 3 Technical Specifications (TS) requests temporary changes to the operability requirements for the Standby Gas Treatment System (SGTS) and Control Room Emergency Ventilation System (CREVS) to allow system modifications and maintenance needed for restart to proceed in parallel with the fuel inspection and reconstitution program. Specifically, the proposed amendments would require only two of the three trains of SGTS to be operable when secondary containment integrity is required. Further, the proposed amendments would allow the CREVS to be inoperable with no fuel in the reactor vessel. These temporary changes will be in effect only until the start of the upcoming fuel load.

Basis for proposed no significant hazards consideration determination: The Commission has provided Standards for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c). 10 CFR 50.91 requires that at the time a licensee requests an amendment, it must provide to the Commission its analyses, using the standards in Section 50.92, on the issue of no significant hazards consideration. Therefore, in accordance with 10 CFR 50.91 and 10 CFR 50.92, the licensee has performed and provided the following analysis:

NRC has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards considerations if 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 an accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

A discussion of these standards, as they relate to this amendment, is as follows.

(1) The proposed amendments do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed temporary changes to the technical specifications involve relaxations to system operability requirements for the SGTS and CREVS Systems during the fuel inspection and reconstitution program in addition to supporting plant activities before fuel load. The fuel being moved in the spent fuel pool has decayed for approximately three years, thus reducing the need for systems required by the technical specifications for postaccident iodine removal.

The fuel handling accident evaluated in the FSAR (Section 14.6.4) represents the most severe event in terms of radioactive release and dose consequences that should be considered applicable to the fuel inspection and reconstitution program or any other plant activity before fuel load. Since movement of irradiated fuel in the spent fuel pool area for a typical refueling operation is the same for the fuel inspection and reconstitution process, the current FSAR analysis is still valid. The current condition of the fuel is well within the bounds of the FSAR analysis. The FSAR calculations used freshly irradiated fuel (unloaded from the core 24 hours after shutdown) which would contain large amounts of fission products, specifically iodine. The irradiated fuel being inspected and reconstituted has decayed for approximately three years and the only remaining volatile fission product of any significance is Kr-85, which is an inert gas. Due to this decay time, there is essentially no iodine present and therefore no need for operability of systems with iodine removal capability.

The proposed temporary changes to the technical specifications do not affect the precursors for any accident analysis and therefore do not involve a significant increase in the probability of an accident previously evaluated. The present required availability of systems in the technical specifications is based on FSAR accident analysis assumptions and limitations. The present condition of the fuel in the spent fuel pool is such that over 300 assemblies would have to fail before the FSAR limiting assumptions for releases and dose consequences could be reached, thus allowing a reduction in the number of systems required to mitigate such a limiting event. The requested reduction in system operability for the SGTS and CREVS Systems has been evaluated and a determination reached that with the proposed temporary technical specification changes present FSAR assumptions and limitations will be maintained. Therefore, the proposed temporary changes do not involve a significant increase in the consequences of an accident previously evaluated.

(2) The proposed change does not create the possibility of a new or different kind of accident from an accident previously evaluated. The proposed temporary changes will reduce present system operability requirements; however, no new modes of plant operation are introduced which could contribute to the possibility of a new or different kind of accident. The fuel inspection and reconstitution program involves handling irradiated fuel which is bounded by present FSAR fuel handling accident assumptions. This is the most severe event that could occur before fuel load therefore any plant activities conducted until then will be also bounded by the FSAR fuel handling accident.

(3) The proposed amendment does not involve a significant reduction in a margin of

safety. The proposed temporary technical specification changes will reduce the operability requirements for the SGTS and CREVS during the fuel inspection and reconstitution program and those plant activities conducted before fuel load for BFN Unit 2. The proposed temporary changes as they relate to the margin of safety are discussed below:

a. SGTS - Based on the current Unit 2 fuel fission inventory (essentially no iodine) the SGTS would not be required to mitigate a fuel handling accident during the fuel inspection and reconstitution program. The most severe accident applicable before fuel load is the fuel handling accident previously evaluated in FSAR Section 14.6.4. The SGTS is still required to maintain the one-quarter inch of water negative pressure when secondary containment integrity is required (Technical Specification 4.7.C). Approximately 10,100 CFM are required to draw the one quarter inch of water negative pressure and each SGTS is rated at 9000 CFM. Therefore, two trains of the SGTS are more than adequate.

b. CREVS - The irradiated fuel has decayed for approximately three years and the only remaining volatile fission product of any significance is Kr-85. Essentially no iodine is present in the decayed fuel. Due to the "scrubbing" effect of the fuel pool water and since Kr-85 is the only radioisotope of any significance, should a fuel handling accident occur virtually no radioactive particulates would be present in the CREVS intake ductwork. Therefore, the filtration function that the CREVS provides would not be needed during the fuel inspection and reconstitution program or any other plant activities before fuel load.

The proposed temporary changes will ensure that the appropriate safety-related systems needed to mitigate the fuel handling accident are operable and will be able to perform their intended safety function if called upon. Therefore, the proposed changes do not represent a significant reduction in a margin of safety.

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Therefore, the staff proposes to determine that the application for amendments involves no significant hazards consideration.

Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, E11 B33, Knoxville, Tennessee 37902.

NRC Assistant Director: Suzanne Black

Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of application for amendment: May 23, 1988

Description of application for amendment: The proposed amendment would revise the Technical Specification to enable the licensee to use reactor replacement fuel of the GE 8x8EB extended burnup fuel design which has several different mechanical and nuclear features than existing Cycle 13 fuel. The GE 8X8EB fuel design, as described in Topical Report NEDE-24011-P-A, "General Electric Standard Application for Reactor Fuel," has been reviewed and approved by the NRC for generic applications and extended burnup operations. Utilization of GE 8X8EB fuel was previously approved for other reactors (e.g. Quad Cities Nuclear Power Station, Unit 1, Fitzpatrick, Peach Bottom, Limerick, and Millstone). The technical specifications would be revised as follows:

1. Revise Limiting Conditions for Operation (LCO) 3.11A to allow the addition of average planar linear heat generation rate (APLHGR) limits for GE 8X8EB fuel types.

2. Revise LCO 3.11B to include vendor recommended linear heat generation rate (LHGR) limiting values for GE 8x8EB fuel types.

3. Revise Design Section 5.5E to specify the peak uncontrolled infinite lattice multiplication factor appropriate for storage of GE 8x8EB fuel types.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if 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; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee, in its May 23, 1988 submittal, provided the following evaluation of the proposed change with regard to these three standards:

(i) The proposed change will not involve any significant increase in the probability or consequences of an accident previously evaluated because: No changes are being made to the facility or its equipment other than the introduction of the GE 8x8EB fuel type. The NRC has separately approved GE's extended burnup fuel design via a letter from H. N. Berkow (NRC) to J.S. Charnley (GE) entitled "Acceptance for Approval of Fuel Designs Described in Licensing Topical Report NEDE-24011-P-A-6, Amendment 10 for Extended Burnup Operation," dated December 3, 1985. This letter and the Safety Evaluation Report are included in Appendix US.C of Reference b).

The NRC specifically found that GE 8x8EB designs are acceptable for operation to extended burnups as defined in Amendment 10.

Operation of the plant with the GE 8x8EB fuel type will not significantly increase the probability or consequences of an accident previously evaluated. Increasing the probability of an accident could only occur if the facility were materially weakened or degraded in some fashion by the introduction of the GE 8x8EB fuel design or by the three administrative changes to the Technical Specifications described above. There is nothing in the GE 8x8EB fuel design that would cause the facility to be materially weakened or degraded. Neither do the three administrative changes weaken or degrade the facility. Rather, they provide controls on the use of the fuel to assure safety limits are not exceeded.

The consequences of an accident will not be significantly increased if the proposed change does not result in a significant increase in the release of fission products from the fuel in the event of a postulated accident. Such a release could be caused by an increase in the total fission product inventory available for release from some specified level of fission product barrier damage, or an increase in the level of fission product barrier damage, or both. The three administrative changes described above will provide assurance that the consequences of accidents previously evaluated will not be increased. Part 1 provides limits that will assure that the requirements of 10 CFR 50.46, which defines the acceptable consequences for a loss-of-coolant accident, are met for plant operation with the new fuel type. Part 2 defines the acceptable value for linear heat generation rate which will assure that the plant is operated within acceptable fuel cladding integrity safety limits as defined in Reference b), thus, ensuring that the consequences of an accident previously analyzed will not be increased. Part 3 provides assurance that the criticality limits for fuel storage are maintained. The consequences of a hypothetical criticality accident are not affected by this change. The probability will be reduced because Part 3 provides an improved method for ensuring compliance with the safety limit.

(ii) The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated because: The facility is not being changed, except for the introduction of the GE 8x8EB fuel type. Since this fuel type is essentially the same as the fuel currently in use and has been found to be acceptable for use per Reference b), there is no possibility that its use will create a new or different kind of accident. Parts 1 and 2 provide fuel thermal limits that are specified to assure the plant does not exceed applicable safety limits and, thus, do not, in and by themselves, create the possibility of a new or different accident from any previously evaluated. Part 3 provides further assurance that the criticality limits for fuel storage are not exceeded and, thus, does not, in and by itself, create the possibility of a new or different accident from any previously evaluated.

(iii) The proposed change will not involve a significant reduction in a margin of safety

because: The GE 8x8EB fuel is designed to the same or higher standards of safety as fuel types previously used. The GE 8x8EB design is an improvement on the GE P8x8R and BP8x8R designs, which were previously approved for use by VYNPC. The NRC has approved the use of this fuel type (Reference b) after considering a wide range of thermal-mechanical issues at extended burnups. Thus, its use will not involve a significant reduction in a margin of safety. Part 1 provides limits which will assure the acceptance criteria of 10CFR50.46 will be met; thus, Part 1 will not involve a reduction in a margin of safety since the margin of safety is defined by the acceptance criteria of 10 CFR 50.46. Part 2 provides assurance that the design basis for the GE 8x8EB fuel is not exceeded, thus assuring that the margin of safety, which has already been found to be acceptable in Reference b), is maintained; thus, Part 2 will not involve a reduction in a margin of safety. Part 3 provides assurance that the margin of safety for fuel storage is maintained. The margin of safety for the spent fuel storage is not being changed; nor is the licensee being relieved of demonstrating compliance with this limit. The proposed substitution of a K" ° method of demonstrating compliance with this limit provides an equivalent and technically more appropriate method of assuring margin to the applicable safety limits. Thus, Part 3 will not involve a reduction in the margin of safety.

The staff has considered the proposed amendment and agrees with the licensee's evaluation with respect to the three standards.

On this basis, the Commission has concluded that the requested change meets the three standards and, therefore, has made a proposed determination that the amendment involves no significant hazards consideration.

Local Public Document Room Location: Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont 05301.

Attorney for licensee: John A Ritscher, Esq., Ropes & Gray, 225 Franklin Street, Boston, Massachusetts 02110.

NRC Project Director: Richard H. Wessman, Director

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

Alabama Power Company, Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Unit 1 and 2, Houston County, Alabama.

Dates of application for amendments: December 8, 1986, and September 16, and November 17, 1987.

Description of amendments: These amendments modify the License Condition sections to conform to the requirements of 10 CFR 73.55.

Date of issuance: May 27, 1988

Effective date: May 27, 1988

Amendment Nos.: 76 and 68

Facility Operating License Nos. NPF-2 and NPF-8: Amendments revised the Licenses.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11362) The Commission's related evaluation of the amendment is contained in a letter to the licensee, and a Safeguards Evaluation Report, dated May 27, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303

Arizona Public Service Company, et al., Docket No. STN 50-528, Palo Verde Nuclear Generating Station, Unit 1, Maricopa County, Arizona

Date of application for amendment: March 2, 1988

Brief description of amendment: The amendment incorporates as a condition to the license the commitments currently in effect for monitoring the reactor coolant pump shaft vibration.

Date of issuance: May 10, 1988

Effective date: May 10, 1988

Amendment No.: 32

Facility Operating License No. NPF-41: Amendment changed the license.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11364). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 10, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529 and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Maricopa County, Arizona

Date of application for amendments: November 21, 1986 and December 7, 1987

Brief description of amendments: The amendments modified paragraph 2.E of each license to require compliance with the amended Physical Security Plan. This Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of these amendments.

Date of issuance: May 12, 1988

Effective date: May 12, 1988

Amendment Nos.: 33, 20 and 7

Facility Operating License Nos. NPF-41, NPF-51 and NPF-74: Amendments changed the licenses.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11363). The Commission's related evaluation of the amendments is contained in a letter to Arizona Nuclear Power Project dated May 12, 1988 and a Safeguards Evaluation Report dated May 12, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Boston Edison Company Docket No. 50-293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: January 25, 1988

Brief Description of amendment: This amendment revises the Technical Specifications to remove misleading references to an average power range monitor (APRM) downscale scram function.

Date of issuance: May 23, 1988

Effective date: 30 days from date of issuance

Amendment No.: 117

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: April 20, 1988 (53 FR 13012) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 23, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Dates of application for amendment: November 26, 1986 and September 23, 1987

Brief description of amendment: The amendment modifies the license in Section 2.E to require compliance with the amended Physical Security Plan.

Date of issuance: May 25, 1988

Effective date: May 25, 1988

Amendment No. 6

Facility Operating License No. NPF-63. Amendment revised the License.

Date of initial notice in Federal Register: April 6, 1988 (53 FR 11366) The Commission's related evaluation of the amendment is contained in a Safeguards Evaluation Report dated May 25, 1988.

No significant hazards consideration comments received: No

Attorney for the Licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

Local Public Document Room location: Richard B. Harrison Library, 1313 New Bern Avenue, Raleigh, North Carolina 27610

Cleveland Electric Illuminating Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No. 50-440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of application for amendment: February 9, 1988

Brief description of amendment: The amendment allows a one-time waiver of the requirement for performing a complete diesel overhaul to like-new condition for the purpose of reducing the diesel generator test failure count as allowed by the footnote to Table 4.8.1.1.2-1 of the Technical Specifications.

Date of issuance: May 18, 1988

Effective date: May 18, 1988

Amendment No. 12

Facility Operating License No. NPF-58. This amendment revised the Technical Specifications.

Date of initial notice in Federal Register: April 4, 1988 (53 FR 11377) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 18, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, Ohio 44081

Commonwealth Edison Company, Docket Nos. 50-373 and 50-374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Date of application for amendments: March 9, 1988

Brief description of amendment: These amendments provide a one-time change to the requirements of Section 4.0.2.b of the Technical Specifications altering certain surveillance intervals.

Date of Issuance: May 24, 1988

Effective Date: May 24, 1988

Amendment Nos. 57, 38

Facility Operating License Nos. NPF-11 and NPF-18: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: April 20, 1988 (53 FR 13012) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 24, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Public Library of Illinois, Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Commonwealth Edison Company, Docket Nos. 50-254 and 50-265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois

Date of application for amendments: November 6, 1987 and supplemented by December 16, 1987.

Brief description of amendments: Technical Specifications were revised for the High Pressure Core Injection and Reactor Core Isolation Cooling Systems high steam line flow instrumentation. The minimum number of operable channels were decreased and the associated time delay setting was made more conservative.

Date of issuance: May 10, 1988

Effective date: May 10, 1988

Amendment Nos.: 107, 102

Facility Operating License Nos. DPR-29 and DPR-30: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: January 13, 1988 (53 FR 621). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 10, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021.

Connecticut Yankee Atomic Power Company, Docket No. 50-213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: February 25, 1988

Brief description of amendment: This amendment renumbers the manual high pressure safety injection (HPSI) throttle valves in Technical Specification 3.6.B.2 to be consistent with the plant loop numbering scheme. Also, the applicability statement for Technical Specification 3.6.B.2 has been changed to be more concise and MODE specific and the Basis for Technical Specification 3.6 has been clarified.

Date of Issuance: May 26, 1988

Effective date: May 26, 1988

Amendment No.: 103

Facility Operating License No. DPR-61: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 23, 1988 (53 FR 9500) The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated May 26, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Connecticut Yankee Atomic Power Company, Docket No. 50-213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: February 9, 1988

Brief description of amendment: The proposed changes to Technical Specification Table 3.22-2 will: (1) add one Halon storage cylinder in the Switchgear Room; (2) increase the number of smoke detectors in the Switchgear Room from 32 to 35; and (3) require 8 of 9 smoke detectors within the Screenwell Building to be in service. In addition, Table 3.22-2 will be revised to reflect new fire areas in the Primary Auxiliary Building and Screenwell Building that agree with the current Fire Hazard Analysis.

Date of Issuance: June 1, 1988

Effective date: June 1, 1988

Amendment No.: 104

Facility Operating License No. DPR-61. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 23, 1988 (53 FR 9500) The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated June 1, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Dairyland Power Cooperative, Docket No. 50-409, La Crosse Boiling Water Reactor, La Crosse, Wisconsin

Date of application for amendment: September 30, 1987 as revised February 22, 1988.

Brief description of amendment: This amendment revises the Technical Specifications (TS) to delete requirements related to core alteration, critical power ratio, cooling system leakage, limiting control rod pattern, linear heat generation rate, partial scram, physics tests, pressure boundary leakage, shutdown margin and thermal power. These definitions and requirements are all related to reactor operation and are no longer applicable with no fuel in the reactor and reactor operations not permitted.

Safety Limits and Limiting Safety System Settings, and associated bases are deleted. These limits and trip setpoints were included to maintain the integrity of the fuel cladding, pressure vessel, and primary piping during abnormal reactor operating conditions and are not applicable with the reactor no longer operable or fueled.

Requirements for control room operator direction of operations with fuel in the reactor and reactor operational instructions in the event of a tornado or high river water level are deleted. These operator requirements are not applicable with the reactor permanently shutdown.

The amendment deletes limiting conditions for operation (LCOs) that are applicable to reactor operations such as surveillance requirements for the reactor cooling system and associated valves, the electrical supply system for reactor safety systems, and the post reactor accident instrumentation.

The amendment also adds requirements for the backup water supply for the Fuel Element Storage Well. This is an additional and more conservative requirement for this water supply. The licensee also proposes added TS requirements for Shift Supervisor authorization to perform any maintenance and for leak testing of the containment freight door after each opening.

Date of issuance: May 31, 1988

Effective Date: May 31, 1988

Amendment No.: 62

Facility Operating License No. DPR-45. This Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 18, 1987 (52 FR 44243) and April 20, 1988 (53 FR 13013). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 31, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601.

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of application for amendment: April 20, 1988.

Brief description of amendment: The amendment revises Technical Specification Table 4.3.1.1-1, "Reactor Protection System Instrumentation Surveillance Requirements," to delete the Daily Channel Check requirements of Note (g) for the Average Power Range Monitor Flow Biased Neutron Flux - High Scram Functional Unit. This change removes a requirement that has been determined to have no meaning because the safety functions are covered elsewhere in the Technical Specifications.

Date of issuance: June 3, 1988

Effective date: June 3, 1988

Amendment No.: 19

Facility Operating License No. NPF-43. The amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** April 29, 1988 (53 FR 15476). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 3, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161.

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: October 29, 1985, as supplemented August 25, 1986, May 26, 1987 and January 19, 1988.

Brief description of amendments: The amendments modified the Technical Specifications to accommodate removal of the resistance temperature detector (RTD) bypass manifold systems and the installation of in-line RTDs.

Date of issuance: May 19, 1988

Effective date: May 19, 1988

Amendment Nos.: 84 and 65

Facility Operating License Nos. NPF-9 and NPF-17: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 10, 1986 (51 FR 32266) The substance of the changes noticed in the Federal Register on September 10, 1986 and the proposed No Significant Hazards determination were not affected by the licensee's letters dated May 26, 1987 and January 19, 1988, which clarified certain aspects of the request. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 19, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223

Duquesne Light Company, Docket No. 50-334, Beaver Valley Power Station, Unit No. 1, Shippingport, Pennsylvania

Date of application for amendment: February 5, 1988

Brief description of amendment: The amendment deletes Section 3.6.4.3, "Hydrogen Purge System", and associated surveillance requirements from the Technical Specifications. Deletion is justified on the basis that a fully redundant hydrogen recombiner system is available.

Date of issuance: May 26, 1988

Effective date: May 26, 1988

Amendment No. 126

Facility Operating License No. DPR-66: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 23, 1988 (53 FR 9501) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 26, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

GPU Nuclear Corporation, Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Date of application for amendment: January 27, 1987, as supplemented March 16, 1988.

Brief description of amendment: The amendment incorporates the requirement to adhere to the "Plan for the Long Range Planning Program for the Oyster Creek Nuclear Generating Station" and the terms therein for implementing changes to its contents.

Date of Issuance: May 27, 1988

Effective date: May 27, 1988

Amendment No.: 122

Provisional Operating License No. DPR-16. Amendment added a license condition.

Date of initial notice in Federal Register: March 12, 1987 (52 FR 7683). The March 16, 1988 submittal provided clarifying information and did not change the substance of the amendment and did not change the finding of no significant hazards consideration in the initial notice. The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated May 27, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

GPU Nuclear Corporation, et al., Docket No. 50-289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of application for amendment: July 13, 1987, as supplemented March 16, 1987.

Brief description of amendment: Adds a license condition providing for adherence to a Long Range Planning Program requiring NRC approval of schedule changes for certain categories of plant projects and commitments.

Date of Issuance: May 27, 1988

Effective date: May 27, 1988

Amendment No.: 140

Facility Operating License No. DPR-50: Amendment added a License Condition.

Date of initial notice in Federal Register: August 12, 1987 (52 FR 29918). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated May 27, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

GPU Nuclear Corporation, et al., Docket No. 50-289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of application for amendment: January 29, 1988

Brief description of amendment: This amendment revises various sections in Chapter 6 of the Technical Specifications (Administrative Controls) with regard to the procedures for review process for procedures, modifications to structures, systems and components, and proposed tests and experiments. These revisions are consistent with the terminology used in the standard Technical Specifications for Babcock and Wilcox reactor plants. This amendment also clarifies the bases for Technical Specification 3.1.6 (Reactor Coolant System Leakage).

Date of Issuance: June 3, 1988

Effective date: June 3, 1988

Amendment No.: 141

Facility Operating License No. DPR-50: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 9, 1988 (53 FR 7593) The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated June 3, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

GPU Nuclear Corporation, et al., Docket No. 50-320, Three Mile Island Nuclear Station, Unit No. 2, Dauphin County, Pennsylvania

Date of application for amendment: April 23, 1987, as revised October 6, November 9 and December 4, 1987.

Brief description of amendment: The amendment modifies Appendix A Technical Specifications Sections 1-Definitions, 2-Safety Limits, 3-Limiting Conditions for Operation, 3/4 Basis for Limiting Conditions for Operations and Surveillance Requirements, and 6-Administrative Controls. The amendment extensively revises the TMI-2 Technical Specifications aligning licensing requirements to appropriate current, as well as future, plant conditions-through the remainder of the current cleanup operations. The amendment allows for the transition from the current defueling phase through the completion of defueling and offsite fuel shipment by incorporating Technical Specifications that are applicable during specific phases or modes of the cleanup.

Date of Issuance: May 25, 1988

Effective date: May 25, 1988

Amendment No.: 30

Facility Operating License No. DPR-73: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: January 13, 1988 (53 FR 823) supplemented February 24, 1988 (53 FR 5491). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated May 25, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: March 22, 1988

Brief description of amendment: The amendment revised the Technical Specifications by correcting the number of fire detectors installed in Fire Zone RAB-2 from 36 to 35.

Date of issuance: May 24, 1988

Effective date: May 24, 1988

Amendment No.: 36

Facility Operating License No. NPF-38. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: April 20, 1988 (53 FR 13107) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: December 1, 1986, December 30, 1987, and March 21, 1988.

Brief description of amendment: The amendment modified paragraph 2.E of the license to require compliance with the amended Physical Security Plan. This Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of this amendment.

Date of issuance: May 24, 1988

Effective date: May 24, 1988

Amendment No.: 37

Facility Operating License No. NPF-38. Amendment revised the license.

Date of initial notice in **Federal Register:** April 20, 1988 (53 FR 13016). The Commission's related evaluation of the amendment is contained in a letter to Louisiana Power and Light dated May 24, 1988 and a Safeguards Evaluation Report dated May 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: January 13, 1988 as supplemented by letter dated May 6, 1988.

Brief description of amendment: The amendment revised the Technical Specifications Table 3.6-2 by adding a new isolation valve to the automatic isolation section and moving an existing valve from manual to the automatic section while changing its identification number. The amendment also revised Table 3.6-1 to add a new containment isolation valve for Type C testing to the table and changes the identification number of an existing valve.

Date of issuance: May 25, 1988

Effective date: May 25, 1988

Amendment No.: 38

Facility Operating License No. NPF-38. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 23, 1988 (53 FR 9506). The licensee's May 6, 1988 submittal did not change or affect the substance of the amendment request or the proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 25, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Mississippi Power & Light Company, System Energy Resources, Inc., South Mississippi Electric Power Association, Docket No. 50-416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Dates of application for amendment: November 24, 1986 and September 1, 1987

Brief description of amendment: The amendment modifies the license to require compliance with the amended Physical Security Plan.

Date of issuance: May 25, 1988

Effective date: May 25, 1988

Amendment No. 44

Facility Operating License No. NPF-29. This amendment revised the License.

Date of initial notice in **Federal Register:** March 9, 1988 (46 FR 7594). The Commission's related evaluation of the amendment is contained in a letter to System Energy Resources, Inc. and in the Safeguards Evaluation Report dated May 25, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Hinds Junior College, McLendon Library, Raymond, Mississippi 39154

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station, Unit No. 1, Oswego County, New York

Date of application for amendment: January 29, 1988

Brief description of amendment: This amendment revises Technical Specifications 3.2.6 and 4.2.6 of NMP-1 concerning the Inservice Inspection (ISI) and Inservice Testing (IST) Programs.

Date of issuance: May 23, 1988

Effective date: May 23, 1988

Amendment No.: 96

Facility Operating License No. DPR-63: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 9, 1988 (52 FR 7595). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 23, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Northeast Nuclear Energy Company, et al., Docket Nos. 50-245, 50-336, and 50-423, Millstone Nuclear Power Station, Unit Nos. 1, 2, and 3, New London County, Connecticut

Date of application for amendment: December 2, 1986, as supplemented by letter dated December 23, 1987.

Brief description of amendment: The License Amendments reflect changes in the requirements associated with plant security as contained in the August 4, 1986 Amendment to 10 CFR Part 73, "Physical Protection of Plants and Materials". The License Amendments modify paragraph 2.C.(4), of Facility Operating License No. DPR-21, paragraph 2.C.(4) of Facility Operating License No. DPR-65 and paragraph 2.E of Facility Operating License No. NPF-49 to require compliance with the revised Millstone Security Plan.

Date of issuance: May 26, 1988

Effective date: May 26, 1988

Amendment Nos.: 17, 129, 19

Facility Operating License Nos. DPR-21, DPR-65 and NPF-49: These amendments revise the licenses.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11373). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 26, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Northeast Nuclear Energy Company, et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of application for amendment: February 18, 1988

Brief description of amendment: The amendment revises Technical Specification Section 3.4.9.3 to change the minimum Reactor Coolant System (RCS) vent area required for cold overpressure protection from 7.0 to 5.4 square inches. In addition, Technical Specification Sections 3.8.1.2, 3.8.2.2 and 3.8.3.1 are changed to make them consistent with the revised Section 3.4.9.3.

Date of issuance: May 19, 1988

Effective date: May 19, 1988

Amendment No.: 18

Facility Operating License No. NPF-49: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11374). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 19, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Rochester Gas & Electric Corporation, Docket No. 50-244, R. E. Ginna Nuclear Plant Wayne County, New York

Date of application for amendment: September 23, 1987

Brief description of amendment: The amendment revised the Technical Specifications to change the reporting requirements for iodine spiking and eliminate the requirement for plant shutdown if iodine activity limits are exceeded for 800 hours in a 12 month period.

Date of issuance: May 31, 1988

Effective date: May 31, 1988

Amendment No.: 27

Facility Operating License No. DPR-18: This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 9, 1988 (53 FR 7600). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 31, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Rochester Public Library, 115 South Avenue, Rochester, New York 14610.

Attorney for licensee: Harry Voigt, LeBoeuf, Lamb, Leiby and McRae, Suite 1100, 1333 New Hampshire Avenue, NW., Washington, DC 20036

NRC Project Director: Richard H. Wessman

Rochester Gas and Electric Corporation, Docket No. 50-244, R. E. Ginna Nuclear Power Plant, Wayne County, New York

Date of application for amendment: December 28, 1987 and clarified on May 5, 1988.

Brief description of amendment: This amendment revises the Technical Specifications to remove the organizational charts and revise other administrative requirements.

Date of issuance: May 31, 1988

Effective date: May 31, 1988

Amendment No.: 28

Facility Operating License No. DPR-18: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 9, 1988 (53 FR 7601). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 31, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Rochester Public Library, 115 South Avenue, Rochester, New York 14610.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Dates of application for amendment: December 12, 1986, October 14, 1987, November 13, 1987 and December 15, 1987

Brief description of amendment: The amendment modifies the license to require compliance with the requirements 10 CFR 73.55.

Date of issuance: May 26, 1988

Effective date: May 26, 1988

Amendment No.: 70

Facility Operating License No. NPF-12. Amendment revised the License.

Date of initial notice in **Federal Register:** March 23, 1988 (53 FR 9514). The Commission's related evaluation of the amendment is contained in a Safeguards Evaluation Report dated May 26, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Southern California Edison Company, Docket No. 50-206, San Onofre Nuclear Generating Station, Unit No. 1, San Diego County, California

Date of application for amendment: August 29, 1977, October 20, 1978, May 8, 1984 and January 21, 1986

Brief description of amendment: The amendment approves changes to the Technical Specifications which incorporate limiting conditions for operation and surveillance requirements for the overpressure mitigation system.

Date of issuance: May 23, 1988

Effective date: May 23, 1988

Amendment No.: 102

Provisional Operating License No. DPR-13. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** June 20, 1984 (49 FR 25373). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 23, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: General Library, University of California, Post Office Box 19557, Irvine, California 92713.

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: February 27, 1987 (TS 87-01)

Brief description of amendments: Tennessee Valley Authority proposes to amend the technical specifications of Sequoyah Nuclear Plant, Units 1 and 2 to ensure that directions given by the technical specifications regarding submittal to the NRC are consistent with those determined in the 10 CFR Parts 50 and 51 Final Rule as published in the **Federal Register** on November 6, 1986, and made effective January 5, 1987.

Date of issuance: May 23, 1988

Effective date: May 23, 1988

Amendment Nos.: 72, 64

Facility Operating Licenses Nos. DPR-77 and DPR-79. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 15, 1987 (52 FR 26597). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 23, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

Toledo Edison Company and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of application for amendment: March 12 and May 19, 1987

Brief description of amendment: The amendment revised Technical Specification Section 3/4.7.7 relating to surveillance and functional testing of snubbers.

Date of issuance: May 25, 1988

Effective date: May 25, 1988

Amendment No.: 111

Facility Operating License No. NPF-3: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 6, 1988 (53 FR 11378). The Commission's related evaluation of the amendment is contained in a letter to the licensee dated May 25, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: University of Toledo Library,

Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: July 31, 1987, as supplemented by letter dated February 19, 1988.

Brief description of amendment: The amendment revised the plant heatup and cooldown curves, revised the maximum allowable power operated relief valve setpoint curve, and revised the reactor vessel surveillance capsule removal schedule.

Date of issuance: May 24, 1988

Effective date: May 24, 1988

Amendment No.: 36

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: October 7, 1987 (52 FR 37555). The February 19, 1988 supplement contained responses to staff questions in clarification of the original application. It was consistent with the staff's original findings. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 24, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251 and the John M. Olin Library, Washington University, Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Virginia Electric and Power Company, et al., Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of application for amendments: April 1, 1987

Brief description of amendments: The amendments modified the NA-1&2 TS 3/4.9.10 to conform to the Standard Technical Specifications for Westinghouse Pressurized Water Reactors, NUREG-0452, Revision 3. The change enhances operating flexibility and the time required for refueling operations while in Mode 6. In addition, the change prevents contamination of the upper internals lifting rig during the removal of the reactor vessel upper internals during refueling operations.

Date of issuance: May 23, 1988

Effective date: May 23, 1988

Amendment Nos.: 102 and 89

Facility Operating License Nos. NPF-4 and NPF-7. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: March 9, 1988 (53 FR 7604). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 23, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Virginia Electric and Power Company, et al., Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of application for amendments: March 18, 1988

Brief description of amendments: The amendments revised the NA-1&2 Table 6.2.1, Minimum Shift Crew Composition in accordance with your commitment to the NA-1&2 10 CFR 50, Appendix R Report. Also, the NA-1 TS 6.13 and the NA-2 Facility Operating License Conditions 4.a, 4.b, 4.d and 4.e were deleted in accordance with 10 CFR 50.49(g). Finally, a more complete list of special reports was provided for the NA-1&2 TS 6.9.2, Special Reports.

Date of issuance: May 26, 1988

Effective date: May 26, 1988

Amendment Nos.: 103 and 90

Facility Operating License Nos. NPF-4 and NPF-7. Amendments revised the Technical Specifications and the License for NPF-7.

Date of initial notice in Federal Register: April 20, 1988 (53 FR 13025). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 26, 1988.

No significant hazards consideration comments received: No.

Local Public Document Room location: The Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia.

Date of application for amendments: March 1, 1988, as clarified on April 8, 1988

Brief description of amendments: These amendments modified Section 4.4, "Containment Test" of the Surry Units 1 and 2 Technical Specifications to reflect the use of the Mass Point method for calculating containment leakage rates, which is described in ANSI/ANS 56.8-1987, "Containment System Leakage Testing Requirements." Also, the Bases Section was changed to reflect the use of ANSI/ANS-56.8/1987 Standard.

Date of issuance: May 24, 1988

Effective date: May 24, 1988

Amendment Nos. 120 and 120

Facility Operating License Nos. DPR-32 and DPR-37: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: March 23, 1988 (53 FR 9519). The April 8, 1988 letter provided clarifying information which did not change the staff's initial determination of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 24, 1988.

No significant hazards consideration comments received: No

Local Public Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185

Washington Public Power Supply System, Docket No. 50-397, WNP-2, Richland Washington

Date of application for amendment: November 12, 1986 and November 18, 1987.

Brief description of amendment: This amendment modified paragraph 2.E of the license to require compliance with the amended Physical Security Plan. This Plan was amended to conform to the requirements of 10 CFR 73.55. Consistent with the provisions of 10 CFR 73.55, search requirements must be implemented within 60 days and miscellaneous amendments within 180 days from the effective date of this amendment.

Date of issuance: May 23, 1988

Effective date: May 23, 1988

Amendment No.: 57

Facility Operating License No. NPF-21: Amendment revised the license.

Date of initial notice in Federal Register: April 20, 1988 (53 FR 13026). The Commission's related evaluation of the amendment is contained in a letter to Washington Public Power Supply System dated May 23, 1988 and a Safeguards Evaluation Report dated May 23, 1988.

No significant hazards consideration comments received: No

Local Public Document Room location: Richland Public Library, Swift and Northgate Streets, Richland, Washington 99352.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND FINAL DETERMINATION OF NO SIGNIFICANT HAZARDS CONSIDERATION AND OPPORTUNITY FOR HEARING (EXIGENT OR EMERGENCY CIRCUMSTANCES)

During the period since publication of the last biweekly notice, the Commission has issued the following

amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual 30-day Notice of Consideration of Issuance of Amendment and Proposed No Significant Hazards Consideration Determination and Opportunity for a Hearing. For exigent circumstances, the Commission has either issued a Federal Register notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendments. By July 15, 1988, 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 petition for leave to intervene. Requests for a hearing and petitions 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. 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 a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (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 fifteen (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, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. 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.

Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

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, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (*Project Director*): petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the 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 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).

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of application for amendments: May 26, 1988, as supplemented May 27, 1988

Brief description of amendments: The amendments revised the total number of channels for the PORV block valve position indicator from 2 per valve to 1 per valve for Unit 2 only. Telephone authorization was granted on an emergency basis on May 27, 1988, and confirmed by letter dated May 27, 1988.

Date of issuance: June 1, 1988

Effective date: May 27, 1988

Amendment Nos.: June 1, 1988

Facility Operating License Nos. NPF-35 and NPF-52: Amendments revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No. The Commission's related evaluation is contained in a Safety Evaluation dated June 1, 1988.

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

NRC Project Director: David B. Matthews

Houston Lighting & Power Company, Docket No. 50-498, South Texas Project, Unit 1 Matagorda, County, Texas

Date of amendment request: May 23, 1988

Description of amendment request: The amendment changed the Technical Specifications to delete all references to the excessive cooldown protection and associated items.

Date of issuance: May 24, 1988

Effective date: May 24, 1988

Amendment No.: 1

Facility Operating License No. NPF-76. Amendment revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No. The Commission's related evaluation of the amendment, finding of emergency circumstances, consultation with State of Texas, and final determination of no significant hazards consideration are contained in a Safety Evaluation dated May 24, 1988.

Local Public Document Room location: Wharton Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488 and Austin Public Library 810 Guadalupe Street, Austin, Texas 78701.

Attorney for licensee: Jack R. Newman, Esq., Newman & Holtzinger, P. C., 1615 L Street, NW., Washington, DC 20036.

NRC Project Director: Jose A. Calvo

Public Service Electric & Gas Company, Docket No. 50-311, Salem Nuclear Generating Station, Unit No. 2, Salem County, New Jersey

Date of Application for amendment: May 10, 1988

Brief description of amendment: The amendment would avoid a shutdown of the unit. The revised Technical Specifications would permit deenergizing the affected circuits by tripping either the primary or backup overcurrent protection devices. The existing Technical Specifications requires that the backup overcurrent protective device be tripped.

Date of Issuance: May 20, 1988

Effective Date: May 12, 1988

Amendment No.: 57

Facility Operating License No. DPR-75: Amendment revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No. The Commission's related evaluation of the amendment finding of emergency circumstances, and final no significant hazards considerations determination are contained in a Safety Evaluation dated May 20, 1988.

Attorney for licensee: Conner and Wetterhahn, 1747 Pennsylvania Avenue, Washington, DC 20006

Local Public Document Room Location: Salem Free Public Library, 112 West Broadway, Salem, New Jersey 08079.

NRC Project Director: Walter R. Butler

Dated at Rockville, Maryland, this 8th day of June, 1988.

For the Nuclear Regulatory Commission

Steven A. Varga,

Director, Division of Reactor Projects-I/II, Office of Nuclear Reactor Regulation

[Doc. 88-13367 Filed 6-14-88; 8:45 am]

BILLING CODE 7590-01-D

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Fitness Determination of Express Air, Inc.

AGENCY: Department of Transportation.

ACTION: Notice of commuter air carrier fitness determination, Order 88-6-10, order to show cause.

SUMMARY: The Department of Transportation is proposing to find that Express Air, Inc., is fit, willing, and able to provide commuter air service under section 419(c)(2) of the Federal Aviation Act.

RESPONSES: All interested persons wishing to respond to the Department of Transportation's tentative fitness determination should file their responses with the Air Carrier Fitness Division, Room 6420, Department of Transportation, 400 7th Street SW., Washington, DC 20590, and serve them on all persons listed in Attachment A to the order. Responses shall be filed no later than June 17, 1988.

FOR FURTHER INFORMATION CONTACT: Janet A. Davis, Air Carrier Fitness Division, Department of Transportation, 400 7th Street SW., Washington, DC 20590 (202) 366-9721.

Dated: June 9, 1988.

Matthew V. Scocozza,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 88-13498 Filed 6-14-88; 8:45 am]

BILLING CODE 4910-62-M

Federal Aviation Administration

[Summary Notice No. PE-88-22]

Petition for Exemption, Summary of Petitions Received Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before July 5, 1988.

ADDRESS: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION: The petition, any comments received and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-10), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202)X267-3636.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC, on June 8, 1988.

Deborah E. Swank,

Acting Manager, Program Management Staff.

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought, disposition
055CE	Swearingen Engineering and Technology, Inc.	23.903(e)(2)	To permit certification of the Model SA-30 airplane with the Williams International Model F044 engines which will not comply with § 23.903(e)(2). The Swearingen Model SA-30 is a twin-engine powered fanjet airplane with a six-to-eight place seating capacity. *Granted: May 13, 1988.*
042CE	British Aerospace	23.807(d)(1)(ii)	To permit certification of the Jetstream 3200 Series Airplanes in the commuter category with a single, larger overwing exit on the side opposite the passenger entrance door in lieu of the required two smaller exists. *Grant: May 20, 1988.*

[FR Doc. 88-13450 Filed 6-14-88; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

Environmental Impact Statement: Mecklenburg County, North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in the City of Charlotte, North Carolina.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Bellamy Divisions Administrator, Federal Highway Administration, Suite 470, 4505 Falls of Neuse Road, P.O. Box 26806, Raleigh, North Carolina 27611, Telephone (919) 790-2850.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the North Carolina Department of Transportation (NCDOT) will prepare an environmental impact statement (EIS) on a proposed Charlotte North Outer Loop in Charlotte. The proposed action would be the construction of a multilane divided, controlled access highway on a new location from I-85 near the US 29 Connector to NC 27. The completed outer belt facilities will provide for circumferential travel and will relieve traffic along the existing inner loop (Eastway Drive and Woodlawn Road). The proposed action is a part of the 1983 Charlotte-Mecklenburg Thoroughfare Plan.

Alternatives under consideration include: (1) The "no-build", (2) improving existing facilities, and (3) a controlled access highway on new location.

Letters describing the proposed action and soliciting comments are being sent to appropriate Federal, State and local agencies. A public meeting with neighborhood groups and local officials will be held in the study area. A public hearing will also be held. Information on the time and place of the public hearing will be provided in the local news media. The draft EIS will be available for public and agency review and comment prior to the public hearing. No formal scoping meeting is planned at this time.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: June 7, 1988.

J. M. Tate,

District Engineer, FHWA, Raleigh, North Carolina.

[FR Doc. 88-13469 Filed 6-14-88; 8:45 am]

BILLING CODE 4910-22-M

Urban Mass Transportation Administration

[Docket No. 88-A]

Determination Concerning Request for Public Interest Waiver of Buy America Requirements

AGENCY: Urban Mass Transportation Administration, DOT.

ACTION: Notice—denial of waiver.

SUMMARY: The Urban Mass Transportation Administration (UMTA) sought comments on whether a public interest waiver to the "Buy America" requirements should be granted to permit the procurement of bus tires produced at several locations in Europe by Michelin Tire Corporation in order to allow increased competition in the bus tire supply industry. This notice announced UMTA's decision concerning the waiver request.

FOR FURTHER INFORMATION CONTACT: Edward J. Gill, Jr., Office of the Chief Counsel, Room 9316, 400 Seventh Street, SW., Washington, DC. 20590, (202) 366–4063.

SUPPLEMENTARY INFORMATION: Section 165(a) of the Surface Transportation Assistance Act of 1982 (STAA) provides that Federal funds may not be obligated for the purchase of manufactured products unless such products are produced in the United States. Section 165(b)(1) of the STAA provides that the general requirements of section 165(a) may be waived in their application would be inconsistent with the public interest. The implementing regulations at 49 CFR 661.7(b) provide that "[i]n determining whether th[e] exception will be granted, [UMTA] will consider all appropriate factors on a case by case basis."

In the preamble to the "Buy America" regulations published in the **Federal Register** on September 15, 1983 (48 FR 41462), UMTA indicated that in certain circumstances in which a public interest waiver is sought under section 165(b)(1), the proposed waiver would be published in the **Federal Register** for comment. Such a procedure is not mandatory before a public interest waiver is granted, but UMTA uses the procedure where the public interest waiver involves important policy considerations or is controversial. It is UMTA's position that these circumstances existed in this case.

On April 13, 1988, the Urban Mass Transportation Administration (UMTA) published a notice in the **Federal Register** (53 FR 12223) seeking comments on whether a public interest waiver to the "Buy America" requirements should be granted to permit the procurement of bus tires produced at several locations in Europe by Michelin Tire Corporation in order to allow increased competition in the bus tire supply industry. The comment period closed on May 13, 1988.

Michelin argues that if the "Buy America" requirements are applied to its bus tires manufactured in various locations in Europe, Michelin is effectively excluded from the U.S. marketplace. Michelin argues that granting a waiver to permit the procurement of Michelin tires produced in Europe would foster competition in the marketplace, and increase the possibility of reduced prices for tires to the recipients of Federal grant funds. In addition, Michelin argues that such a waiver would allow UMTA grant recipients to take advantage of technological advances in the bus tire industry by giving them the opportunity to acquire radial tires as well as the traditional bias-ply tires manufactured in the United States by other companies.

Before determining whether a "public interest" waiver under section 165(b)(1) should be issued, UMTA sought public comment from all interested parties. A total of 26 comments were received from transit authorities or operators of public mass transportation systems, private citizens, unions, members of Congress, and bus manufacturers. Extensive comments were submitted by counsel representing Michelin and representing Firestone and Goodyear, the two principal domestic suppliers of tires for buses.

The private citizen and the union opposed the waiver on grounds that Federal funds should not be made available to foreign manufacturers if domestic manufacturers are present. Of the transit authorities which commented, all but one supported the waiver although a number of the larger transit authorities do not use radial tires on their buses. The two bus manufacturers supported the waiver based on potential technological advances in bus manufacturing which could possibly utilize radial tires. Firestone and Goodyear strongly opposed the waiver.

The thrust of the Firestone/Goodyear objections are as follows:

There is sufficient competition in the marketplace presently, thus there is no need to waive the Buy America requirements in order to provide competition. In this regard, Firestone and Goodyear argue that Michelin could choose to manufacture the radial bus tire at one of its facilities in the U.S thereby increasing competiton without waiving an important Federal statute.

There is no need for a general waiver since the vast majority of transit authorities use bias-ply rather than radial tires. If a transit authority wanted to use a radial tire produced by Michelin in Europe, case-by-case waivers are available under the "Buy America" requirements.

UMTA Analysis

It appears, after reviewing all of the comments received with special emphasis on those received from counsel for the three tire manufacturers, that UMTA is faced with being asked to grant a waiver of a statutory requirement for what is, in essence, a strict commercial argument as to which technology is best for the standard urban transit vehicle. Firestone and Goodyear argue that bias-ply tires are better, while Michelin obviously argues that radial tires are better.

UMTA's overriding concern in this matter is that the granting of a general public interest waiver to allow the use of a foreign product in competition with domestic products would send the wrong message concerning UMTA's enforcement and implementation of the "Buy America" requirements. The intent of the Buy America provision is to foster and encourage production of materials in the United States for use in federally funded mass transit project. The granting of a general waiver to allow a foreign produced item to have equal competitive status with domestically produced items is contrary to the clear intent of the statutory provision.

Michelin has indicated that it would utilize the waiver to determine if a market for its bus tire exists in the United States. Once a determination concerning this market is made by Michelin, Michelin has stated that it would consider establishing a production line for radial bus tires in the United States.

It is UMTA's position that Congress intended that the public interest waiver provision of the Surface Transportation Assistance Act of 1982 be utilized in extremely limited situations. It is UMTA's position that such a waiver was not intended to be used to allow a product manufactured outside of the United States to be market-tested in the United States while the manufacturer of such product made a marketing determination concerning whether it was economically feasible to initiate full-scale production of such product in the United States. Therefore, UMTA is hereby denying Michelin's request for a general public interest waiver to permit the procurement of its radial bus tires produced in various locations in Europe.

UMTA's action in denying this waiver request does not preclude Michelin tires from being considered for any waiver on a case-by-case, individual procurement basis; nor does this action indicate any position of UMTA relative to the merits of a radial bus tire as opposed to a bias-ply bus tire.

Dated: June 10, 1988.
Edward J. Babbitt,
Chief Counsel.
[FR Doc. 88-13452 Filed 6-10-88; 12:53 pm]
BILLING CODE 4910-57-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: June 9, 1988.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 15th and Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515-0043.
Form Number: CF 3311.
Type of Review: Reinstatement.
Title: Declaration for Free Entry of Returned American Products.
Description: The form is a declaration by an importer that certain merchandise was made in the U.S., that no drawback was claimed at the time of exportation, that the merchandise was not advanced in value while outside the U.S. and is not eligible to be into U.S. without paying duty.
Respondents: Businesses or other for-profit, Small Businesses or organizations.
Estimated Number of Respondents: 10,500.
Estimated Burden Hours Per Response: 5 minutes.
Frequency of Response: On occasion.
Estimated Average Reporting Burden: 42,021 hours.
OMB Number: 1515-0065.
Form Number: CF 7501 and CF 7501A.
Type of Review: Reinstatement.
Title: Entry Summary.
Description: The document is used by Customs as a record of the import transaction, to collect the proper duty, taxes, exactions, certifications and enforcement endorsements, and to provide copies to Census for statistical purposes.
Respondents: Businesses or other for-profit, Small Businesses or organizations.
Estimated Number of Respondents: 2,675.
Estimated Burden Hours Per Response: 14 minutes.
Frequency of Response: On occasion.
Estimated Average Reporting Burden: 3,454,852 hours.
Clearance Officer: John L. Poore (202) 566-2491, U.S. Customs Service, Room 6426, 1301 Constitution Avenue, NW., Washington, DC 20229.
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503.
Dale A. Morgan,
Departmental Reports Management Officer.
[FR Doc. 88-13440 Filed 6-14-88; 8:45 am]
BILLING CODE 4810-25-M

Customs Service

Performance Review Boards Appointment of Members

AGENCY: U.S. Customs Service, Department of Treasury.
ACTION: General notice.

SUMMARY: This notice announces the appointment of the members of the United States Customs Service Performance Review Boards (PRBs) in accordance with 5 U.S.C. 4313(c)(4). The purpose of the PRBs is to review senior executives' performance appraisals and make recommendations regarding performance and performance awards.
EFFECTIVE DATE: May 15, 1988.
FOR FURTHER INFORMATION CONTACT: Robert M. Smith, Acting Director, Office of Human Resources, U.S. Customs Service, Post Office Box 636, Washington, DC 20044; (202) 634-5270.
SUPPLEMENTARY INFORMATION:

Background

There are two Performance Review Boards in the U.S. Customs Service.

Performance Review Board 1

The purpose of this Board is to review the performance appraisals of Senior Executives rated by the Commissioner and Deputy Commissioner. The members are:

Chester C. Bryant, Comptroller, Bureau of Alcohol, Tobacco and Firearms,
Stephen E. Higgins, Director, Bureau of Alcohol, Tobacco and Firearms;
John W. Mangels, Director, Office of Operations, Department of Treasury;
John P. Simpson, Deputy Assistant Secretary for Regulations, Trade and Tariff Enforcement, Department of Treasury.

Performance Review Board 2.

The purpose of this Board is to review the performance appraisals of all Senior Executives except those rated by the Commissioner or Deputy Commissioner. All are Assistant Commissioners or Regional Commissioners of U.S. Customs Service. The members are:

Assistant Commissioners:

William P. Rosenblatt, Office of Enforcement;
William Green, Office of Internal Affairs;
Samuel H. Banks, Office of Inspection and Control;
Eugene Mach, Office of Commercial Operations;
James W. Shaver, Office of International Affairs.

Regional Commissioners:

John R. Grimes, South Central Region;
Edward Kwas, New York Region;
George Heavey, Southeast Region;
Richard McMullen, North Central Region;
James Piatt, Southwest Region;
Quintin Villanueva, Jr., Pacific Region.

Dated: May 25, 1988.
William Von Raab,
Commissioner of Customs.
[FR Doc. 88-13465 Filed 6-14-88; 8:45 am]
BILLING CODE 4820-02-M

UNITED STATES INSTITUTE OF PEACE

Bylaws of the Corporation

AGENCY: United States Institute of Peace.
ACTION: Notice of adoption of corporate bylaws.

SUMMARY: This document contains the bylaws of the United States Institute of Peace. The United States Institute of Peace Act, 42 U.S.C. 4601, established the United States Institute of Peace as an independent, nonprofit corporation, governed by a 15-member Board of Directors appointed by the President with the advice and consent of the Senate. Meeting in public session on April 28, 1988, the Board of Directors adopted the following bylaws, which became effective that day.

The Bylaws reconfirm the nature and powers of the corporation, establish definitions, and direct where the Institute's offices may be; describe the Board of Directors, including terms of office, qualification, duties, and compensation, address the question of outside interests of directors and officers; set forth the governing rules for

Board and Board committee meetings, including quorums, rules on public meetings and executive sessions, minutes, and Board action without meetings; prescribe the selection procedure and responsibilities of officers and employees and address their compensation and outside interests; cover periodical financial reports to the Board and the transfer of funds to the Endowment of the United States Institute of Peace; establish prohibitions and standards on the intervention in ongoing conflicts, lobbying, political activity, classified research, and political tests and qualifications; require a corporate seal; cover the question of indemnification; establish the corporation's fiscal year, set forth the Bylaws amendment procedure; and make the Bylaws effective as of their date of adoption.

FOR FURTHER INFORMATION CONTACT: The Institute publishes these Bylaws today as part of its effort to ensure full public notice and also to invite comments. To provide comments or obtain further information, write or call: Charles Duryea Smith, General Counsel, United States Institute of Peace, 1550 M Street, NW., Suite 700, Washington DC. 20005–1708, (202) 457–1700.

Article I—Nature and Powers of the Corporation

Section 1. Nature of the Corporation.

The United States Institute of Peace is the independent, non-profit corporation established by section 1704 of United States Institute of Peace Act, Title XVII, Pub. L. 98–525; 98 Stat. 2492, 2649; 22 U.S.C. 4601 (1984), as amended. The Corporation will serve the people and the Government through the widest possible range of education and training, basic and applied research, and information services on the means to promote international peace and the management and resolution of conflict among the nations and peoples of the world.

Section 2. Powers and Duties.

The powers and duties of the Corporation are as set forth in the Act. The powers of the Corporation include, to the extent consistent with the Act, the powers conferred upon a nonprofit corporation by the District of Columbia Nonprofit Corporation Act.

Article II—Definitions

Section 1. As used in these Bylaws, except where the context otherwise requires—

(a) "Act" means the United States Institute of Peace Act, Title XVII of Pub. L. 98–525; 98 Stat 2492, 2649; 22 U.S.C. 4601 (1984), as it is now or may be amended;

(b) "Board" means the Board of Directors of the Corporation;

(c) "Chairman" means the Chairman of the Board of Directors initially appointed and thereafter elected pursuant to section 1706(h)(1) of the Act;

(d) "Corporation" means the United States Institute of Peace established by section 1704 of the Act;

(e) "Director" means a voting member of the Board of Directors appointed pursuant to section 1706 of the Act;

(f) "Grantee" means an institution or individual who has received a grant from the Institute;

(g) The pronouns "he," "him" and "his" mean, respectively, "he or she," "him or her," and "his or hers";

(h) "Fellow" means an individual who has received a fellowship or other form of support from the Institute as part of the Jennings Randolph Program for International Peace;

(i) "Member of the Board" means a Director or the President of the Corporation;

(j) "Person" means an individual, corporation, association, partnership, trust, or other legal entity;

(k) "President" means the President of the Corporation appointed pursuant to section 1707 of the Act;

(l) "Recipient" means any person receiving financial assistance from the Corporation.

Article III—Offices

Section 1. Principal Offices.

The Corporation shall maintain its principal office in the District of Columbia.

Section 2. Other Offices.

The Corporation may have offices at such other places, either within or without the District of Columbia, as determined by the Board.

Article IV—Board of Directors

Section 1. General Powers.

The powers of the Corporation are vested in the Board, subject to the provisions of the Act.

Section 2. Number, Terms of Office, and Qualifications.

The Board shall consist of fifteen Directors, with appointments, qualifications, and terms of office as provided in section 1706 of the Act. Eleven shall be appointed from outside of federal service by the President of the United States subject to Senate confirmation. The Secretary of State, Secretary of Defense, Director of the Arms Control and Disarmament Agency, and President of the National Defense University, shall, Pursuant to section 1706(b)(1)–(4), be *ex officio* voting members of the Board. Not more than eight voting members of the Board may be members of the same political party. If the president of the National Defense University is a member of the Board and is an active duty military officer, he may assert the tradition of political neutrality of the American military and no political party membership shall be attributed to him. If any of the four *ex officio* voting members elects not to serve, he may designate a Senate-confimed and otherwise eligible subordinate official from his agency or department to serve on the Board. Such designation, in order to be effective, must be in writing, signed by the agency or departemnt head, and received by the Chairman at the Institute's office. The Chairman shall transmit information on the designation to all other members of the Board within 30 calendar days or at the next meeting of the Board, whichever comes first. Changes in the Board's *ex officio* membership shall be announced to the public no later than at the first public meeting of the Board of Directors following receipt of the letter of designation by the Chairman. The President shall serve as a nonvoting member of the Board.

Section 3. The Chairman and Vice Chairman of the Board.

(a) Every three years, commencing with the expiration of the term of the first Chairman appointed by the President of the United States or at such other times as there may be vacancies in such office, the Board shall elect a Chairman from among the Directors appointed from outside of federal service under section 1706(b)(5) of the Act. The Board may also elect a Vice Chairman for a term not to exceed three years from among the Directors appointed from outside of federal service under section 1706(b)(5) of the Act.

(b) The Chairman shall preside, if present, at all meetings of the Board; carry out all other functions required of him by the Act and these Bylaws; and represent the Board in matters concerning the day-to-day operations of the Institute. The Vice Chairman, if any, shall preside in the absence of the Chairman, at meetings of the Board and shall perform such other duties as from time to time may be requested of him by the Chairman.

Section 4. Outside Interests of Directors and Officers.

(a) No members of the Board may participate in any decision, action, or

recommendation with respect to any matter which directly and financially benefits such member or pertains specifically to any public body or any private or nonprofit firm or organization with which the member is then formally associated or has been formally associated within a period of two years, except that this provision shall not be construed prohibit an *ex officio* member of the Board from participation in actions of the Board which pertain specifically to the public body of which that member is an officer.

(b) Pursuant to reporting procedures established from time to time by Board resolution, All Directors and Officers shall, on an annual basis after assuming office, file with the Institute's Ethics Officer (or General Counsel if no Ethics Officer has been designated) a list of those activities and relationships which might reasonably raise an issue of conflict of interest or the appearance of a conflict of interest with respect to the mandate and activities of the Institute.

Section 5. Compensation.

A Director appointed by the President from outside of federal service shall be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule under section 5332 of title 5, United States Code, for each day during which the Director is engaged in the performance of duties as a member of the Board.

Section 6. Travel

While away from his home or regular place of business in the performance of duties for the Institute, a Director shall be allowed travel expenses, including a per diem in lieu of subsistence, not to exceed the expenses allowed persons employed intermittently in Government service under section 5703(b) of title 5, United States Code. All travel, other than to attend meetings of the Board, for whch a Director seeks reimbursement from the Institute shall have the prior authorization of the Chairman or President.

Article V—Meetings of Directors

Section 1. Meetings.

Meetings of the Board shall be held at least two times each calendar year. Meetings shall be held at intervals and locations determined by the Chairman. If any five members of the Board request in writing that a meeting be scheduled, the Chairman shall schedule a meeting to occur within 45 days of receiving such request.

Section 2. Agenda.

The Chairman shall cause to be prepared the agenda for each meeting, and shall include the agenda in the notice of the meeting sent to all Directors. Any matters appearing on the agenda which the Chairman believes should be discussed in a closed session in accordance with section 1706(h)(3) of the Act shall be so noted.

Section 3. Quorum; Manner of Acting.

(a) A majority of the Directors shall constitute a quorum for a Board meeting. Except as otherwise specifically provided by law or these Bylaws, the vote of a majority of the Directors present at the time of a vote, provided that a quorum is present at such time, shall be the act of the Board. A Director who is present at a meeting of the Board but who recuses or abstains from participation in the deliberation or vote on any matter, whether he remains in the meeting room or withdraws therefrom during the deliberation or vote, may be counted for purposes of determining whether or not a quorum is present, and if a quorum is present, the vote of a majority of the then voting Directors shall be the act of the Board. After having convened with a quorum, a meeting may continue without a quorum, but no vote be taken unless a quorum is present.

(b) Each Director is entitled to one vote. Voting rights of Directors may not be exercised by proxy.

Section 4. Public Meetings; Executive Sessions.

All meetings of the Board shall be open to public observation and shall be preceded by reasonable public notice, for which purpose notice in the Federal Register shall be deemed to be reasonable. As provided in section 1706(h)(3) of the Act, the Board may close portions of a meeting, upon a majority vote of its members present and with the vote recorded and taken in public session, which are likely to disclose information likely to affect adversely any ongoing peace proceeding or activity or to disclose information or matters exempted from public disclosure pursuant to subsection (C) of the Government in the Sunshine Act, section 552b of Title 5, United States Code. The chairman of the meeting shall announce the general subject of the closed session prior to such a vote.

Section 5. Minutes.

The Institute shall keep minutes of the proceedings of the Board and of any committee having authority under the Board. The minutes shall record the names of the Directors present, subjects addressed, and any actions taken. The minutes of each meeting shall be available for inspection by the public in the form approved by the Board.

Section 6. Action by Directors Without a Meeting.

In exceptional circumstances, any action which may be taken at a meeting of the Board may be taken without a meeting, if agreement or ratification in writing, setting forth the action taken, is signed by all of the Directors. Any such action so taken shall be included on the agenda of the next meeting of the Board for discussion, ratification, or such other action as may be indicated by the circumstances.

Article VI—Committees

Section 1. Establishment and Appointment of Committees.

The Board shall have the following permanent committees: Education and Training; Research and Studies; Information Services; Institutional Planning; Organization and Administration; and Personnel. The Board may, by resolution of a majority of the full Board, establish (and thereafter dissolve) such other executive, standing, permanent, or temporary committees to perform such functions as the Board may designate. The authority of any such committee shall expire at the time specified in such resolution or subsequently determined by the Board. The Chairman shall appoint Directors to serve on such committees, as well as the members who shall chair such committees. The Chairman shall be a voting member of each committee. The President shall be a nonvoting member of each committee.

Section 2. Committee Procedures.

(a) Except as otherwise provided in these Bylaws or in the resolution establishing the committee, a majority of the voting members of a committee, or one-half of such members if their number is even, shall constitute a quorum. A Director who is present at a meeting of a committee but who refuses or abstains from participation in the deliberation or vote on any matter, whether he remains in the meeting room or withdraws therefrom during the deliberation or vote, may be counted for purposes of determining whether or not a quorum is present, and if a quorum is present, the vote of a majority of the then voting Directors shall be the act of the committee. The vote of a majority of the voting members present at the time of a vote, if a quorum is present at such time, shall be the act of the committee.

After having convened with a quorum, a meeting may continue without a quorum, but no vote may be taken unless a quorum is present.

(b) Each voting member of a committee is entitled to one vote. Voting rights of committee members may not be exercised by proxy.

Section 3. Public Meetings; Executive Sessions.

All meetings of any committee of the Board shall be open to public observation and shall be preceded by reasonable public notice, for which purpose notice in the Federal Register shall be deemed to be reasonable. As provided in section 1706(h)(3) of the Act, a committee may close portions of a meeting, upon a majority vote of its members present and with the vote recorded and taken in public session, which are likely to disclose information likely to affect adversely any ongoing peace proceeding or activity or to disclose information or matters excempted from public disclosure pursuant to subsection (C) of the Government in the Sunshine Act, section 552b of Title 5, United States Code. The chairman of the meeting shall announce the general subject of the closed session prior to such a vote.

Article VII—Officers and Employees

Section 1. Officers.

The officers of the Corporation shall be a President, a Vice President, and such other officers as the Board from time to time shall determine to be necessary. The officers shall have such authority and shall perform such duties, consistent with the Act and these Bylaws, as may be determined by the Board by resolution or, with respect to all officers but the President, by the President consistent with policies established by the Board. The President shall supervise and direct the other officers in the performance of their duties.

Section 2. Appointment, Term of Office, and Qualifications.

The President shall be appointed by majority vote of the full Board for a specific but renewable term of not less than one year and not more than three years. Each officer of the Corporation other than the President shall be appointed by majority vote of the full Board for a specific term or, if not specified, for a term that may not exceed three years without the appointment being reaffirmed by the Board. All officers shall serve at the pleasure of the Board. An officer shall hold office until a successor is duly appointed in his stead or until he resigns or is removed in the manner provided in section 3 of this Article.

Section 3. Removal.

The officers of the Corporation may be removed by a majority vote of the full Board. Such removal shall be without prejudice to the contract rights, if any, of the person so removed, nor shall the appointment itself of the officer be construed to create contract rights.

Section 4. Resignation.

Any officer may resign at any time by giving a written notice of his resignation to the Chairman. An officer other than the President shall also submit written notice of his resignation to the President. Such resignation shall take effect at the time it is received by the Chairman, unless another time is specified therein. The acceptance of such resignation shall not be necessary to make it effective.

Section 5. The President.

The President is a nonvoting member of the Board and the Chief Executive Officer of the Corporation, with the responsibility and authority as provided in the Act, these Bylaws, policies established by the Board, and rules and regulations promulgated pursuant to the Act, these Bylaws, or Board policies for (1) The day-to-day administration of the affairs of the Corporation, (2) the appointment and removal of such employees of the Corporation as he determines necessary to carry out the purposes of the Corporation, and (3) the exercise of such other powers incident to the office of the President and the performance of such other duties as the Board may from time to time prescribe. These powers include those enumerated in section 1707(b), (c), and (d) of the Act, which include the receipt and disbursement of public monies, obtaining and making grants, entering into contracts, establishing and collecting fees, and making personnel decisions.

Section 6. Vice President.

The Vice President shall have such powers and shall perform such duties as the Board has determined and as the President may from time to time prescribe, consistent with policies of the Board. In the absence of and upon delegation by the President, a Vice President shall perform the duties of the President, and when so acting, shall have all the powers of, and shall be subject to all restrictions upon, the President.

Section 7. Compensation of Officers and Employees.

(a) Officers shall be compensated at rates determined by the Board pursuant to section 1707(a) of the Act.

(b) As provided in section 1707(e) of the Act, no officer or other full-time employee of the Corporation may receive any salary or other compensation for services from any sources other than the Corporation during his period of employment by the Corporation, except as authorized by the Board.

Section 8. Outside Interests of Officers and Employees.

Consistent with the Act, the Board may from time to time adopt resolutions governing the conduct of officers or employees with respect to matters in which the officers or employees may have any interests that might be perceived as adverse to the interests of the Corporation.

Article VIII—Transfer of Funds to the Endowment

The President periodically shall report to the Board on the Institute's financial situation, including any statutory requirements, and shall advise the Board on transferring appropriated funds that have not been obligated or expended from the Institute's Treasury account to the Endowment of the United States Institute of Peace, in exercise of the Board's authority under section 1710(b) of the Act.

Article IX—Prohibitions

Section 1. Prohibition Against Intervention in Ongoing Conflicts.

No Director, officer, employee, fellowgrantee, or other individuals, acting on behalf of the Institute, shall intervene directly in any ongoing international conflict without the approval of the Board and the concurrence of the Department of State.

Section 2. Prohibition Against Lobbying.

The institute itself shall not undertake nor shall any funds of the Institute be used to influence the passage or defeat of any legislation by the Congress of the United States or by any State or local legislative bodies, or by the United Nations or any other international governmental body, except that personnel of the Institute may testify or make other appropriate communication when requested to do so by a legislative body, a committee, or a member thereof

Section 3. Prohibition Against Political Activity.

(a) No Director, office, employee, or any other person shall, on behalf of the Institute, take a position for or against any political party or candidate for political office. Nothing in this section shall preclude the right of an individual to express his opinion in his private capacity or in a public capacity separate and distinct from his position with the Institute.

(b) Directors, officers, employees, fellows, and grantees of the Institute shall exercise due care in their professional and private activities—including, where appropriate, by use of a disclaimer—to avoid conveying the impression that their personal views or activities are the views or activities of the Institute.

Section 4. Prohibition Against Classified Research.

The Institute shall not sponsor or support classified research nor shall any officer or employee of the Institute engage in classified research, except with the approval of two-thirds of the bull Board. The Board may discuss such proposed activity in executive session, after indicating the general nature of the proposal in public session. Any decision to engage in classified research in Institute programs shall be reported at the next public session of the Board.

Section 5. Prohibition Against Political Tests or Qualifications.

No political test or political qualification may be used in selecting, appointing, promoting, or taking any other personnel action with respect to any Institute officer, employee, or agent.

Article X—Seal

The Corporation shall have a corporate seal in a form adopted by the Board.

Article XI—Indemnification

Present and past Directors, officers, employees, and agents of the Institute may be indemnified for any and all liabilities and reasonable expenses incurred in connection with any claim, action, suit, or proceeding arising from present or past service for the Institute, in accordance with resolutions adopted by the Board.

Article XII—Fiscal Year

The fiscal year of the Corporation shall be that of the Federal Government.

Article XIII—Amendments

These Bylaws may be amended by a recorded vote of three-quarters of the full Board, which three-quarters shall include no less than two ex officio Directors, at each of two public meetings, at least 30 and not more than 180 calendar days apart, provided that (a) such amendment is not inconsistent with the Act or other applicable provision of federal law, (b) the notice of the meeting at which such action is taken shall have stated the substance of the proposed amendment, and (c) the notice of such meeting shall have been mailed, telegraphed, or delivered to each Director at least five (5) days before the date of the meeting.

Article XIV—Effective Date

These Bylaws are effective when approved by the Board and shall operate prospectively.

Dated: June 9, 1988.

Samuel W. Lewis,

President.

[FR Doc. 88-13493 Filed 6-14-88; 8:45 am]

BILLING CODE 6820-PA-M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 115
Wednesday, June 15, 1988

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

NATIONAL LABOR RELATIONS BOARD

Closed Meeting

June 10, 1988.

TIME AND DATE: 1:45 p.m., Monday June 13, 1988.

PLACE: Board Conference Room, Sixth Floor, 1717 Pennsylvania Avenue, NW.

STATUS: Closed to public observation pursuant to 5 U.S.C. § 552b(c)(2) (internal personnel rules and practices) and (c)(6) (personal information where disclosure would constitute a clearly unwarranted invasion of personal privacy).

MATTERS TO BE CONSIDERED: Selection of Regional Director for Region 34—Hartford, Connecticut.

CONTACT PERSON FOR MORE INFORMATION: John C. Truesdale, Executive Secretary, Washington, DC 20570, Telephone (202) 254–9430.

Dated, Washington, DC, by direction of the Board.

John C. Truesdale,

Executive Secretary, National Labor Relations Board.

[FR Doc. 88–13509 Filed 6–13–88; 9:05 am]

BILLING CODE 7545-01-M

NATIONAL TRANSPORTATION SAFETY BOARD

Open Meeting

TIME AND DATE: 9:30 a.m. Tuesday, June 21, 1988.

PLACE: Board Room, Eighth Floor, 800 Independence Avenue SW., Washington, DC 20594.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Safety Study: Alcohol/Drug Use and Its Impact on Railroad Safety.

2. Railroad Briefs with Alcohol and/or Drug Involvement (In Support of 1987 Study of Alcohol/Drug Use and Its Impact on Railroad Safety).

3. NTSB's Combined Reply to FAA's Response to Safety Recommendations A–87–40, –40 and –42 (Mail Controls 88–359, 87–861, and 87–1380).

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382–6525.

Bea Hardesty,

Federal Register Liaison Officer.

June 10, 1988.

[FR Doc. 88–13510 Filed 6–13–88; 9:05 am]

BILLING CODE 7533-01-M

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of June 13, 1988.

A closed meeting will be held on Tuesday, June 14, 1988, at 2:30 p.m. Open meetings will be held on Thursday, June 16, 1988, at 10:00 a.m. and 2:30 p.m.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Grundfest, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, June 14, 1988, at 2:30 p.m., will be:

Settlement of administrative proceeding of an enforcement nature.
Formal orders of investigations.
Institution of injunctive action.
Settlement of injunctive action.
Consideration of *amicus* participation.
Opinion.

The subject matter of the open meeting scheduled for Thursday, June 16, 1988, at 10:00 a.m., will be:

Consideration of whether to issue a notice and order for hearing under the Public Utility Holding Company Act of 1935 concerning a proposal by Central and South West Corporation, a registered holding company, to expand the scope of factoring activities conducted by its wholly owned nonutility subsidiary, CSW Credit, Inc. For further information, please contact Martha Cathey Baker at (202) 272–2072.

The subject matter of the open meeting scheduled for Thursday, June 16, 1988, at 2:30 p.m., will be:

The Commission will meet with Financial Accounting Standards Board (FASB) to discuss matters of mutual interest. Members and staff of the FASB will inform the Commission about current FASB activities and respond to questions about particular projects the FASB has under active consideration. These joint sessions form a part of the Commission's active oversight of the private sector's standard-setting activities regarding financial accounting and reporting. For further information, please contact Jack Parsons at (202) 272–7343.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Nancy Morris at (202) 272–3085.

Jonathan G. Katz,

Secretary.

June 10, 1967.

[FR Doc. 88–13502 Filed 6–13–88; 9:05 am]

BILLING CODE 8010-01-M

Corrections

Federal Register
Vol. 53, No. 115
Wednesday, June 15, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

48 CFR Parts 204, 205, 206, 219, 226, 235, and 252

Federal Acquisition Regulation Supplement; Contracting With Small Disadvantaged Business Concerns, Historically Black Colleges and Universities, and Minority Institutions

Correction

In rule document 88-12622 beginning on page 20626 in the issue of Monday, June 6, 1988, make the following corrections:

1. On page 20627, in the third column, in the sixth complete paragraph, in the fourth line, "composit" should read "composite". In the same paragraph, in the fifth line, "of" should read "for".

2. On page 20628, in the second column, in amendatory instruction 9, in the 19th line, "item 2" should read "item 3".

3. On page 20631, in the second column, in amendatory instruction 42, in the first line, "Section 252.219-70009" should read "Section 252.219-7009".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

[PF-498; FRL-3380-9]

E.I. Du Pont De Nemours & Co., Inc.; Amended Pesticide Tolerance Petition

Correction

In notice document 88-10993 appearing on page 17244 in the issue of Monday, May 16, 1988, make the following corrections:

1. In the second column, under **SUPPLEMENTARY INFORMATION**, in the second paragraph, in the fourth line, insert " oxy" after "yl".

2. In the same column, in the last paragraph, in the first line, "tolerance" should read "tolerances".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88M-0128]

Bausch & Lomb Optics Center; Premarket Approval of Bausch & Lomb® Renu Lubricant and Rewetting Drops

Correction

In notice document 88-12160 appearing on page 20022 in the issue of Wednesday, June 1, 1988, make the following correction:

On page 20022, in the first column, the Docket Number should read as set forth above.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88N-0202]

Drug Export; Nitropflaster Ratiopharm-5 and 10

Correction

In notice document 88-12158 beginning on page 20021 in the issue of Wednesday, June 1, 1988, make the following correction:

On page 20022, in the first column, in the second line, "D. Hicks" should read "Daniel L. Michels".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88F-0112]

Riken Vitamin Co., Ltd.; Filing of Food Additive Petition

Correction

In notice document 88-11604 appearing on page 18610 in the issue of Tuesday, May 24, 1988, make the following corrections:

1. The company name should read as it appears in the subject heading above.

2. Under **FOR FURTHER INFORMATION CONTACT**, in the third line, "(HFF-355)" should read "(HFF-335)".

BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Antitrust Division

Antitrust Guidelines for International Operations

Correction

In notice document 88-12762 beginning on page 21584 in the issue of Wednesday, June 8, 1988, make the following corrections:

1. On page 21584, in the second column, in the table of contents, on the line following "F. International Trade Friction and the U.S. Trade Laws", insert "Conclusion".

2. On page 21585, in the third column, in footnote 12, in the third line, "section 2Rl.1" should read "section 2R1.1".

3. On page 21605, in the first column, the third line should read "agreement result in the denial of".

4. On page 21615, in the third column, in the first complete paragraph, in the 12th line, "has" should read "had".

5. On page 21615, in the third column, between the first complete paragraph and the heading "Discussion", insert the following text, which was mistakenly omitted:

Case 16—Voluntary Export Restraint

The Association of American X Manufacturers (the "Association"), whose members are suffering from overcapacity slack demand, and the impact of increased X imports from Country A, has been seeking legislated import quotas and has publicly announced that its members may invoke a variety of import-restricting trade laws. United States government trade officials have informed officials of the government of A about the problem and have suggested that some sort of action should be taken to ease trade relations between the two countries.

In an effort to forestall the imposition of U.S. import quotas and respond to the concern of the U.S. government, A's Minister of Trade holds separate

meetings with the presidents of A's five X producers and asks each to reduce his or her company's exports to the United States during the coming year by ten percent. The Minister makes it clear that the government of A views this self-imposed restraint to be crucial to Country A's overall trade relationship with the United States.

Each of the five X producers agrees to reduce its exports to the United States. The Minister so advises U.S. trade officials and publicly announces the voluntary restraint program. Each of the five X producers has a U.S. sales subsidiary.

BILLING CODE 1505-01-D

federal register

Wednesday
June 15, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 355

Anticaries Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N-0042]

Anticaries Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that amends the tentative final monograph (proposed rule) that would establish conditions under which over-the-counter (OTC) anticaries drug products (drug products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA. This proposal deals only with matters regarding final formulation testing, i.e., "Laboratory Testing Profiles" (LTP's), for Category I active ingredients in dentifrice formulations, and issues relating to this testing.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by October 13, 1988. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. New data by June 15, 1989. Comments on the new data by August 15, 1989. Written comments on the agency's economic impact determination by October 13, 1988.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 28, 1980 (45 FR 20666), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC anticaries drug products, together with the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 26, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by July 28, 1980.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. In response to the advance notice of proposed rulemaking, the Panel Chairman, 4 drug manufacturers' associations, 10 drug manufacturers, 1 consumer, 7 health care professionals, 2 health care professional societies, and 1 coalition opposed to fluoridation submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The agency stated in the advance notice of proposed rulemaking that the Panel's recommended LTP's represent a new concept with many technical issues yet to be resolved; therefore, they were not included as part of the proposed monograph in the first segment of the tentative final monograph published in the **Federal Register** on September 30, 1985 (50 FR 39854). The agency stated therein that the tentative final monograph for OTC anticaries drug products would be issued in two segments. The first segment contains the agency's responses to general comments on anticaries drug products, comments on the switch of prescription anticaries drug products to OTC status, comments on specific anticaries active ingredients, comments on dosages for anticaries active ingredients, and comments on the labeling of anticaries drug products. This second segment, which is an amendment to the proposed rule for OTC anticaries drug products, contains the agency's proposals regarding LTP's for Category I active ingredients in dentifrice formulations, and issues relating to this testing. The agency held an open public meeting on September 26 and 27, 1983, regarding unresolved technical issues concerning the LTP's and reopened the administrative record to include the proceedings of the public meeting and to allow comment on matters raised at the meeting (48 FR 38853). In a notice published in the **Federal Register** of October 25, 1983 (48 FR 49304), the agency advised that the administrative record for OTC anticaries drug products would remain open until December 2, 1983, to allow for consideration of data and information that had been filed in the Dockets Management Branch concerning matters raised at the meeting. Data and information received after the administrative record was reopened are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on March 28, 1980 (45 FR 20666), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the notice of proposed rulemaking for OTC anticaries drug products is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In the tentative final monograph (proposed rule) to establish Part 355 (21 CFR Part 355), FDA stated for the first time its position on the establishment of a monograph for OTC anticaries drug products. This document amends the agency's position set forth in the tentative final monograph. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC anticaries drug products.

The previously published tentative final monograph (50 FR 39854) and this amendment constitute FDA's tentative adoption of the Panel's conclusions and recommendations on OTC anticaries drug products, as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking

process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the Federal Register of August 9, 1972 (37 FR 16029), or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Anticaries Drug Products

1. Three comments addressed the importance of the availability of the fluoride ion in establishing the effectiveness of OTC anticaries dentifrices. One comment stated that the Panel recognized this importance and established assays to show that the availability of the fluoride ion is ultimately responsible for the cariostatic effect in anticaries dentifrices, and that the source of the fluoride ion was not an issue in the Panel's deliberations. A second comment acknowledged the importance of the availability of the fluoride ion, but felt that only one concentration of the soluble fluoride ion should be specified in the Panel's tables for each active fluoride compound rather than values for both a freshly-prepared paste and an aged paste. The comment was opposed to the LTP parameters, which it believed imposed arbitrary standards not correlated with clinical data and required the establishment of reference standards. The comment claimed that no one has presented results from the three biological tests in the LTP's that can be correlated with clinical effectiveness. Further, the comment stated that the specification of a minimum available fluoride-compound concentration and an analytical procedure for determining this concentration suffice to ensure an effective anticaries dentifrice.

The third comment agreed that the fluoride ion is solely responsible for the effectiveness of an anticaries dentifrice, but was concerned about the exclusion of organic fluoride compounds as a source of the fluoride ion. The comment did not provide the specific names of any organic fluoride-containing compounds or any data to show that these compounds are safe and effective as anticaries agents. The comment claimed that the Panel was only interested in measuring the amount of available fluoride ion and not the source of the fluoride ion. The comment noted that the Panel did not review any data on organic fluorides because there were none on the United States market at the time of its deliberations. The comment stated that "bioequivalence and bioavailability are the critical factors in determining if the fluoride ion is safe and effective, not the organic or inorganic 'source' of the fluoride ion." The comment suggested that the scientific definition of fluoride should be described as the anion, irrespective of the inorganic or organic source of the fluoride ion. The comment did not submit any data to support its claim of the bioavailability of fluoride ions from an organic fluoride compound.

The agency agrees with the comments that the availability of the fluoride ion in concentrations which are safe and effective is the most important consideration in any fluoride-containing dentifrice. The Panel recognized the significance of the fluoride ion in preventing dental caries and discussed the use of inorganic fluorides in dental products at 45 FR 20675. The Panel was concerned about the bioavailability of the fluoride ion, especially in dental formulations with new abrasives. One of the major problems with fluoride-containing dentifrices is the possible incompatibility of the fluoride ion with the abrasive. Some abrasives may combine with the fluoride ion and decrease its availability to the teeth.

To underscore the importance that the Panel placed on the availability of the fluoride ion, the first analytical test value listed in the LTP tables refers to the concentration of soluble fluoride ion required for each fluoride compound used in dental formulations. The Panel developed LTP's as a way of predicting which dental formulations will be effective without the need for expensive, long-term clinical trials. The test values in the LTP tables were based on certain analytical tests that were obtained from dentifrice formulations that had been proven to be effective through clinical testing. In addition, the bioavailability of the fluoride ion also had been established in biological tests to ensure comparability with the results of clinical testing. The agency concurs with the Panel's recommendation regarding the need for information concerning the availability of the fluoride ion in anticaries dentifrices. Therefore, the agency is proposing to include in the active ingredient section of this tentative final monograph the amount of required available fluoride ion for each Category I fluoride active ingredient in a dentifrice formulation and to require that fluoride dentifrice drug products meet the test requirements of any two of the biological tests set forth by the Panel. (See comments 4 and 7 below.) The agency believes that requirements for parameters other than available fluoride ion and the biological testing, such as specific gravity and pH, are adequately addressed in the current good manufacturing practice for finished pharmaceuticals (21 CFR Part 211) and need not be specifically addressed in the monograph. (See comment 4 below.)

In the LTP tables proposed by the Panel, the soluble fluoride ion values were given for both the fresh and the aged formulation because the Panel believed that the concentration of free fluoride ion will change as the dentifrice ages. The aging time period was different for each of the fluoride-containing compounds and this resulted in different values for free fluoride ion for each of the compounds. The values

in the LTP tables represented the lowest measured values for aged dentifrices that were actually used and found to be effective in clinical trials. However, in its report the Panel did not discuss the amount of time that these dentifrices had aged when the lowest fluoride ion values were measured and did not include in the tables the actual age of the dentifrice at the time the listed "aged minimal" soluble fluoride ion concentration was determined. Because the Panel did not specify the age of the dentifrices at which the soluble fluoride ion values for the dentifrices must meet or exceed the "aged minimal F values" listed in the LTP tables, these values cannot be used to determine if a dentifrice is Category I, safe and effective. However, the agency and manufacturers can use these minimal soluble fluoride ion values to determine expiration dating for fluoride dentifrices that will be covered by the final monograph. (See comment 17 below.)

The agency does not accept one comment's view that only the bioavailability of the fluoride ion, and not the source, is important in determining the effectiveness of a fluoride-containing dentifrice. The inorganic fluorides that are specified in the tentative final monograph have been reviewed by the Panel, and the critical values for soluble fluoride ion for each compound have been established. These values were obtained from an extensive amount of testing, including laboratory, animal, and clinical tests. In order for a fluoride compound other than those listed in the final monograph to be approved for use in a dentifrice, similar data would be required. As stated by the Panel at 45 FR 20677, "If a manufacturer wishes to use an untested chemical compound as a fluoride source, he or she must file to obtain an approved NDA (new drug application) in accordance with FDA's new drug regulations." An alternative procedure is to petition the agency to amend the monograph to include specific organic fluorides as active ingredients for use in dental formulations. With either procedure, the manufacturer must submit data showing the organic fluoride to be safe and effective for its intended use.

2. One comment requested that the allowable upper limit of fluoride concentration in a dentifrice be increased to 1,500 parts per million (ppm). The comment stated that the first fluoride dentifrices on the OTC market contained the minimally effective dosage and that it is time to change the focus toward an optimal, not minimal, concentration. The comment added that dentifrices containing 1,500 ppm fluoride have been advocated in the dental literature and have been widely used in Europe for a number of years without any safety problems. The comment stated that, based on studies cited by the Panel (45 FR 20673), if the amount of fluoride in a dentifrice is 1,500 ppm, then the amount of dentifrice swallowed per average brushing would be 0.38 milligram (mg) or less. The comment contended that this amount is not only safe from a standpoint of enamel mottling, but it is suboptimal from a standpoint of caries prevention because the optimal fluoride intake is no less than 0.50 mg for infants and 1 mg for older children.

When the Panel reviewed fluoride dentifrices, most of the products on the market contained theoretical total fluorine at concentrations between 900 and 1,100 ppm. Based on the submitted data, these products were shown to be safe and effective. Since that time, several comments submitted additional data that are sufficient to expand the theoretical total fluorine concentration range to 850 to 1,150 ppm. (See comments 5 and 6 below.)

While the comment's statement regarding the safety of a dentifrice containing 1,500 ppm theoretical total fluorine is correct, no evidence has been provided in the administrative record to show an added benefit to persons who use a dentifrice containing 1,500 ppm theoretical total fluorine as compared to formulations containing 1,150 ppm theoretical total fluorine. The agency has approved under a new drug application (Ref. 1) the OTC marketing of a fluoride dentifrice containing 1,500 ppm theoretical total fluorine. However, these data are not in the public domain. General recognition of the effectiveness of a drug must be based on adequate published or publicly available medical and scientific data. (*United States v. 41 Cases * * * Naremco,* 420 F.2d 1126 (C.A. 5, 1970); *United States v. An Article of Drug * * * Mykocert,* 345 F. Supp. 571 (D.C. 1972); *United States v. An Article of Drug * * * Asper Sleep,* CCH F.D. and Cosm. L. Rep. 40,821 Civil No. 70–C–196 (N.D. Ill. 1971); *United States v. An Article of Drug * * * Furestrol Vaginal Suppositories,* 294 F. Supp. 1307 (N.D. Ga. 1968).) Therefore, even though a dentifrice containing 1,500 ppm fluoride has been shown, on the basis of proprietary information, to be safe and effective as required by 21 U.S.C. 355(d), there is not adequate information in the administrative record for this rulemaking at this time to demonstrate that such a dentifrice is generally recognized as effective. Because the agency is unable to make a determination at this time that a dentifrice containing more than 1,150 ppm fluoride is generally recognized as safe and effective as an OTC anticaries drug product, FDA is proposing that such products be Category III. Category III status at the tentative final stage of this rulemaking or nonmonograph status at the final stage of this rulemaking would not affect the legal OTC marketing of this drug under an approved application.

At present, a dentifrice containing 1,500 ppm fluoride cannot be lawfully marketed as an OTC anticaries drug product in the absence of an approved application. However, the agency would consider extending the upper limit of acceptable values in the monograph if sufficient data are submitted to the public record demonstrating an added benefit from using a dentifrice with concentrations higher than 1,150 ppm theoretical total fluorine without an increase in risks (safety) to consumers.

Reference

(1) Copy of FDA-approved labeling from NDA 19–518, OTC Volume 08LTPTFM, Docket No. 80N–0042, Dockets Management Branch.

3. One comment from a manufacturers' association recognized the possibility that an inactive ingredient that is not currently contained in marketed fluoride dentifrices might be added to a formulation in the future. The comment recommended that the requirements for new fluoride dentifrices formulations be qualified with the statement "* * * if any ingredient that is known or suspected of interfering with fluoride activity is present in a formulation, appropriate effectiveness testing in addition to the analytical tests included in the profile tables must be conducted."

A comment from a manufacturer agreed with the comment above and stated that an ingredient in a dentifrice could counteract the anticaries effect of the fluoride, even though the product still met the LTP testing standards. As an example, the comment stated that certain soluble materials, such as some of the phosphonates, are known to retard the rate of posteruptive mineralization of the teeth. The comment noted, however, that "mineralization-retarding" ingredients have been used in research investigations and are known to be present in at least one dentifrice sold outside the United States. The comment stated further that it is possible to add enough "retarding agent" to a fluoride dentifrice formulation to reduce the

anticaries effect of such a formulation to zero (as measured by animal caries testing) without affecting the concentration of the fluoride ion as measured in analytical tests.

The comment concluded that the effectiveness of a fluoride dentifrice formulation containing a "retarding agent" could not be adequately assessed by any set of tests that did not include at least an animal caries test and suggested that a human caries test might be required to adequately assess the anticaries effectiveness of such a formulation. The comment also suggested that manufacturers who use an ingredient that is known or suspected to counteract the anticaries effectiveness of the fluoride in a dentifrice should verify the effectiveness of the product by appropriate animal testing or, preferably, clinical testing.

Another comment suggested that fluoride dentifrices that contain those fluoride ingredients listed in the monograph, with "minor formulation changes," be considered "old" drugs if the manufacturer can show that the "old" fluoride ingredient is bioavailable in concentrations sufficient to demonstrate safety and effectiveness. "New" aspects of such drug products would be those aspects that dramatically change the "old formulations." If aspects of the product are "new," only the "new" aspects of the product should be evaluated under the new drug application process, while simultaneously allowing "old" drug issues to be resolved under the monograph. The comment contended that the agency would thus avoid lengthy drug approval problems inherent in 3-year massive clinical studies that merely demonstrate that fluoride is an effective anticaries agent.

The Panel recommended that Category I fluoride ingredient/abrasive combinations in dentifrice formulations that were not specifically reviewed by the Panel be required to contain an amount of available fluoride ion equal to or greater than the highest available fluoride ion value recommended for the specific fluoride ingredient (45 FR 20677). The agency believes that such standards for Category I fluoride ingredient/abrasive combinations in dentifrice formulations are applicable to all new dentifrice formulations that contain Category I fluoride ingredients specified in the monograph (see comment 11 below), including formulations that contain inactive ingredients that are not currently present in marketed fluoride dentifrices. It is therefore unnecessary to address some "new" aspects of such dentifrices under the new drug procedures as suggested by one comment. In addition, regulations in 21 CFR 330.1(e) concerning inactive ingredients, which state that a product may contain only suitable inactive ingredients which do not interfere with the effectiveness of a product or with suitable tests or assays for the product, adequately address concerns raised by two comments that some inactive ingredients may interfere with the fluoride activity in the formulation.

Also, regulations concerning laboratory controls in 21 CFR 211.160(b) require that "laboratory controls shall include the establishment of scientifically sound and appropriate * * * test procedures designed to assure that * * * drug products conform to appropriate standards of identity, strength, quality, and purity." Therefore, manufacturers are responsible for using appropriate test procedures for fluoride dentifrices under this regulation. In its LTP's, the Panel considered an animal caries test as one of the appropriate tests for determining the bioavailability of fluoride ion in Category I fluoride dentifrice formulations, and the agency has included this test in the proposed monograph. If an animal caries test is the appropriate test to demonstrate the possible inhibition of the fluoride ion in a dentifrice formulation containing an inactive ingredient not present in currently marketed fluoride dentifrices, as one comment suggested, then manufacturers are required to use such a test under the proposed monograph and § 211.160(b). Consequently, it is unnecessary to add a specific statement concerning such inactive ingredients in the monograph. In addition, the agency does not believe that clinical testing is necessary for Category I fluoride/abrasive dentifrice formulations that were not specifically reviewed by the Panel. [See comment 11 below.]

B. Comments on Testing Guidelines

4. Several comments objected to the agency's decision not to include the Panel's recommended LTP's for Category I fluoride dentifrices in the anticaries monograph. The comments stated that the dental profession and the industry accept the concept of establishing the effectiveness of the fluoride dentifrices specified in the panel's LTP tables (45 FR 20679 to 20681) by requiring that they meet laboratory testing standards, i.e., LTP's, rather than requiring that they meet lengthy, expensive clinical testing standards. Several comments stated that the concept of using LTP's to establish the effectiveness of fluoride dentifrices is supported by substantial scientific data that show a strong correlation between the efficacy values obtained from clinical testing and those values obtained from specific laboratory tests (LTP's) on dentifrices. Several comments emphasized that the anticaries effectiveness of fluoride dentifrices is dependent on the chemical availability and the bioavailability of the fluoride ion in the dentifrice formulation. They further explained that these availability parameters are adequately measured by chemical and biological testing, obviating the need to perform clinical testing to establish the effectiveness of the fluoride dentifrices that are included in the Panel's LTP tables.

One comment suggested that products containing the same fluoride compound and abrasive combinations as those included in the Panel's recommended LTP tables be required to meet the chemical test requirements, but not the biological test requirements recommended by the Panel. This comment suggested that fluoride/abrasive combinations that are listed in the Panel's LTP tables meet the following requirements:

(1) Theoretical total fluorine concentration between 850 and 1,150 ppm, and

(2) Specific gravity within the range 1.1 to 1.7, and

(3) A fresh soluble fluoride concentration at least as great as the table value for the particular fluoride/abrasive combination, and

(4) An aged minimal soluble fluoride concentration at least as great as the table value for that particular fluoride/abrasive combination, and

(5) A pH value within the range listed in the table for that particular fluoride/abrasive combination;

or

(1) and (2) above, and

(6) Demonstrate through appropriate clinical trials that the formulation is effective.

As stated in the advance notice of proposed rulemaking (45 FR 20666), the agency's intent in excluding the Panel's recommended LTP's from the monograph in that document was to resolve several questions regarding the use of the LTP's in regulating abrasive-containing fluoride dentifrices. The Panel's final formulation testing recommendations represented a new concept for regulating drugs under an OTC drug monograph.

The Panel recognized that the active moiety in abrasive-containing fluoride dentifrices is available fluoride ion and was aware of the problems that can

occur when the abrasive in such dentifrices interacts with the fluoride ion, reducing the amount of available fluoride ion with a concomitant reduction in the effectiveness of the product to prevent caries. With the assistance of members of the drug industry, the Panel developed LTP's for fluoride dentifrices that it believed correlate with the results of clinical testing. These LTP's do not require human testing. The LTP's were formulated by the Panel after reviewing industry submitted laboratory testing results on actual lots of several different types of fluoride dentifrices that had been clinically tested and found effective. The Panel used the actual test values for these clinically effective lots of fluoride dentifrices to develop the LTP's.

The Panel recommended that a fluoride dentifrice product that contains a Category I fluoride ingredient/abrasive combination that is listed in the tables in its report could be marketed if it meets or exceeds the soluble fluoride ion levels listed in the tables in addition to meeting other parameters set by the Panel such as limits for specific gravity and pH, and biological testing standards (45 FR 20677 to 20681). Combinations of Category I ingredients and abrasives that are not listed in the tables in the report are discussed in comment 11 below.

After reviewing the comments submitted in response to the Panel's report, the agency concluded that there were still several unresolved questions concerning the LTP's. In an effort to resolve these questions, the agency announced a public meeting to discuss appropriate LTP's for OTC abrasive-containing fluoride dentifrices in the **Federal Register** of August 26, 1983 (48 FR 38853). Specific agency questions concerning the LTP's were posed in that meeting announcement. The public meeting was held September 26 and 27, 1983. Items discussed at the meeting included the addition of new testing technology, such as remineralization testing for fluoride dentifrices, to the LTP requirements. Also discussed were mechanisms for adding updated specific LTP test methods to those testing methods that were reviewed by the Panel and that are on file in the anticaries drug products rulemaking administrative record in the Dockets Management Branch (Ref. 1). Whether or not specific test methods should be required to obtain LTP test values for fluoride dentifrices was discussed, in addition to the importance of including test parameters such as specific gravity, pH, and stannous ion content in agency requirements for fluoride dentifrices. Participants in the meeting provided a great deal of information regarding the agency's concerns and questions about the LTP's (Refs. 2 and 3). There was general agreement that new testing technology has been developed for fluoride dentifrices since the Panel's review of these dentifrices and that new testing technology continues to evolve. There was a consensus that, although the testing methods reviewed by the Panel are valid techniques, the agency's requirements for testing fluoride dentifrices should not preclude the application of new, advanced technology in testing fluoride dentifrices, nor should the agency require specific test methods to obtain LTP test values for fluoride dentifrices. Most meeting participants agreed that parameters, such as specific gravity, pH, and stannous ion content, specified by the Panel in the LTP tables were based on particular fluoride dentifrice formulations that were in the marketplace during the Panel's deliberations. However, these parameters do not necessarily reflect appropriate test limits for currently marketed fluoride dentifrice formulations that are different from the previous formulations reviewed by the Panel. The majority of the participants believed that these formulation specific parameters have an important impact on the availability of the fluoride ion in a particular fluoride dentifrice formulation. However, these parameters vary from one formulation to another and the most important testing criterion for predicting the effectiveness of a fluoride dentifrice is the availability of the fluoride ion in the formulation.

The agency has carefully reviewed the Panel's recommendations concerning the LTP's, the comments concerning the LTP's, and the information provided during the September 1983 meeting. Prior to the Panel's recommendations, the only accepted methods of assuring the effectiveness of fluoride dentifrice formulations were clinical trials. Such clinical trials are long-term studies that require large numbers of children, the population most vulnerable to caries; are expensive; and require a high level of expertise in employing appropriate criteria to produce conclusive results. The Panel was aware of the problems involved in such extensive clinical trials but was also concerned that the abrasive in the dentifrice could alter the availability of the fluoride ion and therefore the effectiveness of fluoride dentifrices. The Panel sought an alternative to clinical trials that would still ensure the effectiveness of fluoride dentifrices and recommended that fluoride dentifrices meet laboratory testing standards, i.e., LTP's, in lieu of the long, expensive clinical trials.

As one former Panel member stated in his comments to the advance notice of proposed rulemaking, it is clearly not in the best interest of consumers or industry to require additional clinical testing of Category I active ingredients because of formulation changes that can be demonstrated in the laboratory to be inconsequential and not to interfere with the effectiveness of the dentifrices (Ref. 4). The agency agrees with the comments and the Panel that the requirement of lengthy clinical trials is no longer warranted and that appropriate laboratory testing is adequate to assure the effectiveness of fluoride dentifrices containing Category I active ingredients. Therefore, the agency is accepting the Panel's recommendation that fluoride dentifrices meet or exceed the soluble fluoride ion level specified for each particular fluoride ingredient listed in the monograph and meet the test requirements of any two of the following biological tests: (1) Enamel solubility reduction, (2) fluoride uptake by enamel, and/or (3) animal caries reduction. The agency is including these requirements in the monograph.

The Panel's major concern was to assure the availability of fluoride ion in abrasive-containing dentifrices. Based on the fluoride ion values recommended in the Panel's LTP's and in comments submitted in response to the Panel's recommendations (see comment 5 below), the agency is proposing to include in the active ingredient section of the monograph the amount of available fluoride ion required for each Category I fluoride active ingredient in a dentifrice dosage form. As discussed in comment 6 below, the agency is also proposing ranges of concentrations for fluoride ingredients in the monograph that correspond to a range of 850 to 1,150 ppm theoretical total fluorine. In addition, the agency is proposing to include the Panel's recommendations concerning biological test requirements for fluoride dentifrices (45 FR 20677 and 20678) in the monograph. (See comment 7 below.) Thus, the active ingredient list in § 355.10(a) for dentifrices is being amended as follows:

(a) *Dentifrices.* (1) Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration>650 parts per million.

(2) Sodium monofluorophosphate 0.654 to 0.884 percent with an available fluoride ion concentration (consisting of

$PO_3F^=$ and F^- combined)>800 parts per million.

(3) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration>700 parts per million for products containing abrasives other than calcium pyrophosphate.

(4) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration >290 ppm for products containing the abrasive calcium pyrophosphate.

The agency is also adding new Subpart D to Part 355 concerning biological testing requirements to read as follows:

Section 355.70 Testing Procedures for Fluoride Dentifrice Drug Products.

A fluoride dentifrice drug product must meet the test requirements of any two of the following biological tests: Enamel solubility reduction, fluoride uptake by enamel, and/or animal caries reduction. The testing procedures for these biological tests are on file under Docket No. 80N–0042 in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, labeled *Biological Testing Procedures for Fluoride Dentifrices*, and are available on request to that office. Alternative testing procedures may be used. Any proposed modification or alternative testing procedures shall be submitted as a petition under the rules established in § 10.30. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in Part 20 of this chapter.

As with all products covered by OTC drug monographs, it is the responsibility of the manufacturer to assure that its products meet the standards set forth in the appropriate monograph. In the case of fluoride dentifrices, the agency is proposing that manufacturers ensure that their products contain the amount of available fluoride ion and meet the biological testing requirements set forth in the monograph for OTC anticaries drug products.

The agency believes that the Panel's recommended requirements in the LTP tables for parameters other than available fluoride ion and biological test requirements such as specific gravity and pH, that relate to inactive ingredients and appropriate manufacturing procedures, are adequately addressed in the current good manufacturing practice regulations (21 CFR Part 211) and need not be specifically addressed in the monograph. For example, § 211.160(b) states

> Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.

In addition, § 211.165 states in part that "For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release,"; that "The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels,"; and that "The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented." In addition, by regulation (21 CFR 330.1(e)) a product may contain only suitable inactive ingredients which are safe and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity. In conclusion, the agency offers the Panel's recommended testing requirements, as set forth in the LTP tables (45 FR 20679 to 20681) and revised in comments 5 and 6 below, as appropriate testing limits for parameters such as specific gravity, pH, and stannous ion content, but does not find it necessary to include them in a final monograph.

References

(1) OTC Volume 080248.

(2) Minutes of a Public Meeting to Address Laboratory Testing Profiles for OTC Abrasive-Containing Fluoride Anticaries Drug Products, September 26 and 27, 1983, Docket No. 80N–0042, Dockets Management Branch.

(3) Transcripts of a Public Meeting to Address Laboratory Testing Profiles for OTC Abrasive-Containing Fluoride Anticaries Drug Products, September 26 and 27, 1983, Docket No. 80N–0042, Dockets Management Branch.

(4) Comment No. C00001, Docket No. 80N–0042, Dockets Management Branch.

5. One comment from a manufacturers' association noted that the Panel's recommended LTP tables (45 FR 20679 to 20681) are based entirely on data generated by industry and submitted to the Panel. The comment requested that corrections of errors resulting from either misinterpretations of the data submitted by industry or mistranscriptions of the numbers submitted by industry be made as follows: (1) In Table 1 for sodium fluoride dentifrices (45 FR 20679), the test dilutions for both the "Soluble Fluoride Ion" and the "Hydrogen Ion Concentration (pH)" should be 1:3 rather than 1:10; (2) in Table 2 for sodium monofluorophosphate dentifrices (45 FR 20680) under "II. Hydrogen Ion Concentration (pH)," the pH range listed for the abrasive alumina should be 6.4 to 9.0 rather than 5.0 to 9.0 and the pH range listed for the abrasive dicalcium phosphate should be 6.3 to 7.6 rather than 6.5 to 7.8; (3) in Table 3 for stannous fluoride dentifrices (45 FR 20681) under "I. Soluble Fluoride Ion," the test values for fluoride ion listed for the abrasives, insoluble sodium metaphosphate, silica, and others should be 700 ppm for the fresh value and 650 ppm for the aged minimal value, rather than 600 ppm for the fresh value and 500 ppm for the aged minimal value; (4) in Table 3 for stannous fluoride dentifrices (45 FR 20681) under "II. Soluble Stannous Ion," the test dilution for the abrasive calcium pyrophosphate should be 1:3 rather than 1:10; and (5) in Table 3 for stannous fluoride dentifrices (45 FR 20681) under "III. Hydrogen Ion Concentration (pH)," the test dilution for the abrasive calcium pyrophosphate should be 1:3 rather than 1:10 and the test dilution for the abrasives insoluble metaphosphate, silica, and others should be 1:4 rather than 1:10.

Another comment from a manufacturer that provided test data to the Panel stated that the allowable maximum dilution factor of 1:10 weight per weight (w/w) is inappropriate for some dentifrices listed in the LTP tables because the minimum soluble fluoride levels had been actually determined by the manufacturer using a dilution factor of 1:3 (w/w). The comment further stated that as the dilution factor becomes larger, more fluoride ion is likely to become soluble. Therefore, a larger dilution factor (1:10) may give a false, higher measured soluble fluoride ion concentration than a lower dilution factor (1:3) for a particular dentifrice sample. For example, a 1:3 dilution of a sodium fluoride plus high-beta-phase calcium pyrophosphate toothpaste might yield a low unacceptable measured level of soluble fluoride ion of 500 ppm (below an acceptable 648 ppm) for a fresh product, whereas the same product at a 1:10 dilution might well yield an acceptable measured level of soluble fluoride ion of >648 ppm. Thus, there is a risk that the batch of product found acceptable when measured at a 1:10 dilution may not be as effective as dentifrices that have been found to be

clinically effective. Another comment recommended that the changes above requested by the manufacturer and the manufacturers' association be incorporated into the LTP tables.

A fourth comment from a manufacturers' association recommended that in Table 2 for sodium monofluorophosphate dentifrices (45 FR 20680) under "II. Hydrogen Ion Concentration (pH)," the list of specific pH ranges for specific abrasives be replaced by an expanded pH range of 4.2 to 10.0 that is applicable to all abrasives. This comment also requested that the Panel's recommended heading "Maximum test dilution" in Tables I and III be changed to read "Test dilution" and that values in this column be 1:3 and not 1:10 because the test values are actual test values that were determined at a dilution of 1:3 and not theoretical test values.

The agency recognizes that the data the Panel used to establish the LTP tables were developed by industry and submitted to the panel to provide a basis for the LTP tables. The agency has reviewed the industry's corrections of the LTP tables that appear in the advance notice of proposed rulemaking (45 FR 20679 to 20681) and finds them appropriate. In addition, the agency agrees with the one comment that the term "test dilution" is preferable to the term "maximum test dilution" because "test dilution" more accurately indicates the precise dilution factor used.

With respect to one comment's request that the pH ranges specified for particular abrasives listed in Table 2 be replaced by a general expanded pH range of 4.2 to 10 for all abrasives, the agency believes that it is unnecessary to change the Panel's Table 2 because it provides specific pH guidelines for particular fluoride dentifrice formulations that were reviewed by the Panel. The Panel specified the pH ranges for particular abrasives in fluoride dentifrices in the LTP tables because pH has an important role in determining the availability of the fluoride ion in the specific formulations that the Panel reviewed. The agency agrees with the manufacturers' association that an expanded pH range of 4.2 to 10 would apply to all abrasives, but, as explained above, it is not necessary to revise the list of specific pH ranges for specific abrasives in Table 2 (45 FR 20680) because these specific pH ranges provide valid information concerning appropriate pH ranges for the particular fluoride dentifrices that were reviewed by the Panel. Although the agency is not revising the Panel's LTP tables to include a general expanded pH range of 4.2 to 10, this does not preclude the acceptability of a fluoride dentifrice formulation with a pH different from that specified by the Panel, provided that the dentifrice is safe, meets the levels of available fluoride ion and the biologioal testing requirements identified in the final monograph, and meets scientifically sound and appropriate specifications, standards, and test procedures to ensure that the product conforms to appropriate standards under FDA's current good manufacturing practice regulations (21 CFR Part 211). (See comments 4 above and 11 below.)

6. Several comments requested that the agency widen the Panel's recommended acceptable range of specific gravity values for fluoride dentifrices from 1.3 to 1.7 to a range of 1.1 to 1.7 to accommodate new abrasive systems that are based on silica, an abrasive that is less dense than the older phosphate and calcium carbonate abrasives. The comments stated that, because the abrasive is the major inactive and most dense ingredient in dentifrices, the density of the abrasive has a significant impact on the specific gravity of the dentifrice formulation. Fluoride dentifrices with less dense silica abrasive systems have lower specific gravities than fluoride dentifrices with more dense phosphate or calcium carbonate abrasive systems. One comment explained that silica abrasives are more efficient than phosphate abrasives in cleaning the teeth, i.e., less silica abrasive is needed to produce the same cleaning effect that a larger amount of phosphate abrasive produces, and, as a result, silica abrasives are used in dentifrices at roughly half the weight percent as phosphate abrasives. Another comment noted that the Panel offered no analysis or justification for its recommendation that the specific gravity of all fluoride dentifrices be between 1.3 and 1.7 and apparently it based this recommendation solely on the values for the particular dentifrice formulations that it reviewed.

One comment from a manufacturer requested a specific mathematical adjustment of the Panel's recommended range of allowed total fluorine level (900 ppm to 1,100 ppm) to 1,140 ppm for its particular fluoride dentifrice product to accommodate a change in the specific gravity of the product. The comment explained that a change in the formulation of its fluoride dentifrice from a calcium pyrophosphate abrasive (old product) to a silica abrasive (new product) reduces the specific gravity from 1.56 for the old product to 1.37 for the new product. The comment contended that consumers dispense dentifrices onto a toothbrush by volume, not by weight, and thus the same volume of new product would deliver a lower amount of theoretical total fluorine by weight than the old product because of the lower specific gravity of the new abrasive. For example, if 1 gram (g) of the old product with a specific gravity of 1.56 is dispensed on a toothbrush, it will contain 1 mg theoretical total fluorine. However, if 1 g of the new product with the lower specific gravity of 1.37 is dispensed on a toothbrush, it will only contain 0.88 mg theoretical total fluorine. The comment explained that the Panel's recommended range of 900 to 1,100 ppm theoretical total fluorine content does not allow for the addition of an amount of total fluoride compound large enough to produce a product that provides an equal amount of theoretical total fluorine in an equal volume of fluoride dentifrice formulation as was contained in the old calcium pyrophosphate dentifrice. The comment requested that a correction factor (i.e., the old dentifrice specific gravity value divided by the new dentifrice specific gravity value and multiplied by 1,000 to yield a concentration of theoretical total fluorine in ppm) be allowed for its new silica dentifrice to enable the same amount of total fluorine per volume to be delivered on a toothbrush as would be delivered by volume for the old formulation. Alternatively, the comment requested that the range of 900 to 1,100 ppm for theoretical total fluorine be widened to 850 to 1,150 ppm to cover the practical range of specific gravity. In addition, the comment expressed concern that the final rulemaking would require only a single level of fluoride concentration for fluoride dentifrices as set forth in § 355.10 of the Panel's recommended monograph (45 FR 20690). The comment believed that specifying only single fluoride levels in the monograph could lead to the interpretation that the Panel's recommended fluoride level range of 900 to 1,100 ppm is an allowable tolerance for quality control variation rather than an allowable fluoride level range to compensate for variations in specific gravity. Another comment from a manufacturers' association listed the theoretical total fluorine concentration range of 850 to 1,150 ppm as an appropriate parameter for fluoride dentifrices without specifically commenting on the difference between this range and the Panel's range of 900 to 1,100 ppm for theoretioal total fluorine.

Two comments contended that specific gravity is not an important parameter in determining the anticaries effectiveness of fluoride dentifrices. One of these comments submitted three published clinical studies that compare the anticaries effectiveness of fluoride dentifrice formulations with the same fluoride compounds, but different abrasive systems (Refs. 1, 2, and 3). Two of the studies compare 0.4 percent stannous fluoride dentifrices containing phosphate or silica abrasives (Refs. 1 and 2). The third study compares 0.76 percent sodium monofluorophosphate dentifrices containing phosphate or silica abrasives (Ref. 3). The studies do not discuss differences in the specific gravity of the dentifrices studied. All three studies concluded that the effectiveness of the silica-abrasive dentifrices is comparable to the effectiveness of the phosphate-abrasive dentifrices. The comment argued that differences in the specific gravity of the dentifrices tested in the three studies did not result in significant differences in the anticaries effectiveness of the dentifrices. The comment concluded, based on the three studies, that specific gravity is not an important test parameter for fluoride dentifrices and that, because specific gravity does not affect dentifrice efficacy, there is no reason to adjust individual dentifrice formulations to compensate for specific gravity variability. The comment added that the current limits of fluoride concentration have been used, unadjusted, for more than 20 years throughout a series of formulation changes. The comment expressed concern that if FDA were to conclude in one instance that the fluoride concentration in one fluoride dentifrice formulation should be adjusted to compensate for a specific gravity variation, the necessity of adjusting fluoride levels in all dentifrices could be imposed on manufacturers.

The Panel based its recommendations concerning appropriate ranges for the parameters of theoretical total fluorine and specific gravity for fluoride dentifrices on its review of specific dentifrice formulations submitted to it and did not consider the possibility that the use of new, less dense abrasives in effective fluoride dentifrice formulations could lower the specific gravity of the formulation below 1.3 without compromising the anticaries effectiveness of the dentifrice. The Panel recommended an allowable theoretical total fluorine range of 900 to 1,100 ppm and a specific gravity range of 1.3 to 1.7 for fluoride dentifrices (45 FR 20677).

The agency agrees with the comments that the Panel's recommended range of 900 to 1,100 ppm for theoretical total fluorine can be widened to 850 to 1,150 ppm because the most important parameter in determining the effectiveness of such dentifrices is the amount of available fluoride ion content rather than theoretical total fluorine content. The agency is specifically including requirements for the available fluoride ion content of fluoride dentifrices in the tentative final monograph. (See comment 4 above.) Therefore, the agency believes that 850 to 1,150 ppm is an appropriate range for theoretical total fluorine that will accommodate the newer less dense abrasive systems without compromising the effectiveness of fluoride dentifrices.

In response to one comment's concern that adjustments in the theoretical total fluorine levels might be required to compensate for variability in the specific gravity of different fluoride dentifrice formulations, the agency does not intend to require such adjustments. In response to another comment's concern regarding the intent of the fluoride ingredient concentrations specified in the monograph and the intent of the allowable theoretical total fluorine range of 850 to 1,150 ppm, this range is intended to allow a range of theoretical total fluorine levels for formulation purposes, not as a variation for quality control purposes. To avoid possible misinterpretation of the concentrations for fluoride dentifrices, the agency is proposing the following ranges of concentrations for fluoride ingredients in the monograph that correspond to a range of 850 and 1,150 ppm theoretical total fluorine: For sodium fluoride a range of 0.188 to 0.254 percent, for sodium monofluorophosphate a range of 0.654 to 0.884 percent, and for stannous fluoride a range of 0.351 to 0.474 percent.

The agency agrees with the comments that the Panel's recommended limits for specific gravity are inadequate to accommodate new dentifrices utilizing less dense abrasive systems. In addition, the agency believes that changing the Panel's recommended limits for specific gravity from 1.3 to 1.7 to 1.1 to 1.7 to accommodate less dense abrasive systems will not have a significant impact on the effectiveness of a fluoride dentifrice and finds a specific gravity range of 1.1 to 1.7 appropriate for fluoride dentifrices.

However, the agency acknowledges that changes in specific gravity result in a corresponding change in the amount of fluoride contained in a given volume of a dentifrice if the concentration of the fluoride is expressed as a weight to weight measurement such as ppm. As the specific gravity value decreases, the amount of fluoride in a given volume of dentifrice also decreases. Because the agency agrees with one comment that, in general, the consumer is more likely to dispense a dentifrice on a toothbrush on the basis of volume or size of a ribbon, rather than to dispense a dentifrice on the basis of weight, the agency is concerned that at some lower limit of the amount of fluoride in a given volume of dentifrice, the amount of fluoride delivered on the toothbrush may be insufficient to provide an effective anticaries benefit. In addition, at some upper limit of the amount of fluoride in a given volume of dentifrice, the amount of fluoride delivered on the toothbrush will unnecessarily exceed the amount of fluoride needed to provide an effective anticaries benefit. In recommending that limits be required for both the specific gravity and the theoretical total fluorine ppm (a weight to weight measurement), the Panel, in effect, placed limits on the amount of fluorine per unit volume of toothpaste. For example, the Panel's lower limits of 900 ppm and a specific gravity of 1.3 convert to 1.17 mg fluorine per milliliter (mL) toothpaste; while the Panel's upper limits of 1,100 ppm and a specific gravity of 1.7 convert to 1.87 mg fluorine per mL toothpaste. Thus, the Panel's recommendations limit the amount of theoretical total fluorine in a dentifrice to a range of 1.17 to 1.87 mg per mL.

The agency is considering whether, in addition to providing ranges for fluoride dentifrices in terms of specific gravity and theoretical total fluorine measurements, it may be appropriate to provide ranges for fluoride dentifrices in terms of weight to volume measurements that correspond directly to the allowable ranges for specific gravity (1.1 to 1.7) and theoretical total fluorine (850 to 1,150 ppm) for dentifrice formulations utilizing abrasive systems that result in products having a specific gravity lower than 1.1 or higher than 1.7. Such abrasive systems would require modification of the specific gravity range because the specific gravity of the dentifrice is below 1.1 or above 1.7. The agency believes that the following guidelines for such dentifrices can be provided without unduly complicating the requirements for fluoride dentifrices: The lower limits of 850 ppm theoretical total fluorine and a specific gravity of 1.1 convert to a lower limit of 0.935 mg fluorine per mL toothpaste and the upper limits of 1,150 ppm theoretical total fluorine and a specific gravity of 1.7 convert to an upper limit of 1.955 mg

fluorine per mL toothpaste, i.e., a range of 0.935 to 1.955 mg fluorine per mL. These limits would obviate the need to modify these ranges in the future.

The agency believes that a range of 0.935 mg to 1.955 theoretical total fluorine per mL of dentifrice may be an appropriate guideline for all Category I fluoride compounds, formulated in dentifrices with specific gravities less than 1.1 or greater than 1.7. This range ensures that dentifrices with lower or higher specific gravities due to changes in abrasives will remain in the same range of total fluorine per volume of dentifrice as currently marketed fluoride dentifrices that are within the range of 850 ppm to 1,150 ppm total fluorine and the range of 1.1 to 1.7 for specific gravity. In addition, the range above of total fluorine per volume of dentifrice for dentifrices with specific gravities above 1.7 or below 1.1 provides flexibility in the requirements for fluoride dentifrices to accommodate the development of new abrasive systems. The agency requests specific comment on the modification summarized above of the Panel's recommended ranges for theoretical total fluorine and specific gravity as set forth in the advance notice of proposed rulemaking (45 FR 20677) to provide a range of 0.935 to 1.955 mg theoretical total fluorine per mL of dentifrice for dentifrices with a specific gravity lower than 1.1 or higher than 1.7.

References

(1) Fogels, H. R., et al., "The Relative Caries-inhibiting Effects of a Stannous Fluoride Dentifrice in a Silca Gel Base," *Journal of the American Dental Association*, 99:456–459, 1979.

(2) Abrams, R.G., and D.W. Chambers, "Caries-inhibiting Effect of a Stannous Fluoride Silica Gel Dentifrice: A Three-year Clinical Study," *Journal of Clinical Preventive Dentistry*, 2:22–27, 1980.

(3) Triol, C.W., C.J. Wilson, and A.R. Volpe, "Effect on Caries of Two Monofluorophosphate Dentifrices in a Nonfluoridated Water Area: A Thirty-one Month Study," *Journal of Clinical Preventive Dentistry*, 3:5–7, 1981.

7. In an effort to clarify unresolved questions concerning the Panel's recommended LTP standards for fluoride dentifrices, the agency posed specific questions concerning the LTP's for discussion at a public meeting held on September 26 and 27, 1983. The agency questioned whether the Panel's recommended biological testing standards are necessary in addition to analytical testing to ensure the effectiveness of fluoride dentifrices (48 FR 38853).

In response to the agency's questions, the American Dental Association (ADA) submitted a comment (Ref. 1) stating that, ideally, the question of whether fluoride in a dentifrice is taken up by the tooth enamel to produce an effect on tooth structure that will make the tooth resistant to dental caries is best answered through well-controlled clinical tests. ADA added that other in vitro or in situ tests or animal studies, such as the biological tests recommended by the Panel, are also helpful in determining the anticaries effectiveness of fluoride dentifrices. ADA noted that enamel solubility reduction tests are most meaningful for fluoride dentifrices containing stannous fluoride. ADA also suggested that another method, now available, to evaluate the effect of fluoride on tooth structure is an evaluation of the ability of the product to induce remineralization of tooth structure. Another comment stated that the Panel's recommended tests should be continued for anticaries products, but other tests such as remineralization tests can be added to the Panel's recommended tests to demonstrate the clinical effectiveness of fluoride dentifrices. The comment explained that the remineralization test is particularly valuable in demonstrating clinical effectiveness.

A comment from a manufacturers' association agreed with the Panel's recommendation that all Category I fluoride dentifrices must meet the test requirements of any two of the following biological tests: (1) An enamel solubility reduction test, (2) a test for fluoride uptake by enamel; or (3) an animal caries reduction test. However, another manufacturers' association, representing many of the same dentifrice manufacturers, subsequently stated that the biological tests listed above would not be necessary for fluoride dentifrice formulations that are the same as the fluoride ingredients and abrasives listed in the LTP tables because the clinically proven effectiveness of these formulations that were reviewed by the Panel discounts any adverse effects of the abrasive on the biological activity. Therefore, the assurance of sufficient available fluoride ion and appropriate pH and specific gravity of the new formulation are all that is required. The comment recommended that biological testing be required only for new fluoride dentifrice formulations that were not reviewed by the Panel. In addition, the same manufacturers' association later commented that industry believes that other tests, e.g., remineralization tests, while interesting, are still of more academic than practical value. Industry does not consider any particular remineralization test as having been validated, and, therefore, it considers the addition of requirements for testing for remineralization properties to be unacceptable for regulatory purposes.

The Panel believed, and the agency concurs, that the demonstration of the bioavailability of the fluoride ion in two of the three biological tests, i.e., enamel solubility reduction, fluoride uptake by enamel, and/or animal caries reduction, is necessary to ensure the anticaries effectiveness of fluoride dentifrices, and the agency has included this requirement in the proposed monograph. Although the agency commends and encourages the development of additional testing procedures, such as remineralization tests, the agency believes that the three biological tests recommended by the Panel are adequate and sufficient to demonstrate the bioavailability of the fluoride ion in dentifrices. In addition, the Panel's recommendations concerning these three biological tests were based on the results of actual biological tests performed on fluoride dentifrices that had been shown to be clinically effective in preventing caries. The agency does not believe that there are sufficient data to correlate specifically the results of remineralization tests with clinical studies that demonstrate the anticaries effectiveness of fluoride dentifrices. Therefore, at this time, the agency believes that remineralization tests cannot be considered an adequate substitute for the Panel's recommended biological tests or that remineralization tests should be required in addition to the Panel's recommended tests. However, the agency recognizes that testing technology continues to evolve and has provided in the monograph the opportunity for interested persons to propose modifications or alternative testing procedures through the petition process established in 21 CFR 10.30.

With respect to a manufacturers' association's suggestion that biological testing is not necessary for fluoride dentifrice formulations that are the same as those that were reviewed by the Panel and listed in the LTP tables and its suggestion that only the analytical portion of the Panel's recommended testing be required for such dentifrices, the agency at this time does not have adequate information to show that biological testing is not necessary for such dentifrices. The Panel's recommendations were based on the correlation of laboratory testing results with clinical data. The biological portion of the recommended testing provides an important assurance that, in addition to being chemically available as demonstrated by the analytical portion of the testing recommendations, the fluoride is also bioavailable in that it

will alter tooth structure in the biological tests to make the tooth resistant to caries. Therefore, it is the responsibility of manufacturers to ensure that their fluoride dentifrice formulations demonstrate the bioavailability of the fluoride in two of the three biological tests, i.e., enamel solubility reduction, fluoride uptake by enamel, and/or animal caries reduction, as determined by the testing methods on file in the Dockets Management Branch under Docket No. 80N-0042, labeled as *Biological Testing Procedures for Fluoride Dentifrices.*

Reference

(1) Comment No. C00038, Docket No. 80N-0042, Dockets Management Branch.

8. Another question raised by the agency at the public meeting held on September 26 and 27 concerned how reference formulations that are required to interpret the results of biological testing would be available to manufacturers interested in marketing fluoride dentifrices if biological testing is necessary.

In response to the agency's concerns, ADA recommended that consideration be given to establishing United States Pharmacopoeia (USP) reference standards for fluoride dentifrice formulations that have been demonstrated to be clinically effective. ADA stated that manufacturers of these dentifrices should be responsible for establishing the formulas for these products with USP. In addition, the formulas should include complete instructions for their preparation so that USP can maintain appropriately prepared reference standards that are properly aged, freshly prepared, or in a stable formulation as determined by the manufacturer or manufacturers of the clinically tested product. ADA also suggested that the manufacturers, perhaps through a manufacturers' association, could recommend appropriate statistical procedures to be used for evaluating products in the biological tests that utilize the reference formulations.

A comment from a manufacturers' association objected to establishing USP reference standards for use in analytical testing and biological testing of fluoride dentifrices. The association stated that any marketed fluoride dentifrice can be used as a reference standard if it contains a particular fluoride ingredient and abrasive included in the LTP tables that have been demonstrated to be effective by appropriate clinical trials. The association contended that it is the responsibility of the "experimentor" to ensure that the fluoride dentifrice drug product chosen to serve as a reference formulation meets the fresh and aged minimal fluoride values and pH values and that it is within the allowable specific gravity range specified by the LTP's for that particular reference formulation. In addition, the particular fluoride ingredient contained in the chosen reference formulation must be the same as the fluoride ingredient in the dentifrice formulation being tested. The association recommended that, if a manufacturer cannot readily purchase or obtain a particular reference standard, it should be allowed to prepare a reference formulation based on formulas either published in the scientific literature with the results of clinical trials included or submitted to the agency by a manufacturers' association (Ref. 1). Again, the "experimentor" should be responsible for ensuring that the reference dentifrice that is formulated meets the appropriate testing standards set forth by the Panel in the LTP tables. Also, the reference formulation and the new fluoride dentifrice formulation being tested must score significantly higher than a placebo in the biological tests as "a simple check on the effectiveness."

In response to the agency's concerns regarding the stability of reference formulations, the manufacturers' association stated that requirements for minimal aged fluoride concentration in the LTP tables abrogates any concern regarding the stability of a reference formulation. The comment stated that "a candidate formulation that requires only analytical or analytical and biological laboratory testing is to be compared with the reference both fresh and aged, so that questions of stability are automatically answered."

In a later comment to the agency (Ref. 2), the manufacturers' association submitted offers, from four manufacturers, to voluntarily supply reference formulations to requestors having a legitimate interest in the manufacture of fluoride dentifrices. The reference formulations that would be supplied by these manufacturers would be certified that they conform to the monograph definition of effectiveness. These reference formulations would be for use only as a reference formulation in order to conduct required laboratory tests. As proposed by the comment, the manufacturers that volunteered to provide reference formulations could also elect to supply formulation information including exact ingredient percentages for a reference formulation. All of the manufacturers offered to provide fluoride dentifrice reference formulations for products currently manufactured by their company and to supply analytical certification of the reference formulation consisting of actual test values for total fluoride content, available fluoride ion content, pH, and specific gravity, as well as information concerning the date and place of manufacture, date of analysis, and storage recommendations for the reference dentifrice. The comment stated that the only analytical measurements that the manufacturers have agreed to provide for the certified reference formulations are available fluoride ion content, pH, and specific gravity, and that the purpose of the reference formulations is to provide a comparison of the laboratory values obtained in the biological tests. Therefore, it is not appropriate or necessary to require that these reference formulations be used to provide a comparison of the laboratory values obtained in the analytical tests. The manufacturers agreed to supply only an amount of the reference formulation that would be required for laboratory testing and some manufacturers limited the number of times per year that they would be willing to supply reference formulations to a particular requestor. The manufacturers stated that it would be the responsibility of the requestor (1) to allow 90 days for delivery of the reference formulation, (2) to use the reference formulation within a period of 90 days of certification to maintain validity of the certified values, (3) to determine which biological tests are to be performed, and (4) to store the reference formulation in the manner stated in the analytical certification. The costs of the reference formulation, including certification costs, would be borne by the requestor.

The agency agrees with ADA that fluoride dentifrice reference standard formulations that are required to interpret the results of the biological testing proposed in the monograph should be established as USP reference standards for fluoride dentifrice formulations. The validity and reliability of the results of biological testing to establish the effectiveness of fluoride dentifrice formulations are dependent on the quality, uniformity, validity, and reliability of the reference standard formulation used for comparison with the fluoride dentifrice formulation being tested. The agency is currently coordinating with USP to establish fluoride dentifrice reference standard formulations that will be made available to manufacturers interested in manufacturing fluoride dentifrices. Information concerning these reference standards will be on file in the Dockets Management Branch under Docket No.

80N–0042, labeled *Biological Testing Procedures for Fluoride Dentifrices.*

The agency appreciates the offers of several manufacturers to voluntarily provide certified reference formulations for use in the biological testing of fluoride dentifrices to other manufacturers that wish to manufacture fluoride dentifrices, but believes that this is not an appropriate mechanism to make such reference formulations available. The agency also believes that, although many manufacturers who are interested in marketing fluoride dentifrices could formulate adequate reference standard formulations based on information submitted to the Panel (Ref. 1), other manufacturers may not be able to do so. Because the use of an adequate reference standard is pivotal in producing valid results in the biological tests, the agency is proposing that manufacturers be required to establish the effectiveness of their fluoride dentifrice formulations in two of the three biological tests specified in the monograph using a USP fluoride dentifrice reference standard formulation, which should be available before this final monograph becomes effective. The agency clarifies that this requirement is not intended to apply to the use by manufacturers of in-house fluoride dentifrice reference standards for quality control purposes.

References

(1) OTC Volume 080253.

(2) Comment No. C00044, Docket No. 80N–0042, Dockets Management Branch.

9. One comment stated that the availability of reference standard formulations in quantities sufficient to adequately conduct research in developing new anticaries agents is imperative. Although manufacturers have stated that supplying reference formulations in such quantities would be a hardship on manufacturers of the reference formulations, the comment stated that, without such reference formulations, the results of any clinical trial would be ambiguous at best.

The scope of this rulemaking does not address requirements relating to dental research to develop new anticaries agents. Therefore, the agency will not discuss the availability of reference standard formulations for such use in this rulemaking.

10. Two comments requested that the Panel's recommended requirement for the numerical score in the biological tests for all Category I fluoride dentifrices be changed from "no lower than the score for a reference formulation at the 90-percent confidence level" to "not significantly lower than the score for the reference formulation." (See 45 FR 20677 to 20678.) One comment claimed that the 90-percent confidence limit can be misleading and can actually reward a poorly conducted set of laboratory tests. The comments suggested that appropriate statistical methods be used and that the choice of the statistical method be left up to the experimenter.

The agency agrees with the comments. The more general statement "not significantly lower than the score for the reference formulation" allows the application of appropriate statistical criteria to laboratory data to demonstrate that fluoride dentifrices achieve scores in the biological tests that are not significantly lower than the scores for the reference formulations.

The Panel recommended that the numerical score in the biological tests for fluoride dentifrices be "no lower than the score for a reference formulation at the 90-percent confidence level" to demonstrate bioavailability of the fluoride ion in that the dentifrice will alter tooth structure to make the tooth resistant to caries. Although the 90-percent confidence level as a statistical criterion may be acceptable for evaluating some biological test data sets, it is not necessarily acceptable for evaluating all biological test data sets. Therefore, the agency accepts the comment's suggested general statement. Further, as stated in § 211.165(d), appropriate statistical quality control criteria must be used for drug products.

C. Comments on Abrasive Systems for Anticaries Drug Products

11. One comment from a manufacturer disagreed with the Panel's recommendations concerning testing guidelines for Category I fluoride ingredient/abrasive combinations not specifically reviewed by the Panel. The comment contended that the Panel's recommendation to require such a new formulation to have laboratory testing values equal to or greater than the highest fluoride values listed in the Panel's LTP tables for the particular fluoride compound used in the formulation (45 FR 20677) is faulty. The comment stated that this recommended requirement must be changed to further reduce the probability that a clinically ineffective product will be marketed and accepted by consumers as effective. The comment argued that the highest values for fluoride ion in the Panel's LTP tables were based on specific formulations that had been clinically proven effective and that could be compared with appropriate reference formulations. The comment stated that these fluoride ion values would be acceptable for formulations similar to those included in the LTP tables, but would be too low to ensure the effectiveness of Category I fluoride ingredients formulated with an abrasive different from the specific formulations reviewed by the Panel. The comment recommended that such formulations be required either to establish effectiveness in a well-controlled clinical study or to maintain a minimum available fluoride ion level of 80 percent of the theoretical fluoride ion content, i.e., 800 ppm or above, throughout the formulation's proposed life.

In support of its position, the comment pointed out that in a 3-year clinical study submitted to the Panel for a fluoride dentifrice containing sodium fluoride and a magnesium silicate abrasive, the formulation was not significantly different from placebo in reducing caries (Ref. 1). Two other sodium fluoride dentifrice formulations (with high-beta-phase calcium pyrophosphate as the abrasive) were found to be effective in the same clinical study. The comment urged the agency to adopt the more conservative position of requiring either clinical studies or a minimum available fluoride ion level of 80 percent of the theoretical fluoride ion content for a Category I fluoride ingredient/abrasive combination not specifically reviewed by the Panel.

A comment from another manufacturer supported the use of nonclinical LTP's to establish the effectiveness of fluoride dentifrice formulations not specifically reviewed by the Panel and urged the agency to avoid the imposition of unnecessary, burdensome, and costly clinical testing of these drug products. The comment argued that the availability of the fluoride ion in fluoride dentifrice formulations is the essential factor for establishing the effectiveness of such dentifrices. The comment stated that, for the three fluoride ingredients recommended as Category I by the Panel, the ability of a dentifrice to provide available fluoride need not be determined by lengthy, burdensome clinical trials, but can be readily established by laboratory testing procedures designed to determine that the profile of the test dentifrice is comparable to the profile of a reference dentifrice. The comment contended that laboratory testing results for fluoride dentifrices are predictive of effectiveness and, in many instances, are a better indicator of anticaries effectiveness than clinical trials. The comment argued that laboratory tests can be done quickly and under rigid controls, whereas clinical trials take years and create tremendous logistic

difficulties. The comment stated that, because of the difficulties with clinical trials, clinical studies occasionally produce negative results, even where the effectiveness of the fluoride dentifrice is unquestioned. For this reason, the comment questioned the negative results of the clinical study discussed by the first comment above that did not demonstrate an anticaries effect for a sodium fluoride formulation containing a magnesium silicate abrasive. The comment stated that, as a matter of statistical probability, negative clinical results occur with effective dentifrices and cited an example of one such negative study on a dentifrice formulation that is widely accepted as an effective fluoride dentifrice. The comment added, moreover, that the information submitted to the Panel concerning the clinical trial and the laboratory testing data for the questionable sodium fluoride dentifrice containing magnesium silicate is insufficient to adequately evaluate the results of the clinical trial or laboratory testing.

In addition, the comment contended that the requirement of clinical testing for Category I fluoride ingredient/abrasive combinations not specifically reviewed by the Panel, when laboratory testing is adequate to demonstrate effectiveness, would be contrary to established principles of public policy. The comment explained that requiring high cost clinical studies would divert resources away from more worthwhile research; would be a financial burden, especially for smaller manufacturers, and decrease their ability to compete in the marketplace; and would also violate the purpose of the OTC drug monographs to set forth recognized standards of safety and effectiveness that new products can meet without going through full-scale clinical trials. The comment requested the agency to reject a requirement that clinical trials for effectiveness be conducted for Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel. The comment concluded that such a requirement would be unnecessary, burdensome, and cause costly duplicative clinical testing for such formulations.

Comments from a manufacturers' association stated that a new combination of an accepted fluoride source with an abrasive in a dentifrice formulation not specifically reviewed by the Panel should be evaluated as effective if it meets the appropriate parameters for availability of the fluoride ion in the Panel's recommended analytical and biological tests as well as appropriate parameters for theoretical total fluorine content and specific gravity.

The comment specified the following requirements as appropriate for determining the effectiveness of fluoride dentifrice formulations not specifically reviewed by the Panel:

(1) Theoretical total fluorine concentration between 850 and 1,150 ppm, and

(2) Specific gravity within the range 1.1 to 1.7, and

(3) Meet the most stringent of analytical profiles for a fresh and aged product for the particular fluoride ion source, and

(4) Demonstrate that scores on 2 of 3 of the biological tests specified in the monograph are not significantly lower than a reference formulation using the same fluoride source, and are significantly higher than a placebo;

or

(1) and (2) above, and

(5) Demonstrate through appropriate clinical trials that the formulation is effective.

The comment added that "attempting to ensure exact equivalency between various possible reference formulations is not only unwarranted, but could be construed as providing an unfair advantage to existing marketed products, without an adequate scientific basis."

Another comment agreed with the requirements for new fluoride dentifrices that were recommended by the manufacturers' association above. In addition, the comment requested that the agency provide a procedure to add new "reference fluoride/abrasive combinations" to the LTP tables when such fluoride dentifrice formulations are proven effective in a clinical study. The comment suggested a procedure whereby the agency could be petitioned to include a new formulation in the LTP's and supporting documents would be placed in the public docket. A Federal Register notice could be published to advise the public of the petition, to invite comment, and to provide an opportunity for an oral presentation. Based on the information received, the agency could then publish a final decision concerning whether or not to add the new fluoride dentifrice formulation to the LTP's. The comment believed that such a procedure would be particularly appropriate if the LTp's are set out in "guidelines" as opposed to regulations and pointed out that such a procedure is commonly used by other Federal agencies in setting new reference standards.

A comment from ADA suggested that standards for Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel include remineralization testing. ADA added that it will continue to require clinical studies to validate the effectiveness of such new formulations for its "Acceptance Program."

The agency concurs with the panel's recommendations that a Category I fluoride ingredient/abrasive combination in a dentifrice formulation, not specifically reviewed by the Panel, be required to contain an amount of available fluoride ion equal to or greater than the highest available fluoride ion value recommended for the specific fluoride ingredient, i.e., an amount of available fluoride ion equal to or greater than the highest value listed in the active ingredient list in the monograph for the specific fluoride ingredient. This requirement applies to fluoride dentifrices that contain a Category I fluoride ingredient and either a new abrasive ingredient not previously included in marketed dentifrices or an abrasive ingredient included in previously marketed dentifrices in a fluoride ingredient/abrasive combination not specifically reviewed by the panel.

The agency believes that it is unnecessary to require that Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel contain 80 percent of the theoretical amount of total fluorine in the formulation as available fluoride ion throughout the period of intended use, as one comment requested. The comment's contention that data it submitted to the panel show that a sodium fluoride Dentifrice containing a magnesium silicate abrasive is ineffective in a clinical study even though laboratory tests show that the dentifrice would meet the Panel's LTP standards (Ref. 1) was baaed on (1) a table and a short discussion presenting a summary of laboratory test results for the sodium fluoride dentifrice containing magnesium silicate and two other sodium fluoride dentifrices; and (2) a table presenting a summary of the clinical trial results for the same sodium fluoride dentifrice containing magnesium silicate and the two other sodium fluoride dentifrices. Information concerning the details of the laboratory testing methods, the raw data, the analysis of the data for the laboratory tests, the details of the clinical trial for the sodium fluoride dentifrice containing magnesium silicate, and the details of

the statistical analysis of the clinical data for this dentifrice were not submitted. The panel reviewed the information above concerning the sodium fluoride dentifrice containing magnesium silicate and concluded that this information is inadequate to justify changing the Panel's recommendation that Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel be required to contain an amount of available fluoride ion equal to or greater than the highest available fluoride ion value required for the specific fluoride ingredient (Ref. 2). The agency concurs with the Panel and agrees with another comment that the submitted information is inadequate to conclude that the dentifrice was in fact ineffective or that the dentifrice tested in the clinical study did in fact meet the panel's LTP standards.

The panel based its development of LTp's on laboratory testing results from studies on fluoride dentifrice formulations that had actually been clinically treated and found effective. The agency is unaware of any data, other than the data concerning the sodium fluoride dentifrice containing a magnesium silicate abrasive discussed above, that would indicate that a dentifrice which meets the Panel's recommended standards for Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel has been found to be ineffective in preventing caries. To the contrary, the Panel stated that the extensive amount of testing of the Category I fluoride ingredients, which includes laboratory, animal, and clinical tests, allows predictions as to which dentifrice formulations will be effective. The Panel therefore concluded that if certain analytical and biological tests are conducted and acceptable test values are achieved, clinical testing is not required (45 FR 20677).

The agency believes that the Panel's recommended standards are applicable to all new Category I fluoride ingredient/abrasive combinations in formulations that contain a fluoride ingredient specified in the monograph. Therefore, it is unnecessary to specifically add Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel to the LTP tables through a petition procedure as suggested by one comment.

Based on the Panel's recommendations, the agency is proposing that the requirements for available fluoride ion for each fluoride ingredient listed in the monograph without a specified abrasive also apply to Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel. The agency has not included specific abrasives in the active ingredient list with the exception of the special case of a stannous fluoride dentifrice containing calcium pyrophosphate as an abrasive. (See comment 4 above.) In addition, Category I fluoride ingredient/abrasive combinations in dentifrice formulations not specifically reviewed by the Panel must meet the biological testing requirements proposed in the monograph and conform to FDA's current good manufacturing practice regulations (21 CFR Part 211) with respect to other parameters discussed by the Panel such as specific gravity and pH. Such Category I fluoride ingredient/abrasive combinations in dentifrice formulations must also conform to regulations concerning whether inactive ingredients are safe and do not interfere with the effectiveness of the product in preventing caries (21 CFR 330.1(e)). (See comment 4 above.)

While the agency encourages the development of new testing technology for fluoride dentifrices, such as remineralization testing, the agency does not believe it is necessary to add a requirement for such testing for new fluoride dentifrice formulations in addition to the Panel's recommended testing requirements. As stated above, the agency has accepted the Panel's recommended requirements as adequate to demonstrate the anticaries effectiveness of Category I fluoride ingredient/abrasive formulations not specifically reviewed by the Panel.

References

(1) Comment No. C00016, Docket No. 80N-0042, Dockets Management Branch.

(2) OTC Volume 08APA2, Summary Minutes of the 43rd Meeting of the Panel, April 26, 27, and 28, 1978, Docket No. 80N-0042, Dockets Management Branch.

12. Four comments requested that additional abrasive ingredients be included in the laboratory testing profile table for sodium fluoride dentifrices. Three comments expressed concern that silica was not specified in "Table 1—Acceptable Test Values for Sodium Fluoride Dentifrices" (45 FR 20679) as an allowable abrasive for sodium fluoride dentifrices. One of the three comments noted that silica is listed as an abrasive for sodium monofluorophosphate and stannous fluoride dentifrices. The comment stated that because the Panel found silica to be a safe and effective abrasive, as evidenced by its inclusion with the other Category I fluoride dentifrices, there is no reason why it should not be included in sodium fluoride preparations.

The second comment submitted the results of two well-controlled 3-year clinical studies to demonstrate the anticaries effectiveness of a 0.243-percent sodium fluoride/silica dentifrice, and also proposed a testing profile for this formulation, with a pH of 6.0 to 8.5, for inclusion in the laboratory testing profile tables (Ref. 1). The third comment referred to the second comment's submission (Ref. 1), agreed that the proposed testing profile should be adopted (Ref. 2), and added that its own sodium fluoride/silica dentifrice formulation (pH 4.5 to 5.5) was bioequivalent to the dentifrice (pH 7.2) submitted by the second comment with respect to fresh total fluoride, fresh soluable fluoride, and aged soluble fluoride. According to the comment, both formulations, when compared with a placebo dentifrice control, significantly reduced caries ($p<0.05$) in rats, thus meeting the accepted animal caries reduction protocol as specified by the Panel (Ref. 2). Based on the submitted data, the comment requested that the pH range in the test profiles for sodium fluoride/silica dentifrices be expanded to 4.5 to 8.5.

The fourth comment requested that sodium bicarbonate be included in the laboratory testing profile tables as an acceptable abrasive for sodium fluoride dentifrices. The comment submitted data from a 2-year clinical study that showed the sodium fluoride/sodium bicarbonate combination to be effective in reducing calories in school children (Ref. 3) and included a review of this study (Ref. 4). The comment also referred to another submission to the Panel that contained data showing a sodium fluoride/sodium bicarbonate dentifrice to be effective with available fluoride levels between 500 to 1,100 ppm (Ref. 5). The comment recommended raising the minimum available fluoride standards in "Table 1—Acceptable Test Values for Sodium Fluoride Dentifrices" (45 FR 20679) to a level of 850 ppm for both the fresh and the aged dentifrices, and recommended a pH range of 7.5 to 8.5.

As discussed in comment 4 above, the test values listed in the tables represent actual test values obtained from analyzing dentifrices that were used in clinical trials and found to be effective anticaries drug products. The Panel recommended that a fluoride dentifrice product containing a Category I fluoride ingredient/abrasive formulation could be marketed if the product meets or

exceeds the available fluoride ion levels listed in the LTP tables and meets other parameters set by the Panel, such as limits for specific gravity and pH, and biological testing standards (45 FR 20677 to 20681).

After extensive review, the agency has determined that the availability of the fluoride ion in the formulation and meeting the biological testing requirements are the most important testing criteria for predicting the effectiveness of a fluoride dentifrice product and has specified these requirements in the proposed monograph. The agency considers the existing regulations in 21 CFR Parts 211 and 330 adequate to address the product's professed standards of identity, strength, quality, and purity with respect to parameters such as specific gravity and pH. (See comment 4 above.) Therefore, it is not necessary to include such parameters for additional Category I fluoride/abrasive combinations in the monograph; nor is it necessary to change the Panel's recommendations regarding specific pH guidelines for particular fluoride dentifrice formulations. (See comment 5 above.) Because biological testing and the availability of fluoride ion are the key factors in determining the effectiveness of the dentifrice formulation, the agency is proposing to include new § 355.70 concerning biological testing requirements and to include in the active ingredient section of the tentative final monograph (§ 355.10(a)) the required amount of available fluoride ion for each Category I fluoride active ingredient in a dentifrice dosage form. Manufacturers must ensure that their products meet the biological testing requirements and contain the amount of available fluoride ion specified in the final monograph. (See comment 4 above.)

Accordingly, the agency is proposing that any Category I fluoride compound formulated with an appropriate abrasive can be marketed provided the dentifrice meets the biological testing requirements stated in § 355.70 and contains the amount of available fluoride ion stated in § 355.10(a). (See comment 11 above.) Thus, for a sodium fluoride and silica formulation or a sodium fluoride and sodium bicarbonate dentifrice, the formulation must meet the biological testing requirements and the available fluoride ion concentration must be equal to or greater than 650 ppm. (See § 355.70 and § 355.10(a) of this tentative final monograph.)

References

(1) Comment No. C00037, Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. C00044, Docket No. 80N–0042, Dockets Management Branch.

(3) Torell, P., and Y. Ericsson, "Two-Year Clinical Tests with Different Methods of Local Caries-Preventive Fluorine Application in Swedish School Children," *Acta Odontologica Scandinavica*, 23:287–322, 1965.

(4) Comment No. CR0006, Docket No. 80N–0042, Dockets Management Branch.

(5) OTC Volume 080134A.

13. One comment expressed concern that powdered fluoride dentifrices and "sodium bicarbonate-based sodium fluoride dentifrices" would not be covered as anticaries drug products under the recommended monograph. The comment raised this concern because it felt that the Panel's recommended specific gravity limits, while acceptable for normal paste dentifrices, are not reasonable for powdered dentifrices, which have lower densities then those recommended in the Panel's specific gravity standard. The comment suggested that a separate standard for these lower density powders be developed that would provide effective levels of fluoride ion and submitted a chart comparing fluoride dosage limits for powders and pastes (Ref. 1). The comment also suggested that the appropriate parameter for powdered fluoride dentifrices would be a poured-bulk density range between 0.5 and 1.7 grams/milliliter (g/mL) because poured-bulk density is a more well-defined measure of the weight to volume relationship of powders than specific gravity.

The comment recommended two poured-bulk density standards for powdered fluoride dentifrices, i.e., 1.0 to 1.7 and 0.50 to 0.99 g/mL. The comment claimed that if the poured-bulk density is equal to or greater than 1.0 g/mL, the product can deliver an effective level of fluoride per application to the teeth. The comment stated that powdered dentifrices with a lower poured-bulk density (0.5 to 0.99 g/mL), such as sodium fluoride with sodium bicarbonate as an abrasive, could be aproved if it were demonstrated that the product delivers the same effective level of fluoride ion with two applications per brushing as would normally be applied in one application of a product with a bulk density of 1.0 to 1.7 g/mL. The comment suggested that the proper dosage of fluoride ion can be assured for powdered dentifrices by either requiring suitable minimum soluble fluoride specifications for powders and/or by requiring labeling instructions to the consumer to apply the product more than once per brusing. Another suggestion was to drop the Panel's specific gravity recommendations and instead require defined levels of fluoride ion in a set volume of the product, whether powder or paste. In addition, the comment stated that although the users of powdered dentifrices currently do not make up a large percentage of the population, this form of dentifrice may in the future prove ideal for certain beneficial properties, such as the reduced likelihood that the dry ingredients will interact adversely and inactivate the fluoride during storage of the dentifrice.

The agency has reviewed the comments and other information and determined that the information is insufficient to generally recognize powdered fluoride dentifrices as safe and effective. The agency is unaware of data in the literature that address the safety and effectiveness of powdered fluoride dentifrices, and invites submissions of such data if any are available.

The agency agrees that a poured-bulk density range is a more appropriate parameter for powdered fluoride dentifrices than a specific gravity range. However, the agency is unable to conclude that two ranges for poured-bulk density (0.5 to 0.99 g/mL and 1.0 to 1.7 g/mL) are necessary for powdered dentifrices nor is the agency convinced that two applications per brushing with a powdered dentifrice in the lower poured-bulk density range (0.5 to 0.99 g/mL) would provide an appropriate dose of fluoride. The agency is concerned that two applications of a powdered fluoride dentifrice to a toothbrush might provide an unnecessarily high level of the fluoride ion. For example, according to the table submitted by the comment (Ref. 1), powdered fluoride dentifrices with a poured-bulk density of 0.99 g/mL would provide 2,300 micrograms of available fluoride per dose assuming that 2 mL of the product is used per brushing (two 1 mL applications per brushing), whereas currently marketed pastes would provide not more than 1,870 micrograms of available fluoride per dose assuming that 1 mL of the product is used per brushing based on the Panel's recommended standards. The agency needs additional, more specific data (e.g., laboratory studies) demonstrating that a controlled volume of powdered fluoride dentifrice (e.g., 1 mL) consistently delivers a predictable and measurable safe and effective level of fluoride ion.

The comment did not provide directions for how a powdered fluoride dentifrice should be applied to a toothbrush, or provide data demonstrating how much fluoride ion

each brushing would deliver to the teeth. The agency has reviewed the labels for several previously marketed powdered fluoride dentifrices that contained directions for use. These directions varied according to the product's fluoride concentration. For example, the labeling of a 0.5-percent powdered sodium fluoride dentifrice directed the user to "pour ¼ teaspoonful (0.5 grams) in palm of hand. Wet toothbrush with water and brush teeth with this powder in usual manner twice daily, morning and night." The labeling also stated that children under age 6 should not use the product. The labeling directions for another powdered dentifrice containing 0.04 percent sodium fluoride stated "Use a small brush with bristle tufts spaced so that they fit the embrasures between the teeth. Place a thimble full of (product) in the palm of the hand and dip the wet brush into it. Place the bristles firmly on the teeth and with a gentle circular motion, scour the 'between the teeth' spaces. Swishing the brush backward and forward does not clean between the teeth where decay begins. Clean 3 to 4 teeth at a time and slowly brush around the whole mouth. The mouth should be well rinsed to remove all loosened debris. It is recommended that teeth be brushed AFTER breakfast and BEFORE retiring. The proper use of (product) refreshes the mouth and promotes oral hygiene. This dentifrice is not designed for children under 8 years of age." The labeling of a (currently marketed) powdered fluoride dentifrice that is manufactured in England did not contain any directions for use.

As there are several possible methods of applying the powdered dosage form to a toothbrush (e.g., placing the powder on the palm of the hand with a small amount of water and applying the slurry of the powder with a dry toothbrush, pouring the powder on a dampened brush, or dipping a wet brush into a dry powder, etc.), and because there does not appear to be any consistency in the amount of dentifrice that is recommended for use, the amount of fluoride ion delivered to the teeth may vary significantly. From the information available to the agency, there is no indication that previously or currently marketed powdered fluoride dentifrices provided a consistent amount of fluoride per brushing application. The agency cannot determine whether powdered fluoride dentifrices are safe and effective unless specific directions for use and data are provided demonstrating that the powdered fluoride dentifrice used per specific directions can deliver an amount of fluoride ion to the teeth equivalent to an amount delivered by a paste dentifrice. The directions for use need to be either relatable to the method used in a clinical study demonstrating efficacy or to laboratory studies demonstrating that the available fluoride ion is equal to or greater than the Panel's recommended 650 ppm for sodium fluoride.

The comment's submissions did not include directions for use of powdered fluoride dentifrices by children under 12 years of age. The agency is concerned that children under 12 years of age may have considerable difficulty in using a powdered fluoride dentifrice properly because the proper use of powdered dosage forms may require greater manual dexterity than the proper use of paste dosage forms and because of limited experience with this dosage form of a dentifrice. Unless data can be provided to show that children under 12 years of age can use powdered dentifrices properly, the agency believes, for safety and efficacy reasons, that a powdered fluoride dentifrice should not be labeled for use by children under age 6 and should be labeled for use by children ages 6 to 12 with adult supervision. A warning statement against use by children under 6 years of age is currently required by § 310.201(a)(10)(vi) (21 CFR 310.201(a)(10)(vi)) for sodium fluoride dentifrice powders, and the need for adult supervision for children ages 6 to 12 is considered consistent with the requirement for adequate directions for use in § 310.201(a)(10)(v) (21 CFR 310.201(a)(10)(v)). The agency is also concerned that the potential for a young child to accidentally consume a toxic amount of fluoride with a dentifrice in a powdered dosage form may be greater than with a paste dosage form. The agency is aware that paste fluoride dentifrices containing the package size limitations of 260 mg total fluoride have been marketed for many years and have not raised concerns of acute toxicity in young children. Although § 310.201(a)(10)(iv) (21 CFR 310.201(a)(10)(iv)) limits powdered sodium fluoride dentifrices to not more than 5 mg of sodium fluoride per g and not more than 300 mg of sodium fluoride per retail package, powdered fluoride dentifrices have had very limited marketing in this country and the agency is unaware of any data concerning the acute toxicity of powdered fluoride dentifrices in children.

The agency agrees that powdered fluoride dentifrices would probably remain stable for a longer period of time than the paste form because there would be less interaction between dry ingredients during storage of the dentifrice. It also agrees that data submitted to the Panel (OTC Volume 080134A) support the stability of sodium fluoride/sodium bicarbonate toothpaste dentifrices. However, the storage conditions of a powdered fluoride dentifrice would have a significant impact on whether the powdered dentifrice would remain stable longer than the paste form. Storage of the product in the bathroom where the humidity is high due to showering and bathing would require that the container be moisture resistant to prevent moisture contamination of the powdered drug product. Although stability is an important factor, it is governed by the current good manufacturing practice regulations in §211.137(g) (21 CFR 211.137(g)) and is outside the scope of this rulemaking.

The agency is therefore proposing that powdered fluoride dentifrices as anticaries drug products be placed in Category III in this tentative final monograph for OTC anticaries drug products.

The agency's comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 2).

References

(1) Comment No. C00039, Chart labeled "*Table 1*: Comparison of fluoride dosage limits provided under Church & Dwight powder recommendation with level achieved by paste following the OTC Advisory Panel specifications," Docket No. 80N–0042, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to W. R. Sorenson, Church & Dwight Co. Inc., coded LET009, Docket No. 80N–0042, Dockets Management Branch.

14. One comment expressed concern that the term "hydrated silica" is too broad to identify silica abrasives currently used in dentifrices. The comment stated that the Panel may have used this term because the term appeared in the *CTFA Cosmetic Ingredient Dictionary*. The comment noted that, "while this monograph incudes most of the currently used dentifrice silicas, it also includes sand. Further, there are no specific assay tests to identify the product." The comment recommended that the *Food Chemicals Codex* monograph for "silicon dioxide" in Edition III, be used to "define" silicas for dentifrices. The comment stated that this monograph includes most commonly used dentifrice silicas and excludes those silicas containing less than 94 percent silicon dioxide. The comment further explained that the monograph also includes only synthetic amorphous silicas, i.e., "fumed,

precipitated, hydrous silicas, and silica gels."

The agency notes that the terms used to identify ingredients in part I.B. of the Panel's report (45 FR 20669), where the term "hydrated silica" appears, were taken from the actual labels of products or from the lists of ingredients contained in the submissions to the Panel. These terms were listed exactly as they appeared in the product labels or the lists of ingredients in the submissions. The term "hydrated silica" also appears in parts I.C.2. as an inactive ingredient. The Panel did not consider this list all inclusive and took no position as to the value of these ingredients in dental products (45 FR 20669). The lists of ingredients in parts I.B. and I.C. of the Panel's report were not intended to identify specific ingredients that are appropriate for anticaries drug products.

Although the OTC drug review is an active, not an inactive, ingredient review, the Panel did discuss inactive ingredients such as silica that are included in dentifrices as abrasives because they are known to have an impact on the availability of the fluoride ion in fluoride dentifrices and, thus, have an impact on the effectiveness of these drug products (45 FR 20676 to 20677). The agency has found it necessary to include only one abrasive (calcium pyrophosphate for dentifrices containing stannous fluoride as the active ingredient) in the tentative final monograph. (See comment 4 above.) Because other fluoride dentifrices do not require a specific fluoride ion concentration for particular abrasives, it is not necessary for the agency to specify such abrasives in the monograph. In addition, the abrasives used in fluoride dentifrice drug products must meet the requirements for inactive ingredients in § 330.1(e) (21 CFR 330.1(e)) which states that "only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets the professed standards of identity, strength, quality, and purity" may be used. Therefore, defining silicas for dentifrices is outside of the scope of this monograph.

15. One comment submitted an in vitro testing method for determining the abrasiveness of dentifrices on human dentin (Ref. 1).

The testing of the abrasivity of fluoride dentifrices is not being addressed in this tentative final monograph because abrasives are not considered to be active ingredients in these dentifrices. The OTC drug review is an active, not an inactive, ingredient review. Therefore, testing methods to determine the degree of abrasivity of fluoride dentifrices are not included in the tentative final monograph. However, as stated above, inactive ingredients such as abrasives are subject to the provisions in § 330.1(e) and must be safe for use in fluoride dentifrices.

Reference

(1) Comment No. C00042, Docket No. 80N–0042, Dockets Management Branch.

D. Comments on Labeling of Anticaries Drug Products.

16. One comment suggested that the labeling of fluoride dentifrices be based on volume rather than on weight. The comment stated that consumers dispense dentifrices by volume, not by weight, and that the "rest of the world" labels dentifrices by volume.

The agency disagrees with the comment's suggestion to label the amount of dentifrice contained in a package based on a volume measurement rather than a weight measurement. FDA regulations concerning declaration of net quantity of contents in 21 CFR 201.62(a) require that "The label of an over-the-counter drug in package form shall bear a declaration of the net quantity of contents * * * [and] the statement of quantity * * * shall be in terms of weight if the drug is solid, semisolid, or viscous * * *." Under this regulation, fluoride dentifrices in this country have been labeled with weight measurements to specify quantity for many years. Although consumers dispense dentifrices by volume rather than weight and other countries label dentifrices with volume measurements rather than weight measurements, consumers in this country are familiar with purchasing dentifrices based on weight rather than on volume. The comment did not submit any documentation to support this change in labeling from a weight to a volume basis. Accordingly, this suggestion is not being adopted.

17. Four comments expressed concern about the expiration dating for fluoride dentifrices. The comments agreed that the aged minimal fluoride ion values that appear in the Panel's LTP Tables 1, 2, and 3 (45 FR 20679 to 20681), for dentifrices found to be effective in clinical studies, should be used in determining an expiration date for the fluoride/abrasive dentifrices listed in the tables. One comment stated that expiration dating is the only appropriate way to provide the consumer with relevant information regarding the "freshness" of the product on the shelf, whereas "production dating," which provides in the labeling the date that a product was manufactured, is useless and might even mislead consumers because different product formulations will decline in fluoride concentration at different rates. Another comment stated that expiration dating is not needed for fluoride dentifrices that meet the requirements specified for the aged minimal fluoride ion concentration after 3 years, and that expiration dating would only be necessary for a dentifrice that falls below the minimal fluoride ion concentrations specified in the Panel's tables before it is 3 years old.

In response to the Panel's recommendation that expiration dating should conform to "good manufacturing practice," two comments expressed concern that this recommendation would be misunderstood. One comment stated that, although fluoride dentifrices are manufactured under current good manufacturing practice regulations in 21 CFR Part 211, the specific analytical soluble fluoride level that is the basis of an expiration date is different for each fluoride/abrasive combination and is well below an arbitrary level such as 80 or 90 percent of the total fluoride content which is often the intent when the term "good manufacturing practice" is used. The comments also noted that the Panel had recommended that an expiration date need be indicated only on the carton (outer package) of dentifrice drug products, and not on the immediate container. The comments suggested that a new section be added to the monograph as follows: "§ 355.50(g) *Expiration dating.* Any expiration dating required by current good manufacturing practices for drugs may be marked only on the outer package of a dentifrice product so as to be visible at the time of purchase."

The agency agrees with one comment that it is unnecessary to require production dating of dentifrice products. Production dating is not as important to the consumer as an expiration date because the consumer is concerned only with the date after which the product may be ineffective. Production dating does not provide such information and, therefore, it is not being required for dentifrice drug products.

The agency agrees that the manufacturers should use the aged minimal fluoride ion limits provided in the LTP Tables as modified in comment 5 above to determine the expiration dates for fluoride dentifrices that will be covered by the final monograph. However, the agency is not including in the tentative final monograph the aged minimal fluoride ion values from the LTP tables. (See comment 4 above.) These aged minimal fluoride ion values

provide appropriate guidelines for determining the expiration date of a dentifrice and whether the expiration date should appear in the labeling of the product. The expiration date for such fluoride dentifrices should be the date when the soluble fluoride ion level of the aged dentifrice is equal to or lower than the fluoride ion level listed in the tables under "aged minimal fluoride ion value" for the particular fluoride/abrasive combination. FDA regulations concerning expiration dating in § 211.137(g) (21 CFR 211.137(g)) state that, pending consideration of a proposed exemption published in the Federal Register of September 29, 1978 (43 FR 45088), the expiration dating requirements of § 211.137 shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and the products are stable for at least 3 years as supported by appropriate stability data. At this time, in accordance with § 211.137(g), any fluoride/abrasive dentifrices that will maintain, for at least 3 years, levels of fluoride ion equal to or greater than the aged minimal fluoride ion values listed in the LTP tables as modified in comment 5 above will not be required to include an expiration date in the labeling.

For new fluoride/abrasive dentifrice formulations, the criteria for not requiring an expiration date will be dependent upon the product meeting the highest aged minimal value in the LTP tables as modified in comment 5 above for the particular fluoride compound. For example, the aged minimal fluoride ion values listed in Table III and modified in comment 5 above for the combination of stannous fluoride with different abrasives are 108 ppm and 650 ppm. The expiration date for a dentifrice containing stannous fluoride and a new abrasive would be the date after which the fluoride ion concentration falls below 650 ppm, the highest aged minimal fluoride ion value listed for stannous fluroide ion.

Regarding one of the comments' reference to the location of the expiration date in the labeling, § 201.17 (21 CFR 201.17) states that when an expiration date of a drug is required, it shall appear on the immediate container and also on the outer package. Therefore, if a fluoride dentifrice does not contain a fluoride ion level equal to or greater than the aged minimal level after 3 years, it will not meet the criteria of § 211.137(g), and the expiration date must appear on the immediate container and on the outer package under § 201.17. Because expiration dating for OTC drug products is addressed in the current good manufacturing practice regulations, it is unnecessary to include in this tentative final monograph the comment's suggested new § 355.50(g) regarding the requirement of expiration dating on the outside carton only.

18. One comment from a manufacturers' association stated that a Category I fluoride ingredient/abrasive combination not specifically reviewed by the Panel can be evaluated as effective if it gives acceptable results in the Panel's recommended analytical and biological testing. The comment asserted, however, that any extension of this concept, i.e., the use of results of such testing, to a comparative evalaution of effectiveness between different fluoride dentifrices is unwarranted because of the inherent variability of the biological tests with respect to specific fluoride ingredients.

The agency agrees with the comment that the extension of laboratory test data to a comparative evaluation of effectiveness between different fluoride dentifrices is inappropriate. Further, the agency believes that the use of comparative laboratory test data, resulting from the Panel's recommended testing standards for fluoride dentifrices or fluoride active ingredients, to infer that particular fluoride dentifrices or fluoride ingredients are more effective than other fluoride dentifrices or fluoride ingredients in preventing caries is not supportable. The agency is unaware of data that would support the conclusion that a fluoride dentifrice which is shown to be superior in laboratory tests when compared to other fluoride dentifrices is in fact clinically superior in its ability to prevent caries. The agency also believes that such comparative test data do not constitute an adequate basis for labeling claims of superior effectiveness and that such labeling would result in misbranding of the product.

II. The Agency's Tentative Conclusions on Anticaries Drug Products

A. Summary of the Agency's Changes in the Panel's Recommendations

1. The agency is proposing that the active ingredients identified in § 355.10(a) be revised to include the amount of available fluoride ion required for each Category I fluoride active ingredient in a dentifrice dosage form. The agency beliefves that it is necessary to require appropriate levels of available fluoride ion to ensure the anticaries effectiveness of these fluoride dentifrices. The agency has also added new § 355.70, Testing Procedures for Fluoride Dentifrice Drug Products, to include the Panel's recommended biological testing requirements for fluoride dentifrices because they are necessary to ensure the effectiveness of these products. (See comments 4 and 7 above.)

2. The agency is proposing ranges of concentrations for fluoride ingredients in dentifrice dosage forms in § 355.10(a) that correspond to a range of 850 to 1,150 ppm theoretical total fluorine. Providing ranges of concentrations for fluoride ingredients in dentifrices in the monograph clarifies that the allowable theoretical total fluorine range of 850 to 1,150 ppm is intended to allow a range of theoretical total fluorine levels for formulation purposes, not as a variation for quality control purposes. (See comment 6 above).

3. The agency is proposing the Panel's recommended laboratory testing requirements, as set forth in the Panel's LTP tables (45 FR 20679 to 20681) and revised in comments 5 and 6 above, as guidelines of appropriate testing limits for determining the specific gravity and pH of dentifrices containing monograph fluoride ingredients. Because these parameters are adequately addressed by the current good manufacturing practice regulations (21 CFR Part 211), the agency does not find it necessary to codify these LTP tables in the final monograph. (See comment 4 above.)

4. The agency has placed fluoride dentifrices containing theoretical total fluorine concentrations greater than 1,150 ppm, e.g., dentifrices containing 1,500 ppm theoretical total fluorine, in Category III. Data demonstrating an added anticaries benefit to perons who use a dentifrice containing 1,500 ppm theoretical total fluorine as compared to formulations contianing 1,150 ppm theoretical total are not publicly available at this time. (See comment 1 above.)

5. The agency has also placed fluoride dentifrices in a powdered dosage form in Category III. Sufficient data supporting the effectiveness of such dentifrices are necessary before they can be generally recognized as safe and effective. (See comment 13 above.)

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of Februry 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency

therefore concludes that no one of these rules, including the proposed rule for OTC anticaries drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC anticaries drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this amendment to the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this proposed rulemaking would have on OTC anticaries drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC anticaries drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on anticaries drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch, Food and Drug Administration (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Interested persons may, on or before October 13, 1988, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before October 13, 1988. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before June 15, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 15, 1989. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OCT drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 15, 1989. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 355

Labeling, Over-the-counter drugs, Anticaries drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 355 (as established in the tentative final monograph published in the **Federal Register** of September 30, 1985; 50 FR 39854), as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 355 is revised to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 355.10 is amended by revising paragraph (a) to read as follows:

§ 355.10 Anticaries active ingredients.

* * * * *

(a) *Dentifrices.* (1) Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration >650 parts per million.

(2) Sodium monofluorophosphate 0.654 to 0.884 percent with an available fluoride ion concentration (consisting of $PO_3F^=$ and F^- combined) >800 parts per million.

(3) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration >700 parts per million for products containing abrasives other than calcium pyrophosphate.

(4) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration >290 ppm for products containing the abrasive calcium pyrophosphate.

* * * * *

3. New Subpart D is added consisting of § 355.70 to read as follows:

Subpart D—Testing Procedures

§ 355.70 Testing procedures for fluoride dentifrice drug products.

A fluoride dentifrice drug product must meet the test requirements of any two of the following biological tests: enamel solubility reduction, fluoride uptake by enamel, and/or animal caries reduction. The testing procedures for these biological tests are on file under Docket No. 80N–0042 in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, labeled *Bioligical Testing Procedures for Fluoride Dentifrices*, and are available or request to that office.

Alternative testing procedures may be used. Any proposed modification or alternative testing procedures shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in Part 20 of this chapter.

Dated: April 6, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-13431 Filed 6-14-88; 8:45 am]

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federal register

Wednesday
June 15, 1988

Part III

Department of Education

Projects With Industry Program; Proposed Information Collection Request; Notice

DEPARTMENT OF EDUCATION

Projects with Industry Program; Proposed Information Collection Request

AGENCY: Department of Education.

ACTION: Notice of proposed information collection request.

SUMMARY: The Director, Information Technology Services, invites comments on the proposed information collection request as required by the Paperwork Reduction Act of 1980. The information to be collected is necessary to enable the Commissioner of the Rehabilitation Services Administration (RSA) to comply with a statutory requirement to establish minimum compliance indicators for the Projects With Industry (PWI) Program.

DATES: Comments must be received on or before July 15, 1988.

ADDRESSES: All comments concerning this notice should be addressed to the Office of Information and Regulatory Affairs, Attention: Jim Houser, Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place NW., Room 3208, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Margaret B. Webster, Department of Education, 400 Maryland Avenue SW., Room 5624, Regional Office Building 3, Washington, DC 20202. Telephone: (202) 732-3915.

SUPPLEMENTARY INFORMATION: Section 621(f) of the Rehabilitation Act, as added by the Rehabilitation Act Amendments of 1986, requires the Commissioner of RSA to develop indicators of minimum compliance with the PWI evaluation standards developed in 1986. The purpose of the compliance indicators is to implement the program evaluation standards by establishing minimum performance levels in essential program areas to measure the effectiveness of individual projects. If a grantee does not meet the established performance levels, it will not be in compliance with the standards and, thus, cannot receive continuation funding.

RSA has analyzed the standards and identified performance areas that are critical for project success and that must be measured. At this time, however, RSA is unable to establish performance levels in these areas because it lacks sufficient statistical data from currently funded projects. RSA has developed a data collection form that will enable it to obtain from existing grantees the necessary information to establish minimum compliance indicators. The areas in which RSA plans to develop indicators are provided for informational purposes only in an appendix to this notice, as are the evaluation standards. RSA intends to publish proposed compliance indicators in the **Federal Register** for public comment before establishing the indicators in final form.

When OMB has approved the data collection form, a notice will be published in the **Federal Register** notifying all grantees that they will be required to submit to RSA, within 60 days, the required project information for fiscal year 1987 and, separately, for the first six months of fiscal year 1988. This information must be sent to the Commissioner, Rehabilitation Services Administration, 330 C Street SW., Room 3024, Mary E. Switzer Building, Washington, DC 20202.

Paperwork Reduction Act

Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding (1) the Reporting Form for Development of PWI Indicators and (2) Instructions for Completing the Reporting Form.

Dated: June 8, 1988

Carlos U. Rice,

Director for Information Technology Services.

APPENDIX

Evaluation Standards and Project Performance Areas (PPA) for Measuring the Effectiveness of Projects With Industry (PWI) Grantees

Standard 1: "The primary objective of the project shall be to assist individuals with disabilities to obtain competitive employment. The activities carried out by the project shall support the accomplishment of this objective."

PPA 1: The project conducts activities that assist persons with disabilities to obtain competitive jobs

Standard 2: "The project shall serve individuals with disabilities that impair their capacity to obtain competitive employment. In selecting persons to receive services, priority shall be given to individuals with severe disabilities."

PPA 2A: Percent of persons served whose disabilities are severe

PPA 2B: Percent of persons served who have been unemployed for at least six months at time of project entry

PPA 2C: Percent of persons served who received SSI or SSDI benefits in the month prior to project entry

Standard 3: "The project shall ensure the provision of services that will assist in the placement of persons with disabilities."

PPA 3A: The project promotes job placement and retention through systematic follow-up services to employed participants and their employers

PPA 3B: The project provides or ensures the provision of one or more of the following services: job development, vocational evaluation, employability training, occupational skills training, job modification, job placement, and assistance to employers.

Standard 4: "Funds shall be used to achieve the project's primary objective at minimum cost to the federal government."

PPA 4A: PWI cost per placement

PPA 4B: Percent of projected PWI cost per placement that the project actually achieves

Standard 5: "The project's advisory council shall provide policy guidance and assistance in the conduct of the project."

PPA 5: The advisory council provides policy guidance, identifies jobs available within the community and the skills necessary to fill those jobs, and prescribes training and other appropriate services

Standard 6: "Working relationships, including partnerships, shall be established with agencies and organizations in order to expand the project's capacity to meet its objectives."

PPA 6: The project establishes working relationships, including partnerships, with agencies and organizations in order to expand the project's capacity to meet its objectives

Standard 7: "The project shall obtain positive results in assisting individuals with disabilities to obtain competitive employment."

PPA 7A: Placement rate

PPA 7B: Percent of projected placement rate that the project actually achieves

PPA 7C: Change in weekly earnings of placed participants

PPA 7D: Percent of persons placed whose disabilities are severe
PPA 7E: Percent of persons placed who have been unemployed for at least six months at time of project entry
PPA 7F: Percent of persons placed who received SSI or SSDI benefits in the month prior to project entry

Reporting Form for Development of PWI Indicators

1. Describe the main purpose(s) of the PWI project, including the major services and activities.

_____

_____

_____

2. Does the project promote job placement and retention through systematic follow-up services to employed participants and their employers? Answer yes or no.

_____

Standard number of formal follow-up contacts with each employed participant (or employer)

_____

3. Does the project provide, or ensure the provision of, at least one of the following services? Answer yes or no.

_____

Check each service that the project provides:

Job development: _____
Vocational evaluation: _____
Employability training: _____
Occupational skills training: _____
Job modification: _____
Job placement: _____
Assistance to employers: _____

4. Check each function that the advisory council performs:

Provides policy guidance: _____
Identifies jobs available within the community: _____
Identifies the skills necessary to perform available jobs: _____
Prescribes training and other appropriate services: _____

5. Does the project establish working relationships, including partnerships, with agencies and organizations in order to expand the project's capacity to meet its objectives? Answer yes or no.

_____

6. Number of persons projected to be served: _____
7. Number of persons served: _____
8. Number of persons served whose disabilities are severe: _____
9. Number of persons served who had been unemployed six months or more at time of project entry: _____
10. Number of persons served who received SSI or SSDI benefits in the month prior to project entry: _____
11. PWI grant amount: $_____
12. Number of persons placed: _____
13. Number of persons projected to be placed: _____
14. Average weekly earnings of placed participants before entry into the project: $ _____
15. Average weekly earnings of placed participants after employment: $ _____
16. Number of persons placed whose disabilities are severe: _____
17. Number of persons placed who had been unemployed six months or more at time of project entry: _____
18. Number of persons placed who received SSI or SSDI benefits in the month prior to project entry: _____

Instructions for Completing the Reporting Form for Development of PWI Indicators

Please provide information for fiscal year (FY) 19__ for each of the items in the attached form.

Item Number

1 Describe the main purpose(s) of the PWI project, including the major services and activities. The description of purpose should be brief and specific.

2 If the project provides systematic follow-up services to either PWI clients or their employers, enter "Yes." If the project does not engage in this activity, enter "No." "Systematic follow-up services" include follow-up contracts with either the participant or his/her employer occurring any time after a participant starts employment. Contacts include mail, telephone, and face-to-face communication for the purpose of ensuring job retention.

Enter the approximate number of contacts that the project makes for each employed participant. The number should reflect general project policy.

3 If the project provides any of the listed services, enter "Yes." Also enter "Yes" if the project provides technical assistance that ensures the provision of any of these services by other agencies or organizations. Check *all* of the services provided (or whose provision is ensured). If the project does not provide (or ensure the provision of) any of these services, enter "No" and proceed to Item 4.

4 If the advisory council performs any of the functions listed, check the appropriate space. Check *all* functions that are applicable.

5 If the project establishes working relationships or partnerships with other agencies or organizations as indicated, enter "Yes." If the project has no such relationships, enter "No.".

6 Enter the amount of the federal PWI award the project received for use during the reporting period.

7 Enter the number of persons served by the PWI project during the reporting period. "Persons served" should include all persons who completed the project's intake process and whom the project approved for receipt of project services during the reporting period. Do not include persons who (1) were referred to other service providers and were not yet approved for PWI project services, or (2) were approved and/or accepted for PWI services *prior to* the reporting period, even if they continued to receive project services during the reporting period.

8 Enter the number of persons who were projected to be served during the reporting period. This figure should be consistent with previous projections submitted to RSA. For this item and items 9, 10, and 11, use the definition of "served" that is presented in the instructions to item 7.

9 Enter the number of persons served during the reporting period whose disabilities are severe. Use the definition of severe disability that is used by your state's vocational rehabilitation agency.

10 Enter the number of persons served during the reporting period who had been unemployed for a period of at least six months before entering the PWI project. "Unemployed" in this context means not working in any competitive or noncompetitive job. Persons who were employed for less than two weeks during the six months should be counted as "unemployed.".

11 Enter the number of persons served by the PWI project during the reporting period who received SSI or SSDI benefits in the month prior to entering the PWI project.

12 Enter the number of persons whom the project placed in competitive employment during the reporting period. An individual may be counted as "placed" or a "placement" if he or she holds a job for a continuous period of at least 60 days.

13 Enter the number of placements the PWI project planned to achieve during the reporting period. This figure should be consistent with previous projections submitted to RSA.

14 For persons placed during the reporting period, enter the average seekly earnings during the week prior to entry into the PWI project. Include participants with no earnings in this calculation. Earnings should include all income earned from full- or part-time work and should not include benefit payments.

15 For persons placed during the reporting period, enter the average weekly earnings during the first week of employment.

16 Enter the number of persons placed during the reporting period whose disabilities are severe.

17 Enter the number of persons placed during the reporting period who had been unemployed for a period of at least six months before entering the PWI project.

18 Enter the number of persons placed during the reporting period who received SSI or SSDI benefits in the month prior to entering the PWI project.

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federal register

Wednesday
June 15, 1988

Part IV

Department of Commerce

Economic Development Administration

Planning Assistance Program for States and Urban Areas; Availability of Funds; Notice

DEPARTMENT OF COMMERCE

Economic Development Administration

[Docket No. 80588-8088]

Planning Assistance Program for States and Urban Areas; Availability of Funds

AGENCY: Economic Development Administration (EDA), Commerce.

ACTION: Notice.

SUMMARY: The Economic Development Administration (EDA) announces revised policies and application procedures for funds available for the State and Urban Planning Program operated under the authority of section 302(a) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151a. This announcement supersedes EDA's Notice of Availability of funds for Economic Development Assistance Programs for F.Y. 1988, 53 FR 1444, January 19, 1988, at Paragraph III. "Program Planning Assistance for State and Urban Areas" at pp. 1445–1446. All other portions of the notice published at 53 FR 1444, January 19, 1988, are unaffected by this notice.

DATE: Effective Date June 15, 1988.

FOR FURTHER INFORMATION CONTACT: The Appropriate EDA Regional Office or Luis F. Bueso, Director, Planning Division, Economic Development Administration, Room 7319, U.S. Department of Commerce, Washington, DC 20230; telephone, 202–377–2873.

EDA Regional Offices

The EDA Regional Offices and the states they cover are:

Philadelphia Regional Office, Liberty Square, Liberty Square Building, 105 South 7th Street, First Floor, Philadelphia, Pennsylvania 19106, telephone: (215) 597–4603; serving Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Vermont, Virginia, Virgin Islands, and West Virginia.

Atlanta Regional Office, Suite 750, 1365 Peachtree Street, NE., Atlanta, Georgia 30309, telephone: (404) 347–7401; serving Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

Denver Regional Office, Suite 200, Tremont Center, 333 West Colfax Avenue, Denver, Colorado 80204, telephone: (303) 844–4714; serving Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.

Chicago Regional Office, Suite A–1630, 175 West Jackson Boulevard, Chicago, Illinois 60604, telephone: (312) 353–7706; serving Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

Austin Regional Office, Suite 201, Grant Building, 611 East Sixth Street, Austin, Texas 78701, telephone: (512) 482–5461; serving Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

Seattle Regional Office, Suite 1856, Jackson Federal Building, 915 Second Avenue, Seattle, Washington 98174, telephone: (206) 442–0596; serving Alaska, American Samoa, Arizona, California, the Commonwealth of the Northern Mariana Islands, Guam, Hawaii, Idaho, Nevada, Oregon, and Washington, the Federal States of Micronesia, and the Republic of the Marshall Islands.

SUPPLEMENTARY INFORMATION: EDA is changing its Eligibility Criteria to exclude cities and urban counties with populations above 500,000 or below 35,000. The reasons for this change are the scarcity of program funds and EDA's belief that 302(a) grants have a more significant impact on smaller areas with fewer resources to devote to economic development planning and policy making. The Program Objective section is being modified to place greater emphasis on significant planning initiatives, instead of on maintaining current activities. EDA is also placing greater emphasis on State proposals which are innovative and have the potential of being replicated in other areas of the country. This approach, which was developed as a result of past experience, is intended to increase the program's effectiveness.

The Funding Availability section is being changed to leave open the amount of funding available, dependent upon the quality and timing of applications. These changes are necessary because until proposals are received and reviewed, EDA will not know how many qualify for funding and whether grants to finance those proposals can be processed within Departmental and fiscal year deadlines. The purpose of this change is to enable EDA to fund proposals submitted in response to this notice with monies appropriated in FY 1988 and/or FY 1989, if Congress makes FY 1989 funds available even though the Administration has not requested any.

The section on Funding Instruments is being modified to add a ceiling of $200,000 with an intended range of $100,000 to $125,000. The section also makes it clear that consideration will be given to appropriate smaller grants. This change is necessary to emphasize EDA's focus on aid for significant planning initiatives, but not to rule out support for meaningful initiatives that do not require large amounts of Federal support.

EDA is adding to the Project Duration section language indicating that if Congress makes additional funding available, grant renewals could be considered for up to two additional years. This addition is necessary to stress EDA's emphasis on short-term projects that serve as seed money to initiate ongoing or on-time planning efforts. The reason for this emphasis is the limited amount of funds available and EDA's desire to be able to help other areas in the event Congress continues to provide funding for this program.

The Selection Criteria section has been expanded to reflect the revised program objective and provide more detailed information on the criteria to be employed in evaluating proposals. The purpose of the expansion is to help potential grantees understand the standards that will be used to judge their proposals. This section specifies the distress measures EDA will consider and indicates the relative priority of various levels of distress.

In the section on Proposal Submission Procedures, the instructions regarding the content of proposals have been expanded to ensure that information related to the selection criteria are included. Among the requirements are information to reflect the importance of the proposed activities to the highest level official, to indicate how the activities will be financed after the EDA grant expires (if appropriate), and to specify whether the activities will be performed by in-house staff, consultants, etc. The information is intended to help applicants prepare more responsive proposals.

Other additions to this section, including a limitation of 10 pages on the Work Program description, are designed to enable EDA to review proposals more expeditiously and thereby respond more promptly to applicant needs. This section also provides potential applications with a proposal submission deadline. In the section on Formal Application Procedures, language has been added concerning requirements under Executive Order 12372 and delinquent accounts in order to comply with Departmental Requirements. In the January 19, 1988 notice, this information was included in a separate section covering all EDA programs. EDA has

determined that this notice is not a major rule under Executive Order 12291. Accordingly, neither a preliminary nor final Regulatory Impact Analysis has to be or will be prepared.

This notice is exempt from all requirements of 5 U.S.C. 553 including notice and opportunity to comment and delayed effective date, because it relates to public property, loans, grants, benefits and contracts.

No other law requires that notice and opportunity for comment be given for this notice.

Accordingly, the Department's General Counsel has determined and so certified to the Office of Management and Budget, that dispensing with notice and opportunity for comment is consistent with the Administrative Procedure Act (APA) and all other relevant laws.

Since a notice and an opportunity for comment are not required to be given for this notice under section 553 of the APA (5 U.S.C. 553) or any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a), 604(a)), no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

This notice does not contain a collection of information for purposes of the Paperwork Reduction Act (Pub. L. 96–511). This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Eligibility

Eligible applicants under this program are cities and urban counties with populations of at least 35,000 but no more than 500,000, and states.

Program Objective

The primary objective of planning assistance under section 302(a) is to support significant economic development planning and implementation initiatives of states, cities, and urban counties, particularly those experiencing severe economic distress. Planning activities conducted with this assistance must be part of a continuous process involving significant local leadership from public officials and private citizens and should include efforts to reduce unemployment and increase incomes.

Activities eligible for support include economic analysis, definition of development goals, determination of project opportunities, and formulation and implementation of a development program. Because of the limited funds available, support will only be provided for eligible activities not currently being undertaken. The intention of this program is to help eligible entities undertake significant new planning efforts—not continue or maintain existing ones. These new efforts may involve (but are not limited to) the establishment or major restructuring of an ongoing economic development planning process or the conduct of discrete planning tasks that are integrally related to such a process. Program funds will not be used to provide technical assistance associated with individual economic development projects. Funds for that purpose were announced in the January 19, 1988 Federal Register notice cited above.

EDA is interested in proposals for planning activities designed to address problems confronting economically distressed segments of the population. In the case of proposals from States, EDA is particularly interested in innovative approaches to planning and implementing economic development initiatives, as well as efforts that lend themselves to replication in other areas.

Funding Availability

No specific level of FY 1988 funding has been established for support of section 302(a) grants under these revised procedures. FY 1988 obligations under this program will depend on the quality and timing of proposal and application submissions. Any awards of FY 1988 monies will not be made until the final two months of the fiscal year. If Congress makes funds available for this program in FY 1989, it is expected that they will be used to finance proposals solicited through this announcement. Given the recent funding history of this program and the status of other EDA planning programs, it is not expected that FY 1989 funds, which have not been requested by the Administration, will exceed $3.5 million.

Funding Instrument

Grant assistance may be provided for up to 75 percent of project costs. A ceiling of $200,000 has been established for individual grants. Because of the emphasis on supporting significant planning efforts, it is envisioned that the average grant size will be between $100,000 and $125,000. EDA expects, however, to receive and consider proposals for smaller grants to support appropriate activities. Applicants will be required to provide a minimum of 25 percent of project costs.

Project Duration

Assistance under this program will normally be limited to a period of twelve months without renewal funding. If Congress makes monies available for this program in subsequent years, grant renewals can be considered for up to two additional years if circumstances warrant.

Selection Criteria

The content of the proposal and the economic distress of the area will be the principal factors considered in evaluating proposals from eligible entities.

In assessing the distress factor, priority consideration will be given to proposals from urban areas and states experiencing substantial economic distress. In the case of urban areas, high priority will be given to those with unemployment rates two or more percentage points higher than the U.S. average and per capita income levels 80 percent or less of the U.S. average. For states, high priority will be given to those that meet both of the above criteria, as well as those that meet one of the above criteria and have distress equal to or greater than the national average with regard to the other criterion.

The most recent per capita and 12-month unemployment data available will be used to measure economic distress. Proposals from states or urban areas which do not exhibit significant distress on the basis of unemployment or income data will not be considered unless other acceptable evidence of substantial distress can be provided (e.g., large numbers of agricultural and business failures, recent plant closings, large numbers of low income families, drastically reduced tax bases, etc.) Proposals from states or urban areas which are both below the U.S. average in unemployment and above the U.S. average per capita income level are unlikely to be funded.

Proposals will be judged on the basis of: 1. Appropriateness of the work program to the 302(a) program objectives;

2. Extent to which the proposed planning activities are expected to impact upon the service area's economic development needs, and the extent to which the proposal addresses the problems of the unemployed and underemployed of the area, including the farm families, minorities, workers displaced by plant closings, etc.;

3. Other characteristics, such as involvement of private sector in the proposed activities, and particularly for states, innovativeness of the proposed approach and replicability of process and/or results.

The other major factor on which proposals will be judged is the commitment of high level government

officials to the proposed work program as demonstrated by such evidence as amount of local funding, intent to continue the planning activities beyond the EDA funding period, degree of interest displayed by the chief executive, and the proximity of official with responsibility for the activities to the chief executive (i.e., likehihood that the activities will have a significant influence on the decision making process).

Proposal Submission Procedures

Potential applicants should submit proposals that include: 1. A letter signed by the head of the applicant organization indicating: A desire to receive funds to carry out the planning activities outlined in the proposal; where the funded planning program will be placed in the organization, to include the name and title of the person to be responsible for program implementation; for what period funding is requested; and the anticipated funding arrangement if the planning activity is to continue beyond the period of EDA support.

2. Significant, verifiable information on the level of economic distress in the area, including unemployment and income data. Any major changes in distress levels during the past year should be described.

3. A work program of no more than 10 pages which outlines the specific planning activities that will be carried out under the grant and specifies whether they will be handled by in-house staff, consultants, etc. The work program should also explain the need for the proposed activities, expected impacts and their timing, target population(s), and other characteristics related to the selection criteria presented above. An original and two copies of the proposal are to be submitted to the appropriate EDA Regional Office. Proposals postmarked after September 15, 1988 may not be considered. Proposals submitted by July 31, 1988, may receive early consideration for funding.

Formal Application Procedures

EDA will evaluate proposals using the selection criteria cited above and any other criteria developed and subsequently explained in writing to grantees. Following the review of proposals, EDA will invite those whose proposals are selected for funding consideration to submit formal applications, which will include an SF-424 or similar form as currently approved by the Office of Management and Budget and other application materials.

Applications proposed for funding under this program are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." Applicants who have delinquent accounts receivable with the Department of Commerce will not receive new awards until these debts have been paid or arrangements to pay them have been approved by the Department of Commerce.

Date: June 10, 1988.

Orson G. Swindle,

Assistant Secretary for Economic Development.

[FR Doc. 88-13424 Filed 6-14-88; 8:45 am]

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federal register

Wednesday
June 15, 1988

Part V

Department of Agriculture

Cooperative State Research Service

Small Business Innovation Research Program for Fiscal Year 1989; Solicitation of Applications; Notice

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

Small Business Innovation Research Program for Fiscal Year 1989; Solicitation of Applications

Notice is hereby given that under the authority of the Small Business Innovation Development Act of 1982 (Pub. L. 97–219), as amended (15 U.S.C. 638) and section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Pub. L. Number 99–591, 100 Stat. 3341, the U.S. Department of Agriculture (USDA) expects to award project grants for certain areas of research to science-based small business firms through Phase I of its Small Business Innovation Research (SBIR) Program. This program will be administered by the Office of Grants and Program Systems, Cooperative State Research Service. Firms with strong scientific research capabilities in the topic areas listed below are encouraged to participate. Objectives of the three-phase program include stimulating technological innovation in the private sector, strengthening the role of small businesses in meeting Federal research and development needs, increasing private sector commercialization of innovations derived from USDA-supported research and development efforts, and fostering and encouraging minority and disadvantaged participation in technological innovation.

The total amount expected to be available for Phase I of the SBIR Program in fiscal year 1989 is approximately $1,266,000. The solicitation is being announced to allow adequate time for potential recipients to prepare and submit applications by the closing date of September 1, 1988. The research to be supported is in the following topic areas:

1. Forests and Related Resources
2. Plant Production and Protection
3. Animal Production and Protection
4. Air, Water, and Soils
5. Food Science and Nutrition
6. Rural and Community Development.

The award of any grants under the provisions of this solicitation is subject to the availability of appropriations.

This program is subject to the provisions found at 7 CFR Part 3403. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of grant projects. In addition, USDA Uniform Federal Assistance Regulations, as amended, (7 CFR Part 3015) apply to this program. Copies of 7 CFR Part 3403 and 7 CFR Part 3015 may be obtained by writing or calling the office indicated below.

The solicitation, which contains research topic descriptions and detailed instructions on how to apply, may be obtained by writing or calling the office indicated below. Please note that applicants who submitted SBIR proposals for 1988, or who have recently requested placement on the list for 1989, will automatically receive a copy of the 1989 solicitation.

Proposal Services Unit, Grants Administrative Management, Cooperative State Research Service, U.S. Department of Agriculture, 901 D Street SW., Room 303, Washington, DC 20251–2200, Telephone: (202) 475–5048.

Done at Washington, DC, this 10th day of June 1988.

John Patrick Jordan,

Administrator, Cooperative State Research Service.

[FR Doc. 88–13501 Filed 6–14–88 8:45 am]

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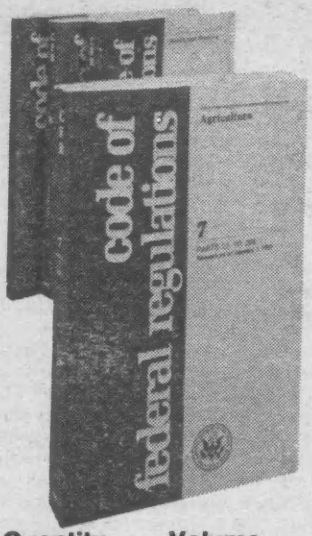

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