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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

Delegations of Authority

AGENCY: Office of the Secretary, USDA.
ACTION: Final rule.

SUMMARY: This rule delegates authority to the Assistant Secretary of Agriculture for Natural Resources and Environment and thence to the Chief of the Forest Service to designate specially trained officers and employees of the Forest Service to have the powers and authorities enumerated in the National Forest System Drug Control Act of 1986 (16 U.S.C. 559b–f).

EFFECTIVE DATE: This rule is effective September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Cecil L. Wilson, Law Enforcement Branch Chief, Fiscal & Public Safety Staff, Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090 (703/235–8484).

SUPPLEMENTARY INFORMATION: The National Forest System Drug Control Act of 1986, Pub. L. 99–570, Title XV (16 U.S.C. 559b–f) authorizes the Secretary of Agriculture, in connection with the administration of the National Forest System, to take actions necessary to prevent the manufacture, distribution, or dispensing of marijuana or other controlled substances.

The Act also provides authority for the Secretary to designate not more than 500 specially trained officers and employees of the Forest Service to have the authorities and powers enumerated within the Act when in the performance of their duties within the boundaries of the National Forest System.

The Act also provides for the Secretary to authorize the Forest Service to cooperate with any other Federal law enforcement agency, State, or political subdivision, in the investigation of violation of and enforcement of section 401 of the Controlled Substance Act (21 U.S.C. 841), other laws and regulations relating to marijuana and other controlled substances, and State laws or ordinances, within the boundaries of the National Forest System.

This rule delegates the authorities in the Act to the Assistant Secretary for Natural Resources and Environment and thence to the Chief of the Forest Service. Because the rule relates solely to internal agency management, pursuant to 5 U.S.C. 533, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register.**

Further, since this rule relates to internal management, it is exempt from the provisions of Executive Order 12291. Finally, this action is not a rule as defined by the Regulatory Flexibility Act, and thus, is exempt from the provisions of that Act.

List of Subjects in 7 CFR Part 2

Authority delegations (Government agencies).

Therefore, for the reasons set forth in the preamble, Part 2, Subtitle A, of Title 7 of the Code of Federal Regulations is hereby amended as follows:

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

1. The authority citation for Part 2 continues to read:

Authority: 5 U.S.C. 301 and reorganization plan No. 2 of 1953 unless otherwise noted.

Subpart C—Delegations of Authority to the Deputy Secretary, the Under Secretary for International Affairs and Commodity Programs, the Under Secretary for Small Community and Rural Development, and Assistant Secretaries

2. Amend § 2.19 by adding paragraphs (d)(27) and (28) to read as follows:

§ 2.19 Assistant Secretary for Natural Resources and Environment.

* * * * *

(d) * * *

(27) For the purposes of the National Forest System Drug Control Act of 1986, 16 U.S.C. 559b–f, specifically designate certain specially trained officers and employees of the Forest Service, not exceeding 500, to have authority in the performance of their duties within the boundaries of the National Forest System.

(1) To carry firearms;

(2) To conduct investigations of violations of and to enforce section 401 of the Controlled Substance Act (21 U.S.C. 841) and other criminal violations relating to marijuana and other controlled substances that are manufactured, distributed, or dispensed on National Forest lands;

(3) To make arrests with a warrant or process for misdemeanor violations, or without a warrant for violations of such misdemeanors that any such officer or employee has probable cause to believe are being committed in that employee's presence or view, or for a felony with a warrant or without a warrant, if the employee has probable cause to believe that the person being arrested has committed or is committing such felony;

(4) To serve warrants and other process issued by a court or officer of competent jurisdiction;

(5) To search, with or without a warrant or process any person, place, or conveyance according to Federal law or rule of law; and

(6) To seize with or without a warrant or process any evidentiary item according to Federal law or rule of law.

(28) Authorize the Forest Service to cooperate with the law enforcement officials of any Federal agency, State, or political subdivision, in the investigation of violations of and enforcement of section 401 of the Controlled Substances Act (21 U.S.C. 841), other laws and regulations relating to marijuana and other controlled substances, and State drug control laws or ordinances, within the boundaries of the National Forest System.

Subpart G—Delegations of Authority By the Assistant Secretary for Natural Resources and Environment

3. Amend § 2.60 by adding paragraphs (a)(29) and (30) to read as follows:

§ 2.60 Chief, Forest Service.

(a) * * *

(29) For the purposes of the National Forest System Drug Control Act of 1986, 16 U.S.C. 559b-f, specifically designate

certain specially trained officers and employees of the Forest Service, not exceeding 500, to have authority in the performance of their duties within the boundaries of the National Forest System:

(i) To carry firearms;

(ii) To conduct investigations of violations of and enforce section 401 of the Controlled Substance Act (21 U.S.C. 841) and other criminal violations relating to marijuana and other controlled substances that are manufactured, distributed, or dispensed on National Forest lands;

(iii) To make arrests with a warrant or process for misdemeanor violations, or without a warrant for violations of such misdemeanors that any such officer or employee has probable cause to believe are being committed in that employee's presence or view, or for a felony with a warrant or without a warrant if that employee has probable cause to believe that the person being arrested has committed or is committing such felony;

(iv) To serve warrants and other process issued by a court or officer of competent jurisdiction;

(v) To search with or without a warrant or process any person, place, or conveyance according to Federal law or rule of law; and

(vi) To seize with or without warrant or process any evidentiary item according to Federal law or rule of law.

(30) Authorize the Forest Service to cooperate with the law enforcement officials of any Federal agency; State, or political subdivision, in the investigation of violations of and enforcement of section 401 of the Controlled Substances Act (21 U.S.C. 841), other laws and regulations relating to marijuana and other controlled substances, and State drug control laws or ordinances, within the boundaries of the National Forest System.

* * * * *

For Subpart C.

Richard E. Lyng,

Secretary.

Date: August 24, 1987.

For Subpart G.

George S. Dunlop,

Assistant Secretary, Natural Resources and Environment.

Date: August 21, 1987.

[FR Doc. 87-20122 Filed 9-3-87; 8:45 am]

BILLING CODE 3410-11-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Regulation 577]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: Regulation 577 establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 283,781 cartons during the period September 6 through September 12, 1987. Such action is needed to balance the supply of fresh lemons with market demand for the period specified, due to the marketing situation confronting the lemon industry.

DATES: Regulation 577 (§ 910.877) is effective for the period September 6 through September 12, 1987.

FOR FURTHER INFORMATION CONTACT: James M. Scanlon, Acting Chief, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2523, South Building, P.O. Box 96456, Washington, DC 20090-6456, telephone; (202) 447-5697.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory action to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

This regulation is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act (the "Act", 7 U.S.C. 601-674), as amended. This action is based upon the recommendation and information submitted by the Lemon Administrative Committee and upon other available information. It is found that this action will tend to effectuate the declared policy of the Act.

This regulation is consistent with the marketing policy for 1987-88. The committee met publicly on September 1, 1987, in Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended by an 11 to 1 vote a quantity of lemons deemed advisable to be handled during the specified week. The committee reports that the market is fair.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice, and engage in further public procedure with respect to this action and that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the Act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

For the reasons set forth in the preamble, 7 CFR Part 910 is amended as follows:

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

1. The authority citation for 7 CFR Part 910 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 910.877 is added to read as follows:

§ 910.877 Lemon Regulation 577.

The quantity of lemons grown in California and Arizona which may be handled during the period September 6 through September 12, 1987, is established at 283,781 cartons.

Dated: September 2, 1987.

Ronald L. Cioffi,

Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 87-20569 Filed 9-3-87; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 91

[Docket No. 87-115]

Ports Designated for Exportation of Animals; Deletion of Alex Nichols Agency

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the Inspection and Handling of Livestock for Exportation by removing the Alex Nichols Agency, Glen Head, New York, from the list of ports that have export inspection facilities and are designated as ports of embarkation. This action is necessary because the facility no longer exists.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Dr. William Parham, Staff Veterinarian, Import-Export Emergency Planning Staff, VS, APHIS, USDA, Room 810, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8695.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR Part 91, "Inspection and Handling of Livestock for Exportation," prescribe conditions for exporting animals from the United States. Section 91.14(a) of the regulations lists ports that have export inspection facilities and are designated as ports of embarkation.

On May 11, 1987, we published in the **Federal Register** (52 FR 17597, Docket Number 87-017) a document proposing to revise § 91.14(a) to remove the Alex Nichols Agency, P.O. Box 283, Glen Head, New York, from the list of ports that have export inspection facilities and are designated as ports of embarkation. This was necessary because the facility no longer exists. We did not receive any comments by the close of the comment period on July 10, 1987. We are therefore adopting the proposal as a final rule.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers; individual industries, Federal, state, or local government agencies, or geographical regions; and will 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.

Because the Alex Nichols Agency facility at Glen Head, New York, does not exist, removing it from the list of ports of embarkation will have no effect on the exporters. Alternate ports of embarkation are available in New York.

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

Paperwork Reduction Act

This 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 9 CFR Part 91

Animal diseases, Animal welfare, Exports, Livestock and livestock products, Transportation.

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

Accordingly, 9 CFR Part 91 is amended as follows:

1. The authority citation for Part 91 continues to read as follows:

Authority: 21 U.S.C. 105, 112, 113, 114a, 120, 121, 134b, 134f, 612, 613, 614, 618, 46 U.S.C. 466a, 466b; 49 U.S.C. 1509(d); 7 CFR 2.17, 2.51, and 371.2(d).

§ 91.14 [Amended]

2. In § 91.14, paragraph (a)(8)(ii)(B) is removed.

Done in Washington, DC, this 1st day of September, 1987.

J.K. Atwell,

Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc. 87-20471 Filed 9-3-87; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Red No. 33 and D&C Red No. 36; Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 33 and D&C Red No. 36 for use as color additives in drugs and cosmetics. The new closing date will be November 3, 1987. FDA has decided that this brief postponement is necessary to provide time for the preparation of documents that will explain the bases for the agency's decisions concerning the conditions under which these color additives may be safely used.

EFFECTIVE DATE: Effective September 4, 1987, the new closing date for D&C Red No. 33 and D&C Red No. 36 will be November 3, 1987.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5676.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of September 4, 1987, for the provisional listing of D&C Red No. 33 and D&C Red No. 36 by regulation published in the **Federal Register** of July 6, 1987 (52 FR 25209). FDA extended the closing date for these color additives until September 4, 1987, to provide time for completion of the agency's review and evaluation of the data concerning the drug and cosmetic uses of these color additives, and for publication of a regulation in the **Federal Register** regarding the agency's final decision on the petitions for the permanent listing of these color additives. The regulation set forth below will postpone the September 4, 1987, closing date for the provisional listing of these color additives until November 3, 1987.

FDA has essentially completed its review and evaluation of available information relevent to the use of these color additives in drugs and cosmetics. The agency has concluded that the drug and cosmetic uses of D&C Red No. 33 and D&C Red No. 36 are safe. Thus, the agency has decided to permanently list the color additives for these uses. New certification specifications are also being developed for these color additives.

The agency has not yet completed documents fully describing the bases for each of these decisions and setting forth detailed conditions for use. Therefore, FDA believes that it is reasonable to postpone the closing date for these color additives until November 3, 1987, to provide time for the preparation and publication of appropriate **Federal Register** documents. The agency intends to publish these documents as soon as possible. FDA concludes that this short extension is consistent with the public health and the standards set forth for continuation of provisonal listing in *McIlwain* v. *Hayes*, 690 F.2d 1041 (D.C. Cir. 1982).

Because of the shortness of time until the September 4, 1987, closing data, FDA concludes that notice and public procedure on this regulation are impracticable and that good cause exists for issuing the postponement as a final rule and for an effective date of September 4, 1987. This regulation will permit the uninterrupted use of these color additives until further action is taken. In accordance with 5 U.S.C. 553(b) and (d)(1) and (3), this postponement is issued as a final regulation, effective on September 4, 1987.

List of Subjects in 21 CFR Part 81

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 81 is amended as follows:

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

1. The authority citation for 21 CFR Part 81 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note); 21 CFR 5.10.

§ 81.1 [Amended]

2. In § 81.1 *Provisional lists of color additives* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" appearing in the table in paragraph (b) to read "November 3, 1987."

§ 81.27 [Amended]

3. In § 81.27 *Conditions of provisional listing* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" in paragraph (d), introductory text table, to read "November 3, 1987."

Dated: August 19, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-20380 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 177

[Docket No. 86F-0075]

Indirect Food Additives; Polymers

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 Nylon 6/66 copolymer resins as the non-food-contact layer in multilayer film structures intended for use in the cooking and holding of food. This action responds to a petition filed by Allied Corp.

DATES: Effective September 4, 1987; objections by October 5, 1987.

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: Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFF-335), 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 March 14, 1986 (51 FR 8898), FDA announced that a petition (FAP 6B3913) had been filed by Allied Corp., Morristown, NJ 07960, proposing that the food additive regulations be amended to provide for the safe use of Nylon 6/66 copolymer resins as the non-food-contact layer in film structures in which ionomeric resins complying with 21 CFR 177.1330 of the food additive regulations are the food-contact surface. The multilayer film structure is intended for cooking and holding food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended as set forth below.

Because the Nylon 6/66 copolymer resin evaluated in this petition may only be used as the non-food-contact layer in multilayer film structures, and because it has significantly different specifications than the Nylon 6/66 that is currently approved for use in direct contact with food, FDA is amending § 177.1500 *Nylon resins* (21 CFR 177.1500) to clearly differentiate between the two types of Nylon 6/66. Nylon 6/66 resins that comply with § 177.1500, item 4.1, may be used in direct contact with food. Nylon 6/66 resins that comply with § 177.1500, item 4.2, may be used only as the non-food-contact layer in multilayer film structures.

FDA is also establishing a new food additive regulation, § 177.1395 *Laminate structures for use at temperatures between 120 °F* and 250 *°F* (21 CFR 177.1395), to specify the conditions of use for the new multilayer film structure with Nylon 6/66. The agency is also changing the section heading of § 177.1390 *High-temperature laminates* (21 CFR 177.1390) to read § 177.1390 *Laminate structures for use at temperatures of 250 °F and above*, to clearly differentiate the temperatures under which these packaging materials may be used. The agency also wishes to make it clear that adoption of new § 177.1395 does not revoke prior FDA opinions stating that other multilayer film structures may be safely used in contact with food.

The filing notice for this petition specified that the food-contact layer of the petitioned laminate would be ionomeric resins complying with 21 CFR 177.1330. FDA determined, during the review of this petition, that the inclusion in new § 177.1395 of a limitation on the migration of residual *epsilon*-caprolactam monomer from the Nylon 6/66 resin to food obviates the need to list in the regulation the specific material that is to be used as the food-contact surface. Therefore, in addition to ionomeric resins, other approved food-contact materials may be used as the food-contact layer with Nylon 6/66 in multilayer structures (see § 177.1395(b)).

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 (address above) by

appointment with the information contact person listed above. As provided in 21 CFR 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 October 5, 1987, 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 177

Food additives, Food packaging.

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 Food Safety and Applied Nutrition, Part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR Part 177 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 177.1390 is amended by revising the section heading to read as follows:

§ 177.1390 Laminate structures for use at temperatures of 250° F and above.

* * * * *

3. By adding new § 177.1395 to Subpart B to read as follows:

§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

(a) The laminates identified in this section may be safely used at the specified temperatures. These articles are layered structures that are optionally bonded with adhesives. In these articles, the food-contact layer does not function as a barrier to migration of components from non-food-contact layers. The layers may be laminated, extruded, coextruded, or fused.

(b) Laminate structures may be manufactured from:

(1) Polymers and adjuvants complying with § 177.1390 of this chapter.

(2) Any polymeric resin listed in these regulations so long as the use of the resin in the structure complies with the conditions of use (food type and time/temperature) specified in the regulation for that resin.

(3) Optional adjuvant substances used in accordance with § 174.5 of this chapter.

(4) The following substances in non-food-contact layers only:

Substances	Limitations
Nylon 6/66 resins complying with § 177.1500(b), item 4.2, of this chapter (CAS Reg. No. 24993-04-2).	For use with nonalcoholic foods at temperatures not to exceed 82.2 °C (180 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of *epsilon*-caprolactam per square inch when extracted with water at 82.2 °C (180 °F) for 5 hours.

4. Section 177.1500 is amended by revising paragraph (a)(4) and in paragraph (b) by amending the table to revise the heading in the fifth column and by revising item 4 to read as follows:

§ 177.1500 Nylon resins.

* * * * *

(a) * * *

(4) Nylon 6/66 resins manufactured by the condensation and polymerization of Nylon 66 salts and *epsilon*-caprolactam.

* * * * *

(b) * * *

Nylon resins	Specific gravity	Melting Point (degrees Fahrenheit)	Solubility in boiling 4.2N HCl	Maximum extractible fraction in selected solvents (expressed in percent by weight of resin)			
				Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
* * *		*	*	*	*		
4.1 Nylon 6/66 resins, *epsilon*-caprolactam monomer content not to exceed 0.7 percent by weight	1.13±.015	440–460	.....do	2.0	2.0	1.5	1.5
4.2 Nylon 6/66 resins with combined caprolactam content greater than 60 percent and residual *epsilon*-caprolactam monomer content not to exceed 0.4 percent by weight. For use only as specified in § 177.1395 of this chapter (CAS Reg. No. 24993-04-2	1.14±.015	380–400	.....do	0.8	1.0	0.5	0.5
* *		*	*	*	*		

Dated: August 25, 1987.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-20374 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 331

[Docket No. 78N-0263]

Antacid Drug Products for Over-the-Counter Human Use; Final Classification of Category III Antacid Ingredients and Labeling Claims

AGENCY: Food and Drug Administration.

ACTION: Denial of petition and final decision.

SUMMARY: This notice denies a petition to amend the final monograph for over-the-counter (OTC) antacid drug products to include the ingredient alginic acid and the labeling claim "floating," and contains a final decision on the use of this ingredient and labeling claim for OTC antacid drug products. This notice is part of the ongoing review of OTC drug products conducted by FDA.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA published the final monograph for OTC antacid drug products (21 CFR Part 331). Alginic acid was classified as a Category III ingredient and "floating" as a Category III labeling claim. At that time, OTC drug regulations in 21 CFR Part 330 provided for a 2-year period following the publication of a final monograph for manufacturers to conduct testing to upgrade Category III conditions (conditions for which there were insufficient data to determine general recognition of safety and effectiveness). During the testing period that had been established for OTC antacid drug products, a petition to amend the final monograph for OTC antacid drug products was submitted by Marion Laboratories, Inc., in support of its foam-forming floating antacid combination product containing the ingredients aluminum hydroxide dried gel, magnesium trisilicate, alginic acid, and sodium bicarbonate.

The Marion Laboratories' antacid combination product did not pass the in vitro effectiveness test set forth in the antacid final monograph (21 CFR 331.10(a)). The petition contained clinical studies in support of the product's antacid effectiveness and clarified the rationale for including alginic acid in the formulation, i.e., to react with the sodium bicarbonate in the formulation to form a foam that carries the antacid ingredients and floats on the stomach contents. The petition stated that no claim was being made that alginic acid has any antacid activity and that, therefore, alginic acid was an inactive ingredient. The petitioner called this product a foam-forming floating antacid.

In the **Federal Register** of September 5, 1978 (43 FR 39427), the agency published a final classification of Category III antacid ingredients and labeling cliams. All Category III ingredients and labeling claims except those covered by petitions to amend the antacid final monograph were reclassified in Category II (not generally recognized as safe and effective). Alginic acid and the labeling claim for "*floating*" *were excluded from the* agency's final classification of antacid conditions because the data contained in Marion Laboratories' petition were under review. The agency stated that its findings on the petition would be set forth in a future **Federal Register** publication following completion of its review of the data contained in the petition. In the interim, products affected by the pending petition were allowed to remain in the marketplace under 21 CFR 330.10(a).

After reviewing the petition, FDA informed Marion Laboratories, in a letter dated March 23, 1979, that the studies submitted were inadequate to support the effectiveness of its combination product. FDA suggested further clinical studies and provided Marion Laboratories with 2 years from the date of the letter to obtain and submit additional data demonstrating the product's effectiveness. The agency also stated that marketing of the product would be allowed to continue during the testing period (Ref. 1).

Not long after the above letter was issued, the United States District Court for the District of Columbia entered its opinion in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). In this case, the plaintiffs alleged that 21 CFR 330.10 was unlawful because it authorized the marketing of Category III drugs after publication of a final monograph. The Court concluded that "* * * the FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action," (*Cutler, supra*, 475 F. Supp. at 856). The Court issued an order declaring the FDA OTC drug regulations, 21 CFR 330.10, unlawful to the extent that they authorize the marketing of Category III drugs after a final monograph. The Court also enjoined FDA from implementing any portion of the regulation that authorizes such marketing.

In conformance with the Court's decision, the agency established that any OTC drug product with a condition not included in Category I in a final OTC drug monograph was a new drug requiring an approved new drug application (NDA) as a condition of marketing. FDA then informed Marion Laboratories that its OTC antacid combination product containing alginic acid, which had been marketed under Category III conditions, was now considered a new drug without an approved NDA and that an NDA for the product should be submitted (Ref. 2).

In September 1981, Marion Laboratories submitted an NDA for two products containing alginic acid, i.e., Gaviscon Antacid Tablets and Gaviscon-2 Antacid Tablets. The agency found the data adequate to support the effectiveness of the products for the temporary relief of heartburn (acid indigestion) due to acid reflux, and the NDA was approved on December 9, 1983 (Ref. 3).

With this NDA approval, Marion Laboratories may now market the product without further consideration of the petition to amend the OTC antacid final monograph. However, the agency has not issued a final response to the original petition and has not completed action on the final classification of Category III ingredients and labeling claims excluded from the 1978 final classification (see above). In this notice, for the reasons given below, FDA denies Marion Laboratories' petition to amend the OTC antacid final monograph to include the combination product containing alginic acid and the "floating" labeling claim. Accordingly, the ingredient alginic acid and the term "floating" are not included in the final monograph for OTC antacid drug products.

As explained above, in its petition Marion Laboratories clarified that alginic acid is an inactive ingredient and no claims regarding antacid activity are made for this ingredient. Although originally reviewed as an active antacid ingredient, alginic acid is now classified as an inactive ingredient in OTC antacid drug product formulations and is labeled as such in marketed products. Because the OTC drug review establishes allowable active ingredients, not inactive ingredients, the agency will not consider this ingredient for inclusion in the antacid drug products monograph. Alginic acid, like any other inactive

ingredient, may be used in OTC drug formulations in compliance with the requirements for inactive ingredients set forth in 21 CFR 330.1(e), i.e., that they are safe and do not interfere with the effectiveness of the product or with tests to be performed on it.

Marion Laboratories' submission to the Advisory Review Panel on OTC Antacid Drug Products included labeling relating the property of "floating" to its product's effectiveness (Ref. 4). The Panel recognized that alginic acid-containing products may produce a layer of material floating on top of the contents of the stomach (April 5, 1973; 38 FR 8722), but concluded that there was insufficient evidence to support the claim that such a property contributed to the product's effectiveness (38 FR 8723). The agency notes that OTC drug monographs directly address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. These labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action. The agency considers the term "floating" to be a product attribute which describes a physical property. Normally, such product attributes are considered to be outside the scope of OTC drug monographs when the labeling does not relate the attribute to the effectiveness of the product. The agency has no objection to the use of terms describing product attributes of OTC drug product formulations as long as they do not imply that any therapeutic effect might occur, are not false or misleading, and are not intermixed with labeling established by the monograph. However, labeling relating "floating" to a product's antacid effectiveness, such as that submitted by Marion Laboratories, remains a condition which requires supporting data.

Marion Laboratories claimed that the property of floating added to the efficacy of its combination antacid drug product, i.e., that "floating" was more than simply a product attribute because it was directly related to effectiveness. Additional data in support of this claim were submitted by Marion Laboratories to the agency, and the NDA was approved. However, the contribution of the floating property as related to antacid effectiveness is not generally recognized. Therefore, in order to use labeling suggesting that "floating" uniquely contributes to an antacid's effectiveness, any other antacid drug product would need to have supporting data. Any interested person who believes that "floating" supports or enhances antacid effectiveness may submit an NDA or petition the agency to amend the final monograph for OTC antacid drug products. Such petition should include appropriate data to establish general recognition of safety and effectiveness, e.g., an appropriate in vitro or in vivo test.

The agency has examined the economic consequences of this notice in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 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 this notice for OTC antacid 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, the requirement for a Regulatory Flexibility Analysis under the Regulatory Flexibility Act does not apply to this notice for OTC antacid drug products because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

The agency has determined under 21 CFR 25.24(c)(6) 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.

References

(1) Letter from J.R. Crout, FDA, to J.E. Budde, Marion Laboratories, Inc., dated March 23, 1979, coded LET, Docket No. 78N-0263, Dockets Management Branch.

(2) Letter from J.R. Crout, FDA to J.E. Budde, Marion Laboratories Inc., dated March 3, 1980, coded LET005, Docket No. 78N-0263, Dockets Management Branch.

(3) Letter from R. Temple, FDA, to J.E. Budde, Marion Laboratories, Inc., dated December 9, 1983, coded LET007, Docket No. 78N-0263, Dockets Management Branch.

(4) Copy of original labeling submitted to the Panel included in Docket No. 78N-0263, Docket Management Branch.

Dated: August 25, 1987.

John A. Norris,

Acting Commissioner of Food and Drugs.

[FR Doc. 87-20376 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8158]

Income Taxes; Tax on Unearned Income of Certain Minor Children

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document provides temporary regulations relating to the tax on unearned income of certain minor children. Changes to the applicable law were made by the Tax Reform Act of 1986. The regulations affect minor children who, at the close of the taxable year, have not attained age 14; have at least one living parent; and realize at least $1,000 of unearned income and provide the guidance needed to comply with the law.

DATES: The regulations are effective for taxable years beginning after December 31, 1986.

FOR FURTHER INFORMATION CONTACT: William A. Jackson of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Attention: CC:LR:T (LR-112-86) (202) 566-4336, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

This document contains temporary regulations relating to the tax on unearned income of certain minor children under section 1(i) of the Internal Revenue Code of 1986 (Code), as amended by section 1411 of the Tax Reform Act of 1986 (Pub. L. 99-514; 100 Stat. 2714).

These temporary regulations are presented in the form of questions and answers. Taxpayers may rely on these questions and answers for guidance. No inference, however, should be drawn regarding questions not addressed in the temporary regulations.

In General

For taxable years beginning after December 31, 1986, section 1(i) provides that the tax imposed on the net unearned income of a child who at the close of the taxable year is under 14 years of age and has at least one living parent, shall be no less than the additional tax that would have been imposed on the child's net unearned income if such income had been added to such parent's taxable income. If the parent has two or more children subject to section 1(i), the tax imposed on each is the child's proportionate share of additional tax that would have been imposed on the net unearned income of all such children if such income were aggregated and added to the parent's taxable income.

Net unearned income is the excess of the portion of the child's adjusted gross income for the taxable year that is not earned income (as defined in section 911(d)(2)), over the sum of the standard deduction amount allowed in the case of certain dependents under section 63(c)(5)(A) ($500 for 1987 and 1988 (indexed for inflation beginning after 1988)), plus the greater of such standard deduction amount or the child's itemized deductions for the taxable year that are directly connected with the production of unearned income. A child's net unearned income for the taxable year cannot exceed such child's taxable income for the tax year. Further, if the child has itemized deductions, the child may offset unearned income with the greater of the amount of such itemized deductions that is equal to the standard deduction or the amount of allowed deductions directly connected with the production of unearned income.

Unearned Income Subject to Tax

The regulations explain that the tax imposed by section 1(i) of the Code applies to net unearned income for taxable years beginning after December 31, 1986, even though it is attributable to property transferred to the child prior to 1987. (See A-7). Further, the regulations illustrate that the tax under section 1(i) applies to net unearned income that is attributable to gifts from persons other than the child's parents as well as to unearned income derived with respect to assets from earned income of the child. (See A-8). In addition, the regulations clarify that unearned income includes social security and pension payments received by a child to the extent such amounts are included in the child's adjusted gross income.

Parent's Taxable Income

In the case of parents who file a joint return, the parental taxable income to be taken into account in determining the tax liability of a child is the joint taxable income of the parents. If the child's parents are married to each other but file separate returns, the taxable income of the parent with the greater taxable income is taken into account. In the case of parents who are not married to each other, treated as not married under section 7703(b) (relating to certain married individuals living apart), or divorced or legally separated, the taxable income of the custodial parent is taken into account. (See A-12). If a custodial parent files a joint return with a spouse who is not a parent of the child, the parental taxable income to be taken into account is the total joint taxable income of the custodial parent and his or her spouse. (See A-13.)

The regulations provide that a child subject to tax under section 1(i) may, upon written request to the Internal Revenue Service, obtain sufficient information regarding the parent's return so that the child can properly file his or her return. (See A-22). The Service recognizes that under certain unusual circumstances a child may not be able to obtain sufficient information regarding the parent's tax return directly from the parent. In such cases, it may be difficult for such child to file an accurate return in a timely manner. Accordingly, the Service is considering the possibility of providing special rules for hardship cases. If special rules are subsequently determined by the Service to be appropriate, such rules will be provided in future regulations or revenue rulings and will be applied retroactively. The Service welcomes comments as to whether special rules are needed, what type of rules are appropriate, and which children should qualify for the special rules.

Income From a Trust

The regulations provide that in the case of a trust with children subject to tax under section 1(i) as income beneficiaries, such children will be taxed on the trust income to the extent of distributable net income that is included in the child's gross income. (See A-16). The regulations clarify that unearned income attributable to a gift to a child under the Uniform Gift to Minors Act is treated as the child's unearned income and is subject to tax under section 1(i). (See A-15).

The regulations include no provision regarding the application of the tax imposed by section 1(i) to accumulation distributions of a trust (as defined in section 665(b) of the Code). The Service believes that most accumulation distributions received by a child from a trust will not be included in the child's gross income because of the minority exception under section 665(b) and thus will not be subject to section 1(i). However, to the extent that an accumulation distribution does not fall within the minority exception, the Internal Revenue Service will issue guidance in the future (by revenue ruling or other means) with respect to how section 1(i) applies in such situations.

Effect of Adjustments to the Parent's Taxable Income

The regulations provide that if the parent's taxable income is adjusted and if a child of the parent paid tax under section 1(i) for the same taxable year with reference to such parent's taxable income, the child's tax liability under section 1(i) must be recomputed using the parent's taxable income as adjusted. (See A-17). A similar recomputation must be made with respect to that child if there is an adjustment to the net unearned income of another child who used the same parent's taxable income to determine any allocable parental tax. (See A-18). Further, any additional tax liability to the child resulting from an adjustment to the parent's taxable income or another child's net unearned income shall be treated as an underpayment of tax and interest shall be imposed on such underpayment. However, the child will not be subject to any penalties on such underpayment as a result of additional tax being imposed on the child because of such an adjustment. (See A-19).

Phase-Out of Rate Bracket and Limitations on Deductions and Credits

The regulations provide that the allocable parental tax, computed by adding the net unearned income of all children of a parent who are subject to section 1(i) to such parent's taxable income, reflects any phase-out of the 15 percent rate bracket or personal exemptions under section 1(g). Thus, the child is liable for any addition to tax resulting from any phase-out. (See A-20). However, the regulations provide that a child's net unearned income is not taken into account in computing any limitation on a deduction or credit, such as the phase-out of the $25,000 passive loss allowance for active rental real estate activities or the 2 percent of adjusted gross income floor on miscellaneous deductions, for purposes of determining either the parent's tax liability or the child's allocable parental tax. (See A-21).

Need for Temporary Regulations

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is found impracticable to issue it with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

Special Analysis

No general notice of proposed rulemaking is required by 5 U.S.C. 553 (b) for temporary regulations. Accordingly, the Regulatory Flexibility Act does not apply and no Regulatory Flexibility Analysis is required for this rule. The Commissioner of Internal Revenue has determined that this temporary rule is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required.

Drafting Information

The principal author of these temporary regulations is William A. Jackson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

List of Subjects in 26 CFR 1.01-1.58-9

Income taxes, Tax liability, Tax rates, Credits.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Part 1 is amended as follows:

PART 1—[AMENDED]

Paragraph 1. The authority for Part 1 continues to read in part:

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

Par. 2. A new § 1.1(i)-1T is added immediately following § 1.1-3 to read as set forth below.

§ 1.1(i)-1T Questions and answers relating to the tax on unearned income certain minor children (Temporary).

In General

Q-1. To whom does section 1(i) apply?

A-1. Section 1(i) applies to any child who is under 14 years of age at the close of the taxable year, who has at least one living parent at the close of the taxable year, and who recognizes over $1,000 of unearned income during the taxable year.

Q-2. What is the effective date of section 1(i)?

A-2. Section 1(i) applies to taxable years of the child beginning after December 31, 1986.

Computation of Tax

Q-3. What is the amount of tax imposed by section 1 on a child to whom section 1(i) applies?

A-3. In the case of a child to whom section 1(i) applies, the amount of tax imposed by section 1 equals the greater of (A) the tax imposed by section 1 without regard to section 1(i) or (B) the sum of the tax that would be imposed by section 1 if the child's taxable income was reduced by the child's net unearned income, plus the child's share of the allocable parental tax.

Q-4. What is the allocable parental tax?

A-4. The allocable parental tax is the excess of (A) the tax that would be imposed by section 1 on the sum of the parent's taxable income plus the net unearned income of all children of such parent to whom section 1(i) applies, over (B) the tax imposed by section 1 on the parent's taxable income. Thus, the allocable parental tax is not computed with reference to unearned income of a child over 14 or a child under 14 with less than $1,000 of unearned income. *See* A-10 through A-13 for rules regarding the determination of the parent(s) whose taxable income is taken into account under section 1(i). *See* A-14 for rules regarding the determination of children of the parent whose net unearned income is taken into account under section 1(i).

Q-5. What is the child's share of the allocable parental tax?

A-5. The child's share of the allocable parental tax is an amount that bears the same ratio to the total allocable parental tax as the child's net unearned income bears to the total net unearned income of all children of such parent to whom section 1(i) applies. See A-14.

Example (1). During 1988, D, and a 12 year old, receives $5,000 of unearned income and no earned income. D has no itemized deductions and is not eligible for a personal exemption. D's parents have two other children, E, a 15 year old, and F, a 10 year old. E has $10,000 of unearned income and F has $100 of unearned income. D's parents file a joint return for 1988 and report taxable income of $70,000. Neither D's nor his parent's taxable income is attributable to net capital gain. D's tax liability for 1988, determined without regard to section 1(i), is $675 on $4,500 of taxable income ($5,000 less $500 allowable standard deduction). In applying section 1(i), D's tax would be equal to the sum of (A) the tax that would be imposed on D's taxable income if it were reduced by any net unearned income, plus (B) D's share of the allocable parental tax. Only D's unearned income is taken into account in determining the allocable parental tax because E is over 14 and F has less than $1,000 of unearned income. *See* A-4. D's net unearned income is $4,000 ($4,500 taxable unearned income less $500). The tax imposed on D's taxable income as reduced by D's net unearned income is $75 ($500×15%). The allocable parental tax is $1,225, the excess of $16,957.50 (the tax on $74,000, the parent's taxable income plus D's net unearned income) over $15,732.50 (the tax on $70,000, the parent's taxable income). *See* A-4. Thus, D's tax under section 1(i) (1) (B) is $1,300 ($1,225+$75). Since this amount is greater than the amount of D's tax liability as determined without regard to section 1(i), the amount of tax imposed on D for 1988 is $1,300. *See A-3.*

Example (2) H and W have 3 children, A, B, and C, who are all under 14 years of age. For the taxable year 1988, H and W file a joint return and report taxable income of $129,750. The tax imposed by section 1 on H and W is $35,355. A has $5,000 of net unearned income and B and C each have $2,500 of net unearned income during 1988. The allocable parental tax imposed on A, B, and C's combined net unearned income of $10,000 is $3,300. This tax is the excess of $38,655, which is the tax imposed by section 1 on $139,750 ($129,750+10,000), over $35,355 (the tax imposed by section 1 on H and W's taxable income of $129,750). *See* A-4. Each child's share of the allocable parental tax is an amount that bears the same ratio to the total allocable parental tax as the child's net unearned income bears to the total net unearned income of A, B, and C. Thus, A's share of the allocable parental tax is $1,650 (5,000÷10,000×3,300) and B and C's share of the tax is $825 (2,500÷10,000×3,300) each. *See* A-5.

Definition of Net Unearned Income

Q-6. What is net unearned income?

A-6. Net unearned income is the excess of the portion of adjusted gross income for the taxable year that is not "earned inocme" as defined in section 911(d)(2) (income that is not attributable to wages, salaries, or other amounts received as compensation for personal services), over the sum of the standard deduction amount provided for under section 63 (c)(5)(A) ($500 for 1987 and 1988; adjusted for inflation thereafter), plus the greater of (A) $500 (adjusted for inflation after 1988) or (B) the amount of allowable itemized deductions that are directly connected with the production of unearned income. A child's net unearned income for any taxable year shall not exceed the child's taxable income for such year.

Example (3). A is a child who is under 14 years of age at the end of the taxable year 1987. Both of A's parents are alive at this time. During 1987, A receives $3,000 of interest from a bank savings account and earns $1,000 from a paper route and performing odd jobs. A has no itemized

deductions for 1987. A's standard deduction is $1,000, which is an amount equal to A's earned income for 1987. Of this amount, $500 is applied against A's unearned income and the remaining $500 is applied against A's earned income. Thus, A's $500 of taxable earned income ($1,000 less the remaining $500 of the standard deduction) is taxed without regard to section 1 (i); A has $2,500 of taxable unearned income ($3,000 gross unearned income less $500 of the standard deduction) of which $500 is taxed without regard to section 1(i). The remaining $2,000 of taxable unearned income is A's net unearned income and is taxed under section 1(i).

Example (4). B is a child who is subject to tax under section 1(i). B has $400 of earned income and $2,000 of unearned income. B has itemized deductions of $800 (net of the 2 percent of adjusted gross income (AGI) floor on miscellaneous itemized deductions under section 67) of which $200 are directly connected with the production of unearned income. The amount of itemized deductions that B may apply against unearned income is equal to the greater of $500 or the deductions directly connected with the production of unearned income.*See* A–6. thus, $500 of B's itemized deductions are applied against the $2,000 of unearned income and the remaining $300 of decuctions are applied against earned income. As a result, B has taxable earned income of $100 and taxable unearned income of $1,500. Of these amounts, all of the earned income and $500 of the unearned income are taxed without regard to section 1(i). The remaining $1,000 of unearned income is net unearned income and is taxed under section 1(i).

Unearned Income Subject to tax Under Section 1(i)

Q–7. Will a child be subject to tax under section 1(i) on net unearned income (as defined in section 1(i) (4) and A–6 of this section) that is attributable to property transferred to the child prior to 1987?

A–7. Yes. The tax imposed by section 1(i) on a child's net unearned income applies to any net unearned income of the child for taxable years beginning after December 31, 1986, regardless of when the underlying assets were transferred to the child.

Q–8. Will a child be subject to tax under section 1(i) on net unearned income that is attributable to gifts from persons other than the child's parents or attributable to assets resulting from the child's earned income?

A–8. Yes. The tax imposed by section 1(i) applies to all net unearned income of the child, regardless of the source of the assets that produced such income. Thus, the rules of section 1(i) apply to income attributable to gifts not only from the parents but also from any other source, such as the child's grandparents. Section 1(i) also applies to unearned income derived with respect to assets resulting from earned income of the child, such as interest earned on bank deposits.

Example (5). A is a child who is under 14 years of age at the end of the taxable year beginning on January 1, 1987. Both of A's parents are alive at the end of the taxable year. During 1987, A receives $2,000 in interest from his bank account and $1,500 from a paper route. Some of the interest earned by A from the bank account is attributable to A's paper route earnings that were deposited in the account. The balance of the account is attributable to cash gifts from A's parents and grandparents and interest earned prior to 1987. Some cash gifts were received by A prior to 1987. A has no itemized deductions and is eligible to be claimed as a dependent on his parent's return. Therefore, for the taxable year 1987, A's standard deduction is $1,500, the amount of A's earned income. Of this standard deduction amount, $500 is allocated against unearned income and $1,000 is allocated against earned income. A's taxable unearned income is $1,500 of which $500 is taxed without regard to section 1(i). The remaining taxable unearned income of $1,000 is net unearned income and is taxed under section 1(i). The fact that some of A's unearned income is attributable to interest on principal created by earned income and gifts from persons other than A's parents or that some of the unearned income is attributable to property transferred to A prior to 1987, will not affect the tax treatment of this income under section 1(i). *See* A–8.

Q–9. For purposes of section 1(i), does income which is not earned income (as defined in section 911(d)(2)) include social security benefits or pension benefits that are paid to the child?

A–9. Yes. For purposes of section 1(i), earned income (as defined in section 911(d)(2)) does not include any social security or pension benefits paid to the child. Thus, such amounts are included in unearned income to the extent they are includible in the child's gross income.

Determination of the Parent's Taxable Income

A–10. If a child's parents file a joint return, what is the taxable income that must be taken into account by the child in determining tax liability under section 1(i)?

A–10. In the case of parents who file a joint return, the parental taxable income to be taken into account in determining the tax liability of a child is the total taxable income shown on the joint return.

Q–11. If a child's parents are married and file separate tax returns, which parent's taxable income must be taken into account by the child in determining tax liability under section 1(i)?

A–11. For purposes of determining the tax liability of a child under section 1(i), where such child's parents are married and file separate tax returns, the parent whose taxable income is the greater of the two for the taxable year shall be taken into account.

Q–12. If the parents of a child are divorced, legally separated, or treated as not married under section 7703(b), which parent's taxable income is taken into account in computing the child's tax liability?

A–12. If the child's parents are divorced, legally separated, or treated as not married under section 7703(b), the taxable income of the custodial parent (within the meaning of section 152(e)) of the child is taken into account under section 1(i) in determining the child's tax liability.

Q–13. If a parent whose taxable income must be taken into account in determining a child's tax liability under section 1(i) files a joint return with a spouse who is not a parent of the child, what taxable income must the child take into account?

A–13. The amount of a parent's taxable income that a child must take into account for purposes of section 1(i) where the parent files a joint return with a spouse who is not a parent of the child is the total taxable income shown on such joint return.

Children of the Parent

Q–14. In determining a child's share of the allocable parental tax, is the net unearned income of legally adopted children, children related to such child by half-blood, or children from a prior marriage of the spouse of such child's parent taken into account in addition to the natural children of such child's parent?

A–14. Yes. In determining a child's share of the allocable parental tax, the net unearned income of all children subject to tax under section 1(i) and who use the same parent's taxable income as such child to determine their tax liability under section 1(i) must be taken into account. Such children are taken into account regardless of whether they are adopted by the parent, related to such child by half-blood, or are children from a prior marriage of the spouse of such child's parent.

Rules Regarding Income From a Trust or Similar Instrument

Q–15. Will the unearned income of a child who is subject to section 1(i) that is attributable to gifts given to the child under the Uniform Gift to Minors Act (UGMA) be subject to tax under section 1(i)?

A–15. Yes. A gift under the UGMA vests legal title to the property in the child although an adult custodian is

given certain rights to deal with the property until the child attains majority. Any unearned income attributable to such a gift is the child's unearned income and is subject to tax under section 1(i), whether distributed to the child or not.

Q-16. Will a child who is a beneficiary of a trust be required to take into account the income of a trust in determining the child's tax liability under section 1(i)?

A-16. The income of a trust must be taken into account for purposes of determining the tax liability of a beneficiary who is subject to section 1(i) only to the extent it is included in the child's gross income for the taxable year under sections 652(a) or 662(a). Thus, income from a trust for the fiscal taxable year of a trust ending during 1987, that is included in the gross income of a child who is subject to section 1(i) and who has a calendar taxable year, will be subject to tax under section 1(i) for the child's 1987 taxable year.

Subsequent Adjustments

Q-17. What effect will a subsequent adjustment to a parent's taxable income have on the child's tax liability if such parent's taxable income was used to determine the child's tax liability under section 1(i) for the same taxable year?

A-17. If the parent's taxable income is adjusted and if, for the same taxable year as the adjustment, the child paid tax determined under section 1(i) with reference to that parent's taxable income, then the child's tax liability under section 1(i) must be recomputed using the parent's taxable income as adjusted.

Q-18. In the case where more than one child who is subject to section 1(i) uses the same parent's taxable income to determine their allocable parental tax, what effect will a subsequent adjustment to the net unearned income of one child have on the other child's share of the allocable parental tax?

A-18. If, for the same taxable year, more than one child uses the same parent's taxable income to determine their share of the allocable parental tax and a subsequent adjustment is made to one or more of such children's net unearned income, each child's share of the allocable parental tax must be recomputed using the combined net unearned income of all such children as adjusted.

Q-19. If a recomputation of a child's tax under section 1(i), as a result of an adjustment to the taxable income of the child's parents or another child's net unearned income, results in additional tax being imposed by section 1(i) on the child, is the child subject to interest and penalties on such additional tax?

A-19. Any additional tax resulting from an adjustment to the taxable income of the child's parents or the net unearned income of another child shall be treated as an underpayment of tax and interest shall be imposed on such underpayment as provided in section 6601. However, the child shall not be liable for any penalties on the underpayment resulting from additional tax being imposed under section 1(i) due to such an adjustment.

Example (6). D and M are the parents of C, a child under the age of 14. D and M file a joint return for 1988 and report taxable income of $69,000. C has unearned income of $3,000 and no itemized deductions for 1988. C properly reports a total tax liability of $635 for 1988. This amount is the sum of the allocable parental tax of $560 on C's net unearned income of $2,000 (the excess of $3,000 over the sum of $500 standard deduction and the first $500 of taxable unearned income) plus $75 (the tax imposed on C's first $500 of taxable unearned income). *See* A-3. One year later, D and M's 1988 tax return is adjusted on audit by adding an additional $1,000 of taxable income. No adjustment is made to the amount reported as C's net unearned income for 1988. However, the adjustment to D and M's taxable income causes C's tax liability under section 1(i) for 1988 to be increased by $50 as a result of the phase-out of the 15 percent rate bracket. *See* A-20. In addition to this further tax liability, C will be liable for interest on the $50. However, C will not have to pay any penalty on the delinquent amount.

Miscellaneous Rules

Q-20. Does the phase-out of the parent's 15 percent rate bracket and personal exemptions under section 1(g), if applicable, have any effect on the calculation of the allocable parental tax imposed on a child's net unearned income under section 1(i)?

A-20. Yes. Any phase-out of the parent's 15 percent rate bracket or personal exemptions under section 1(g) is given full effect in determining the tax that would be imposed on the sum of the parent's taxable income and the total net unearned income of all children of the parent. Thus, any additional tax on a child's net unearned income resulting from the phase-out of the 15 percent rate bracket and the personal exemptions is reflected in the tax liability of the child.

Q-21. For purposes of calculating a parent's tax liability or the allocable parental tax imposed on a child, are other phase-outs, limitations, or floors on deductions or credits, such as the phase-out of the $25,000 passive loss allowance for rental real estate activities under section 469(i)(3) or the 2 percent of AGI floor on miscellaneous itemized deductions under section 67, affected by the addition of a child's net unearned income to the parent's taxable income?

A-21. No. A child's net unearned income is not taken into account in computing any deduction or credit for purposes of determining the parent's tax liability or the child's allocable parental tax. Thus, for example, although the amounts allowable to the parent as a charitable contribution deduction, medical expense deduction, section 212 deduction, or a miscellaneous itemized deduction are affected by the amount of the parent's adjusted gross income, the amount of these deductions that is allowed does not change as a result of the application of section 1(i) because the amount of the parent's adjusted gross income does not include the child's net unearned income. Similarly, the amount of itemized deductions that is allowed to a child does not change as a result of section 1(i) because section 1(i) only affects the amount of tax liability and not the child's adjusted gross income.

Q-22. If a child is unable to obtain information concerning the tax return of the child's parents directly from such parents, how may the child obtain information from the parent's tax return which is necessary to determine the child's tax liability under section 1(i)?

A-22. Under section 6103(e)(1)(A)(iv), a return of a parent shall, upon written request, be open to inspection or disclosure to a child of that individual (or the child's legal representative) to the extent necessary to comply with section 1(i). Thus, a child may request the Internal Revenue Service to disclose sufficient tax information about the parent to the child so that the child can properly file his or her return.

Lawrence B. Gibbs,

Commissioner of Internal Revenue.

Approved: August 25, 1987.

O. Donaldson Chapoton,

Acting Assistant Secretary of the Treasury.

[FR Doc. 87-20459 Filed 9-3-87; 8:45 am]

BILLING CODE 4830-01-M

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26 CFR Part 31

[T.D. 8156]

Employment Taxes and Collection of Income Tax at Source; Interest on Hospital Insurance Taxes on Wages of State and Local Government Employees

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that relate to interest-free adjustments of underpayments of hospital insurance taxes (Medicare) with respect to wages of State and local government employees hired after March 31, 1986. Changes to the hospital insurance tax law were made by the Consolidated Omnibus Budget Reconciliation Act of 1985.

DATES: These regulations are effective with respect to State and local government employees hired after March 31, 1986, for services performed after that date.

FOR FURTHER INFORMATION CONTACT: Laura Ann M. Lauritzen of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 (Attention: CC:LR:T) (202-566-3459, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations under section 6205 of the Internal Revenue Code of 1954 to provide for making interest-free adjustments of certain underpayments of hospital insurance taxes. Section 3121 of the Code as amended by section 13205 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272, 100 Stat. 313) provides that hospital insurance taxes are to be withheld from, and paid by the employer, pursuant to section 3101(b) and 3111(b), with respect to, the wages of State and local government employees hired after March 31, 1986. It was determined that no notice and public comment procedure is necessary since this document will not be detrimental to any taxpayer.

Explanation of Provisions

Section 6205(a)(1) authorizes the Secretary to issue regulations prescribing the manner and time for making interest-free adjustments of underpayments of taxes imposed by sections 3101 or 3111. Section 3121 of the Code has been amended to provide for the withholding and payment under sections 3101(b) and 3111(b) of the hospital insurance taxes on wages of State and local government employees hired after March 31, 1986.

The Consolidated Omnibus Budget Reconciliation Act of 1985 was enacted on April 7, 1986. On July 14, 1986, the Internal Revenue Service published Revenue Ruling 86-88, 1986-28 I.R.B. 10, to provide guidelines concerning the applicability of the hospital insurance taxes to employees of States and local governments. Generally, the ruling states that the Service will automatically waive penalties for failure to pay and for failure to make timely deposits of the hospital insurance taxes with respect to services performed through the fourth quarter of 1986, so long as all payments due for April through December of 1986 are paid by February 2, 1987.

In view of the unique circumstances surrounding the application of the new FICA tax provisions, it appears appropriate as well for the Service to permit interest-free adjustments of underpayments of these taxes. Accordingly, this Treasury decision makes a technical amendment to the regulations under section 6205 to provide that interest will not be imposed for the failure to timely pay these new taxes required to be reported on returns due July 31, 1986, October 31, 1986, or February 2, 1987, provided all such taxes were paid on or before February 2, 1987. The right to the interest-free adjustments, however, will not be lost if the only amount not paid by February 2, 1987, is itself eligible for, and paid pursuant to, an interest-free adjustment under § 31.6205-1.

Non-Applicability of Executive Order 12291

The Commissioner of Internal Revenue has determined that this rule is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required.

Regulatory Flexibility Analysis

A regulatory flexibility analysis is not required by 5 U.S.C. 553 for final regulations not preceded by notice because notice would be unnecessary. Accordingly, the regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these regulations is Laura Ann M. Lauritzen of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service.

However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations on matters of both substance and style.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Lotteries, Railroad retirement, Social security, Unemployment tax, Withholding.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Part 31 is amended as follows:

PART 31—[AMENDED]

Paragraph 1. The authority for Part 31 is amended by the adding the following citation:

Authority: 26 U.S.C. 7805. * * * Section 31.6205-2 also issued under 26 U.S.C. 6205(a)(1). * * *

Par. 2. A new § 31.6205-2 is added immediately after § 31.6205-1, to read as follows:

§ 31.6205-2 Adjustments of underpayments of hospital insurance taxes that accrue after March 31, 1986, and before January 1, 1987, with respect to wages of State and local government employees.

(a) *Adjustments without interest.* A State or local government employer who makes, or has made, an undercollection or underpayment of the hospital insurance taxes imposed by sections 3101(b) and 3111(b) that—

(1) Are required to be paid by reason of section 3121(u)(2), and

(2) Are required to be reported on returns due July 31, 1986, October 31, 1986, or February 2, 1987.

may make an adjustment without interest with respect to such taxes provided that all such taxes for the time period specified in paragraph (a)(2) (except for amounts that are subsequently paid pursuant to an interest-free adjustment under § 31.6205-1) are paid on or before February 2, 1987.

(b) *Example.* The application of the provisions of this section are illustrated by the following example:

Example. A State or local government employer should have withheld and paid $100 dollars in hospital insurance taxes for the quarter beginning April 1, 1986, and ending June 30, 1986. The due date for the return and payment for that period is July 31, 1986. If the employer made the payment by February 2, 1987, then, under section 6601, interest is not assessable with respect to the underpayment of the hospital insurance taxes. If the employer did not make the payment by February 2, 1987, the interest is assessable for the period from July 31, 1986, until the time of payment.

Lawrence B. Gibbs,

Commissioner of Internal Revenue.

Approved: August 25, 1987.

O. Donaldson Chapoton,

Acting Assistant Secretary of the Treasury.

[FR Doc. 87-20458 Filed 9-3-87; 8:45 am]

BILLING CODE 4830-01-M

26 CFR Parts 41 and 602

[T.D. 8159]

Excise Taxes; Reduction of Heavy Vehicle Use Tax for Foreign-Based Vehicles

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary and final regulations relating to the imposition of the heavy vehicle use tax on foreign-based highway motor vehicles. Changes to the applicable law were made by the Surface Transportation and Uniform Relocation Assistance Act of 1987. The regulations affect owners of highway motor vehicles that have a base for registration purposes in a contiguous foreign country and provide them with the guidance needed to comply with the law. The text of the temporary regulations set forth in this document also serves as the text of the proposed regulations cross-referenced in the Notice of Proposed Rulemaking in the Proposed Rules section of this issue of the **Federal Register**.

EFFECTIVE DATE: The regulations are effective for taxable periods beginning after June 30, 1987.

FOR FURTHER INFORMATION CONTACT: William A. Jackson of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Attention: CC:LR:T (LR-32-87) (202) 566-4336, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

This document contains temporary regulations relating to the imposition of the heavy vehicle use tax on foreign-based highway motor vehicles under section 4481 of the Internal Revenue Code of 1986 (Code), as amended by section 507 of the Highway Revenue Act of 1987 (Title V of the Surface Transportation and Uniform Relocation Assistance Act of 1987) (Pub. L. 100-17, 101 Stat. 260) (Act). The regulations will remain in effect until superseded by final regulations on this subject.

Explanation of Provisions

Section 4481(a) of the Code imposes a tax on the use of any highway motor vehicle that (together with the semitrailers and trailers customarily used in connection with highway motor vehicles of the same type as such highway motor vehicle) has a taxable gross weight of at least 55,000 pounds. For taxable periods beginning after June 30, 1987, section 4481(b) of the Code provides that the heavy vehicle use tax imposed by section 4481(a) shall be paid by the person in whose name the highway motor vehicle is registered, or is required to be registered, under the law of the State or contiguous foreign country in which such vehicle is registered or required to be registered. Section 4483(f) of the Code provides that if the base for registration purposes of any highway motor vehicle is in a contiguous foreign country for any taxable period, the tax imposed by section 4481 for such period shall be 75 percent of the tax that would otherwise be imposed.

Prior to the Act, § 41.4481-1(a)(2) of the regulations provided that for taxable periods after June 30, 1985, any highway motor vehicle that is issued a base plate by a Canadian province under the International Registration Plan (IRP) or similar agreement and has a proportional registration under such agreement to satisfy the registration laws of any of the United States shall be exempt from the tax imposed by section 4481. Under the temporary regulations, this exemption is effective for taxable periods beginning after June 30, 1985, and before July 1, 1987. The temporary regulations further provide under § 41.4481-1(a)(2)(ii) that for taxable periods beginning after June 30, 1987, the tax imposed by section 4481 shall apply to any highway motor vehicle that has a base for registration purposes in a contiguous foreign country upon the first use of such vehicle on the public highways in the United States during such period.

Reduction in Tax for Foreign-based Vehicles

Section 41.4483-7T of the regulations provides that in the case of a highway motor vehicle that has a base for registration purposes in a contiguous foreign country for any taxable period, the tax imposed by section 4481 for such taxable period shall be 75 percent of the tax that would otherwise be imposed. A highway motor vehicle has a base for registration purposes in a contiguous foreign country in any taxable period in which such vehicle is registered under the laws of a contiguous foreign country and is not registered under the laws of any of the United States other than under a proration agreement (such as the International Registration Plan). Further, a highway motor vehicle is not considered to have a base for registration purposes in a contiguous foreign country if the vehicle is registered under the laws of any of the United States and such State is required to receive proof of payment of the tax imposed by section 4481 with respect to such vehicle as a condition for registration in that State.

Proof of Payment for Entry into the United States

Section 41.6001-3T(a) of the regulations generally provides that proof of payment of the heavy vehicle use tax must be presented with respect to any highway motor vehicle subject to the tax imposed by section 4481 that has a base for registration purposes in a contiguous foreign country, upon entry of such vehicle into the United States. Section 41.6001-3T(b) provides generally that if proof of payment of the heavy vehicle use tax is not presented with respect to any highway motor vehicle with a base for registration purposes in a contiguous foreign country upon attempting to enter such vehicle into the United States, such vehicle may be denied entry into the Unites States.

Section 41.6001-3T(a)(2) of the regulations provides that no proof of payment is required to be presented upon entry of a highway motor vehicle into the United States if, as of the date of such entry, the period of time for filing the heavy vehicle use tax return with respect to such vehicle for the taxable period that includes the date of such entry has not expired. Section 41.6001-3T(a)(2) of the regulations further provides that, under this exception to the proof of payment requirement, a written declaration must be presented upon entry into the United States stating that, as of the date of such entry, the period for filing the heavy vehicle use tax return for such vehicle has not expired. Such declaration must include: (1) The name, address, and taxpayer identification number of the person liable for the heavy vehicle use tax imposed on such vehicle; (2) the vehicle identification number of the vehicle; (3) a statement of the date such vehicle was first used on the public highways in the United States during the taxable period; and (4) an acknowledgement by the person liable for the tax that the misuse of the declaration will subject such person to fine or imprisonment. The declaration must be signed by the person liable for the tax imposed on such vehicle and must be retained as part of such person's records.

Section 41.6001-3T(c)(1) of the regulations provides that proof of payment of the heavy vehicle use tax shall consist of a receipted Schedule 1 (Form 2290) that is returned by the Internal Revenue Service to a taxpayer

that files a Form 2290 and pays the amount of tax due with such return. A photocopy of such receipted Schedule 1 shall also serve as proof of payment. In addition, a receipted Schedule 1 (or photocopy thereof) shall serve as proof of suspension of the heavy vehicle use tax under § 41.4483–3 for vehicles for which tax has been suspended. The regulations further provide that the vehicle identification number of any vehicle for which a return is being filed, whether tax is being paid or suspended with respect to such vehicle, must appear on the Schedule 1 (or an attached page) in order for the Schedule 1 to be valid proof of payment for such vehicle. Section 41.6001–3T(c)(2) of the regulations provides that a photocopy of the Form 2290 (with Schedule 1 attached) that is filed with the Internal Revenue Service for a vehicle being entered into the United States with sufficient documentation of payment of the tax due at the time the Form 2290 is filed (such as a photocopy of both sides of a cancelled check) shall be accepted as a substitute proof of payment. The regulations also provide that no documentation of payment of the tax is required with the substitute proof of payment if at the time the Form 2290 is filed the tax is suspended with respect to the vehicle entering the United States.

Special Analysis

No general notice of proposed rulemaking is required by 5 U.S.C. 553(b) for temporary regulations. Accordingly, the Regulatory Flexibility Act does not apply and no Regulatory Flexibility Analysis is required for this rule. The Commissioner of Internal Revenue has determined that this temporary rule is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required.

Paperwork Reduction Act

The collection of information requirements contained in these temporary regulations have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980. These regulations have been approved by OMB.

Drafting Information

The principal author of these regulations is William A. Jackson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations both on matters of substance and style.

List of Subjects

27 CFR Part 41

Excise taxes, Motor vehicles.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Parts 41 and 602 are amended as follows:

PART 41—[AMENDED]

Paragraph 1. The authority for Part 41 is amended by adding the following citation:

Authority: 26 U.S.C. 7805. * * * Section 41.6001–3T also issued under 101 Stat. 260.

Par. 2. Section 41.4481–1 is amended by substituting "1993" for "1988" every place it appears and by revising paragraph (a)(2) to read as set forth below:

§ 41.4481–1 Imposition of tax.

(a) *In general.* * * *

(2)(i) For taxable periods beginning after June 30, 1985, and before July 1, 1987, any highway motor vehicle that is issued a base plate by a Canadian province under the International Registration Plan (IRP) or similar agreement and has a proportional registration under such agreement to satisfy the registration laws of any of the United States shall be exempt from the tax imposed by section 4481(a).

(ii) For each taxable period beginning after June 30, 1987, the tax imposed by section 4481(a) shall apply to any highway motor vehicle that has a base for registration purposes in a contiguous foreign country upon the first use of such vehicle on the public highways in the United States during such period. See § 41.4483–7T relating to a reduction of the tax in the case of a highway motor vehicle that has a base for registration purposes in a contiguous foreign country.

* * * * *

Par. 3. Section 41.4481–3 is amended by revising the first sentence of paragraph (a) (consisting of (a) introductory text, and (a) (1) and (2)) to read as set forth below:

§ 41.4481–3 Registration.

(a) For purposes of the regulations in this part, the term "registered" when used in reference to a highway motor vehicle means—

(1) Registered under the law of any State or Territory of the United States, the District of Columbia, or contiguous foreign country, or

(2) Required to be registered under the law of any State or Territory of the United States or contiguous foreign country in which such highway motor vehicle is operated or situated or, in case the vehicle is operated or situated in the District of Columbia, under the law of the District of Columbia.

* * * * *

Par. 4. Section 41.4482 (c)–1 is amended by substituting "1993" for "1988" every place it appears in paragraph (b).

Par. 5. Section 41.4483–5 is amended by substituting "1993" for "1988" where it appears.

Par. 6. A new § 41.4483–7T is added immediately after § 41.4483–6 to read as follows:

§ 41.4483–7T Reduction in tax for vehicles registered in a contiguous foreign country (temporary).

(a) *In general.* In the case of a highway motor vehicle that, for any taxable period, has a base for registration purposes in a contiguous foreign country, the tax imposed by section 4481 for such taxable period shall be 75 percent of the tax that would be imposed but for this section. A highway motor vehicle has a base for registration purposes in a contiguous foreign country in any taxable period in which such vehicle is registered under the laws of a contiguous foreign country and such vehicle is not registered under the laws of any of the United States other than proportionately registered under a proration agreement (such as the International Registration Plan). A highway motor vehicle is not considered to have a base for registration purposes in a contiguous foreign country in any taxable period in which such vehicle is registered under the laws of any of the United States and such State is required under § 41.6001–2(b) to receive proof of payment of the tax imposed by section 4481(a) with respect to such highway motor vehicle. For purposes of this paragraph (a), a highway motor vehicle that is allowed to operate in a State under a reciprocity agreement is not considered to be registered under the laws of that State.

(b) *Contiguous foreign country.* The term "contiguous foreign country" means Canada or Mexico.

Par. 7. A new § 41.6001–3T is added immediately after § 41.6001–2 to read as follows:

§ 41.6001-3T Proof of payment for entry into the United States (temporary).

(a) *In general.* (1) Except as otherwise provided in paragraph (a)(2) of this section, proof of payment of the tax imposed by section 4481(a) must be presented to United States Customs officials with respect to any highway motor vehicle subject to the tax imposed by section 4481(a) that has a base for registration purposes in a contiguous foreign country upon entry of such vehicle into the United States during any taxable period to which this section applies. Such proof of payment must relate to tax paid (or suspended under § 41.4483-3) for the taxable period that includes the date of entry into the United States. See paragraph (c) of this section for the definition of the term "proof of payment."

(2) No proof of payment is required upon entry of a highway motor vehicle described in paragraph (a)(1) of this section into the United States if, as of the date of such entry, the period of time for filing a return of the tax imposed on such vehicle by section 4481(a) for the taxable period that includes the date of such entry has not expired and a written declaration is presented to United States Customs officials. Such declaration must state that, as of the date of such entry, the period of time for filing a return of the tax imposed on such vehicle by section 4481(a) for the taxable period that includes the date of such entry has not expired. The written declaration must include (i) the name, address, and taxpayer identification number of the person liable under § 41.4481-2 for the tax imposed on such vehicle; (ii) the vehicle identification number of such vehicle; (iii) the date on which such vehicle was first used on the public highways in the United States during the taxable period (or a statement that the current entry is the first use on the public highways in the United States during the taxable period); (iv) an acknowledgment by the person liable for the tax imposed on such vehicle that the willful use of the declaration to evade or defeat the tax otherwise applicable under section 4481(a) will subject such person to a fine or imprisonment or both; and (v) the signature of the person liable for the tax imposed on such vehicle. A copy of the written declaration shall be retained in the records of the person liable for the tax imposed on such vehicle under the rules of § 41.6001-1. See § 41.6071(a)-1 for rules regarding the time for filing a return of the tax imposed by section 4481(a).

(b) *Failure to provide proof of payment.* If, upon attempting to enter the United States, the operator of a highway motor vehicle described in paragraph (a) of this section is unable to present proof of payment of the tax imposed by section 4481(a), or documentation described in paragraph (a)(2) of this section, with respect to such vehicle, then such vehicle may be denied entry into the United States.

(c) *Proof of payment*—(1) *In general.* For purposes of this section, the proof of payment required in paragraph (a) of this section shall consist of a receipted Schedule 1 (Form 2290) that is returned by the Internal Revenue Service to a taxpayer that files a return of tax under section 4481(a) and pays the amount of tax (or installment thereof) due with such return. A photocopy of such receipted Schedule 1 shall also serve as proof of payment. Such proof of payment shall also serve as proof or suspension of the tax under § 41.4483-3 for the number of vehicles entered in that part of the Schedule 1 designated for vehicles for which tax has been suspended. The vehicle identification number of any vehicle for which a return is being filed, whether tax is being paid with respect to such vehicle or tax is suspended on such vehicle, must appear on the Schedule 1 (or an attached page) in order for the Schedule 1 to be a valid proof of payment for such vehicle.

(2) *Acceptable substitute for receipted Schedule 1.* For purposes of this section, a photocopy of the Form 2290 (with the Schedule 1 attached) that is filed with the Internal Revenue Service for a vehicle being entered into the United States with sufficient documentation of payment of tax due at the time the Form 2290 is filed (such as a photocopy of both sides of a cancelled check) shall be accepted as proof of payment. No documentation of payment of tax is required with the substitute proof of payment if at the time the Form 2290 is filed the tax imposed by section 4481(a) is suspended under § 41.4483-3 with respect to the vehicle entering the United States. This substitute proof of payment may be used to enter a vehicle into the United States when, for example, the receipted Schedule 1 has been lost, or if the taxpayer that filed a Form 2290 with respect to such vehicle has not received a receipted Schedule 1 at the time such vehicle enters the United States.

(d) *Taxable periods to which this section applies.* This section shall apply to any taxable period beginning on or after July 1, 1987.

Par. 8. Section 41.6091-1 is amended as follows:

a. The second sentence of paragraph (a) is revised to read as set forth below.

b. The second sentence of paragraph (b) is revised to read as set forth below.

§ 41.6091-1 Place for filing returns.

(a) * * * If the person has no principal place of business or legal residence in any internal revenue district, the return shall be filed with the Internal Revenue Service Center, Philadelphia, PA.

(b) * * * If a corporation has no principal place of business or principal office or agency in any internal revenue district, the return shall be filed with the Internal Revenue Service Center, Philadelphia, PA.

PART 602—[AMENDED]

Par. 9. The authority for 26 CFR Part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 10. Section 602.101(c) is amended by inserting the following item in the appropriate place in the table:

§ 41.6001-3 1545-0143

* * * * *

Lawrence B. Gibbs,
Commissioner of Internal Revenue.

Approved: August 6, 1987.

O. Donaldson Chapoton,
Acting Assistant Secretary of the Treasury.

[FR Doc. 87-20455 Filed 9-3-87; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 161

[CGD 85-076]

Berwick Bay Vessel Traffic Service

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations which apply to towing operations during periods of high water in the area covered by Berwick Bay Vessel Traffic Service (VTS) at Morgan City, Louisiana. A review of recent casualties within the VTS area indicated the need to tailor the regulations to better address the nature of the problems actually experienced. In addition, the present regulations have proven to be complex and difficult to apply. These amendments focus on actual needs and deficiencies, eliminate unreasonable burdens resulting from the present system of determining required horsepower for towboats, and simplify

implementation of the high water limitations.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Michael J. Powers, Office of Navigation, (202) 267-0415.

SUPPLEMENTARY INFORMATION: Berwick Bay VTS (VTS) regulations were originally published on January 5, 1984, to replace a Coast Guard local order outlining procedures to be followed when transiting the VTS. Since publication, meetings between industry representatives and the Coast Guard and the conduct of a study of casualties in the Berwick Bay area highlighted the need to make the regulations more accurately reflect actual operating conditions on the waterway. Changes recommended were published in a Notice of Proposed Rulemaking (NPRM) on January 9, 1987 (52 FR 806) with a sixty day comment period. Two letters were received in response to the NPRM.

Drafting information

The principal persons involved in drafting this final rule are Mr. Michael J. Powers, Project Manager, LCDR Richard E. Ford, PSSTA Houston, and Mr. Stephen H. Barber, Project Counsel, Office of Chief Counsel.

Discussion of Comments

Both of the letters received concurred with the intent of the changes, one specifically saying so and the other not voicing opposition to the substance of the changes. One comment recommended removing the last sentence in the note to § 161.767, which recommends, rather than requires, barges to have draft and beam variations not exceeding 10% of the draft of the barge drawing the most water and 10% of the beam of the widest barge. This recommendation, it is contended, may be construed by vessel operators to have the force of a regulation. The Coast Guard concurs with this recommendation. Therefore, this sentence is removed.

Two comments made recommendations as to the placement of mooring buoys for the fleeting of barges. The Coast Guard is aware of the interest in the placement of mooring buoys in the Berwick Bay area. These comments will be considered should barge fleeting areas be established in the Berwick Bay area.

The Coast Guard is correcting the description, in § 161.768, of the two highway bridges crossing Berwick Bay. This change will reflect that there are two bridges, one is the U.S. Highway 90 bridge, while the other is the LA Route 187 bridge.

Regulatory Evaluation

This final rule is considered to be non-major under Executive Order 12291 and non-significant under the DOT regulatory policies and procedures (44 FR 11034; February 26, 1979). A Regulatory Impact Analysis under Executive Order 12291 is not required. The economic impact of this final rule has been found to be so minimal that further evaluation is unnecessary.

The amendments will affect only towing operations during periods when the High Water Towing Limitations are in effect. These amendments, as do the existing regulations, restrict length, horsepower, and configuration of vessels with tows and may require certain operations to break up tows or add power. However, because the amendments will replace the existing fixed horsepower requirements based on a range of lengths (e.g., 1,200 horsepower for a 400' to 600' range) with a direct horsepower to length requirement, some operations will be permitted to operate with more barges or less available horsepower than permitted under the existing regulations. In other words, depending on the circumstances of the particular operation, the changes will increase the operational costs for some operations but could reduce them for others. Because of the numerous variables from one operation to the next, the overall extent of these benefits and burdens is not precisely quantifiable. No information was received in response to the Coast Guard's specific solicitation for comments on this point. However, an estimate of the savings can be made from the expected decrease in the number of tripping operations that will occur when these changes are implemented.

"Tripping" is the operation whereby a tow too long for the available horsepower of the towing vessel must be broken up into two or more segments for transiting the bridges, and then reassembled. It is known that tripping through the VTS Area can take up to twelve hours and cost an additional $800 to $3,000 in manhours, fuel, and revisions to schedules. If the average tripping cost is $1,900 per trip (midway between $800 and $3,000) and this figure is multiplied by 60 (the estimated number of operations per year that require tripping under the existing regulations but would not require tripping under these amendments), the total savings could be approximately $114,000 per year. However, as mentioned earlier, some operations not requiring tripping under the existing regulations might require it under this final rule.

In any event, the real benefits of this rulemaking are to make the limitations more fair and less arbitrary and to make them easier to understand and apply in the field. Savings which one operator may incur on a particular operation would be, under the broad scheme, only a secondary benefit.

Also, because these amendments are keyed to the results of the Coast Guard study based on actual usage of the VTS Area, these amendments should, in some instances, improve safety but, in all cases, maintain at least the present level of safety without unnecessary "overkill".

No comments were received to the regulatory evaluation in the NPRM.

Regulatory Flexibility Analysis

As discussed above in the final Regulatory Evaluation, these amendments should not have a significant economic effect. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605 (b)) that this final rule will not have a significant economic impact on a substantial number of small entities.

Reporting and Recordkeeping Requirements

This rule contains no reporting or recordkeeping requirements.

Environmental Impact

This action has been thoroughly reviewed by the Coast Guard and it has been determined to be categorically excluded from further environmental documentation, in accordance with Section 2.B.2 (1) of Commandant Instruction (COMDTINST) M16475.1B.

List of Subjects in 33 CFR Part 161

Hazardous materials transportation, Navigation (water), Vessels.

For reasons set forth in the preamble, Title 33, Part 161 of the Code of Federal Regulations is amended as follows:

PART 161—VESSEL TRAFFIC MANAGEMENT

1. The authority citation for Part 161 is revised to read as follows and all other authority citations are removed:

Authority: 33 U.S.C. 1231; 49 CFR 1.46.

2. By revising in the table of contents for Part 161, the entries under Berwick Bay Vessel Traffic Service, High Water Towing Limitations, to read as follows:

* * * * *

Berwick Bay Vessel Traffic Service

* * * * *

High Water Towing Limitations

161.761 Applicability.
161.762 Precautionary notices.
161.764 When limitations are in effect.
161.765 Notice of when limitations are in effect.
161.767 Operational limitations.
161.768 Horsepower limitations.

* * * * *

3. By removing the term "Integrated tow" from § 161.703 and by adding in alphabetical order a definition for the term "length of tow" to read as follows:

§ 161.703 Definitions.

* * * * *

"Length of tow" means the combined length in feet of all barges in the tow, excluding the length of hawsers and the length of the tug.

* * * * *

4. By revising § 161.761 to read as follows:

§ 161.761 Applicability.

The high water towing limitations (§§ 161.761 through 161.768) apply to the operation of vessels with tows intending to transit under the lift span of the SPRR bridge or through the navigational openings of either the U.S. Highway 90 bridge or the LA Route 187 bridge, both to the north of the SPRR bridge, when those limitations are in effect.

5. By revising §§ 161.767 and 161.768 to read as follows:

§ 161.767 Operational limitations.

(a) Towing on a hawser in either direction is prohibited, with the exception of one self-propelled vessel towing one other vessel upbound.

(b) Barges and towing vessels must be arranged in tandem, with the exception of one vessel towing one other vessel alongside.

(c) A towing vessel or vessels and tow must not exceed an overall length of 1,180 feet.

(d) Tows with a box end in the lead must not exceed two barges in length.

Note.—The variation in draft and beam of the barges in a multibarge tow should be minimized in order to avoid unnecessary strain on the coupling wires.

§ 161.768 Horsepower limitations.

(a) All tows carrying a cargo of particular hazard must have available horsepower of at least 600 or three times the length of tow, whichever is greater.

(b) All tows not carrying a cargo of particular hazard must have available horsepower of at least the following:

Direction of transit	Available horsepower for daytime transit	Available horsepower for nighttime transit
Upbound	400 or three times (length of tow minus 300 ft.), whichever is greater	600 or three times (length of tow minus 200 ft.), whichever is greater.
Downbound	600 or three times (length of tow minus 200 ft.), whichever is greater	600 or three times length of tow, whichever is greater.

"Daytime" means sunrise to sunset. "Nighttime" means sunset to sunrise.

(c) A 5% variance from the available horsepower required under paragraphs (a) and (b) of this section is permitted.

(d) Tows with 3,000 or more available horsepower need not comply with paragraphs (a) and (b) of this section.

§ 161.769 [Removed]

6. By removing § 161.769, *Northbound limitations.*

161.770 [Removed]

7. By removing § 161.770, *Extreme high water limitations.*

Dated: August 6, 1987.

Martin H. Daniell,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation.

[FR Doc. 87-20333 Filed 9-3-87; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Parts 166 and 167

[CGD 84-004]

Shipping Safety Fairways; Approach to New York

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This rule establishes two new parallel fairways to connect the Eastern approach off Nantucket and the Eastern approach off Ambrose lanes of the traffic separation scheme (TSS) Off New York. The intended effect of this rule is to enhance navigational safety by providing a corridor free from fixed offshore structures. This action is necessary to allow vessels to navigate safely in the approach to New York. This rule will repromulgate the TSS Off New York under the Ports and Waterways Safety Act (PWSA) and incorporate it into Part 167 Title 33 Code of Federal Regulations. This action is administrative in nature and will make the regulations in 33 CFR Part 167 for PWSA established TSSs applicable to the Off New York TSS (which was originally established prior to the PWSA). This final rule will also renumber the one TSS in 33 CFR Part 167. This action is administrative in nature and will allow TSSs to be numbered according to their geographic area.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Lieutenant (j.g.) Daphne Reese, Project Manager, Office of Navigation (G-NSS-2), Room 1606, U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, DC 20593-0001, (202) 267-0365.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking (NPRM) concerning the shipping safety fairway in this final rule was published on December 8, 1986 (51 FR 44072). Interested parties were given until February 6, 1987, to submit comments. A public hearing was not held.

The Coast Guard is making an administrative change to 33 CFR Part 167 in this final rule which will renumber the Galveston Bay approach TSS and precautionary areas. This change will place all future TSSs in sequence according to their corresponding Coast Guard District. As a result, the section numbers for the Off New York TSS and precautionary areas published in this final rule are different from the section numbers given in the NPRM of December 8, 1986.

Drafting Information

The principal persons involved in drafting this rulemaking are: Lieutenant (j.g.) Daphne Reese, Project Manager, and Lieutenant Sandra Sylvester, Project Attorney, Office of Chief Counsel.

Background

The Ports and Waterways Safety Act (PWSA) (33 U.S.C. 1223) authorizes the Coast Guard to designate shipping safety fairways to allow vessels an area free of fixed structures for safe access to U.S. ports. The regulation governing shipping safety fairways (33 CFR Part 166) provide that fixed offshore structures, temporary or permanent, are not permitted within designated safety fairways, and are only permitted within fairway anchorages if the structures are two miles apart. The shipping safety fairways exist to provide an obstruction

free corridor for navigation during development and production of offshore resources. The Coast Guard also has the authority, in accordance with the PWSA, to modify or relocate existing safety fairways to improve navigation safety or to accommodate offshore mineral exploitation and exploration.

The authority to create a fairway may be exercised by the Coast Guard only after a study of potential traffic density and use conflicts has been conducted to determine the need for designated safe access routes for vessels proceeding to and from U.S. ports. One such conflict can occur when vessels navigate in an area which is subject to offshore development. Shipping safety fairways can interfere with the direct exploration for and production of oil and gas on the Outer Continental Shelf (OCS). In conducting a port access route study, the Coast Guard attempts to recognize and minimize each identifiable cost impact as balanced against the needs of save navigation. The results of a port access route study can cause restrictions in the manner in which specific offshore areas are leased after the date of the study. The study which identified the need for this rulemaking was initiated by a notice in the **Federal Register** on February 9, 1984 (49 CFR Part 5017), and corrected on February 22, 1984 (49 FR 6593).

The Third Coast Guard District performed the study after the Minerals Management Service (MMS) scheduled Outer Continental Shelf (OCS) lease sale 82 for May 9, 1984. The sale included blocks in the area between the existing portions of the Off New York TSS and posed a potentially significant impact on navigation.

Study Results were published in the **Federal Register** on December 13, 1985, (50 FR 50925). The study recommended the TSS Off New York remain as presently established; the lanes of the two sections of the TSS Off New York be connected by two new parallel shipping safety fairways; and the TSS Off New York be repromulgated and published in Part 167 of Title 33, Code of Federal Regulations.

This rulemaking establishes a new shipping safety fairway in the approach to New York. The fairway connects the Eastern approach, off Nantucket segment, of the Off New York TSS to the Eastern approach, off Ambrose segment, of the TSS. The fairway design consists of two parallel fairways, each approximately two-miles wide, except over the final five miles at each end where they gradually expand to connect with the five-nautical-mile-wide lanes of the existing TSS, creating a funneling effect. The fairway runs generally east-west for approximately 130 miles and is located approximately 10 miles offshore (at its closest point). The fairway totally or partially includes the following blocks as described by the MMS:

Mid-Atlantic	No. of blocks
NK 18-12:	
418-419	2
424-437	14
462-480	19
506-509	4
550-551	2
558-570	13
594-614	21
638-643	6
NK 19-10:	
406-423	18
537-555	19
581-599	19
Total	137

North Atlantic	No. of blocks
NK 19-10:	
392-393	2
424-437	14
479-481	3
524-525	2
556-569	14
600-613	14
Total	49

Total Atlantic Blocks Affected = 186

The PWSA stipulates future development of these blocks be in accordance with fairway restrictions based on the announcement of the study for this rulemaking. This new fairway will provide a corridor free from fixed structures for vessel traffic in the approach to New York.

The MMS received only one bid on lease sale 82, which was returned unopened. Lease sale 82 has been cancelled. The MMS has postponed leasing in the North Atlantic until lease sale 96, scheduled for November, 1987. At this time, it is impossible to determine what resources, if any, would be inaccessible as a result of this rulemaking.

The original New York TSS was established in May, 1967 and was approved by the International Maritime Organization (IMO) prior to the promulgation of the PWSA. IMO approved TSSs and precautionary areas established after the PWSA are contained in 33 CFR Part 167. For consistency among TSSs, New York TSS is incorporated into 33 CFR Part 167 by this rulemaking under the authority of the PWSA. Eventually, all other pre-PWSA TSSs will be incorporated into 33 CFR Part 167 by rulemaking.

This rulemaking also renumbers the Galveston approach TSS in 33 CFR Part 167 from 33 CFR 167.100 to 33 CFR 167.350. This action is administrative in nature and will allow all TSSs in Part 167 to have section numbers according to geographic area. The section numbers given in this final rule for the Off New York TSS reflect this administrative change in numbering.

Discussion of Comments

One comment was received in response to the NPRM. The comment was in favor of the rulemaking and was from a maritime trade association. The comment supported the rulemaking as published because it will "increase navigational safety by providing a corridor free from fixed offshore structures and have the least impact on development of the OCS." Based on a review of the need for our proposal and the comment to the NPRM, the Coast Guard believes the shipping safety fairway in the approach to New York is necessary.

Regulatory Evaluation

This rulemaking will not have adverse environmental impact. To the contrary, the risk of environmental damage will decrease because vessels will have an established access route where structures will not be permitted, allowing for safer maritime navigation. While there is potential energy impact from this rulemaking, none has been identified or can be determined from the available information.

The Coast Guard is directed by the PWSA to anticipate development on the OCS and to reconcile the potential conflict with navigation by establishing routing measures in frequently used corridors. The fairway was designed to have the least adverse impact upon future blocks and leaseholders. Although shipping safety fairways may interfere with direct exploration and production of oil and gas on the OCS, there is no indication that the establishment of this fairway will interfere with OCS development. The precise location of resources in the fairways is unknown; the outcome of future lease sales on blocks within the fairway is uncertain; and indirect access to resources is technically feasible through most of the two-mile-wide fairway.

When there is evidence fixed structures must be placed in an area designated as a fairway to gain access to significant quantities of oil or gas, a request for an adjustment to a fairway will be given the appropriate consideration by the Coast Guard. The request will be handled in accordance with the PWSA and rulemaking procedures to determine whether navigation safety will be jeopardized by a modification of the fairway. In most cases a fairway modification will

require a PWSA port access study before rulemaking can be commenced.

This shipping safety fairway will overlay traditional traffic routes and will not alter applicable navigation rules or cause interference with fishing activities.

These regulations are considered to be non-major under Executive Order 12291 and non-significant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). This designation will contribute to navigation safety without significantly interfering with development of the OCS. The economic impact of this regulation has been found to be minimal and further evaluation is unnecessary. Since the impact of this rulemaking has been found to be minimal, the Coast Guard certifies it will not have a significant economic impact on a substantial number of small entities.

List of Subjects

33 CFR Part 166

Anchorage grounds, Marine safety, Navigation (water), Waterways, Shipping safety fairways.

33 CFR Part 167

Navigation (water), Vessel, Traffic Separation Scheme.

In consideration of the foregoing, Parts 166 and 167 of Title 33, Code of Federal Regulations are amended as follows:

PART 166—SHIPPING SAFETY FAIRWAYS

1. The authority citation for Part 166 continues to read as follows:

Authority: 33 U.S.C. 1223; 49 CFR 1.46(n)(4).

2. Section 166.500 is added to read as follows:

§ 166.500 Areas along the Atlantic Coast.

(a) *Purpose.* Fairways, as described in this section are established to control the erection of structures therein to provide safe vessel routes along the Atlantic Coast.

(b) *Designated areas.*—(1) *Off New York Shipping Safety Fairway.*

(i) Ambrose to Nantucket Safety Fairway. The area enclosed by rhumb lines, [North American Datum of 1927 (NAD-27)], joining points at:

Longitude	*Longitude*
40°32.20'N	73°04.57'W
40°30.58'N	72°58.25'W
40°34.07'N	70°19.23'W
40°35.37'N	70°14.09'W
40°30.37'N	70°14.00'W
40°32.07'N	70°19.19'W
40°28.58'N	72°58.25'W
40°27.20'N	73°04.57'W

(ii) Nantucket to Ambrose Safety Fairway. The area enclosed by rhumb lines, NAD-27, joining points at:

Latitude	*Longitude*
40°24.20'N	73°04.58'W
40°22.58'N	72°58.26'W
40°26.07'N	70°19.09'W
40°27.37'N	70°13.46'W
40°22.37'N	70°13.36'W
40°24.07'N	70°19.05'W
40°20.58'N	72°58.26'W
40°19.20'N	73°04.58'W

PART 167—OFFSHORE TRAFFIC SEPARATION SCHEMES

3. The authority citation for Part 167 is amended to read as follows:

Authority: 33 U.S.C. 1223; 49 CFR 1.46(n).

§ 167.100 [Redesignated as § 167.350].

4. In Subpart B, § 167.100 is redesignated as § 167.350 and an undesignated heading is added preceeding § 167.350 to read as follows:

Atlantic Gulf Coast

* * * * *

5. In Part 167, the heading of Subpart B is revised to read as follows:

Subpart B—Description of Traffic Separation Schemes and Precautionary Areas. (All geographic positions are based on North American Datum of 1927)

6. In Subpart B, an undesignated heading and §§ 167.150 to 167.155 are added to read as follows:

Atlantic East Coast

§ 167.150 Off New York Traffic Separation Scheme and Precautionary Areas.

The specific areas in the Off New York Traffic Separation Scheme and Precautionary Areas are described in §§ 167.151, 167.152, 167.153, 167.154, and 167.155 of this chapter.

§ 167.151 Precautionary areas.

(a) A circular precautionary area with a radius of seven miles is established centered upon Ambrose Light in geographical position 40°27.50'N, 73°49.90'W.

(b) A precautionary area is established between the traffic separation scheme "Eastern Approach, off Nantucket" and the traffic separation scheme "In the Approach to Boston, Massacnusetts." (1) The precautionary area is bounded to the east by a circle of radius 15.5 miles, centered upon geographical position 40°35.00'N, 69°00.00'W, and is intersected by the traffic separation schemes "In the Approach to Boston, Massachusetts" and "Off New York" at the following geographic positions:

Latitude	*Longitude*
40°50.33'N	68°57.00'W
40°23.75'N	69°14.63'W

(2) The precautionary area is bounded to the west by a line connecting the two traffic separation schemes between the following geographical positions:

Latitude	*Longitude*
40°36.75'N	68°15.16'W
40°48.00'N	69°03.33'W

§ 167.152 Eastern approach, off Nantucket.

(a) A separation zone is established bounded by a line connecting the following geographical positions:

Latitude	*Longitude*
40°28.75'N	69°14.83'W
40°27.62'N	70°13.77'W
40°30.62'N	70°14.00'W
40°31.75'N	69°14.97'W

(b) A traffic lane for westbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°36.75'N	69°15.17'W
40°35.62'N	70°14.15'W

(c) A traffic lane for eastbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°22.62'N	70°13.60'W
40°23.75'N	69°14.63'W

§ 167.153 Eastern approach, off Ambrose Light.

(a) A separation zone is established bounded by a line connecting the following geographical positions:

Latitude	*Longitude*
40°24.33' N.	73°04.97' W.
40°24.20' N.	73°11.50' W.
40°26.00' N.	73°40.93' W.
40°27.00' N.	73°40.75' W.
40°27.20' N.	73°11.50' W.
40°27.33' N.	73°04.95' W.

(b) A traffic lane for westbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°32.33' N.	73°04.95' W.
40°32.20' N.	73°11.50' W.
40°28.00' N.	73°40.73' W.

(c) A traffic lane for eastbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°25.05' N.	73°41.32' W.
40°19.20' N.	73°11.50' W.
40°19.33' N.	73°04.97' W.

§ 167.154 South-eastern approach.

(a) A separation zone is established bounded by a line connecting the following geographical positions:

Latitude	*Longitude*
40°03.10′ N.	73°17.93′ W.
40°06.50′ N.	73°22.73′ W.
40°22.45′ N.	73°43.55′ W.
40°23.20′ N.	73°42.70′ W.
40°24.20′ N.	73°04.58′ W.
40°08.72′ N.	73°20.10′ W.

(b) A traffic lane for north-westbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°08.98′ N.	73°10.87′ W.
40°12.42′ N.	73°15.67′ W.
40°24.02′ N.	73°41.97′ W.

(c) A traffic lane for south-eastbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°21.82′ N.	73°44.55′ W.
40°02.80′ N.	73°27.15′ W.
39°59.43′ N.	73°22.35′ W.

§ 167.155 Southern approach.

(a) A separation zone is established bounded by a line connecting the following geographical positions:

Latitude	*Longitude*
39°45.70′ N.	73°48.00′ W.
40°20.63′ N.	73°48.33′ W.
40°20.87′ N.	73°47.07′ W.
39°45.70′ N.	73°44.00′ W.

(b) A traffic lane for northbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
39°45.70′ N.	73°37.70′ W.
40°21.25′ N.	73°45.85′ W.

(c) A traffic lane for southbound traffic is established between the separation zone and a line connecting the following geographical positions:

Latitude	*Longitude*
40°20.53′ N.	73°49.65′ W.
39°45.70′ N.	73°54.40′ W.

Note.—Use of LORAN C enables masters of appropriately equipped vessels to be informed highly accurately and continuously about the vessel's position in the area covered by this scheme.

7. In Part 167, the table of contents for Subpart B is revised to read as follows:

Subpart B—Description of Traffic Separation Schemes and Precautionary Areas. (All geographic positions are based on North American Datum of 1927).

Atlantic Coast East

Sec.
167.150 Off New York Traffic Separation Scheme and Precautionary Areas.
167.151 Precautionary areas.
167.152 Eastern approach, off Nantucket.
167.153 Eastern approach, off Ambrose Light.
167.154 South-eastern approach.
167.155 Southern approach.

Atlantic Gulf Coast

167.350 Galveston Bay Approach Traffic Separation Scheme and Precautionary Areas.

Dated: July 31, 1987.

A.B. Smith,

Captain, U.S. Coast Guard, Acting Chief, Office of Navigation.

[FR Doc. 87-20334 Filed 9-3-87; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-5-FRL-3250-3]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Final rulemaking.

SUMMARY: Today's final rulemaking pertains to rules developed by Indiana to satisfy the Clean Air Act's (ACT) Reasonably Available Control Technology (RACT) requirements for Stage I Gasoline Dispensing Regulations. USEPA's final approval of this action is based upon a revision which was submitted by the State to satisfy the requirements of Part D of the ACT and USEPA's October 27, 1982 (47 FR 47554) and February 10, 1986 (51 FR 4912), conditional approval of Indiana's plan.

EFFECTIVE DATE: This final rulemaking becomes effective on October 5, 1987.

ADDRESSES: Copies of the SIP revision, public comments on the notice of proposed rulemaking and other materials relating to this rulemaking are available for inspection at the following addresses: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V Office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604

Office of Air Management, Indiana Department of Environmental Management, 105 South Meridian Street, P.O. Box 6015, Indianapolis, Indiana 46206-6015

A copy of today's revision to the Indiana SIP is also available for inspection at:

U.S. Environmental Protection Agency, Public Information Reference Unit, 401 M Street, SW., Washington, DC 20460

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, (312) 886-6031.

SUPPLEMENTARY INFORMATION:

Part I—Background

Under section 107 of the Clean Air Act, USEPA has designated certain areas in Indiana as not attaining the National Ambient Air Quality Standards (NAAQS) for ozone. See 43 FR 8962 (March 3, 1978), and 43 FR 45993 (October 5, 1978). Part D of the ACT requires the State to revise its SIP to meet specific requirements for areas designated as nonattainment. These SIP revisions must demonstrate attainment of the ozone NAAQS as expeditiously as practicable, but not later than December 31, 1982 (in certain cases by December 31, 1987). The requirements for an approvable SIP are described in a General Preamble for Part D Rulemaking published on April 4, 1979 (44 FR 20372), and at 44 FR 38583 (July 2, 1979), 44 FR 50371 (August 28, 1979), 44 FR 53761 (September 17, 1979), and 44 FR 67182 (November 23, 1979).

An adequate SIP for ozone is one that includes sufficient control of VOC emissions for stationary and mobile sources to provide for attainment of the ozone standard. For stationary sources, the plan must include, at a minimum, legally enforceable requirements reflecting the application of RACT for those sources for which USEPA has published Control Technique Guidelines (CTGs).[1] In general, where the State regulations are not supported by the information in the CTGs, the State must provide a demonstration that its regulations represent RACT or amend the regulations to be consistent with the information in the CTGs.

In response to the requirements of Part D of the Act, the State of Indiana revised its SIP to require control of VOC emissions from the stationary industrial sources addressed in USEPA's Group I CTGs. On February 11, 1980, the State submitted to USEPA a revision to the ozone portion of its SIP for the Group I sources of VOC emissions. USEPA took final action to conditionally approve the Group I sources' regulations on October 27, 1982 (47 FR 47552).[2]

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[1] CTGs published before January 1, 1978, are referred to as "Group I CTGs" and pertain to "Group I Sources", and CTGs published between January 1, 1978, and January 1, 1979, are "Group II CTGs" and pertain to "Group II Sources".

[2] For more detail on conditional approvals, see 44 FR 38583 (July 2, 1979), and 44 FR 38583 (November 23, 1979).

On November 25, 1980, the State submitted to USEPA as a revision to its ozone SIP, amendments to its VOC regulation, now codified as 325 IAC Article 8,[3] which controlled VOC emissions from the Group II sources. USEPA took final action to conditionally approve this revision on January 18, 1983 (48 FR 2124). Both of the conditional approvals were based upon a commitment from the State to correct deficiencies in the regulation.

In response to these conditional approvals, on November 7, 1984, Indiana promulgated revised VOC regulations 325 IAC 8-1.1, 8-2, 8-3, 8-4, and 8-5. The State submitted these revisions to USEPA on July 3, 1984, and January 30, 1985, to satisfy certain conditions of USEPA'a approval. In addition, the applicability of the regulations was extended to cover St. Joseph and Elkhart Counties. On February 10, 1986 (51 FR 4912), USEPA approved Indiana's revised VOC RACT I and II regulations and the St. Joseph and Elkhart Counties RACT regulations, leaving two RACT deficiencies for future rulemaking. Today's final rulemaking concerns one of the remaining outstanding conditional approval items, which pertain to Stage I vapor control recovery systems at gasoline dispensing facilities. This condition was set forth in the October 27, 1985, **Federal Register** and was later cited in the February 10, 1986, **Federal Register.** This condition was codified at 40 CFR 52.777(c)(1)(i) and reads as follows:

(c)(1) The plan for stationary source volatile organic compound control must contain the following:

(i) For regulation 325 IAC 8-4, Petroleum Sources, the State must conduct a study to demonstrate that the 20,000 gallons per months [SIC] throughput exemption meets RACT requirements and submit the results to EPA within 6 months of the effective date of final rulemaking on Group I CTG source categories. If the demonstrated emissions resulting from the State's exemption are not essentially equivalent to those resulting from the RACT requirements, then the State must submit to EPA a rule which requires control of emissions from storage tanks at gasoline dispensing facilities with either 10,000 gallons per month [SIC] or more throughput or 2,000 gallons capacity.

[3] On October 6, 1980, the State resubmitted 1980 APC 15, recodified as 325 IAC Article 8. USEPA approved the State's recodification, but not the underlying regulations, on July 16, 1982 (47 FR 30972). On January 18, 1983, when USEPA codified its conditional approval of the RACT II regulations, it additionally revised the codification of the conditions of its October 27, 1982, approval of the RACT I regulation, 1980 APC 15, to reflect Indiana's recodification of that regulation to 325 IAC Article 8.

In response to this condition, Indiana chose to lower the throughput exemption to 10,000 gallons per month. The Indiana Air Polution Control Board (Board) submitted revised rules incorporating this change to USEPA on January 23, 1986. This submittal consisted of revised Rule 325 IAC 8-4-6 (requirements for gasoline dispensing facilities State I vapor recovery systems) and revised Rule 8-1.1-3, which includes subsections (f), (g), and (h) (compliance date extensions for gasoline dispensing facilities). On October 24, 1986, USEPA published a notice of proposed rulemaking proposing to approve the variance request for Indiana's Stage I Vapor Recovery Rules (51 FR 37758). During the 30-day public comment, USEPA received no comments. Today, USEPA is approving Indiana's revised rules. These revised rules are discussed in Part II of this notice.

Part II—Description of the Revisions and USEPA's Evaluation of Them

Rule 325 IAC 8-4-6, Gasoline Dispensing Facilities was amended to reflect the minimum throughput of 10,000 gallons per month for gasoline dispensing facilities that would be subject to the RACT regulations. The amendment of this rule changes it such that it conforms with USEPA's CTG and, thus, satisfies one of the requirements of the conditional approval of the Part D Plan for ozone in Indiana (51 FR 4913). USEPA is approving the revised Rule 325 IAC 8-4-6.

Rule 325 IAC 8-1.1-3 (f) and (g) were revised and new paragraph (h) was added to revise the compliance schedule portion of all rules such that a reasonable time was given for sources between 10,000 and 20,000 gallons per month to come into compliance, i.e., December 31, 1987. This rule has no effect on Indiana's new source review requirements.

USEPA is approving these subsections for the following reasons: (1) They require an expeditious compliance schedule for sources with throughputs from 10,000 gallons per month to 20,000 gallons per month; and (2) the compliance schedules are generally consistent with the amount of time that sources have been given to comply with VOC RACT I and RACT II regulations. USEPA is approving revised rules 325 IAC 8-4-6 and 325 IAC 8-1.1-3.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 3, 1987. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone.

Note.—Incorporation by reference of the State Implementation Plan for the State of Indiana was approved by the Director of the Federal Register on July 1, 1982.

Dated: August 17, 1987.

A. James Barnes,

Acting Administrator.

Title 40 of the Code of Federal Regulations, Chapter I, Part 52, Subpart P, is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart P—Indiana

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.770 is amended by adding new paragraph (c)(63) to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

(63) On January 23, 1986, the State submitted revisions to its Stage I Gasoline Dispensing regulations, which replace those conditionally approved at (c)(33), (C)(35)—Codification only, and (C)(55).

(i) *Incorporation by reference.* (A) Letter of January 23, 1986 to EPA from the State of Indiana, and Title 325 Air Pollution Control Board Rule 325 IAC 8-4-6, Gasoline Dispensing Facilities, which was promulgated on January 14, 1986.

(B) Title 325 Air Pollution Control Board Rule 8-1.1-3, Compliance Schedules, subsections (f), (g), and (h), which was promulgated on January 14, 1986.

§ 52.777 [Amended]

3. Section 52.777 is amended by removing and reserving paragraph (c)(1)) (i).

[FR Doc. 87-19311 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[A-4-FRL-3238-6; KY-033]

Approval and Promulgation of Implementation Plans; Kentucky; Stack Height Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, EPA is approving revisions to the Kentucky State Implementation Plan (SIP) submitted to EPA on July 15, 1986. Kentucky has revised its SIP to include regulations for good engineering practice stack height. These regulations are equivalent to EPA requirements promulgated at Part 51 of Chapter I, Title 40, of the Code of Federal Regulations.

DATE: This action will be effective on November 3, 1987, unless notice is received within 30 days that adverse or critical comments will be submitted.

ADDRESSES: Copies of the materials submitted by Kentucky may be examined during normal business hours at the following locations:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

Air Programs Branch, Region IV, Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365

Kentucky Natural Resources and Environmental Protection Cabinet, 18 Reilly Road, Building #2, Fort Boone Plaza, Frankfort, Kentucky 40601

FOR FURTHER INFORMATION CONTACT: Beverly T. Hudson, EPA, Region IV, Air Programs Branch at the above listed address, telephone (404) 347-2864 or FTS 257-2864.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 1985 (50 FR 27892), EPA published final regulations to implement section 123 of the Clean Air Act (CAA), which regulates the manner in which dispersion of pollutants from a source may be considered in setting emission limitations. Pursuant to these regulations and the Clean Air Act Amendments of 1977, all states were required to (1) review and revise, as necessary, their state implementation plans (SIPs) to include provisions that limit stack height credit and dispersion techniques in accordance with the revised regulations and (2) review all existing emission limitations to determine whether these limitations have been affected by stack height credits above GEP or any other dispersion techniques. For any limitations so affected, states were to prepare revised limitations consistent with their revised SIPs. All SIP revisions and revised emission limits were to be submitted to EPA within nine months of promulgation.

Subsequently, EPA issued detailed guidance on carrying out the necessary reviews. For review of emission limitations, states were to prepare inventories of stacks greater than 65 meters in height and sources with emissions of sulfur dioxide (SO_2) in excess of 5,000 tons per year. These limits correspond to the *de minimis* GEP stack height and the *de minimis* SO_2 emission exemption from prohibited dispersion techniques. These sources were then subjected to detailed review for conformance with the revised regulations. State submissions were to contain an evaluation of each stack and source in the inventory.

State Submission

On July 15, 1986, the Kentucky Natural Resources and Environmental Protection Cabinet submitted State Implementation Plan revisions for good engineering practice stack height. A public hearing was held on these revisions on May 17, 1986. The regulations as proposed became effective on June 10, 1986.

These regulations (401 KAR 50:042) limit the amount of stack height or dispersion credit (dispersion techniques) a source can claim in the process of establishing its emission limitation. Dispersion techniques include the use of stack heights greater than 65 meters and use of other techniques to increase the dispersion of emissions rather than continously reducing emissions from a source. These regulations do not limit the physical stack height of any source, or the actual use of dispersion techniques at a source, nor do they require any specific stack height for any source. Instead, they set limits on the maximum credit for stack height and other dispersion techniques to be used in ambient air modeling for the purpose of setting an emission limitation and calculating the air quality impact of a source. Sources are modeled at their actual physical stack height unless that height exceeds their GEP stack height. The regulations apply to all stacks not in existence on December 31, 1970, and all dispersion techniques implemented since December 31, 1970. The regulation applies to both new and existing sources, thereby satisfying requirements for state new source review regulations at 40 CFR 51.164.

Kentucky has adopted definitions corresponding to EPA's GEP regulations. The State's regulations define a number of specific terms, including, "excessive concentration," "dispersion techniques," and "nearby." Kentucky's revisions bring their existing regulations into conformance with the federal stack height rule. The State will submit their final revised emission limits for those sources affected under the new stack height regulations at a later date.

Final Action

EPA has reviewed the submittal and found it to be in conformance with EPA's stack height requirements. Therefore, EPA is today approving Kentucky's regulations on stack height.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial issue and anticipates no adverse comments. This action will be effective 60 days from the date of this **Federal Register** notice unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective November 3, 1987.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 3, 1987. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control, Intergovernmental relations, Incorporation by reference.

Note.—Incorporation by reference of the Kentucky State Implementation Plan was approved by the Director of the **Federal Register** on July 1, 1982.

Dated: July 21, 1987.

Lee M. Thomas,

Administrator.

Part 52 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart S—Kentucky

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.920 is amended by adding paragraph (c)(47) to read as follows:

§ 52.920 Identification of plan.

* * * * *

(c) * * *

(47) Stack height regulations were submitted to EPA on July 15, 1986, by the Kentucky Natural Resources and Environmental Protection Cabinet.

(i) *Incorporation by reference.* (A) Regulation 401 KAR 50:042, which became effective on June 10, 1986.

(ii) Other material—none.

[FR Doc. 87-16951 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 86-447; RM-5427 and 5757]

Radio Broadcasting Services; Newberry and Munising, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allocates FM Channel 250C2 to Newberry, Michigan, as that community's second FM service in response to a petition filed by Leon B. Van Dam. In response to a counterproposal filed by Munising Radio, Inc., we shall substitute FM Channel 252C2 for Channel 252A at Munising, Michigan and modify the license of Station WQXO(FM), to specify operation on Channel 252C2. Concurrence of the Canadian government has been obtained for the allocation of both channels. With this action, this proceeding is terminated.

DATES: Effective October 13, 1987. The window period for filing applications for Channel 250C2 at Newberry, Michigan will open on October 14, 1987, and close on November 13, 1987.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 86-447, adopted August 6, 1987, and released August 28, 1987. 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 contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments for Michigan is amended by removing Channel 252A and adding 252C2 at Munising, and by adding Channel 250C2 at Newberry.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-20434 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 86-437; RM-5392]

Radio Broadcasting Services; Warsaw, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allocates Channel 229A to Warsaw, Missouri, as that community's second FM broadcast service, in response to a petition filed by Mid-Mo Broadcasting Company. There is a site restriction 1 kilometer northwest of the community. With this action, this proceeding is terminated.

DATES: Effective October 13, 1987. The window period for filing applications will open on October 14, 1987, and close on November 13, 1987.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 86-437, adopted July 30, 1987, and released August 28, 1987. 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 contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. In § 73.202(b), the Table of FM Allotments is amended under Warsaw, Missouri, by adding Channel 229A.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-20435 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611 and 663

[Docket No. 70101-7001]

Pacific Coast Groundfish Fishery

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

ACTION: Notice of final reassessment.

SUMMARY: NMFS issues this notice announcing the final reassessment of domestic annual harvest (DAH) and domestic annual processing (DAP) for Pacific whiting taken in the exclusive economic zone (EEZ) off the coasts of Washington, Oregon, and California. Of the 39,000 metric tons (mt) of Pacific whiting in the reserve, 2,250 mt will be added to DAH to accommodate additional joint venture processing (JVP) needs, and the remaining 36,750 mt will be added to the total allowable level of foreign fishing (TALFF). This action will allow the Department of State to allocate additional tonnage of Pacific whiting to foreign countries, if appropriate.

EFFECTIVE DATE: September 1, 1987.

FOR FURTHER INFORMATION CONTACT: Rolland A. Schmitten (Director, Northwest Region, NMFS), 206-526-6150.

SUPPLEMENTARY INFORMATION: A notice of preliminary reassessment and request for comments was published in the **Federal Register** on August 10, 1987 (52 FR 29528). This notice discussed the results of an industry survey conducted in June 1987 to reassess the 1987 fishing year initial specifications for Pacific whiting (52 FR 682, January 8, 1987), and announced NMFS' intent to add 2,250 mt to DAH for projected JVP needs for the remainder of the fishing year. The remaining 36,750 mt of the 39,000 mt reserve surplus to domestic needs will be released to TALFF. Domestic annual processing (DAP) and optimum yield (OY) would not change. No comments were received during the public comment period for this notice.

The Pacific Fishery Management Council considered the preliminary reassessment at its July 8–10, 1987 meeting and recommended release of the Pacific whiting reserve to TALFF, since at that time no firm commitments had been made for any portion of the projected increase to go to JVP needs. Total allowable level of foreign fishing will be increased from 27,000 to 63,750 mt, the total amount request by foreign nations, and JVP will be increased from 114,000 to 116,250 mt to allow for later commitments.

This notice hereby announces revised specifications for Pacific whiting as follows: OY—195,000 mt (no change), DAH—131,250 mt, DAP—15,000 mt (no change), JVP—116,250 mt, TALFF—63,750 mt, and Reserve—0 mt. Performance of the foreign fleet in taking the first half-year allocation of whiting will largely determine whether NMFS recommends that the Department of State allocate all or part of the added TALFF to foreign fishermen.

Classification

Release of the Pacific whiting reserve to TALFF is based on the most recent data available. The action is authorized by 50 CFR 611.70(d) (1) and (2), is in compliance with Executive Order 12291, and is covered by the regulatory flexibility analysis and environmental impact statement prepared for the authorized regulations.

List of Subjects

50 CFR Part 611

Fisheries, Foreign relations, Reporting and recordkeeping requirements.

50 CFR Part 663

Fishing, Fisheries, Reporting and recordkeeping requirements.

(16 U.S.C. 1801 *et seq.*)

Dated: September 1, 1987.

Bill Powell,

Executive Director, National Marine Fisheries Service.

[FR Doc. 87-20431 Filed 9-1-87; 3:02 pm]

BILLING CODE 3510-22-M

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50 CFR Part 642

[Docket No. 70605-7141]

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic

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

ACTION: Final rule; correction.

SUMMARY: This document corrects the commercial quotas for the Gulf migratory group of king mackerel that appeared in the **Federal Register** on July 2, 1987 (52 FR 25012).

SUPPLEMENTARY INFORMATION: NOAA published a final rule on July 2, 1987 (52 FR 25012) to change the total allowable catch and bag limits for king and Spanish mackerel. Under the fishery management plan for coastal migratory pelagic species, the quotas for the eastern and western zones of the commercial fishery for the Gulf migratory group of king mackerel are determined in accordance with fixed percentages. To adhere to these percentages, calculations should be rounded to the nearest hundredth of a million pounds. The eastern and western zone quotas contained in the final rule published July 2, 1987, were incorrect as a result of having been rounded to the nearest tenth of a million pounds. This rule corrects that error by respecifying the quota for the eastern zone as 0.48 million pounds and for the western zone as 0.22 million pounds.

The following corrections are made in rule document 87-15112 on page 25013, column 3:

§ 642.21 [Corrected]

1. In § 642.21(a)(1)(i), change "0.5" to "0.48".

2. In § 642.21(a)(1)(ii), change "0.2" to "0.22".

(16 U.S.C. 1801 et seq.)

Dated: September 1, 1987.

James E. Douglas, Jr.,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 87-20432 Filed 9-3-87; 8:45 am]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

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.

FEDERAL HOME LOAN BANK BOARD

12 CFR Ch. V

[No. 87-941]

Regulations Required by the Competitive Equality Banking Act of 1987

Date: August 28, 1987.

AGENCY: Federal Home Loan Bank Board.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Federal Home Loan Bank Board ("Board") is issuing this advance notice of proposed rulemaking to inform the public of its intention to promulgate regulations required by the Competitive Equality Banking Act of 1987 ("CEBA" or "Act"). Within 2 to 6 months of the date of CEBA's enactment, the Board is required to issue regulations or guidelines in the following areas: qualified thrift lender test; classification of assets; appraisals; uniform generally accepted acounting principles ("GAAP"); gain and loss deferrals; capital forbearance; minimum capital requirements; procedures setting the limits for approval or disapproval of applications submitted to the Board; and asset disposition. The Board is requesting comment on these areas and others to assist it in implementing the requirements of the CEBA. Additionally, the Board is soliciting comment on the possible promulgation of other regulations not covered by this notice as well as amendments to existing regulations that may be necessary to implement the provisions of the Act in the most effective way.

DATE: Comments must be received on or before October 5, 1987.

ADDRESS: Send comments to Director, Information Services Section, Office of the Secretariat, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552. Comments will be available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Christina M. Gattuso, Acting Regulatory Counsel, (202) 377-6649; Carol J. Rosa, Paralegal Specialist, (202) 377-7037; or Karen Knopp O'Konski, Acting Director, (202) 377-7240, Regulations and Legislation Division, Office of General Counsel, Federal Home Loan Bank Board, at the above address.

SUPPLEMENTARY INFORMATION:

A. Background

The Competitive Equality Banking Act of 1987, Pub. L. No. 100-86, 101 Stat. 552, was signed into law on August 10, 1987. The purpose of the CEBA is to facilitate the provision of additional financial resources to the Federal Savings and Loan Insurance Corporation ("FSLIC") and, for purposes of strengthening the reserves of the FSLIC, to establish a forbearance program for thrift institutions, and to provide additional congressional oversight of the Board and the Federal Home Loan Bank System. This advance notice of proposed rulemaking sets forth a list of the regulations and guidelines to be promulgated by the board pursuant to the Act. Part 1 of the list contains regulations and guidelines that the CEBA explicitly requires the Board to Implement within specified deadlines. Part 2 contains regulations and guidelines that the Board is required, without a time deadline, to promulgate. Part 3, entitled "Other Board Action," lists new regulations, amendments to existing regulations, or guidelines that may be required by the CEBA to implement provisions of the Act.

As indicated above, the CEBA requires the Board to implement certain regulations and guidelines within specified deadlines ranging from 60 days to 6 months from August 10, 1987, the date of enactment of the Act. In addition, the CEBA requires the Board to submit to Congress no later than November 8, 1987, proposed regulations in some of the areas mentioned above. The Board intends to issue, as promptly as possible, regulations addressing those areas listed below in Parts 1 and 2. The Board will, consistent with the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*, seek and consider public comment on those regulations. Because of the statutorily mandated deadline for publication of final rules on certain subjects, the Board will probably set a 30-day comment period on its proposed rules in those areas set forth in the footnote.[1]

Today, the Board is soliciting general comment on the most effective way to implement the requirements of the CEBA. The Board requests that interested parties identify specific substantive and procedural issues that should be addressed in formal notices of proposed rulemaking concerning implementation of those regulations and guidelines listed in Parts 1 and 2, below. Finally, the Board is soliciting comment on the possible promulgation of other regulations not covered by this notice as well as amendments to existing regulations in order implement provisions of the Act effectively. Because of the statutorily mandated deadlines established by the CEBA, the Board is adopting a 30-day comment period for public response to this notice. The Board notes that, to the extent possible, it will consider all comments received on this notice prior to issuing any proposed regulations. However, to the extent statutorily imposed deadlines preclude consideration of all such comments prior to issuance of the proposed regulations, the Board will consider such comments, in addition to comments received on the proposed regulations, prior to the issuance of any final regulations. The Board encourages all interested parties to consult the CEBA and to comment on any aspect of this notice.

The Board notes that the CEBA directs it specifically to issue rules on classification of assets, appraisal standards, and accounting standards that are consistent with what is required by the Federal banking regulatory agencies. CEBA, sections 402(a) and (b). The banking regulators have not, however, published rules with respect either to classification of assets or appraisal standards. Therefore, the Board invites commenters specifically to address how it might best comply with the statutory mandate to achieve conformity with the banking regulators.

[1] A 30-day comment period will probably apply to proposals on: classification of assets, appraisals, accounting rules, capital forbearance, and implementation of the qualified thrift lender test. The Board will probably publish proposals in each of these areas in the Federal Register by October 9, 1987.

B. Board Action under the CEBA

1. Mandatory Board Action

Title I

a. Section 104—Qualified Thrift Lender ("QTL") test—Regulations to define terms and implement the requirements of the QTL test. Regulations which tie Federal Home Loan Bank ("FHLBank") advances to members' ability to meet the QTL test.

Deadline: Institutions have until January 1, 1988, to satisfy the QTL test.

Title IV

b. Section 402—Regulations on classification of assets; appraisal standards; reappraisal upon foreclosure; use of the Statements of Financial acconting Standards No. 5 and No. 15 for troubled debt restructurings; uniform GAAP accounting; asset evaluations; and loan loss deferrals.[2]

Deadline: Must be "implemented" by January 7, 1988; except that GAAP accounting rule "shall take effect" on December 31, 1987. Proposals due to Congress by November 8, 1987.

c. Section 404—Regulations implementing Capital Forbearance provisions.

Deadline: Regulations must be "implemented" by January 7, 1988. Proposal due to Congress by November 8, 1987.

d. Section 410—Guidelines for approval and disapproval procedures for all applications to the Board.

Deadline: Guidelines must become "effective" by October 9, 1987.

e. Section 411—Guidelines for asset disposition.

Deadline: Guidelines must be "promulgated" by February 6, 1988.

f. Section 415—Guidelines for employment of outside accountants, attorneys, conservators, other consultants, and outside professionals.

Report on guidelines to be submitted to Congress by February 6, 1988.

2. Required Board Action Without Specified Time Frames

Title III

a. Section 302—Regulations to avoid conflicts of interest with respect to disclosure to and use by members of the FSLIC Industry Advisory Committee or information relating to Board, FSLIC, FHLBanks, and the Federal Asset Disposition Association.

Title IV

b. Section 406—Regulations implementing Board's authority to set minimum capital requirements.

c. Section 407—Guidelines providing greater supervisory flexibility including: flexible approval procedures for renegotiated loans; recognition of the additional financial capacity of the borrower; appraisal review system; elimination of scheduled items except for I-4 family residences; and informal review procedures for appeal of Principal Supervisory Agent decisions.

3. Other Board Action

Title I

a. Section 104—Regulations or amendments to existing requlations concerning Savings and Loan Holding Company activities and grandfathering regulations; anti-tying regulations; treatment of Federal Deposit Insurance Corporation ("FDIC") insured savings banks and cooperative banks as FSLIC-insured institutions upon application to the Board; and new exceptions to interstate acquisitions.

b. Section 105—Regulations concerning advances to insured institutions from FHLBanks (tied to the QTL test).

c. Section 106—Regulations or amendments to existing regulations concerning securities affiliations of FSLIC-insured institutions.

d. Section 107—Regulations or amendments to existing regulations concerning establishment of holdiong companies for FSLIC-insured or FDIC-insured mutual savings and loans.

e. Section 110—Regulations or amendments to existing regulations concerning exemption from affiliate transaction restrictions.

f. Section 111—Regulations or amendments to existing regulations concerning consideration of tax implications on FSLIC-arranged and emergency acquisitions.

Title III

g. Sections 302, 304-307—Regulations concerning the establishment and authority of the financing corporation and related matters.

h. Section 306—Regulations on exit fees.

Title IV

i. Section 405—Regulations or guidelines to govern a capital instrument purchase program to complement the capital forbearance program.

j. Section 406—Regulations or guidelines establishing minimum capital requirements.

k. Section 413—Regulations or guidelines concerning the disclosure requirements of the authority for those acting on behalf of the Board.

l. Section 414—Regulations or guidelines regarding the extension of forbearance provisions granted prior to March 31, 1987.

Title VI

m. Section 603-605—Regulations, in conjunction with or patterned after those of other banking regulatory agencies, concerning expedited funds availability and automatic teller machine provisions.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 87-20487 Filed 9-3-87; 8:45 am]

BILLING CODE 6720-01-M

[2] Section 402 also contains provisions requiring regulations on the treatment of loan loss reserves as regulatory capital and accounting for subordinated debt and good will. This required regulatory action has already been taken in the Board's final regulation on the definition of regulatory capital. Board Res. No. 87-529, 52 FR 18340 (May 15, 1987).

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Reg. Z; Doc. No. R-0612]

Truth in Lending; Intent To Make Determination of Effect on State Law; Indiana

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of intent to make preemption determination.

SUMMARY: The Board is publishing for comment a proposed determination that a provision in the law of Indiana is inconsistent with the Truth in Lending Act and Regulation Z and therefore preempted. A final determination that the provision is preempted would have an effective date of October 1, 1988, although compliance may begin from the date of the Board's determination.

This notice also includes a discussion of the procedures that the Board follows upon receipt of a request for a determination and a statement of the principles used in making preemption determinations.

DATE: Comments must be received on or before November 3, 1987.

ADDRESS: Comments should be mailed to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC, 20551, or delivered to the 20th Street courtyard entrance, on 20th Street between C Street and Constitution Avenue NW., Washington, DC, between 8:45 a.m. and 5:15 p.m. weekdays. Comments should include a reference to Docket No. R-0612. Comments may be inspected in

Room B-1122 between 8:45 a.m. and 5:15 p.m. weekdays.

FOR FURTHER INFORMATION CONTACT: Sharon Bowman, Attorney, Division of Consumer and Community Affairs, at (202) 452-3667 For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Earnestine Hill or Dorothea Thompson, at (202) 452-3544, Board of Governors of the Federal Reserve System, Washington, DC, 20551.

SUPPLEMENTARY INFORMATION:

(1) General

The Board has received a request for a determination as to whether a provision of Indiana law is inconsistent with the Truth in Lending Act or Regulation Z, and therefore preempted. Section 111(a)(1) of the Truth in Lending Act authorizes the Board to determine whether any inconsistency exists between Chapters 1, 2, and 3 of the federal act or the implementing provisions of the regulation and any state law relating to the disclosure of information in connection with consumer credit transactions. These proposed preemption determinations are issued under authority delegated to the Director of the Division of Consumer and Community Affairs, as set forth in the Board's Rules Regarding Delegation of Authority (12 CFR 265.2(h)(3)).

The procedures for requesting a determination and the general procedures followed in making a determination are contained in Appendix A to 12 CFR Part 226.

(2) Principles Followed in Preemption Analysis

In determining whether a state law is inconsistent with federal provisions, § 226.28(a)(1) of Regulation Z, which implements § 111 of the act, provides that state requirements are inconsistent with, and therefore preempted by, the federal provisions if the state law requires a creditor to make disclosures or take actions that contradict the requirements of the Federal law. A state law is contradictory, and therefore preempted, if it significantly impedes the operation of the Federal law or interferes with the ppurposes of the Federal statute. Two examples of contradictory state laws are included in § 226.28(a)(1). They are (1) a law that requires the use of the same term to represent a different amount or a different meaning than the Federal law, or (2) a law that requires the use of a term different from the Federal term to describe the same item.

In previous preemption determinations (48 FR 4454, February 1, 1983) the Board developed the following principles that are applied in making preemption determinations:

- For purposes of making preemption determinations, state law is deemed to require the use of specific terminology in the State disclosures if the State statute uses certain terminology in the disclosure provision.
- A State disclosure does not "describe the same item," under § 226.28(a)(1), if it is not the functional equivalent of a Federal disclosure.
- Preemption occurs only in those transactions in which an actual inconsistency exists between the State law and the Federal law.
- A State law is not inconsistent merely because it requires more information than Federal law or requires disclosure in transactions where Federal law requires none.

In general, preemption determinations will be limited to those provisions of State law identified in the request for a determination. At the Board's discretion, however, other State provisions that may be affected by the Federal law will also be addressed.

(3) Effect of Preemption Determination

If the Board determines that a state-required disclosure is inconsistent with the Federal law, the State law is preempted to the extent of the inconsistency. Disclosures using the inconsistent term or form may not be given, even on a separate document from the Federal disclosures. Preemption determinations have an effective date of the October 1 that follows the determination by at least 6 months, as required by section 105(d) of the act. This proposed determination, if adopted, will have an effective date of October 1, 1988, although compliance with the determination may begin before that time.

A determination on provisions in the law of one State will have no effect on the validity of similar provisions in other States.

(4) Discussion of Specific Request and Proposed Determination

The Board has been asked to examine section 8(d) of the recently amended Indiana "Loan Broker" statute, Ind. code section 23-2-5-1 *et seq.* The requesting party believes that section 8(d) of the Indiana statute, as amended, requires certain disclosures that contradict the disclosures required under the Federal act and regulation.

The relevant provisions of the State statute (which has an effective date of September 1, 1987) are as follows:

23-2-5-8. *Disclosure statement.*

(d) A loan broker shall deliver to any person who proposes to become obligated for a loan an estimated disclosure statement if the creditor would be required to deliver to the person a disclosure statement under the Truth-in-Lending Act (15 U.S.C. 1601-1667e) for the transaction. The estimated disclosure statement:

(1) shall be delivered to the person before the person becomes contractually obligated on the loan; or

(2) shall be delivered or placed in the mail to the person not later than three (3) business days after the person enters into an agreement with the loan broker; whichever occurs first. The estimated disclosure statement must contain all of the information and be in the form required by the Truth-in-Lending Act (15 U.S.C. 1601-1667e) and regulations under the Act. However, the annual precentage rate, finance charge, total of payments, and other matters required under the Truth-in-Lending Act (15 U.S.C. 1601-1667e) shall be adjusted to reflect the amount of all fees and charges of the loan broker that the creditor could exclude from a disclosure statement. The disclosure statement must state at the top in at least 10 point type: "The following is an estimated disclosure statement showing your loan transaction as if the fees and charges you are scheduled to pay us were charged to you directly by the creditor." After the estimated disclosure statement is delivered to any person, the loan broker shall deliver to the person an additional statement redisclosing all items if the actual annual precentage rate will vary from the annual percentage rate contained in the original estimated disclosure by more than one-eighth of one percent (0.125%). Any required additional disclosure statement shall be delivered or placed in the mail before consummation of the loan or the elapse of three (3) days after the information that requires redisclosure becomes available, whichever occurs first.

The requesting party has asked for a determination as to whether the requirement imposed by this section that loan brokers reflect all of their fees and charges in their calculation of, among other items, the finance charge and annual percentage rate that must be disclosed to potential borrowers is preempted by the Truth-in-Lending Act and Regulation Z. Sections 106(a) and 226.4(a) of the Federal statute and regulation, respectively, state that, in any consumer credit transaction, the finance charge includes charges paid by the consumer that are imposed by the creditor as an incident to the extension of credit. Under Regulation Z, charges imposed by third parties are not finance charges as long as the creditor does not require the parties services or retain the charges. Thus, fees charged by a loan broker are not finance charges provided that the creditor does not require the use of the broker. (See Official Staff Commentary, 12 CFR 226.4(a)-3.)

Since the State statute requires that loan brokers include their fees in calculating the finance charge and annual percentage rate in cases where the creditor would exclude such fees in calculating those same items, the Board proposes to determine that the State disclosure requirement is preempted in those instances where the State law would require the use of the same term to disclose a different amount than would be disclosed under Federal law. The Board recognizes that the State disclosure serves a useful purpose in informing consumers about costs that they may incur in such credit transactions. The Board, however, believes that the approach chosen by the State will confuse consumers who will receive two different sets of figures, described by the same terminology. In such cases, it appears that the State disclosure would contradict the disclosures required under Federal law and interfere with the intent of the Federal scheme.

(5) Comment Requested

Interested persons are invited to submit comments regarding the proposed determination. Since this request concerns a State law governing disclosures by loan brokers, who are not considered "creditors" and therefore are not themselves subject to the requirements of Regulation Z, the question arises as to whether the State law is subject to the Board's preemption authority. (See § 226.28(a) of Regulation Z, which provides that "a State law is inconsistent if it requires a creditor to make disclosures * * * that contradict the requirements of the Federal law.") Although the Board, in the past, has made preemption determinations concerning laws whose coverage may extend to parties who are not considered creditors for purposes of Regulation Z (for example, Arizona in 1985 and South Carolina in 1983), the Board specifically requests comment on this issue. The Board has assumed, however, for purposes of this proposed determination, that the law in question is subject to the Board's preemption authority. After the close of the comment period and analysis of the comments received, notice of final action on the proposal will be published in the **Federal Register.**

List of Subjects in 12 CFR Part 226

Advertising, Banks, Banking, Consumer protection, Credit, Federal Reserve System, Finance, Penalties, Truth in Lending.

Board of Governors of the Federal Reserve System, August 31, 1987.

William W. Wiles,

Secretary of the Board.

[FR Doc. 87-20368 Filed 9-3-87; 8:45 am]

BILLING CODE 6210-01-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 107

Small Business Investment Companies; Extension of Comment Period on Proposed Rulemaking

AGENCY: Small Business Administration.

ACTION: Notice of extension of comment period on proposed rulemaking.

SUMMARY: On August 4, 1987, the Small Business Administration (SBA) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) regarding an increase in the examination fees imposed upon small business investment companies (see 52 FR 28842).

That publication provided that comments on the NPRM would be received for a period of 30 days from the date of publication. This Notice extends the comment period pertaining to the NPRM for an additional 30 days to allow the public more time to consider this proposal.

DATE: Comments on the above-referenced proposed rule should be submitted in duplicate by October 3, 1987.

ADDRESS: Written comments should be addressed to: Robert G. Lineberry, Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Room 808, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: John L. Werner, Director, Office of Investment, (202) 653-6584.

SUPPLEMENTARY INFORMATION: In order to provide more time for public comment on the above-referenced proposed rule, SBA is hereby extending the comment period relative to the proposal for an additional 30 days. The public is encouraged to supply written comments to the address indicated above so that a complete record can be established in this rulemaking.

Date: August 29, 1987.

James Abdnor,

Administrator.

[FR Doc. 87-20417 Filed 9-3-87; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 352

[Docket No. 78N-0038]

Discussion of Appropriate Testing Procedures for Over-the-Counter Sunscreen Drug Products; Public Meeting and Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Public meeting and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a public meeting will be held to discuss recommendations of the Advisory Review Panel on Over-the-Counter (OTC) Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products regarding final product testing (i.e., testing procedures for determination of the sun protection factor (SPF) value and related claims) of OTC sunscreen drug products. The meeting will be structured to discuss the specific topics and to seek answers to the specific questions listed in this notice.

DATES: Meeting date January 26, 1988; Time 9:00 a.m. The agency anticipates that the meeting will last one day. However, if there is sufficient interest in participation, the meeting will be extended an additional day at the discretion of the chairperson. Relevant data and notice of participation by December 3, 1987. Administrative record to remain open until April 26, 1988. Comments regarding matters raised at the meeting by April 26, 1988.

ADDRESSES: Relevant data, notice of participation, and comments to the Dockets Management Branch, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857. Meeting to be held in Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Saul Bader or Jeanne Rippere, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md 20857, 301-295-8003.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 1978 (43 FR 38206), FDA published an advance notice of proposed rulemaking on OTC sunscreen drug products based on the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products. In that report, the Panel

recommended final product testing of each sunscreen drug product. In its recommended monograph, the Panel included testing procedures for the determination of the sun protection factor (SPF) value and of related labeling claims for all sunscreen drug products containing Category I (generally recognized as safe and effective) ingredients (43 FR 38265 to 38267). The Panel included these testing procedures to assure the uniform evaluation of all sunscreen products.

In response to the Panel's report; the agency received a number of comments regarding statistical and technical aspects of the sunscreen product testing procedures (Refs. 1 through 9). The comments questioned these aspects of the testing procedures and offered many suggestions, ranging from requiring a minimum of 8 subjects per test (Ref. 2) to proposing alternated statistical methods for evaluating the test data (Refs. 2 and 7). One technical aspect of the sunscreen testing procedures is the use of an 8 percent standard homosalate formulation to validate a laboratory's testing methods. The agency believes that data submitted to the Panel and the agency on the 8 percent standard homosalate formulation (Refs. 6, 9, and 10) are too variable to estimate accurately the SPF of this formulation. The agency believes that it is necessary to analyze more data on the 8 percent homosalate formulation before officially designating this formulation as the standard formulation.

The Panel's recommendations represent a first attempt to standardize testing for sunscreen drug products, and many technical issues are left to be resolved. Because the testing procedures for sunscreen drug products will be included in the agency's tentative final monograph, the agency feels that it is important to try to resolve the majority of these issues regarding sunscreen testing before the tentative final monograph is proposed.

In addition, the agency is aware that, recently, a number of sunscreen drug products have been marketed with SPF values greater than 15, which was the Panel's highest classifiction. The agency believes that consideration needs to be given to modifying the Panel's recommended monograph in order to address these higher SPF values. However, to date, no data on products with such SPF values have been submitted to the rulemaking for OTC sunscreen drug products, and the agency is not able to make any determinations regarding such products.

Therefore, under 21 CFR 10.65, the agency has concluded that it would be in the public interest to hold an open public meeting to discuss these and related issues. The agency is inviting interested individuals or groups to discuss these and related issues at an open meeting to be held on January 26 1988.

Topics and questions to be considered during the meeting include:

1. Procedures and Statistical Methods

Are the Panel's proposed general procedures and statistical methods for sunscreen testing valid? Some comments questioned the soundness of the Panel's proposed procedures and statistical methods for determining the SPF and the Product Category Designations (PCD) of a sunscreen drug product (Refs. 2 and 7). One comment (Ref. 2) suggested categorizing a product into a PCD on the basis of a 90 percent confidence interval computed for the product's mean SPF. To categorize a product into a particular PCD, the entire confidence interval would have to fall within the range of values included in that PCD. The other comment (Ref. 7) suggested the use of binomial (nonparametric) analysis instead of parametric analysis of sunscreen testing data.

Based upon the comments and because the testing procedures represent a first attempt to standardize sunscreen testing methods, the agency believes that it may be necessary to revise the Panel's proposed testing procedures. However, the agency believes that the confidence interval procedure suggested by the first comment may be too stringent for use in assigning PCD's because the criterion of having the entire confidence interval fall within the PCD would never, or only rarely, be satisfied. For example, if the true mean SPF is 6, then 90 percent of the time the confidence interval will straddly two PCD's (i.e., moderate (SPF of 4 to 6) and extra (SPF of 6 to 8)).

The agency believes that the binomial procedure suggested by the second comment has merit, but that the binomial procedure may not be as statistically powerful as the procedure described below, which involves a confidence interval for the mean SPF.

Therefore, in this notice, the agency is setting forth for comment two different approaches to analyzing the data generated by sunscreen drug product testing. The first method utilizes the testing procedures proposed by the Panel but adds one step to the determination of the PCD. The added step is equivalent to performing a one-sided t test at the 0.05 level of significant where the null hypothesis is that the mean SPF is less than the minimal SPF of the assigned PCD.

The full statistical procedure would be as follows: First, select at least 20 subjects, with n representing the number of subjects selected, and for each subject compute the SPF value in the manner described in the Panel's report (43 FR 38213). Second, compute the mean SPF value, $\bar{x}$, and the standard deviation, s, for these subjects. Third, obtain the upper 5 percent point from the t distribution with $n-1$ degrees of freedom. Denote this value by little t. Fourth, compute $ts/\sqrt{n}$. Let this quantity be denoted by A (i. e., $A=ts/\sqrt{n}$). Fifth and last, the drug product is classified into a PCD as follows: if $15+A\leq\bar{x}$, the PCD is Ultra; if $8+A\leq\bar{x}<15+A$, the PCD is Maximal; if $6+A\leq\bar{x}<8+A$, the PCD is Extra; if $4+A\leq\bar{x}<6+A$, the PCD is Moderate; if $2+A\leq\bar{x}<4+A$, the PCD is Minimal; if $\bar{x}<2+A$, the PCD is Below Minimal. (Note: The procedure proposed by the Panel has $A=0$ which is equivalent to a test of hypothesis with the level of significant equal to 0.50.)

The above fifth step can also be written in the following equivalent fashion: if $15\leq\bar{x}-A$, the PCD is Ultra; if $8\leq\bar{x}-A<15$, the PCD is Maximal; if $6\leq\bar{x}-A<8$, the PCD is Extra; if $4\leq\bar{x}-A<6$, the PCD is Moderate; if $2\leq\bar{x}-A<4$, the PCD is Minimal; if $\bar{x}-A<2$, the PCD is Below Minimal.

The following numerical example is provided: Take 20 subjects with a mean SPF value of 6.40 and a standard deviation of 1.60. Here $n=20$, $\bar{x}=6.40$, $s=1.20$, and the standard error is $s/\sqrt{n}=1.2/\sqrt{20}=0.268$. The procedure proposed by the Panel would stop here and classify the product in the PCD "Extra" ($6\leq\bar{x}<8$). The procedure set forth above goes one step further by testing whether the observed mean of 6.4 really reflects a true population mean of at least 6. To do this testing, the third to fifth steps, outlined above would be carried out as follows: The upper 0.05 point from the t distribution with 19 degrees of freedom is 1.729. The A value of the fourth step is $A=1.729(0.268)=0.46$. The mean SPF value minus A is $\bar{x}-A=6.40-0.46=5.94$. We thus find $\bar{x}-A$ satisfies the $4\leq\bar{x}-A<6$ interval ($4<5.94<6$). Thus, the product would be classified as "Moderate." The observed mean value of 6.40 is not significantly large enough to establish that the true population means SPF value is 6 or larger.

The second method that the agency is proposing concentrates on the boundaries between the PCD's rather than on the actual SPF values of the sunscreen drug product. After the minimal erythema dose for unprotected

skin (MED(US)) has been established (see 43 FR 38213), the protected skin is tested at exposure times chosen so that the corresponding SPF's are slightly less than the lower bounds of the intervals defining the various PCD's. For example, the protected skin could be tested at 1.9 x MED(US), 3.9 x MED(US), 5.9 x MED(US), 7.9 x MED(US), and 14.9 x MED(US). Thus, if a subject's MED(US) were 1.5, the subject's protected skin exposure times would be 2.85(=1.9x1.5), 5.85(=3.9x1.5), 8.85(=5.9x1.5), 11.85(=7.9x1.5) and 22.35(=14.9x1.5). For each subject who experiences erythema, the calculated "SPF" (being the minimal erythema dose of the protected skin (MED(PS) divided by the MED(US)) would be either 1.9, 3.9, 5.9, 7.9, or 14.9. If a subject's "SPF," calculated in this manner, is 5.9, then that subject received Moderate (i.e., 4 to less than 6) protection and is assigned a score of 4, the lower bound of the interval defining the Moderate PCD. Thus, a subject with a calculated "SPF" of 1.9 is not in any of the PCD's and is assigned a 0; an "SPF" of 3.9 is in the Minimal PCD and is assigned a 2; an "SPF" of 5.9 is in the Moderate PCD and is assigned a 4; an "SPF" of 7.9 is in the Extra PCD and is assigned a 6; an SPF of 14.9 is in the Maximal PCD and is assigned an 8; and if erythema is not found on the protected skin at 14.9 x MED(US), then the product is in the Ultra PCD and is assigned a 15.

This procedure does not distinguish between SPF's in the same PCD such as 4.1, 4.5, 5.0, or 5.9. It does distinguish between SPF's in different PCD's, such as 5.9 and 6.1. The agency considers this procedure's ability to make this distinction important because products are labeled in terms of their PCD, not their SPF. Thus, there is no need to distinguish between two products whose true SPF's are 4.1 and 5.9 because they are both labeled as Moderate. However, there is a need to distinguish between two products whose true SPF's are 5.9 and 6.1 because the former is labeled as Moderate, and the latter is labeled as Extra.

The PCD assigned to a test preparation is the largest PCD for which one would, using a one-sided binomial test at $p = 0.5$, reject the hypothesis that the probability is not greater than 50 percent that an individual will receive the protection of the assigned PCD. This procedure is the same as assigning the largest PCD for which the lower limit of a 95 percent confidence interval on the percentage of subjects that received protection at least as great as that defining the PCD exceeds 50 percent.

In a panel of 20 subjects, the product is assigned the PCD corresponding to the sixth smallest score (disregarding ties) from among the 20 subjects. In a panel of 25 subjects, the product is assigned the PCD corresponding to the eighth smallest score. A few examples are shown below.

Product 1:
2 2 2 4 4 *6* 6 6 6 6 6 6 8 8 8
8 8 8 8 8

Product 2:
0 0 2 2 4 *4* 4 4 4 6 6 6 6 6 6
6 6 6 6 6

Product 3:
4 4 4 4 4 6 6 *8* 8 8 8 8 8 8 8
8 8 8 8 8 15 15 15 15 15

Product 1 would be assigned the Extra PCD, Product 2 the Moderate PCD, and Product 3 the Maximal PCD.

The agency is requesting comments on the Panel's proposed procedure for sunscreen testing as well as on the two methods outlined above.

2. Standard Formulation

The agency's evaluation of the Panel's report and of the comments received has raised some questions regarding the use of the 8 percent homosalate formulation as the standard for the validation of sunscreen product testing. Results from two collaborative studies that were designed to establish an SPF value for a standard sunscreen formulation, each study involving six participating laboratories, were submitted to the Panel and to the agency (Refs. 6, 9, and 10). The standard sunscreen formulation used in these studies was an 8 percent homosalate formulation that was endorsed by the Panel for use as a standard in such testing. In the collaborative studies, however, the results obtained by the laboratories involved were inconsistent, producing SPF values that place the 8 percent homosalate standard formulation into different PCD's. The agency believes that the variability of the SPF values obtained in these studies demonstrates that the SPF and PCD of the 8 percent homosalate standard formulation have not been precisely established and may be incorrect. Therefore, the agency is asking whether new data have become available since the 8 percent homosalate standard formulation was originally tested that would provide additional information regarding the reliability of the 8 percent homosalate standard formulation. If such data are available, they should be submitted to the agency.

The agency is also concerned about using a standard preparation that may have a relatively low SPF of 4 to validate a sunscreen testing procedure that is supposed to determine a wide range of SPF's (currently SPF 2 up to SPF 30). Would standard formulations with SPF values higher than 4 make the determination of SPF values higher than 8 and 15 more accurate? The agency believes that two or three standard preparations should be available having SPF's that represent the entire range of possible SPF's (e.g., SPF 8 and SPF 20 or SPF 4, SPF 15, and SPF 25). Are sunscreen preparations with relatively high SPF values available that would be appropriate for use as standard preparations when testing sunscreen drug products with estimated SPF's greater than 15? Data on such preparations should be submitted.

3. Number of Subjects.

The Panel recommended that groups of twenty subjects should be used for each test panel but added that "the standard error shall not exceed +5 percent of the mean. An appropriate number of additional subjects shall be used to determine the PCD, if a PCD does not fall within the limits of the standard error." Comments submitted to the agency (Refs. 2, 5, and 11) revealed substantial confusion regarding the standard error criterion proposed by the Panel. Additionally, one comment suggested that determination of the SPF of a sunscreen could be accurately done with only 8 subjects.

The agency believes that the number of subjects for a test panel should be fixed before the test and should not be changed. The sample size must be large enough to give a sense that it is not a unique, atypical subset of the target population. The agency believes that 20 subjects is the minimum number of subjects that may be used to make a test panel.

Regarding the standard error criterion for determining the precision of an assay, the agency believes that the data submitted to the Panel do not support use of the standard error. Furthermore, because the agency is proposing more elaborate statistical calculations for determining SPF's and PCD's, the standard error criterion is no longer necessary. Therefore, the agency is considering revising the Panel's recommended § 352.42(g) as follows: "Number of subjects. Groups of at least 20 subjects shall be used for each test panel. The panel size shall be fixed in advance and additional subjects shall not be added."

The agency invites comment on this possible change. If this change is not acceptable, what is the best method for evaluating sunscreen test data to determine if additional subjects are needed to obtain a valid SPF value?

What is the minimum number of subjects required?

4. Exposure Times

The Panel's protocol for sunscreen testing calls for a geometric series of increments in ultraviolet (UV) exposures (e.g., 1, 1.25, 1.56, 1.96, and 2.44 minutes). One comment (Ref. 5) recommended the use of time increments smaller than 25 percent. Other comments (Refs. 1, 4, and 6) recommended shorter time intervals and the use of an arithmetic rather than geometric progression of UV doses for the determination of SPF values above 8.

The agency believes that there is little justification for a geometrically increasing series of time intervals. Geometrically increasing intervals offer less precision in the upper ranges, and precision has become increasingly important because of the appearance on the OTC market of sunscreens with SPF values much higher than 15 (i.e., up to 30). Conversely, the MED can be measured with equal precision across the full range of an arithmetically arranged series of exposure times.

The agency believes that exposure times are crucial to the accurate determination of SPF values and PCD's. Therefore, FDA is considering revising the discussion of the determination of SPF value using an artificial light source in proposed § 352.43 to state:

A series of UV light exposures (units of time) are administered to the subsite areas on each subject with a solar simulator. One series of exposures shall be administered to the untreated, unprotected skin to determine the subject's inherent MED (MED (US)). The time intervals selected shall be an arithmetic series with 11 exposures, increasing in 4 second increments, beginning with 10 seconds and ending with 50 seconds (i.e., 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, and 50 seconds). This series would be suitable for a normal person exposed to a 150-watt xenon lamp solar simulator. Usually the MED of a subject's unprotected skin is determined the day before the testing of a product. The protected test sites (standard sunscreen and test sunscreen product) usually are exposed to UV light the next day. [NOTE: The foregoing procedure is applicable only for the PDC determination based on the lower confidence limit for the mean SPF. The protected skin exposure times appropriate for the PCD determination based on the lower confidence limit for the percentage of patients that receive a given level of protection has already been specified.] The exact series of exposures to be given shall be determined by the MED of the unprotected skin and the expected SPF of the test product. There should be at least 11 exposures. The difference between successive exposure times should be consistent. The exposure times should be densely clustered around the expected MED of the protected skin (MED(PS)). Preliminary testing using more widely spaced exposure times may be necessary to roughly determine an expected SPF value. The increment interval (I) for the series of UV exposures of the protected skin is determined from the MED(US) and the upper and lower limit of the expected testing range of SPF values. Each expected SPF has a testing range of SPF values defined by a lower value (L) and an upper value (U). The following example is provided for guidance:

Expected SPF	Testing range of SPF, L to U
2	1 to 5.
4	3 to 7.
6	5 to 10.
8	6 to 12.
15	10 to 18.
22	16 to 24.
30	25 to 35.

Based on the above, the exposure times for an expected SPF would be calculated as follows:

L×MED(US); L×MED(US)+I;
L×MED(US)+2I; L×MED(US)+3I; . . .
L×MED(US)+10I, where

$$I = \frac{U \times MED(US) - L \times MED(US)}{10}$$

and MED (US) is the observed MED (US) value from the previous day. For example, if the MED (US) is 30 seconds, and the product being tested has an expected SPF of 8, then L=6 and U=12. From these values, the interval (I) can be computed as follows:

$$I = \frac{U \times MED\ (US) - L \times MED\ (US)}{10} = \frac{12 \times 30 - 6 \times 30}{10} = 18$$

Thus the increment used to establish the exposure times is 18 seconds. Therefore, the calculated exposure times would be as follows:

L×MED (US)=180 seconds
L×MED (US)+I=180+18=198 seconds
L×MED (US)+2I=216 seconds
L×MED (US)+3I=234 seconds
L×MED (US)+4I=252 seconds
L×MED (US)+5I=270 seconds
L×MED (US)+6I=288 seconds
L×MED (US)+7I=306 seconds
L×MED (US)+8I=324 seconds
L×MED (US)+9I=342 seconds
L×MED (US)+10I=360 seconds

At 16 to 24 hours after exposure, the shortest exposure time must produce no effect (i.e., no erythema) on the skin. The longer exposure times should produce light and moderately red exposure sites. The MED is the time of exposure the produces the minimally perceptible erythema at 16 to 24 hours postexposure. The SPF value of the test sunscreen is then the ratio of the exposure time interval required to produce the MED of the protected skin to the exposure time interval required to produce the MED of the unprotected skin (control site) as follows:

$$\text{SPF value} = \frac{MED\ (PS)}{MED\ (US)}$$

5. Amount of Sunscreen.

In its report, the Panel recommended that the amount of test sunscreen and the standard sunscreen per application should be 2 miligrams (mg) or 2 microliters (ul) per square centimeter (cm^2). An expert on sunscreen testing procedures who is not affiliated with FDA suggested to the agency that 1 mg/cm^2 rather than 2 mg/cm^2 is a more appropriate amount of sunscreen to use in the sunscreen testing procedure because 1 mg/cm^2 more accurately reflects the amount of sunscreen drug product normally used by a consumer (Ref. 12). The agency notes that use of 1 mg/cm^2 would undoubtedly produce lower SPF values and believes that this may be a way to accommodate the new higher SPF values because using 1 mg/cm^2 of the product may produce SPF value that more closely approximate the time a product will provide protection. Is 2 mg/cm^2 an appropriate amount of sunscreen product to use for the testing procedure?

6. SPF Value Higher Than 15

According to the Panel's report (43 FR 38267 and 38268), a product containing active sunscreen ingredients that provide an SPF of 15 or greater may be labeled as an "Ultra Sun Protection Product (15)—stay in the sun 15 times as long as before without sunburning." The Panel recommended that such products be allowed the following indications, among others: (1) "Affords the most protection against sunburn;" (2) "provides the highest degree of sunburn

protection. . . ;" and (3) "provides the highest degree of sunscreen protection* * *" What benefit is provided to the consumer by sunscreen drug products claiming to have SPF values greatly in excess of 15 (i.e., 23 or even 30) if, as the Panel claims, SPF 15 offers the maximum possible protection? Can these higher SPF values be accurately determined using currently available sunscreen testing procedures? Companies marketing such products should provide supporting data. If the currently recognized sunscreen testing procedures are not adequate, what tests are necessary to determine SPF values higher than 15?

7. Product Category Designations

The agency notes that the Panel's recommended Product Category Designations do not adequately accommodate sunscreen drug products with high SPF values of 25 or 30. If products having SPF values much higher than 15 are determined to be rational, how should the Panel's recommended PCD's be modified to include these higher SPF values?

One example might be as follows:

PCD	SPF
Minimal	2 to under 4.
Moderate	4 to under 8.
Extra	8 to under 12.
Maximal	12 to under 20.
Ultra	20 and above.

8. "Sweat Resistant," "Water Resistant," and "Waterproof" Labeling

The agency notes that the Panel's recommended criteria for a sunscreen drug product to be labeled as "sweat resistant," "water resistant," or "waterproof" are based on the product's ability to maintain its original PCD after testing procedures that are specified for each of the above three claims. The agency believes that there are situations in which the Panel's recommendation could lead to labeling that would be misleading to the consumer. For example, a product in the Moderate PCD ($4 \leq$ SPF <6) that maintained its PCD after 40 minutes of water immersion could be labeled "water resistant," whereas a product in the Ultra PCD ($15 \leq$ SPF) that fell into the Maximal PCD ($8 \leq$ SPF <15) after the water immersion could not. The fact that the latter product would provide more sun protection after immersion than would the former would not be reflected by the Panel's labeling proposal. One way of avoiding such a situation involves labeling a product with a PCD established under the ordinary test conditions and with a PCD established under the "sweat resistant," "water resistant," or "waterproof" test conditions. The agency is requesting comments on this situation or other possible solutions to this problem.

Because the final formulation of a sunscreen drug product affects the performance of the active ingredient in the product, the agency concludes that testing procedures for sunscreen drug products are necessary. It is important for the safe and effective use of these products by consumers that these testing procedures result in labeling that accurately reflects the characteristics of a particular sunscreen formulation. Consumers should have assurance that using any sunscreen displaying an SPF value of 8 will indeed provide protection in the sun for 8 times longer than using no sunscreen. An inaccurately labeled sunscreen may cause a consumer to remain in the sun too long and may result in a painful burn. The long effects of using an improperly labeled sunscreen could include premature aging of the skin and skin cancer.

The agency requests information on the recommended sunscreen testing procedures from any interested person. Any individual or group wishing to submit data relevant to the questions above should send them on or before December 3, 1987 to Docket No. 78N-0038, Dockets Management Branch, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Any individual or group wishing to make a presentation at the meeting should contact Saul Bader or Jeanne Rippere, Division of OTC Drug Evaluation (HFN-210), Office of Drug Standards, Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8003. Interested persons who wish to participate must also send a notice of participation on or before December 3, 1987 to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this notice and should contain the following information: Name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation, and the approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record of the OTC sunscreen drug products rulemaking is being reopened to specifically include only the proceedings of this pubic meeting. The administrative record will remain open until April 26, 1988, to allow comments on matters raised at the meeting.

References

(1) *Comment No. C00004*, Dockets No. 78N-0038, Dockets Management Branch.
(2) *Comment No. C00008*, Dockets No. 78N-0038, Dockets Management Branch.
(3) *Comment No. C00009*, Dockets No. 78N-0038, Dockets Management Branch.
(4) *Comment No. C00016*, Dockets No. 78N-0038, Dockets Management Branch.
(5) *Comment No. C00031*, Dockets No. 78N-0038, Dockets Management Branch.
(6) *Comment No. C00046*, Dockets No. 78N-0038, Dockets Management Branch.
(7) *Comment No. C00049*, Dockets No. 78N-0038, Dockets Management Branch.
(8) *Comment No. C00075*, Dockets No. 78N-0038, Dockets Management Branch.
(9) *Comment No. SUP002*, Dockets No. 78N-0038, Dockets Management Branch.
(10) *OTC Volume 060169*, Dockets No. 78N-0038, Dockets Management Branch.
(11) *Comment No. C00068*, Dockets No. 78N-0038, Dockets Management Branch.
(12) Memorandum from J. Rippere to S. Bader, dated December 3, 1986, coded M00001, Dockets No. 78N-0038, Dockets Management Branch.

Dated: August 25, 1987.

John A. Norris,

Acting Commissioner of Food and Drugs.

[FR Doc. 87-20377 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 41

[LR-33-87]

Excise Taxes; Reduction of Heavy Vehicle Use Tax for Foreign-Based Vehicles

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue of the **Federal Register**, the Internal Revenue Service is issuing temporary regulations relating to the imposition of the heavy vehicle use tax on foreign-based highway motor vehicles. The temporary regulations also serve as the text for this Notice of Proposed Rulemaking.

DATE: Written comments and requests for a public hearing must be delivered or mailed November 3, 1987.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, 1111 Constitution Avenue, NW., Attention: CC:LR:T (LR-33-87), Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: William A. Jackson of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Attention: CC:LR:T (LR-33-87). Telephone 202-566-4336 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations in the Rules and Regulations portion of this issue of the **Federal Register** amend Part 41 of Title 26 of the Code of Federal Regulations. The final regulations which are proposed to be based on the temporary regulations would amend Part 41 of Title 26 of the Code of Federal Regulations. The regulations provide rules relating to the imposition of the heavy vehicle use tax on foreign-based vehicles under section 4481 of the Internal Revenue Code of 1986 (Code), as amended by section 507 of the Highway Revenue Act of 1987 (Title V of the Surface Transportation and Uniform Relocation Assistance Act of 1987) (Pub. L. 10017, 101 Stat. 260). For the text of the temporary regulations see T.D. 8159 published in the Rules and Regulations portion of this issue of the **Federal Register**. The preamble to the temporary regulations provides a discussion of the rules.

Special Analysis

The Commissioner of Internal Revenue has determined that this proposed rule is not a major rule as defined in Executive Order 12291 and that a Regulatory Impact Analysis is therefore not required. Although this document is a notice of proposed rulemaking that solicits public comments, the Internal Revenue Service has concluded that the notice and public procedure requirements of 5 U.S.C. 553 do not apply. Accordingly, these regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Comments and Requests for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably eight copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register**.

The collection of information requirements contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget (OMB) for review under section 3504 (h) of the Paperwork Reduction Act. Comments on these requirements should be sent to the Office of Information and Regulatory Affairs of the Office of Information and Regulatory Affairs of OMB, Attention: Desk Office for Internal Revenue Service, New Executive Office Building, Washington, DC 20503. The Internal Revenue Service request that persons submitting comments on these requirements to OMB also send copies of those comments to the Service.

Drafting Information

The principal author of these proposed regulations is William A. Jackson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

List of Subjects in 26 CFR Part 41

Excise taxes, Motor vehicles.

Lawrence B. Gibbs,

Commissioner of Internal Revenue.

[FR Doc. 87-20456 Filed 9-3-87; 8:45 am]

BILLING CODE 4830-01-M

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, and 7

[Notice No. 638]

Disclosure of FD&C Yellow No. 6 in the Labeling of Wine, Distilled Spirits, and Malt Beverages

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms is proposing to amend the regulations in 27 CFR Parts 4, 5, and 7, by requiring the mandatory disclosure of FD&C Yellow No. 6 on labels of alcoholic beverages, because of evidence indicating the possibility of allergic-type reactions to the color additive.

DATE: Written comments must be received on or before October 5, 1987.

ADDRESS: Send written comments to: Chief, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20004-0385, Attn: Notice No. 638.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e)(2), vests broad authority in the Director of the Bureau of Alcohol, Tobacco and Firearms, as a delegate of the Secretary of the Treasury, to prescribe regulations which will provide the consumer with "adequate information" as to the identity and quality of alcoholic beverages. Under this authority, labeling requirements are prescribed in Title 27, Code of Federal Regulations, Parts 4, 5, and 7 for wines, distilled spirits, and malt beverages, respectively. The regulations requiring basic mandatory labeling information for alcohol beverage products have been effect for over 50 years.

In recent years, the Bureau has considered numerous petitions for regulation changes with respect to the labeling of ingredients in alcoholic beverages, including requests to require full ingredient labeling, partial ingredient labeling, even health warning statements for specific ingredients found in alcoholic beverages which were alleged to be a health hazard. In response to such requests, the Bureau has established a regulatory policy with respect to ingredient labeling, and the need to disclosure to consumers the presence of specific ingredients found to be present in alcohol beverage products which have been determined to pose health risks.

The Bureau, on October 6, 1983, published a final rule (T.D. ATF-150, 48 FR 45549), rescinding the ingredient labeling regulations for alcohol beverage products. However, mandatory label disclosure was required for alcoholic beverages containing the color additive FD&C Yellow No. 5. The Bureau found, as a result of its rulemaking effort, that there was evidence establishing that consumers of the few alcohol beverage products containing that color additive could have adverse reactions to the ingredient. The Bureau also determined

that there was no clear evidence in the record, at that time, that any other ingredient being used in the production of alcohol beverages posed a recognized health problem.

Pursuant to T.D. ATF-150, the Bureau specifically stated it "will look at the necessity of mandatory labeling of other ingredients on a case-by-case basis through its own rulemaking initiative, or on the basis of petitions for rulemaking under 5 U.S.C. § 553(e) and 27 CFR 71.41(c)."

In that regard, ATF has published a final rule in the Federal Register requiring mandatory label disclosure of saccharin for alcoholic beverages containing that artificial sweetener (T.D. ATF-220; December 20, 1985, 50 FR 51851). The Bureau has also published a final rule requiring label disclosure of sulfites when present in alcoholic beverages at a level of ten or more parts per million (T.D. ATF-236; September 30, 1986, 51 FR 34706).

Recently, on November 19, 1986, the Food and Drug Administration (FDA) published a final rule in the Federal Register (51 FR 41765) requiring, in part, mandatory disclosure of FD&C Yellow No. 6 on labels of food products, because of evidence of possible allergic-type reactions to the color additive. In the preamble of this rule, FDA stated that "because there is a possible relationship between FD&C Yellow No. 6 and allergic-type responses in some individuals, ... action should be taken to inform the public of the presence of color additive in food or drugs." FDA believes that a label declaration would enable individuals who may be allergic to FD&C Yellow No. 6 to minimize their exposure to that ingredient.

In view of the above, ATF believes there is now official recognition of evidence linking the presence of FD&C Yellow No. 6 in food and beverages to allergic-type responses in a small percentage of consumers. Therefore, ATF is proposing specific label disclosure of FD&C Yellow No. 6 for alcoholic beverages containing that color additive.

Transition Time

As with the color additive FD&C Yellow No. 5, ATF believes Yellow Dye No. 6 is used infrequently in the production of alcoholic beverages, being limited to mostly cocktails, liqueurs, and other specialty products. Therefore, as in the case of FD&C Yellow No. 5, the Bureau is proposing a one year transition period following the date of publication of a final rule in the Federal Register, for industry to meet the new requirements of specifically disclosing FD&C Yellow No. 6.

Executive Order 12291

In compliance with Executive Order 12291, 46 FR 13193 (1931), ATF has determined that this proposal is not a major rule since it will not result in:

(a) An annual effect on the economy of $100 million or more;

(b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(c) 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.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 630, 604) are not applicable to this proposal because the notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities. The proposal will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposal is not expected to have significant secondary or incidential effects on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of Section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities. Paperwork Reduction Act

The requirement to collect information proposed in this notice has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. 3504(h). Comments relating to ATF's compliance with 5 CFR Part 1320— Controlling Paperwork Burdens on the Public should be submitted to: Office of Information and Regulatory Affairs, Attention: ATF Desk Office, Officer of Management and Budget, Washington, DC 20503.

Public Participation

ATF requests comments from all interested persons. All comments received on or before the closing date will be carefully considered. Comments received after the closing date and too late for consideration will be treated as possible suggestions for future action.

ATF will not recognize any material as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure should not be included in the comment. The name of the person submitting the comment is not exempt from disclosure.

During the comment period, any person may request an opportunity to present oral testimony at a public hearing. However, the Director reserves the right, in light of all circumstances, to determine if a public hearing is necessary.

Disclosure

Copies of this notice and the written comments will be available for public inspection during normal business hours at: ATF Reading Room, Disclosure Branch, Room 4406, Ariel Rios Federal Building, 1200 Pennsylvania Avenue, NW., Washington, DC.

Drafting Information

The author of this document is Coordinator James P. Ficaretta, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, Wine.

27 CFR Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, Packaging and containers.

27 CFR Part 7

Advertising, Beer, Consumer protection, Customs duties and inspection, Imports, and Labeling.

Authority and Issuance.

27 CFR Part 4, *Labeling and Advertising of Wine,* is amended as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for 27 CFR Part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 4.32 is amended by redesignating existing paragraph (c) as (c)(1), and by adding a new paragraph (c)(2) as follows:

§ 4.32 Mandatory label information.

* * * * *

(c) * * *

(2) There shall be stated on the brand label or on a back label a statement that the product contains FD&C Yellow No. 6, where that coloring material is used in the product.

* * * * *

27 CFR Part 5, *Labeling and Advertising of Distilled Spirits*, is amended as follows:

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Par. 3. The authority citation for 27 CFR Part 5 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 4. Section 5.32 is amended by redesignating existing paragraph (b)(5) as (b)(5)(i), and by adding a new paragraph (b)(5)(ii) as follows:

§ 5.32 Mandatory label information.

* * * * *

(b) * * *

(5) * * *

(ii) A statement that the product contains FD&C Yellow No. 6, where that coloring material is used in the product.

* * * * *

27 CFR Part 7, *Labeling and Advertising of Malt Beverages*, is amended as follows:

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

Par. 5. The authority citation for 27 CFR Part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 6. Section 7.22 is amended by redesignating existing paragraph (b)(4) as (b)(4)(i), and by adding a new paragraph (b)(4)(ii) as follows:

§ 7.22 Mandatory label information.

(b) * * *

(4) * * *

(ii) A statement that the product contains FD&C Yellow No. 6, where that coloring material is used in the product.

Signed: July 8, 1987.

Stephen E. Higgins,

Director.

Approved: July 13, 1987.

Francis A. Keating II,

Assistant Secretary, (Enforcement).

[FR Doc. 87-20445 Filed 9-3-87; 8:45 am]

BILLING CODE 4810-31-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA Docket No. AM205PA; FRL-3256-3]

Section 111(d)—TRS Emissions From Kraft Pulp Mill; PA

AGENCY: Environmental Protection Agency.

ACTION: Proposed rulemaking.

SUMMARY: EPA is today proposing to approve regulations submitted by the Commonwealth of Pennsylvania. These regulations will reduce kraft pulp mill Total Reduced Sulfur (TRS) emissions as required under section 111(d) of the Clean Air Act. The intent of this notice is to discuss the results of EPA's review and to solicit public comments on the regulations and EPA's proposed action.

DATE: Comments must be received on or before October 5, 1987. Public comments on this document are requested and will be considered before taking final action on these regulations.

ADDRESSES: Copies of the proposed regulations and accompanying support material are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region III, Air Management Division, 841 Chestnut Building, Eighth Floor, Philadelphia, PA 19107, Attn: Esther Steinberg (3AM11)

Commonwealth of Pennsylvania, Department of Environmental Resources, Bureau of Air Quality Control, 200 North 3rd Street, Harrisburg, PA 17120, Attn: Mr. Gary Triplett.

FOR FURTHER INFORMATION CONTACT: Eileen M. Glen (3AM11) at the EPA, Region III address given above or at (215) 597-8379. All written comments should be sent to Mr. Joseph W. Kunz, Chief, PA/WV Section at the EPA Regional III address shown above.

SUPPLEMENTARY INFORMATION: Section 111(d) of the Clean Air Act requires that pollutants regulated under the standards of performance for new sources also regulated for existing sources of the same category. On May 12, 1979, EPA announced the availability of the final guidelines for the control of TRS emissions from existing kraft pulp mills.

In compliance wtih section 111(d), the Commonwealth of Pennsylvania submitted draft regulations for TRS emissions from kraft pulp mills to the EPA on October 3, 1985. EPA recommended several revisions which were subsequently incorporated into the final draft.

The following table lists the proposed limits for the individual process facilities of a kraft pulp mill:

Facility	Parts per million (ppm) (volume) dry	Condition
Recovery furnace (old design).	20	12-hour average corrected to 8 percent oxygen by volume.
Recovery furnace (new design).	5	Do.
Lime klin	20	Never to be exceeded.
Digester system	5	Do.
Multiple effect evaporator system.	5	Do.
Smelt dissolving tank	20	Do.

All the proposed limits are in compliance with the EPA guideline document except for the smelt dissolving tank value of 20 ppm. Unless substantive adverse comments are received, this higher limit will be approved by EPA because continuous compliance with the more stringent guideline limit of 8.4 ppm by new sources has not been achieved. EPA deems the higher limit to be a reasonable choice of an attainable limit for existing sources in the Commonwealth, based in part on the reasons provided in the May 20, 1986 **Federal Register** notice proposing the relaxation of the NSPS standard from 8.4 ppm to 16 ppm for new smelt dissolving tanks.

Final approval of these regulations by EPA is contingent on the Pennsylvania Department of Environmental Resources redefining the valid 12-hour average as a discrete 12-hour period in the Department's "Continuous Source Monitoring Manual". In addition, it should be noted that the term "New Source" in § 129.20(c) of the regulations refers to the replacement of an old recovery furnace by a new one with a capacity no greater than the original. As stated in the regulation, this replacement clause is valid for only six months following the promulgation of the regulation. Furthermore, it should be noted that any recovery furnace or other affected facility as defined in the New Source Performance Standards (NSPS) for Kraft Pulp Mills, 40 CFR Part 60 Subpart BB, that is new, modified, or reconstructed must comply with the NSPS.

EPA is soliciting public comments on this notice and on issues relevant to EPA's proposed action. Comments will be considered before taking final action. Interested parties may participate in the federal rulemaking procedure by submitting written comments to the address above.

The revisions are being proposed under a procedure called "parallel processing" (47 FR 27073). If the proposed revisions are substantially changed in areas other than those identified in this notice, EPA will evaluate those changes and may publish a revised Notice of Proposed Rulemaking. If no substantial changes are made, EPA will publish a Final Rulemaking Notice on these revisions. The final rulemaking action by EPA will occur only after the regulations have been adopted by Pennsylvania and submitted to EPA. Parallel processing will reduce the time necessary for final approval of these plan revisions by three to four months.

Proposed Action

The EPA proposes to approve the submitted kraft pulp mill regulations, but final action will occur only after all submitted comments are reviewed.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under 5 U.S.C. 605(b), the Administrator has certified that plan approvals do not have a significant economic impact on a substantial number of small entities (See 46 FR 8709).

List of Subjects in 40 CFR Part 62

Air pollution control, Fluoride, Administrative practice and procedure, Intergovernmental relations, Reporting and recordkeeping requirements, Phosphate, Aluminum, Fertilizers, Paper and paper products industry, Sulfuric oxides, Sulfuric acid plants.

Authority: 42 U.S.C. 7401–7642.

Date: April 29, 1987.

Alvin Morris,

Acting Regional Administator.

[FR Doc. 87–20424 Filed 9–3–87; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR PART 721

[OPTS-50562; FRL-3257-5]

1-Chloro-2-Bromoethane; Proposed Determination of Significant New Use

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 1-chloro-2-bromoethane (CBE) (CAS No. 107–04–0). The Agency believes that this substance may be hazardous to human health and/or the environment and that the use described in this proposed rule may result in significant human or environmental exposure. As a result of this rule, certain persons who intend to manufacture, import, or process this substance for a significant new use would be required to notify EPA at least 90 days before commencing that activity. The required notice would provide EPA with the opportunity to evaluate the intended use and, if necessary, prohibit or limit that activity before it occurs.

DATE: Written comments should be submitted to EPA by October 5, 1987.

ADDRESS: Since some comments are expected to contain confidential business information (CBI), all comments should be sent in triplicate to: Document Control Officer (TS–790), Office of Toxic Substances, Environmental Protection Agency, Rm. E–209, 401 M St., SW., Washington, DC 20460.

Comments should include the docket control number OPTS–50562. Nonconfidential comments and sanitized versions of confidential comments received on this proposed rule will be available for reviewing and copying from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, in Rm. NE–G004 at the address given above. For further information on submitting comments containing confidential data, see Unit X of this preamble.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404.

SUPPLEMENTARY INFORMATION: The proposed Significant New Use Rule (SNUR) for 1-chloro-2-bromoethane would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of CBE for any use.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR Part 720. Once EPA receives a SNUR notice, the Agency may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires the Agency to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707. Persons who intend to import a chemical substance are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Persons who import a substance identified in a final SNUR must certify that they are in compliance with the SNUR requirements. The EPA policy in support of the import certification requirements appears at 40 CFR Part 707.

II. Applicability of General Provisions

In the **Federal Register** of September 5, 1984 (49 FR 35011), EPA promulgated general regulatory provisions applicable to SNURs (40 CFR Part 721, Subpart A). The general provisions are discussed in detail in that **Federal Register** notice, and interested persons should refer to that document for further information. On April 22, 1986 (51 FR 15104), EPA proposed revisions to the general provisions, some of which would apply to this proposed SNUR.

III. Summary of This Proposed Rule

The chemical substance which is the subject of this proposed SNUR is 1-chloro-2-bromoethane (CBE) (CAS No. 107–04–0). EPA is proposing to designate any use of CBE as a significant new use of the substance. This proposed rule would require persons who intend to manufacture, import, or process CBE for any use to notify EPA at least 90 days before such manufacture, import, or processing.

If any ongoing uses are identified for CBE, EPA may issue a final section 8(a) rule, or a final section 8(a) rule and

SNUR in place of this proposed SNUR. If EPA decides to issue a final section 8(a) rule for CBE, the requirements specified in 40 CFR Part 704, Subpart A, would apply.

IV. Background

A. Production and Use Data

EPA reviewed both the TSCA Chemical Substance Inventory data base and other information sources to identify current manufacturers, importers, and processors of CBE.

Apparently, CBE is no longer produced in the United States and currently there are no commercial uses, though small amounts are imported and used for research and development. Because of health concerns about the chemical substance, substitutes have been found for commercial applications. CBE is registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) for use as an active pesticide ingredient and has been used in the United States as a fumigant for fruits and vegetables. However, there is no evidence that CBE is currently used as a pesticide in the United States. It has potential use in plant growth and fruit maturity enhancement agents, as well as in agents to regulate plant metabolism. Such uses also would be regulated under FIFRA. CBE can be used as a solvent for cellulose esters and ethers and as an intermediate in chemical synthesis, especially of compounds containing haloalkylamino groups. It is conceivable that CBE could also be used as a substitute for ethylene dibromide (EDB) and ethylene dichloride (EDC) as a lead scavenger in gasoline, and as an intermediate in the production of numerous pharmaceutical agents, such as analgesics, antihistamines, and tranquilizers.

B. Health Effects

CBE has demonstrated mutagenic activity in the Ames *Salmonella* assay and the Chinese hamster ovary cell HGPRT assay. It also showed activity in a deoxyribonucleic acid (DNA) repair assay with *E. coli* and caused *in vivo* DNA damage in mice comparable in degree to that caused by EDB.

No studies examining the relationship between human exposure to CBE and the incidence of human cancer were found in the literature. No animal carcinogenicity studies on CBE were reported in the literature. However, based on its mutagenic activity and structural similarity to EDB, CBE is a suspect carcinogen as well as a potential mammalian mutagen. For these reasons, EPA has concluded that exposure to CBE may present a risk of injury to human health.

C. Exposure

Although present exposure to CBE is thought to be minimal, because of the high probability of carcinogenic activity implied by the *in vitro* results and CBE's close structural analogy to the known carcinogens EDB and EDC, there is concern for exposures from any future use of CBE.

V. Determination of Proposed Significant New Uses

To determine what would constitute a significant new use of CBE, EPA considered relevant information on the toxicity of the substance, likely exposures and releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA expects to achieve the following objectives with regard to the significant new use that is designated in this proposed rule:

1. The Agency wants to ensure that it would receive notice of any company's intent to manufacture, import, or process CBE for a significant new use before that activity begins. Potential uses of CBE as a solvent, as a chemical intermediate, or as a substitute for EDB and EDC could also result in significant human exposure. Risk from these releases cannot be assessed without detailed data on worker exposure, potential releases to the environment, and the substance's fate in these uses.

2. The Agency wants to ensure that it would have an opportunity to review and evaluate data submitted in a significant new use notice before the notice submitter begins manufacturing, importing, or processing CBE for the significant new use.

3. The Agency wants to ensure that it would be able to regulate prospective manufacturers, importers, or processors of CBE before a significant new use of this substance begins, provided that the degree of potential health and environmental risk is sufficient to warrant such regulation.

CBE has demonstrated mutagenic activity and is a close structural analogue to the known carcinogens EDB and EDC. There is concern that CBE may find new markets and that this increased usage could occur without notification of appropriate regulatory authorities. CBE is not subject to any federal regulation that would notify the government of activities that might result in adverse exposures to CBE or provide a regulatory mechanism that could protect human health from potentially adverse exposures before they occurred.

EPA believes that the significant new use and associated manufacture, import, or processing of CBE have a high potential to increase the magnitude and duration of exposure to this substance. Also, given the toxicity of this chemical substance, the reasonably anticipated situations that could result in exposure, and the lack of sufficient existing regulatory controls, individuals could be exposed to CBE at levels which may result in adverse effects.

The consideration of these factors has resulted in EPA's decision to propose that any use of CBE be designated a significant new use of this chemical substance.

VI. Alternatives

EPA is considering alternative regulatory actions for CBE.

1. One alternative is to promulgate a section 8(a) reporting rule for this substance. Under such a rule, EPA could require any person to report to the Agency when they manufacture, import, or process CBE. However, the use of section 8(a) rather than SNUR authority would have several drawbacks. First, EPA would not be able to receive advance notification of the intended activity, nor would it be able to take immediate follow-up regulatory action under section 5(e) or 5(f) as it can under a SNUR to prohibit or limit the activity. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from section 8(a) reporting requirements. In view of the level of health and environmental concern for CBE, the Agency believes that a section 8(a) rule for this substance would not be the most effective choice. However, if, as a result of this proposed rule, any ongoing uses are identified for CBE, EPA may decide to issue a final section 8(a) reporting rule, or both a final 8(a) reporting rule and a SNUR.

2. The Agency also has the authority to regulate substances under section 6 of TSCA. However, the Agency may regulate under section 6 only if there is a reasonable basis to conclude that the manufacture, importation, processing, distribution in commerce, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to human health or the environment. Presently, there is insufficient information about prospective manufacturing, importation, or processing operations, or human health or environmental effects to enable EPA to make a conclusive determination of risk. Therefore, the Agency is not able at this time to take action under section 6 to regulate CBE.

VII. Applicability of Proposed Rule to Uses Occurring Before Promulgation of Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the promulgation of the final rule. If uses begun during the proposal period of a SNUR were considered ongoing, any person could defeat the SNUR by initiating the proposed significant new use before the rule became final. This would make it extremely difficult for the Agency to establish SNUR notice requirements.

Thus, persons who begin commercial manufacture, importation, or processing of CBE for the significant new use designated in this proposed rule between proposal and promulgation of the SNUR would have to cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expired.

EPA recognizes that this interpretation of TSCA may disrupt the commercial activities of persons who begin manufacturing, importing, or processing CBE for a significant new use during the proposal period of this SNUR. However, this proposed rule constitutes notice of that potential disruption, and persons who commence the proposed significant new use prior to promulgation of the SNUR do so at their own risk.

VIII. Test Data and Other Information

EPA recognizes that under TSCA section 5(a)(2), persons are not required to develop any particular test data before submitting a significant new use notice. Rather, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them.

However, in view of the potential risks that may be posed by a significant new use of CBE, EPA encourages SNUR notice submitters to conduct tests that would permit a reasoned evaluation of risks posed by this substance when utilized for an intended use. SNUR notices submitted without accompanying test data may increase the likelihood that EPA would take action under section 5(e).

EPA encourages persons to consult with the Agency before selecting a protocol for testing the substance. As part of this optional prenotice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the substance. Test data should be developed according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792. Failure to do so may lead the Agency to find such data to be insufficient to evaluate reasonably the health or environmental effects of the substance.

EPA urges SNUR notice submitters to provide detailed information on human exposure and environmental release that may result from the significant new use of CBE. In addition, EPA encourages persons to submit information on potential benefits of the substance and information on risks posed by the substance compared to risks posed by potential substitutes.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing significant new use notice requirements for potential manufacturers, importers, and processors of CBE. The Agency's complete economic analysis is available in the rulemaking record for this proposed rule (OPTS-50562).

X. Confidential Business Information

Any person who submits comments claimed as CBI must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the itme of submission will be placed in the public version of the rulemaking record. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR Part 2. EPA requests that any party submitting confidential comments prepare and submit a sanitized version of the comments that EPA can place in the public record.

XI. Rulemaking Record

EPA has established record for this rulemaking (docket control number OPTS-50562). The record includes basic information considered by the Agency in developing this proposed rule. EPA will supplement the record with additional information as it is received. The record now includes the following:

1. This proposed rule.
2. The economic analysis of this proposed rule.
3. A summary of data on CBE prepared by Tracor Jitco/Technical Resources, Inc.

The Agency will accept additional materials for inclusion in the record at any time between this proposal and designation of the complete record. EPA will identify the complete rulemaking record by the date of promulgation. A public version of this record containing sanitized copies from which CBI has been deleted is available to the public in the OTS Public Information Office from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The OTS Public Information Office is located in Rm. NE-G004, 401 M St., SW., Washington, DC.

XII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this proposed rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the reporting cost for submitting a significant new use notice would be approximately $1,400 to $8,000. EPA believes that, because of the nature of the rule and the substance involved, there would be few significant new use notices submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605 (b)), EPA has determined that this proposed rule would not have a significant impact on a substantial number of small businesses. The Agency cannot determine whether parties affected by this proposed rule are likely to be small businesses. However, EPA expects to receive few SNUR notices for the substance since the Agency has no evidence of recent commercial manufacture, import, or processing of CBE. Therefore, EPA believes that the number of small businesses affected by this proposed rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.)* and has assigned OMB control number 2070-0038 to this proposed rule. Comments on these requirements should be submitted to the

Office of Information and Regulaotry Affairs of OMB, marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, significant new uses.

Dated: August 25, 1987.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for Part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

2. By adding new § 721.648 to read as follows:

§ 721.648 1-Chloro-2-bromoethane.

(a) *Chemical substance and significant new use subject to reporting.*

(1) The chemical substance 1-chloro-2-bromoethane (CAS No. 107-04-0) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: any use.

(b) *Specific requirements.* The provisions of Subpart A of this Part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* Section 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture, import, or process for commercial purposes the substance identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

(Approved by the Office of Management and Budget under control number 2070-0038)

[FR Doc. 87-20418 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 87-332, RM-5751]

Radio Broadcasting Services; Oildale, CA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Buckley Broadcasting Corporation, proposing the substitution of FM Channel 237B1 for Channel 237A at Oildale, CA, and mofidication of the license of Station KLLY(FM) accordingly, to provide that community with its first wide coverage area FM service.

DATES: Comments must be filed on or before October 19, 1987, and reply comments on or before November 3, 1987.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Martin R. Leader, Esq., John Joseph McVeigh, Esq., Fisher, Wayland, Cooper & Leader, 1255-23rd Street NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 87-332, adopted August 5, 1987, and released August 28, 1987. 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 contractors, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-20437 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 87-331, RM-5867]

Radio Broadcasting Services; L'Anse, MI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Aaron J. Coffey, proposing the allocation of FM Channel 291C2 to L'Anse, Michigan, as that community's first FM broadcast service. Concurrence of the Canadian government is required for the allotment of FM Channel 291C2 at L'Anse.

DATES: Comments must be filed on or before October 19, 1987, and reply comments on or before November 3, 1987.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Lauren A. Colby, 10 E. Fourth Street, P.O. Box 113, Frederick, Maryland 21701, (Counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 87-331, adopted August 5, 1987, and released August 28, 1987. 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 contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-20438 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 87-341, RM-5779]

Radio Broadcasting Services; Wichita Falls, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Wichita Falls Communications, licensee of Station KTLT(FM), Channel 292A, Wichita Falls, Texas, proposing the substitution of Channel 292C2 for 292A at Wichita Falls and modification of its license to specify the higher class frequency. The proposal would provide a fourth wide coverage area FM station at Wichita Falls.

DATES: Comments must be filed on or before October 19, 1987, and reply comments on or before November 3, 1987.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: Edward W. Hummers, Jr., Esquire, Frank R. Jazzo, Esquire, Fletcher, Heald & Hildreth, 1225 Connecticut Avenue NW., Suite 400, Washington, DC 20036 (Counsels to petitioner).

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 87-341, adopted August 3, 1987, and released August 28, 1987. 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 contractors, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Mass Media Bureau.

[FR Doc. 87-20439 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 80

[PR Docket No. 87-275; FCC 87-255]

Maritime Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rules.

SUMMARY: The amended rules would designate VHF marine channel 13 in lieu of channel 16 as the bridge-to-bridge channel on the Great Lakes. This proposal is in keeping with informal coordination between the Canadian and U.S. Coast Guards.

DATES: Comments must be received on or before October 13, 1987 and reply comments must be received on or before October 28, 1987.

ADDRESS: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jim Shaffer (202) 632-7197 or Maureen Cesaitis (202) 632-7175, Federal Communications Commission, Private Radio Bureau, Washington, DC 20554.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, adopted July 24, 1987 and released August 24, 1987. The complete text of the Commission decision including the rule amendments 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 proposal including the rule amendments may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Summary of Notice of Proposed Rule Making

1. The Vessel Bridge-to-Bridge Radiotelephone Act requires that the Commission designate a specific frequency to be used in U.S. waters by approaching vessels to communicate their intentions to one another. VHF marine channel 13 has been designated for this purpose. However, the Great Lakes were exempted from the terms of the Bridge-to-Bridge Act because under the Great Lakes Radio Agreement channel 16, the distress, safety and calling channel, is also used for bridge-to-bridge communications. Increasing congestion on channel 16 prompted the Canadian Coast Guard and the U.S. Coast Guard to discuss designating channel 13 as the bridge-to-bridge frequency. As a result of these negotiations, the Commission and the Canadian Department of Communications are preparing companion proposals that would specifically designate channel 13 as the bridge-to-bridge frequency in the Great Lakes.

2. Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. 605, it is certified that the amended rules will not have a significant impact on a substantial number of small entities. The only vessels affected by the rule change are those subject to the Great Lakes Radio Agreement.

3. The rule amendments contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980 and found to impose no new information collection and record keeping requirement.

4. This Notice of Proposed Rule Making is issued under the authority of 47 U.S.C. 154(i) and 303(r).

The authority citation for Part 80 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, unless othewise noted. Interpret or apply 48 Stat. 1064-1068, 1081-1105, as amended; 47 U.S.C. 151-155, 301-609; 3 UST 4726, 12 UST 2377, unless otherwise noted.

5. A copy of this Notice of Proposed Rule Making will be served on the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 80

Bridge-to-bridge, Canada, Great Lakes.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-20436 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 172

[Docket No. HM-126C; Notice No. 87-10]

Emergency Response Communication Standards; Extension of Comments Period and Corrections

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed rulemaking: Extension of comment period; corrections.

SUMMARY: On August 20, 1987 RSPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (52 FR 31486). The NPRM proposed to amend the Hazardous Materials Regulations (HMR) by requiring additional emergency response information on shipping papers and placement of response action information in all places, including vehicles, where hazardous materials are transported in commerce. This document extends the comment period and makes two corrections to the NPRM.

DATE: By this document, RSPA extends the comment period of Notice No. 87-10 from September 21, 1987 to December 22, 1987.

FOR FURTHER INFORMATION CONTACT: Lee Jackson, (202) 366-4488, Office of Hazardous Materials Transportation, RSPA, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Representatives of various industries and corporations have contracted RSPA stating that additional time is necessary to fully evaluate the proposals contained in the NPRM. RSPA agrees that additional time should be provided to interested persons so that they are afforded adequate time to comment on the proposals. Therefore, RSPA is extending the closing date for comments on Notice No. 87-10 to December 22, 1987. In addition, RSPA is correcting two errors which appeared in the NPRM.

In Docket No. HM-126C, Notice No. 87-10, which begins on page 31486 of the August 20, 1987 **Federal Register**, the following are corrected:

1. On page 31490, in the third line of the second column, the reference to "Section 1910.1200" is changed to read "Section 1910.120".

2. In § 172.301 (c) introductory text on page 31493, the first sentence in the first column is changed to read: "If the hazardous material is a mixture of two or more hazardous materials, the technical name of at least two components most predominantly contributing to the hazard or hazards of the mixture must be marked in parentheses immediately following the proper shipping name."

Issued in Washington, DC on August 31, 1987.

Alan I. Roberts,

Director, Office of Hazardous Materials Transportation.

[FR Doc. 87-20388 Filed 9-3-87; 8:45 am]

BILLING CODE 4910-60-M

Notices

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

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

Office of the Secretary

Review of the United States Sugar Import Quota System

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: This notice sets forth the annual determination of the Secretary of Agriculture concerning the continued operation of the U.S. sugar import quota system established by Presidential Proclamation 4941 of May 5, 1982 (47 FR 19661).

FOR FURTHER INFORMATION CONTACT: John Nuttall, Chief, Sugar Group, Foreign Agricultural Service, Room 6095, South Building, Department of Agriculture, Washington, DC 20250, Telephone: (202) 447-2916.

SUPPLEMENTARY INFORMATION: In accordance with paragraph (f) of Headnote 3, subpart A, part 10, schedule 1 of the Tariff Schedules of the United States (TSUS), the Secretary of Agriculture has consulted with the U.S. Trade Representative, the Department of State, and other concerned agencies on the operation of the sugar import quota system established under the authority of Headnotes 2 and 3 of subpart A of part 10 of schedule 1 of the TSUS, the now-expired International Sugar Agreement, 1977, Implementation Act, and Section 201 of the Trade Expansion Act of 1962. After reviewing the operation of the sugar import quota system, the Secretary of Agriculture has determined that the system should be continued in effect in order to give due consideration to the interests in the United States sugar market of domestic producers and materially affected contracting parties to the General Agreement on Tariffs and Trade (GATT). The rationale for this decision is based on the following analysis.

A. Current World and U.S. Sugar Market Situation

World sugar production for 1986/87 once again exceeded consumption. This has been the case for every year in the 1980's. As a result, the world sugar market continues to be depressed. World production in 1986/87 is estimated at 101.7 million metric tons, while consumption is estimated at around 100.0 million metric tons. Ending stocks should increase by 1.7 million metric tons and will continue to exceed 40 percent of estimated consumption. The continued high stock levels will prevent any sustained recovery in world sugar prices. Accordingly, the world price (f.o.b.s., Caribbean, No. 11 spot contract as published by the New York Coffee, Sugar and Cocoa Exchange) averaged 6.72 cents per pound during the January 1, 1987 through July 31, 1987 period, compared to 6.49 cents per pound during the same period of the previous year, and prices recently have dropped to as low as 5.03 cents per pound. U.S. centrifugal sugar production is estimated at 6.75 million short tons (6.13 million metric tons), and domestic utilization is expected to be 7.85 million short tons (7.13 million metric tons).

During the period January 1, 1987 through August 15, 1987, 686,901 short tons were charged against the quotas for the 39 countries which have allocations totalling 1,001,430 short tons. The domestic price of raw sugar (c.i.f., duty and fee paid, No. 14 contract nearby futures, January 1, 1987 through July 31, 1987, as published by the New York Coffee, Sugar and Cocoa Exchange) averaged 21.85 cents per pound for the first seven months of the quota year.

B. Outlook for World and U.S. Sugar Market

World centrifugal sugar production and consumption may be close to being balanced in 1987/88. Prospective production increases around the world coupled with a moderate increase in consumption indicate that there will not be a dramatic change in world stocks in 1987/88. However, large world sugar stocks will continue to prevent a substantial recovery in prices. This is relfected in world sugar futures prices which currently range from 5.2 cents per pound for contracts due in September 1987 to 7.1 cents per pound for contracts due to mature in October 1988.

Given these factors, we anticipate that world prices will remain at levels that make it impossible to achieve market conditions that give due consideration to the interests of domestic producers in the U.S. sugar market without a continuation of the current sugar import quota system.

Notice

In accordance with paragraph (f) of Headnote 3, subpart A, part 10, schedule 1 of the TSUS, I have determined that the continued operation of paragraphs (b), (c), (d) and (e) of Headnote 3 gives due consideration to the interests in the U.S. sugar market of domestic producers and materially affected contracting parties to the GATT, and that paragraph (9) of that headnote, which would allow entry of sugar into the United States of not to exceed 6.90 million short tons, would not give due consideration to such interests.

Signed at Washington, DC, on August 31, 1987.

Peter Meyers,

Acting Secretary of Agriculture.

[FR Doc. 87-20392 Filed 9-1-87; 12:04 pm]

BILLING CODE 3410-10-M

COMMISSION ON CIVIL RIGHTS

Meetings; Arizona Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Arizona Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 4:00 p.m., on September 23, 1987, at the Woolley's Petit Suites, 3211 East Pinchot Street, Phoenix, Arizona 85018. The purpose of the meeting is to plan activities and programming for the coming year.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, John While or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, September 1, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20395 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Meetings; Colorado Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Subcommittee of the Colorado Advisory Committee to the Commission will convene at 9:30 a.m. and adjourn at 3:30 p.m. on September 8, 1987, at the Pueblo Holiday Inn, 4001 North Elizabeth, Pueblo, Colorado 81008. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20397 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Meetings; Colorado Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Subcommittee of the Colorado Advisory Committee to the Commission will convene at 9:00 a.m. and adjourn at 12:00 Noon on September 9, 1987, at the Ouray Room, Sky Ute Lodge, Southern Ute Reservation, Ignacio, Colorado 81137. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20399 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Meetings; Colorado Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Subcommittee of the Colorado Advisory Committee to the Commission will convene at 2:00 p.m. and adjourn at 5:00 p.m. on September 9, 1987, at the County Commission Room, 109 West Main, Cortez, Colorado 81321. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20396 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Meetings: Colorado Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that the Colorado Advisory Committee to the Commission will convene at 9:00 a.m. and adjourn at 5:00 p.m. on September 10, 1987 and reconvene at 9:00 a.m. and adjourn at 12 noon on September 11, 1987, at the Radisson Hotel, 1550 Court Place, Denver, Colorado 80202. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20398 Filed 9-3-87;8:45 am]

BILLING CODE 6335-01-M

Colorado Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Subcommittee of the Colorado Advisory Committee to the Commission will convene at 10:00 a.m. and adjourn at 4:30 p.m. on September 9, 1987, at the Greeley Holiday Inn, 609 8th. Avenue, Greeley, Colorado 80631. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign leanguage interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20400 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Colorado Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Subcommittee of the Colorado Advisory Committee to the Commission will convene at 9:30 a.m. and adjourn at 3:30 p.m. on September 8, 1987, at the Grand Junction Holiday Inn, 755 Horizon Dr., Grand Junction, Colorado 81506. The purpose of the meeting is to gather information on the impact in Colorado of the implementation of the Immigration Reform and Control Act.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Maxine Kurtz, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20401 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Nebraska Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Nebraska Advisory Committee to the Commission will convene at 10:00 a.m. and adjourn at 4:00 p.m., on September 18, 1987, at the Scottsbluff Inn, 1901 21st Avenue, Scottsbluff, Nebraska. The purpose of the meeting is to hear presentations on the status of civil rights in Nebraska. Presenters include representatives of the Scottsbluff Police Department, Scotts Bluff Sheriff Department, Nebraska Mexican American Affairs Commission, Scotts Bluff County Clerk, Nebraska Association of Farmworkers and the American Indian community. In addition, program ideas and activities for fiscal year 1988 will be discussed.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Richard F. Duncan, or Melvin Jenkins, Director of the Central Regional Division (816) 374-5253, (TDD 816/374-5009). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rule and regulations of the Commission.

Dated at Washington, DC, September 1, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20402 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

North Dakota Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the North Dakota Advisory Committee to the Commission will convene at 1:00 p.m. on September 19, 1987, at the Doublewood Ramada Inn, Board Room, 1400 East Interchange Avenue, Bismark, North Dakota. The purpose of the meeting it to plan activities and programming for the coming year.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Modesto Del Busto or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rule and regulations of the Commission.

Dated at Washington, DC, September 1, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20403 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Tennessee Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Tennessee Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 3:30 p.m., on September 23, 1987, at the Vanderbilt Plaza Hotel, 2100 West End Avenue, Nashville, Tennessee. The purpose of the meeting is to receive background information on desegregation in public higher education in the State and finalize plans for a community forum on that subject.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, James F. Blumenstein, or Melvin Jenkins, Director of the Central Regional Division (816) 374-5253, (TDD 816/374-5009). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, September 1, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20404 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

Utah Advisory Committee; Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Utah Advisory Committee to the Commission will convene at 7:00 p.m. and adjourn at 9:00 p.m. on September 16, 1987 at the Cotillion A Room, Airport Holiday Inn, 1659 W. North Temple, Salt Lake City, Utah 84116. The purpose of the meeting is to conduct program planning.

Persons desiring additional information, or planning a presentation to the Committee should contact Committee Member Shu H. Cheng, or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, August 31, 1987.

Susan J. Prado,

Acting Staff Director.

[FR Doc. 87-20405 Filed 9-3-87; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[P373]

Marine Mammals; Permit Modification; Dr. Lanny Cornell and Mr. Edward Asper

Notice is hereby given that pursuant to the provisions of § 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), Scientific Research Permit No. 549 issued to Dr. Lanny H. Cornell and Mr. Edward Asper, 1720 South Shores Road, San Diego, California 92109, on June 3, 1986 (51 FR 19883), is modified as follows:

Section A.2 is added:

2. An unspecified number of specimens taken from live marine mammals of the Order Cetacea and Pinnipedia (except walrus) be imported and exported for research purposes provided:

(a) The specimens are taken by scientists/veterinarians for usual and customary veterinary or curatorial purposes;

(b) The specimens are taken from animals which are not listed as endangered, threatened or depleted;

Section B.14 is added:

14. This importation/exportation shall be conducted for the purposes set forth in the application and modification request.

This modification became effective on August 26, 1987.

Documents submitted in connection with the above modification are available for review in the following offices:

Office of Protected Resources and Habitat Programs, National Marine Fisheries Service, 1825 Connecticut Ave., NW., Room 805, Washington, DC 20009;

Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, Florida 33702;

Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way, NE., BIN C15700, Seattle, Washington 98115–0070;

Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731;

Director, Northeast Region, National Marine Fisheries Service, 14 Elm Street, Federal Building, Gloucester, Massachusetts 01930;

Director, Alaska Region, National Marine Fisheries Service, P.O. Box 1668, Juneau, Alaska 99802; and

Director, U.S. Fish and Wildlife Service, 1000 Glebe Road, Room 611, Arlington, Virginia 22201.

Date: August 26, 1987.

Nancy Foster,

Director, Office of Protected Resources and Habitat Programs, National Marine Fisheries Service.

[FR Doc. 87–20413 Filed 9–3–87; 8:45 am]

BILLING CODE 3510-22-M

[P8F]

Marine Mammals; Issuance of Permit; Naval Ocean Systems Center

On July 10, 1987, notice was published in the **Federal Register** (52 FR 26056) that an application had been filed by the Naval Ocean Systems Center, P.O. Box 997, Kailua, Hawaii 96734 for a permit to import four (4) false killer whales (*Pseudorca crassidens*) and four (4) Grampus (*Grampus griseus*) from Japan for scientific research.

Notice is hereby given that on August 28, 1987, as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407) the National Marine Fisheries Service issued a Permit for the above taking subject to certain conditions set forth therein.

The Permit is available for review by interested persons in the following offices:

Office of Protected Resources and Habitat Programs, National Marine Fisheries Service, 1825 Connecticut Avenue, NW., Room 805, Washington, DC 20009; and

Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731–7415.

Date: August 28, 1987.

Nancy Foster,

Director, Office of Protected Resources and Habitat Programs, National Marine Fisheries Service.

[FR Doc. 87–20414 Filed 9–3–87; 8:45 am]

BILLING CODE 3510-22-M

COMMODITY FUTURES TRADING COMMISSION

Chicago Board of Trade Proposed Futures Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures contract.

SUMMARY: The Chicago Board of Trade ("CBT") has applied for designation as a contract market in the CBOE (Chicago Board Options Exchange) 50 Stock Index. The Director of the Division of Economic Analysis of the Commodity Futures Trading Commission ("Commission"), acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposal for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATE: Comments must be received on or before November 3, 1987.

ADDRESS: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Reference should be made to the CBT CBOE 50 Stock Index futures contract.

FOR FURTHER INFORMATION CONTACT: Naomi Jaffe, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, (202) 254–7227.

Copies of the terms and conditions of the proposed futures contract will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address or by phone at (202) 254–6314.

Other materials submitted by the CBT in support of the application for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR Part 145 (1984)), except to the extent they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Acts Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views or arguments on the terms and conditions of the proposed futures contract, or with respect to other materials submitted by the CBT in support of the application, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, by November 3, 1987.

Issued in Washington, DC on September 1, 1987.

Paula A. Tosini,

Director, Division of Economic Analysis.

[FR Doc. 87-20449 Filed 9-3-87; 8:45 am]

BILLING Code 6351-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting; Task Force on Process for Ada 9X

ACTION: Notice of Meeting.

SUMMARY: A meeting of Task Force on Process for Ada 9X will be held Wednesday, September 16, 1987 from 9:00-5:00 p.m. at the Software Engineering Institute, 4500 Fifth Avenue, Pittsburgh, PA 15213, to discuss the process for developing Ada 9X and to develop recommendations to be forwarded to the Ada Board.

FOR FURTHER INFORMATION CONTACT: Ms. Jackie Rota, IIT Research Institute, Ada Information Clearinghouse, 4550 Forbes Boulevard, Suite 300, Lanham, Maryland 20706, (703) 685-1477.

Linda M. Bynum,

Alternate Office of the Secretary of Defense, Federal Register Liaison Office, Department of Defense.

August 31, 1987.

[FR Doc. 87-20407 Filed 9-3-87; 8:45 am]

BILLING CODE 3810-01-M

Membership of the Defense Contract Audit Agency (DCAA) Performance Review Board; Membership

AGENCY: Defense Contract Audit Agency, DOD.

ACTION: Notice of Membership of the Defense Contract Audit Agency Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) of the Defense Contract Audit Agency (DCAA). The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). The Performance Review Board provides fair and impartial review of Senior Executive Service (SES) Performance appraisals and makes recommendations to the Director, Defense Contract Audit Agency, regarding final performance ratings and performance awards for DCAA SES members.

EFFECTIVE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Roger D. Kriesch, Personnel Management Specialist, Office of the Director of Personnel and Security, Defense Contract Audit Agency, Department of Defense, Cameron Station, Alexandria, Virginia, 202/274-5798.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the following are the names and titles of the executives who have been appointed to serve as members of the DCAA Performance Review Board. They will serve a one-year term, effective upon publication of this notice.

Mr. John Quill, General Counsel, Defense Legal Services Agency, Chairperson

Ms. Joanne Shuck, Director, Resources Management, Assistant Secretary of Defense (Command, Control, Communications and Intelligence), member

Mr. Peter H. Tovar, Chief, Accounting and Finance Division, Office of the Comptroller, Defense Logistics Agency, member

Linda M. Bynum,

Alternate Office of Secretary of Defense Federal Liaison Officer, Department of Defense.

September 1, 1987.

[FR Doc. 87-20408 Filed 9-3-87; 8:45 am]

BILLING CODE 3810-01-M

Per Diem, Travel and Transportation Allowance Commitee; Publication of Changes in Rates

AGENCY: Per Diem, Travel and Transportation Allowance Committee, DOD.

ACTION: Publication of Changes in Per Diem Rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 141. This bulletin lists changes in per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and possessions of the United States. Bulletin Number 141 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

EFFECTIVE DATE: September 1, 1987.

SUPPLEMENTARY INFORMATION: This document gives notice of changes in per diem rates prescribed by the Per Diem, Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. Distribution of Civilian Per Diem Bulletins by mail was discontinued effective June 1, 1979. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of change in per diem rates to agencies and establishments outside the Department of Defense.

The text of the Bulletin follows:

Civilian Personnel Per Diem Bulletin Number 141 to the Heads of the Executive Departments and Establishments

SUBJECT: Maximum Per Diem Rates for Official Travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government Civilian Employees

1. This bulletin is issued in accordance with Executive Order 12561, dated July 1, 1986, which delegates to the Secretary of Defense the authority of the President in 5 U.S. Code 5701(a) to set maximum per diem rates and actual expense reimbursement ceilings for Federal civilian personnel traveling on official business in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands, and possessions of the United States. When appropriate and in accordance with regulations issued by competent authority, lesser rates and ceilings may be prescribed.

2. The maximum per diem rates shown in the following table are continued from the preceding Bulletin Number 140 except for the cases identified by asterisks which rates are effective on the date of this Bulletin unless otherwise indicated.

3. Each Department or establishment subject to these rates shall take appropriate action to disseminate the contents of this Bulletin to the appropriate headquarters and field agencies affected thereby.

4. The maximum per diem rates referred to in this Bulletin are:

Locality	*Maximum rate*
Alaska:	
Adak [1]	$25
Anaktuvuk Pass	140
Anchorage	125
Atqasuk	215
Barrow	150
Bethel	124
Bettles	110
Cold Bay	120
Coldfoot	122
College	105
Cordova	118
Deadhorse	113
Dillingham	114
Dutch Harbor-Unalaska	127
Eielson AFB	105
Elmendorf	125
Fairbanks	105

Locality	Maximum rate
Ft. Richardson	125
Ft. Wainwright	105
Homer	115
Juneau	109
Katmai National Park	148
Kenai	104
Ketchikan	105
King Salmon [3]	134
Kodiak	118
Kotzebue [3]	136
Kuparuk Oilfield	127
Murphy Dome [3]	105
Noatak	136
Nome	129
Noorvik	136
Petersburg	113
Point Hope	160
Point Lay	179
Prudhoe Bay	113
St. Paul Island	115
Sand Point	103
Shemya AFB [3]	30
Shungnak	136
Sitka-Mt. Edgecombe	110
Skagway	113
Spruce Cape	118
St. Mary's	100
Tanana	129
Umiat	160
Unakakleet	105
Valdez	147
Wainwright	165
Walker Lake	136
Wrangell	113
Yakutat	110
All other localities [3,4]	91
American Samoa	81
Guam M. I.*	96
Hawaii:	
Hawaii, Island of:	
Hilo	66
Other	88
Kauai, Island of:	
12-20—3-31	127
4-1—12-19	91
Oahu, Island of	102
All other Islands	88
Johnston Atoll [2]	23
Midway Islands [1]	13
Northern Mariana Islands:	
Rota	76
Saipan	92
Tinian	68
All other Islands	20
Puerto Rico:	
Bayamon:	
12-16—5-15	134
5-16—12-15	107
Carolina:	
12-16—5-15	134
5-16—12-15	107
Fajardo (including Luquillo):	
12-16—5-15	134
5-16—12-15	107
Ft. Buchanan (including GSA Service Center, Guaynabo):	
12-16—5-15	134
5-16—12-15	107
Roosevelt Roads:	
12-16—5-15	134
5-16—12-15	107
Sabana Seca:	
12-16—5-15	134
5-16—12-15	107
San Juan (including San Juan Coast Guard Units):	
12-16—5-15	134
5-16—12-15	107
All other localities	107
Virgin Islands of U.S.:	
12-1—4-30	156
5-1—11-30	126
Wake Island [2]	20
All other localities	20

[1] Commercial facilities are not available. The per diem rate covers charges for meals in available facilities plus an additional allowance for incidental expenses and will be increased by the amount paid for Government quarters by the traveler. For Adak, Alaska: on any day when Government quarters are not used and quarters are obtained at a construction camp, a daily travel per diem allowance of $69 is prescribed to cover the costs of lodging, meals and incidental expenses.

[2] Commercial facilities are not available. Only Government-owned and contractor operated quarters and mess are available at this locality. This per diem rate is the amount necessary to defray the cost of lodging, meals and incidental expenses.

[3] On any day when U.S. Government or contractor quarters and U.S. Government or contractor messing facilities are used, a per diem rate of $13 is prescribed to cover meals and incidental expenses at Shemya AFB and the following Air Force Stations: Cape Lisburne, Cape Newenham, Cape Romanzof, Clear, Cold Bay, Fort Yukon, Galena, Indian Mountain, King Salmon, Kotzebue, Murphy Dome, Sparrevohn, Tatalina and Tin City. This rate will be increased by the amount paid for U.S. Government or contractor quarters and by $4 for each meal procured at a commercial facility. The rates of per diem prescribed herein apply from 0001 on the day after arrival through 2400 on the day prior to the day of departure.

[4] On any day when U.S. Government or contractor quarters and U.S. Government or contractor messing facilities are used, a per diem rate of $34 is prescribed to cover meals and incidental expenses at Amchitka Island, Alaska. This rate will be increased by the amount paid for U.S. Government or contractor quarters and by $10 for each meal procured at a commercial facility. The rates of per diem prescribed herein apply from 0001 on the day after arrival through 2400 on the day prior to the day of departure.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

August 31, 1987.

[FR Doc. 87-20406 Filed 9-3-87; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF EDUCATION

Notice Inviting Public Comment on the Condition of American Education

AGENCY: Department of Education.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Secretary of Education invites public comment on the condition of American education, to help in the preparation of a report requested by the President on the state of American education five years after release of *A Nation At Risk*, the 1983 report of the National Commission on Excellence in Education.

The Secretary's forthcoming report will include an examination of progress on issues raised by the 1983 report, including its recommendations on the content of curricula; standards and expectations for American schools; time allocted to learning and instruction; the quality of teaching; and leadership and fiscal support.

The forthcoming report may also address issues not prominently featured in the 1983 report, and the Secretary invites additional comment on these as well. In this category may be included the role of parents in education; the conditions of elementary and higher education; the role of schools in developing character and citizenship; the influence of the wider culture on educational achievement; and changes in education policy arising since release of the 1983 report. The Secretary also invites comment on opportunities for future improvement in the American education system.

DATES: Comments are requested by October 5, 1987.

ADDRESSES: Public comments should be addressed to "1988 Report," U.S. Department of Education, 555 New Jersey Avenue, NW., Room 304-E, Washington, DC 20208.

FOR FURTHER INFORMATION CONTACT: Ann Swift, Information Services, 555 New Jersey Avenue, NW., Room 300-I, Washington, DC 20208. Telephone: (202) 537-6651 or 800-424-1616.

Dated: September 2, 1987.

William J. Bennett,

Secretary of Education.

[FR Doc. 87-20594 Filed 9-3-87; 8:51 am]

BILLING CODE 4000-01-M

[CFDA No. 84.072A]

Applications for New Awards Under the Indian Education Act of 1972, as Amended, Part A—Indian Controlled Schools for Fiscal Year 1988; Correction

AGENCY: Department of Education.

ACTION: Correction Notice.

SUMMARY: This notice corrects an error made in the application notice published on August 31, 1987, in the **Federal Register** on page 32831. The applications available date is corrected to read September 30, 1987, and the deadline for transmittal of applications date is corrected to read November 16, 1987.

FOR APPLICATIONS OR FURTHER INFORMATION CONTACT: Elsie Janifer, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2166, Washington, DC 20202. Telephone: (202) 732-1918.

Program authority: 20 U.S.C. 241bb(b).

Dated: August 31, 1987.

Beryl Dorsett,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 87-20475 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No. 84.061A]

Applications for New Awards Under the Indian Education Act of 1972, as Amended, Part B—Educational Services Projects for Fiscal Year 1988; Correction

AGENCY: Department of Education.

ACTION: Correction notice.

SUMMARY: This notice corrects an error made in the application notice published on August 31, 1987, in the **Federal Register** on page 32831. The applications available date is corrected to read September 30, 1987, and the deadline for transmittal of applications date is corrected to read November 16, 1987.

FOR APPLICATIONS OR FURTHER INFORMATION CONTACT: Elsie Janifer, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2166, Washington, DC 20202. Telephone: (202) 732-1918.

Program authority: 20 U.S.C. 3385 (a), (c).

Dated: August 31, 1987.

Beryl Dorsett,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 87-20477 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No. 84.061C-E]

Applications for New Awards Under the Indian Education Act of 1972, as Amended, Part B—Planning, Pilot and Demonstration Projects for Fiscal Year 1988; Correction

AGENCY: Department of Education.

ACTION: Correction Notice.

SUMMARY: This notice corrects an error made in the application notice published on August 31, 1987, in the Federal Register on page 32831. The applications available date is corrected to read September 30, 1987, and the deadline for transmittal of applications date is corrected to read November 16, 1987.

FOR APPLICATIONS OR FURTHER INFORMATION CONTACT: Elsie Janifer, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2166, Washington, DC 20202. Telephone: (202) 732-1918.

Program authority: 20 U.S.C. 3385(a)(1), (b).

Dated: August 31, 1987.

Beryl Dorsett,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 87-20475 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No. 84.062A]

Applications for New Awards Under the Indian Education Act of 1972, as amended, Part C—Educational Services Projects for Fiscal Year 1988; Correction

AGENCY: Department of Education.

ACTION: Correction Notice.

SUMMARY: This notice corrects an error made in the application notice published on August 31, 1987, in the **Federal Register** on page 32830. The applications available date is corrected to read September 30, 1987, and the deadline for transmittal of applications date is corrected to read November 16, 1987.

FOR APPLICATIONS OR FURTHER INFORMATION CONTACT: Elsie Janifer, U.S. Department of Education, 400 Maryland Avenue, SW., Room 2166, Washington, DC 20202. Telephone: (202) 732-1918.

Program authority: 20 U.S.C. 1211a(b).

Dated: August 31, 1987.

Beryl Dorsett,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 87-20476 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

Intergovernmental Advisory Council on Education; Meeting

AGENCY: Intergovernmental Advisory Council on Education, Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Intergovernmental Advisory Council on Education. This notice also describes the functions of the council. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATE: September 21-22, 1987.

ADDRESS: Sept. 21, 10:00 am-5:00 pm: The Washington Marriott, 1221 22nd Street, NW., Washington, DC 20037.

Sept. 22, 10:00 am-Noon: Department of Education, 400 Maryland Avenue, SW., Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Jacqueline McGregor, Executive Director, Intergovernmental Advisory Council on Education, 413 Reporters Building, 300 Seventh Street, SW., Washington, DC 20202, 472-6464.

SUPPLEMENTARY INFORMATION: The Intergovenmental Advisory Council on Education was established under section 213 of the Department of Education Organization Act (20 U.S.C. 3423). The Council was established to provide assistance and make recommendations to the Secretary and the President concerning intergovernmental policies and relations pertaining to education.

The meeting is open to the public. The proposed agenda includes:

—Swearing-in of new members

—Old Business

—New Business

Records are kept of all council proceedings, and are available for public inspection at the office of the Intergovernmental Advisory Council on Education, 413 Reporters Building, 300 Seventh Street, SW., Washington, DC 20202, from the hours of 9:00 a.m. to 5:00 p.m.

Dated: September 1, 1987.

Peter R. Greer,

Deputy Under Secretary for Intergovernmental and Interagency Affairs.

[FR Doc. 87-20482 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

Senior Executive Service, Membership of the Performance Review Board

AGENCY: Department of Education.

ACTION: Notice of membership of the Performance Review Board.

SUMMARY: Notice is hereby given by the names of members of the Department of Education Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Martha C. Brooks, Director, Executive Resources Staff, Office of Personnel Resource Management Service, Office of Management, Department of Education, [Room 1085, FOB 6], 400 Maryland Avenue, SW., Washington, DC 20202, Telephone: [202] 472-3567.

SUPPLEMENTARY INFORMATION: Section 4314(c) (1) through (5) of Title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards. The Board shall review and evaluate the initial rating, any written response by the senior executive, any further reply by a higher level executive,

and will conduct such further review as the Board finds necessary.

Membership

The following executives of the Department of Education have been selected to serve on the Performance Review Board of the Department of Education: Mary Rose, Co-Chair; Ronald Kimberling, Co-Chair; Charles J. O'Malley, Kenneth Whitehead, Henry Curry, Milton Goldberg, Emerson Elliott, Thomas Skelly, Carol Cichowski, Leroy Cornelsen, Theodore Sky, Jack Klenk, Mary Jean LeTendre, Daniel Lau, Ernest Canellos, Alicia Coro, Lois Bowman, John Pucciano, Charles Kolb, Diane Weinstein, Patrick Pizzella, William Smith, Thomas Bellamy, Arthur Sinai, Carlos Rice, Ronald Oleyar, Sylvia Pate, Ex-Officio Member.

Dated: August 31, 1987.

Mary M. Rose,

Deputy Under Secretary for Management.

[FR Doc. 87-20479 Filed 9-3-87; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[ERA Docket No. 87-46-NG]

Application To Import Natural Gas From Canada; Williams Gas Marketing Co.

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of application for blanket authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt on August 26, 1987, of an application filed by Williams Gas Marketing Company (Williams), for blanket authorization to import Canadian natural gas for short-term and spot market sales in the United States. Authorization is requested to import up to 200 Bcf for a two-year term beginning on the date of the first delivery. The gas would be sold on a short-term or spot basis to U.S. purchasers including pipelines, local distribution companies, electric utilities and commercial and industrial end-users. Williams, a wholly-owned subsidiary of Williams Companies, Inc., of Tulsa, Oklahoma, would import gas for its own account or act as a broker for U.S. purchasers as well as Canadian suppliers. The specific terms of each import and sale would be negotiated on an individual basis, including price and volumes. Williams intends to utilize existing pipeline facilities for transportation of the volumes imported.

DATE: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed no later than October 5, 1987.

FOR FURTHER INFORMATION CONTACT:

Tom Dukes, Natural Gas Division, Economic Regulatory Administration, Forrestal Building, Room GA-076, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586-9590

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E-042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-6667

SUPPLEMENTARY INFORMATION: The decision on this application will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that this import arrangement is competitive. Parties opposing the arrangement bear the burden of overcoming this assertion.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. yThe filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate procedural action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA-076, RG-23, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9478. They must be filed no later than 4:30 p.m. e.d.t., October 5, 1987.

The Administrator intends to develop a decisional record on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or a trial-type hearing. A request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Williams' application is available for inspection and copying in the Natural Gas Division Docket Room, GA-076-A at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, August 31, 1987.

Constance L. Buckley,

Director, Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 87-20451 Filed 9-3-87; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER87-599-000, et al.]

Electric Rate and Corporate Regulation Filings: Gulf States Utilities Co. et al.

August 31, 1987.

Take notice that the following filings have been made with the Commission.

1. Gulf States Utilities Company

[Docket No. ER87-599-000]

Take notice that on August 25, 1987, Gulf States Utilities Company (GSU) tendered for filing a contract for purchases of economic energy by Florida Power and Light Company from GSU.

GSU requests an effective date of August 18, 1987, for the contract.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

2. Arizona Public Service Company

[Docket No. ER87-603-000]

Take notice that on August 27, 1987, Arizona Public Service Company (APS) tendered for filing Supplemental Agreement No. 3 to the Wholesale Power Supply Agreement between Arizona Public Service Company (APS) and Arizona Power Authority (APA) executed August 4, 1987.

In the event APA loses a portion of its load served by Electrical District No. 4 (District) as a result of redevelopment of a portion of said District's service area from agricultural to non-agricultural proposes and APS becomes the supplier for such new load, APA may reduce its Contract Demand at the appropriate delivery point up to the amount of the kW load lost by the District.

APS requested that this Agreement become effective 60 days from the date of filing with FERC.

Copies of this filing are being served upon APA and the Arizona Corporation Commission.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this document.

3. Arizona Public Service Company

[Docket No. ER87-602-000]

Take notice that on August 26, 1987, Arizona Public Service Company (Company) tendered for filing, pursuant to 18 CFR 35.15 Notices of Cancellation of Wholesale Power Agreements (Current Agreement) for Maricopa County Municipal Water Conservation District No. (MCM), (FPC Rate Schedule No. 14); Roosevelt Irrigation District (RID) (FPC Rate Schedule No. 15) and Buckeye Water Conservation and Drainage District (BCD), (FPC Rate Scedule No. 16) (Collectively referred to as "Districts") in the form set forth in 18 CFR 131.53.

The Company states that it presently provides wholesale electrical power and operating and wheeling services to the Districts under the Current Agreements. And by letters dated October 1, 1984, the Company notified the districts of its intent to cancel the Current Agreements pursuant to Article XXII of the Agreement for MCM and Article XXI of the Agreements for RID and BCD. The Current Agreements provide for termination at midnight on December 31, 1987.

The Company requests waiver of the notice requirements under 18 CFR 35.15 to allow sufficient time for the Commission to act on the matter to ensure that these Notices of Cancellation become effective as of the December 31, 1987 date of expiration of the Current Agreements.

Copies of this filing have been served upon the Districts and the Arizona Corporation Commission.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

4. Cambridge Electric Light Company

[Docket No. ER87-600-000]

Take notice that on August 25, 1987, Cambridge Electric Light Company (Cambridge) tendered for filing, pursuant to § 35.12 of the Commission's regulations, a proposed tariff for the provision of non-firm transmission services at wholesale. Cambridge states that its proposed tariff is intended to be generally-available to investor-owned utilities, municipalities operating an electric distribution system and "Qualifying Facilities". The tariff proposes a cost of service formula rate to be implemented on an annual basis. If implemented based upon data applicable to calendar 1986, such rate would be $2.14 per kilowatt per month. Cambridge proposes that its tariff become effective upon November 1, 1987, an even date slightly in excess of sixty days following the instant filing.

Cambridge states that copies of the tendered filing have been served upon the Massachusetts Department of Public Utilities.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

5. Commonwealth Electric Company—Boston Edison Company and Montaup Electric Company

[Docket No. ER87-601-000]

Take notice that on August 25, 1987, Commonwealth Electric Company (Commonwealth) tendered for filing on behalf of itself, Montaup Electric Company and Boston Edison Company supplemental data pertaining to their applicable gross investments, combined Federal income and franchise tax rates, and local tax rates for the twelve-month period ending December 31, 1986. Commonwealth states that this supplemental data is submitted pursuant to a letter order of the Federal Power Commission in Docket No. E-7981 dated April 26, 1973 accepting for filing Commonwealth's Rate Schedule FERC No. 21, Boston Edison Company's Rate Schedule FERC No. 67, and Montaup Electric Company's Rate Schedule No. 27.

Commonwealth states that these rate schedules have previously been similarly supplemented for the calendar years 1972 through 1985.

Copies of said filing have been served upon Boston Edison Company, Montaup Electric Company, Northeast Utilities and the Massachusetts Department of Public Utilities.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

6. Connecticut Light and Power Company et al.

[Docket No. ER87-604-000]

Take notice that on August 26, 1987, Connecticut Light and Power Company (CL&P) tendered for filing proposed amendments (Amendments) to various rate schedules with respect to system sales agreements.

CL&P states that the Amendments reduce the capacity charge and/or energy reservation charge in each of the rate schedules to a maximum of $10.00 per megawatt-hour when CL&P and Western Massachusetts Electric Company (WMECO) (collectively called the "NU Companies") are the seller.

CL&P requests that the Commission waiver its standard notice period and permit the Amendments to become effective as of July 1, 1987.

WMECO has filed a Certificate of Concurrence in this docket.

CL&P states that copies of this Amendment have been mailed or delivered to each of the affected parties.

CL&P further states that the filing is in accordance with Section 35 of the Commission's Regulations.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

7. Pacific Power & Light Company, an assumed business name of PacifiCorp

[Docket No. ER87-521-000]

Take notice that on August 26, 1987, Pacific Power & Light Company (Pacific), an assumed business name of PacifiCorp, tendered for filing Amendment No. 1 dated August 21, 1987, to the Long-Term Power Sales Agreement dated June 30, 1987, between Pacific and Southern California Edison Company (Edison).

Copies of this filing were supplied to the Public Utilities Commission of the State of California and Edison.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

8. Idaho Power Company

[Docket No. ER87-598-000]

Take notice that on August 24, 1987, Idaho Power Company tendered for filing pursuant to section 205(c) of the Federal Power Act and in accordance with the provisions of § 35.30 of the Commission's Rules of Practice and Procedure, copies of Idaho's agreement with and/or objections to the Average System Cost adjustments made by BPA in its Average System Cost Report for Idaho Power's Idaho residential jurisdiction.

This report contains:

1. BPA's Average System Cost Report for Idaho Power Company—Idaho Jurisdiction, dated August 3, 1987.

2. An Appendix 1 for the Company's Idaho jurisdiction which demonstrates an ASC of 17.83 mills per kwh pursuant to BPA's 1984 ASC Methodology. Also attached are supplemental schedules which detail the allocation and functionalization of each cost item referenced in the Appendix 1. Included are detailed tables which indicated the jurisdictional separation study results using the same allocation methods and procedures used by the Idaho Public Utility Commission in its Order Nos. 20610 and 20924, and reviewed by BPA in its ASC Report dated August 3, 1987.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

9. Southern California Edison Company

[Docket No. ER87-365-000]

Take notice that on August 25, 1987, Southern California Edison Company tendered for filing an amendment to its filing in Docket No. ER87-365-000 to make proposed changes in its FERC Electric Service Tariff, Time-of-Use Resale Service, Schedule R-4.1. The proposed changes incorporated in proposed Schedule R-4.2 would decrease revenues for the 12-month period ending December 31, 1986, from jurisdictional sales and service by $6.3 million from revenues at present rates, Schedule R-4.1, to reflect the first-year impact of the Tax Reform Act of 1986 on the resale revenue requirement.

These proposed rates, Schedule R-4.2, are to become effective on January 1, 1987, in accordance with terms of a settlement agreement approved by the FERC in Docket No. ER86-271-000.

Also filed were proposed rates, Schedule R-4.3, which would decrease revenues for the 12-month period ending December 31, 1986, by an additional $5.4 million to become effective on January 1, 1988, to reflect the second year impact of the Tax Reform Act of 1986 on the resale revenue requirement. As rates for all resale customers except the City of Vernon have been changed effective June 1, 1987, in Docket No. ER87-483-000, the Schedule R-4.3 rates would be applicable only to the City of Vernon, and only if rates established in Docket No. ER86-271-000 were still in effect on that date.

Copies of this amendment were served upon the public utility's jurisdictional customers, the California Public Utilities Commission, and the Arizona Corporation Commission.

Comment date: September 14, 1987, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 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 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-20484 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP87-224-001 et al.]

Natural Gas Certificate Filings; Northwest Pipeline Corp. et al.

Take notice that the following filings have been made with the Commission:

1. Northwest Pipeline Corporation

August 28, 1987.

[Docket No. CP87-224-001]

Take notice that on August 7, 1987, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP87-224-001 an amendment to its pending application filed on February 27, 1987, in Docket No. CP87-224-000 pursuant to section 7(b) of the Natural Gas Act for a certificate of public convenience and necessity granting permission and approval to partially abandon the transportation and delivery of the direct sale of natural gas to Chevron Chemical Company (Chevron), all as more fully set forth in the amendment which is on file with the Commission and open to public inspection.

Northwest states that in its application filed in Docket No. CP87-224-000, it proposed to immediately reduce its authorized maximum delivery of gas to Chevron's Finley ammonia plant from 160,000 therms per day of firm and 40,000 therms per day of interruptible service to a total of 50,000 therms per day which would be available on a firm basis until February 28, 1988, and on an interruptible basis thereafter.

Northwest's amended application requests that its currently authorized 160,000 therms per day of firm service and 40,000 therms of interruptible be abandoned down to a total service level of 140,000 therms per day, of which 50,000 therms per day would be firm and 90,000 per day would be interruptible from June 21, 1987 to February 29, 1988, with the full 140,000 therms per day being available only on an interruptible basis thereafter, all pursuant to an Amendatory Agreement dated June 21, 1987. Further, Northwest states that the Amendatory Agreement revised the commodity charges applicable to volumes of gas sold and delivered from June 21, 1987 to February 29, 1988. Northwest states that the commodity charge would be the lower of Rate Schedule ODL-1 Commodity Charge or the actual weighted average cost of gas for Northwest's system plus a variable operation and maintenance cost of 2.3 cents per MMBtu plus GRI charges plus fuel.

Comment date: September 18, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

2. Tennessee Gas Pipeline Company a Division of Tenneco Inc.

August 28, 1987.

[Docket No. CP87-494-000]

Take notice that on August 13, 1987, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Applicant), P.O. Box 2511, Houston, Texas 77001, filed in Docket No. CP87-494-000 a request, pursuant to § 284.223 of the regulations under the Natural Gas Act, to provide an interruptible transportation service on behalf of Phillips Petroleum Company (Phillips) under the authorization issued in Docket No. CP87-115-000 pursuant to section 7(c) of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Applicant states that pursuant to a transportation agreement dated June 25, 1987, it proposes to transport natural gas on behalf of Phillips from a receipt point located in South Marsh Island Block 274, offshore Louisiana, to a delivery point located in Vermilion Block 131, offshore Louisiana. The Applicant further states that the maximum daily quantity would be 4,272 dt equivalent of natural gas per day and 1,009,590 dt equivalent of natural gas on an annual basis. Service under Section 284.223(a) commenced June 27, 1987, as reported in Docket No. ST87-3515-000, it is stated.

Comment date: October 13, 1987, in accordance with Standard Paragraph G at the end of this notice.

3. Southern Natural Gas Company

August 28, 1987.

[Docket No. CP87-487-000]

Take notice that on August 7, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202-2563, filed in Docket No. CP87-487-000 an application pursuant to section 7(c) of the Natural Gas Act for a limited-term certificate of public convenience and necessity authorizing Southern to transport natural gas on behalf of Atlanta Gas Light Company (Atlanta), acting as agent for Burgess Pigment Company (Burgess), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that Atlanta would cause gas purchased by Burgess from SNG Trading Inc., Entrade Corporation, and End Users Supply System to be delivered to Southern at various existing points of delivery on Southern's contiguous pipeline system in onshore and offshore Louisiana, Mississippi, and Alabama. Southern proposes to transport on an interruptible basis up to 1.5 billion Btu equivalent of gas per day for Atlanta to Atlanta's Sandersville Meter Station in Washington County, Georgia for ultimate delivery by Atlanta to Burgess' plant in Sandersville.

Southern requests that the proposed transportation be authorized for a term expiring on October 31, 1988.

Southern states that its agreement with Atlanta provides that Atlanta shall pay Southern each month the following rates for performing the proposed transportation service:

(a) Where the aggregate of the volumes transported and redelivered by Southern on any day to Atlanta under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to Atlanta do not exceed the daily contract demand of Atlanta, the transportation rate shall be 48.2 cents per million Btu; and

(b) Where the aggregate of the volumes transported and redelivered by Southern on any day to Atlanta under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to Atlanta exceed the daily contract demand of Atlanta, the transportation rate for the excess volumes shall be 77.6 cents per million Btu.

Additionally, Southern indicates that it would collect from Atlanta the GRI surcharge of 1.52 cents per Mcf, of such other GRI funding unit or surcharge as the Commission or other government authority may from time to time, by order or specific applicability or otherwise, prescribe or approve.

Southern states that the proposed transportation service would be conditioned upon the availability of capacity sufficient for Southern to perform the proposed services without detriment or disadvantage to Southern's obligations to its customers who are dependent on its general system supply.

Comment date: September 18, 1987, in accordance with Standard Paragraph F at the end of this notice.

4. ANR Pipeline Company

August 28, 1987.

[Docket No. CP87-442-000]

Take notice that on July 13, 1987, as supplemented July 17, 1987, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed an application in Docket No. CP87-442-000 pursuant to section 7(c) of the Natural Gas Act to transport gas on a firm and interruptible basis for Standard Oil Chemial Company (SOCC) and to continue to operate any jurisdictional facilities needed to implement the service, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

More specifically, ANR proposes to implement transportation contracts dated October 10, 1986, as amended on April 23, 1987, and October 14, 1986, as amended on November 24, 1986, and April 24, 1987, which provide for the transportation for SOCC of 90,000 dekatherm equivalent (dt) of gas per day on an interruptible basis and 550,000 dt equivalent of gas per day on a firm basis, respectively. ANR states that under the transportation agreements, as amended, it would receive volumes of gas from 424 and 326 receipt points, respectively, specified in the agreements as amended, and redeliver thermally equivalent volumes to SOCC at three specified delivery points located in Paulding and Definance Counties, Ohio.

ANR proposes rates for the interruptible and firm transportation service as provided by ANR's Rate Schedules ITS-1 and FTS-1, respectively. In each case ANR proposes a primary term expiring December 31, 1989, but which would continue on a month to month basis until terminated by ANR or SOCC on thirty days written notice. It is indicated that ANR's contract also provides that ANR may terminate the agreements if it also terminates like service for others on a non-discriminatory basis which is consistent with applicable regulatory law and regulations.

Comment date: September 18, 1987, in accordance with Standard Paragraph F at the end of this notice.

5. Citrus Interstate Pipeline Company

August 28, 1987.

[Docket No. CP87-415-000]

Take notice that on June 30, 1987, Citrus Interstate Pipeline Company (CIPCO), P.O. Box 1188, Houston, Texas, 77251-1188, filed in Docket No. CP87-415-000 an application pursuant to section 7(c) of the Natural Gas Act requesting (1) authorization to construct and operate a total of approximately 51.9 miles of 30-inch pipeline, consisting of 51.3-mile and 0.6-mile segments, together with metering and appurtenant facilities, in Mobile County, Alabama, to connect reserves to be produced in the vicinity of Mobile Bay; (2) approval of its FERC Gas Tariff, Original Volume No. 1, including its proposed transportation Rate Schedules FTS-1

and ITS-1 and initial rates; and (3) authorization to transport gas for certain shippers, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

In addition to the proposals set forth above and in the Notice of Application issued in Docket No. CP87-415-000 (52 Fed. Reg. 27241) CIPCO states that in ordre to provide all potential shippers an opportunity to obtain initial transportation services from CIPCO, CIPCO is proposing (1) to accept requests for both firm and interruptible transportation services on a first-come, first-served basis for all requests received within 60 days of the date the notice of this application is published in the **Federal Register** (Request Period) and (2) to request authorization to transport gas for any shippers requesting services and excuting a precedent agreement within that time and to file all executed precedent agreements within 15 days of the end of the Request Period. CIPCO further states for any shippers requiring downstream transportation services, CIPCO anticipates that any required applications for authorization to render such services for these shippers would be filed with the Commission.

Comment date: September 18, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

6. Algonquin Gas Transmission

August 31, 1987.

[Docket No. CP87-492-000]

Take notice that on August 12, 1987, Algonquin Gas Transmission Company (Algonquin), 1284 Soldiers Field Road, Boston, Massachusetts 02135, filed in Docket No. CP87-492-000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing Algonquin to provide an existing customer, Commonwealth Gas Company (Commonwealth), with a firm transportation service for a primary term of 20 years starting upon the commencement date which is contemplated to be November 1, 1988, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Algonquin states that the proposed service would allow Commonwealth a means of delivering peak season supply owned by Commonwealth to existing points of delivery between Algonquin and Commonwealth. The proposal would involve receipt firm transportation and delivery of up to 40,000 MMBtu per day of gas, it is stated. Algonquin indicates that such deliveries would be subject to fuel reimbursement in accordance with the provisions of Section 29 of the General Terms and Conditions of Algonquin's FERC Gas Tariff Second Revised Volume No. 1. It is further stated that the gas would be received from Commonwealth at a new receipt point in Hopkinton, Massachusetts, referred to as the Marathon Station, transported through the Algonquin system and redelivered at six (6) existing points of delivery between Algonquin and Commonwealth. Algonquin also proposes to make deliveries on an interruptible basis under existing Rate Schedules at the new Marathon Station.

To order such service, Algonquin proposes to construct and operate certain facilities including 8.0 miles of 12-inch pipeline connecting its existing 24-inch mainline and 30-inch mainline loop in Medway, Massachusetts to the new Marathon Station receipt point in Hopkinton, Massachusetts. Algonquin's proposal would also involve replacement of approximately 0.4 miles of 3-inch pipeline with a new 10-inch pipeline on Algonquin's H system in Medway, Massachusetts, it is stated.

Algonquin estimates that the total cost of the proposed pipeline system to be $10,823,000. It further states that initial financing would be through revolving credit arrangements, short term loans, and from funds on hand.

Algonquin states that the Gas Transportation Agreement would be designated as Rate Schedule X-33 and would be contained in Algonquin's FERC Gas Tariff Original Volume No. 2. Charges related to the service would be set forth in Rate Schedule, it is stated. Algonquin proposes to recover its facilities costs through a monthly demand charge, the deviation of which is set forth in the application. Algonquin indicates it would also charge a commodity charge for transportation quantities within the Maximum Daily Quantity (MDQ). It is further stated that quantities in excess of the MDQ would be subject to overturn charges. Algonquin asserts that the rates of such commodity related charges are based upon those set forth in Algonquin's pending Section 4 rate filing in Docket No. RP87-14-000.

Comment date: September 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

Columbia Gas Transmission Corporation

August 31, 1987.

[Docket No CP73-302-002]

Take notice that on August 19, 1987, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP73-302-002 a petition to amend the order issued March 21, 1977, in Docket No. CP73-302, as amended, pursuant to section 7(c) of the Natural Gas Act a request to extend the period of time in which to complete Phase II development of Crawford Storage Field located in Fairfield and Hocking Counties, Ohio, all as more fully set forth in the petition to amend on file with the Commission and open to public inspection.

Specifically, Columbia requests a three-year extension of time from October 31, 1987 to October 31, 1990 in which to complete the Phase II development of Crawford Storage Field. Columbia states that during the contruction and operation of its Phase II facilities, subsequent monitoring of pressures and volumes indicated that the geographic area and reservoir capacity of the field were larger than originally estimated. Columbia further states that data from drilling and electric logging indicate the geology of the field to be much more complex than as stated in the original application and that studies involving reservoir simulation by computer modeling is required to provide the most economical final design of the storage field for complete integration into its pipeline operations. Columbia states that no further development of the Crawford Storage Field should be undertaken until such time as the reservoir simulation studies are completed.

Columbia estimates that an additional two years are required to perform the simulation studies and an additional twelve months to analyze the studies and prepare any necessary applications to amend its present authorization for construction and operation of the field.

Comment date: September 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

8. El Paso Natural Gas Company; Northern Natural Gas Company, Division of Enron Corp.

August 31, 1987.

[Docket Nos. CP61-92-016 and CP61-139-013]

Take notice that on August 11, 1987, El Paso Natural Gas Company (El Paso), a Delaware Corporation, whose mailing address is P.O. Box 1492, El Paso, Texas 79978 and Northern Natural Gas Company, Division of Enron Corp. (Northern), a Delaware Corporation, whose mailing address is 2223 Dodge

Street, Omaha, Nebraska 68102, hereinafter referred to jointly as Petitioners, filed at Docket No. CP61-92-016, *et al.*, pursuant to section 7(c) of the Natural Gas Act and Rules 212 and 2001, *et seq.*, of the Commission's Rules of Practice and Procedure, a joint motion to amend the order heretofore issued on January 11, 1965, as amended, in the above proceeding.

The instant joint motion states that by Commission order issued on January 11, 1965 at 33 FPC 34, as later amended, at Docket Nos. CP61-92-000 and CP61-139-000, El Paso and Northern, respectively, received permanent certificate authorization to: (1) Construct and operate certain facilities; (2) deliver natural gas, on an exchange basis, by use of existing capacity in either El Paso's or Northern's gathering system at certain designating points; (3) establish a specified area of interest; and (4) provide for blanket authorization for the addition and deletion of delivery points from time-to-time, all pursuant to the 1963 Services Agreement dated August 17, 1962, as amended (Agreement) between El Paso and Northern.

The instant joint motion states further that El Paso and Northern have reviewed the operational needs of each party to the Agreement and have agreed that certain modifications are necessary in order for the Agreement to continue to serve each party's needs. Petitioners state that, based upon that review and analysis, it has been specifically determined that: (1) A need continues for the subject exchange arrangement encompassed by the Agreement; (2) a need exists for certain operational aspects of the exchange arrangement to be modified by the parties to reflect current measurement and balancing philosophies; and (3) a need has arisen to delete the lease of capacity and facilities provision of the Agreement. To satisfy these needs, it is asserted that Petitioners have entered into an Amendatory Agreement dated April 1, 1987 wherein the parties agreed to revise the Agreement to set forth the proposed changes. More particularly, it is stated that El Paso and Northern each have comprehensively reviewed the exchange arrangement based upon each party's goal to obtain optimum operations for its system relative to the location of gas supply sources and to assure compliance with existing contract obligations, market requirements, and economically sound and prudent operating practices. Petitioners state that the review was undertaken by each party because the Agreement's term currently would expire on April 13, 1988, and because of significant changes that have occurred in the industry affecting all aspects of each company's operations.

It is stated that the results of this review by Petitioners reveals a continuing need by Petitioners for the exchange arrangement and, therefore, the parties seek to extend the primary term of the Agreement for an additional two years from and after April 1, 1987, and thereafter to continue further the Agreement on a year-to-year basis, until terminated by either party. Additionally, Petitioners indicate that, as a part of such review, they have determined that the exchange arrangement should be modified so deliveries of natural gas at the delivery points specified in Articles II and III of the Agreement and balancing under the Agreement, respectively, be on thermally equivalent volumes to properly reflect the actual treatment on an MMBtu basis by the parties for deliveries and balancing under similar arrangements being conducted in today's business. It is further indicated that Northern has advised El Paso that it no longer wishes to lease El Paso's facilities as provided by Article IX, Section 1 to Rate Schedule Z-1, commencing with the effective date of the instant proposal and extending through the extended term of the arrangement. El Paso has agreed the exchange should be accomplished without charge by either party for the remaining term because the exchange is a best-efforts arrangement and that benefits are shared by both parties, it is asserted.

Accordingly, Petitioners jointly request that the amended authorization requested herein, when issued, specifically permit: (1) Extension of the primary term of the Agreement for an additional two years from and after April 1, 1987, thereafter continuing in effect on a year-to-year basis until terminated by either party; (2) deletion of the lease of capacity and facilities provision under the Agreement; (3) delivery between the parties of thermally equivalent exchange volumes; and (4) balancing of deliveries under the Agreement on an MMBtu basis. Consistent with the proposed extension of the primary term from and after April 1, 1987 under item (1) above, El Paso and Northern also jointly request that the amended authorization be effective as of April 1, 1987 for items (2), (3) and (4) above.

Comment date: September 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

9. Natural Gas Pipeline Company of America

August 31, 1987.

[Docket No. CP86-375-004]

Take notice that on August 17, 1987, Natural Gas Pipeline Company of America (Natural), 701 East 22nd Street Lombard, Illinois 60148, filed in Docket No. CP86-375-004, a petition to amend the order issued October 7, 1986, in Docket No. CP86-375-000, as amended on March 13, 1987, in Docket No. CP86-375-001 pursuant to section 7 of the Natural Gas Act so as to authorize the transportation of natural gas on an interruptible basis for Hawkeye Chemical Company (Hawkeye) for an extended term ending October 7, 1989, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Natural indicates that in Docket No. CP86-375-001 it was previously authorized to transport up to a maximum of 22,000 MMBtu per day for Hawkeye for ultimate delivery to Hawkeye at its Clinton County, Iowa plant for a term ending on the earlier of October 7, 1987, or the date on which Natural accepts a blanket certificate under Order No. 436 in Docket No. CP86-582-000.

Natural states that pursuant to the gas transportation agreement dated February 27, 1986, Natural and Hawkeye seek to extend the transportation service authorized in Docket Nos. CP86-375-000 and CP86-375-001 until October 7, 1989.

No other changes are proposed.

Comment date: September 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

10. Northern Natural Gas Company, Division of Enron Corp.

August 31, 1987.

[Docket No. CP87-490-000]

Take notice that on August 11, 1987, Northern Natural Gas Company, Division of Enron Corp. (Northern), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP87-490-000, an application pursuant to section 7(b) and 7(c) of the Natural Gas Act requesting permission and approval to abandon Rate Schedules X-17, X-23, X-35 and X-86 and the services thereunder which Northern currently is providing to Westar Transmission Company and for a Certificate of Public Convenience and Necessity authorizing the sale of natural gas by Northern to Westar pursuant to a new gas sales agreement dated

February 12, 1987 (Gas Sales Agreement).

Pursuant to the Gas Sales Agreement, Northern proposes to sell and deliver to Westar up to 25,000 MMBtu of natural gas per day on a firm basis. Northern states that each MMBtu of gas delivered to Westar will be billed at the Field Sales rate set forth on sheet No. 1c of Northern's Volume No. 2 FERC Gas Tariff. It is further stated that prior to June 1, 1988, Westar may negotiate with Northern to increase the daily contract quantity from 25,000 MMBtu per day up to a maximum of 75,000 MMBtu per day. The term also may be extended, from December 31, 1988, for an additional three years at Westar's option, it is indicated. Northern is requesting pregranted abandonment of this service upon its termination.

Comment date: September 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

11. Panhandle Eastern Pipe Line Company

August 31, 1987.

[Docket No. CP87-491-0000]

Take notice that on August 11, 1987, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251, filed in Docket No. CP87-491-000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon an exchange service authorized under Docket No. CP70-51 and related facilities thereof located in Melvindale, Michigan and St. Clair County, Michigan, respectively, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Panhandle states that the specific arrangement it requests to abandon is pursuant to an August 29, 1969 Exchange Agreement whereby Panhandle is authorized to exchange certain volumes of gas with Michigan Consolidated Gas Company (MichCon) for redelivery by Panhandle to Southeastern Michigan Gas Company (Southeastern) at the Adair Metering and Regulating Station in St. Clair County. Panhandle explains that Southeastern uses such gas in its Port Huron Market Area. Because Southeastern has negotiated with Panhandle a sale price of $197,000 for Adair station, Southeastern would no longer require Panhandle's service to deliver such gas to the Adair station, it is asserted. As a result, the volumes could now be delivered directly to the Port Huron Station for Southeastern use, it is stated.

Panhandle also states that this abandonment would cause no decrease in deliveries to Southeastern.

Comment date: September 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

12. Southern Natural Gas Company)

August 31, 1987.

[Docket No. CP86-210-003]

Take notice that on August 13, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202 2563, filed in Docket No. CP86-210-003 a petition to amend the order issued December 30, 1985 in Docket No. CP86-210-000, as amended on November 14, 1986 in Docket No. CP86-210-001, pursuant to section 7 (c) of the Natural Gas Act, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

By its Order Amending Certificate issued November 14, 1986 in this proceeding, the Commission authorized Southern to provide interruptible transportation of up to 20,000 MMBtu equivalent of natural gas per day of Georgetown Seel Corporation (Georgetown) for a term expiring November 14, 1987.

In its petition to amend, which is the subject of the present filing, Southern, in accordance with an amended agreement with Georgetown, requests that the authorized term be extended for a limited term ending October 31, 1988, and that additional existing delivery points on Southern's system in onshore and offshore Louisiana and Mississippi be authorized.

Southern states that Georgetown has obtained additional sources of supply from Exxon Corporation, and that the addition of the proposed existing delivery points would permit Southern to transport the gas for Georgetown from this alternative supply source.

Comment date: September 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

Southern Natural Gas Company

August 31, 1987.

[Docket No. CP87-497-000]

Take notice that on August 18, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP87-497-000 an application pursuant to section 7(c) of the Natural Gas Act for a limited-term certificate of public convenience and necessity authorizing Southern to transport gas on behalf of Bishop Pipeline Corporation (Bishop) as agent in arranging for the transportation of natural gas supplies for Nicholson File, and operating unit of Cooper Industries, Inc., (Nicholson) for use at its plant in Cullman, Alabama, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Southern proposes to transport natural gas for Nicholson in accordance with the terms and conditions of a transportation agreement between Bishop, the Cullman-Jefferson Counties Gas District (Cullman-Jefferson) and Southern, dated July 24, 1987. Southern states it has agreed to transport on an interruptible basis up to 1,000 MMBtu equivalent of gas per day purchased by Nicholson from Bishop. Southern requests that the Commission issue a limited-term certificate for a term expiring on October 31, 1988.

Southern states that the transportation agreement provides for Bishop to cause natural gas to be delivered to Southern for transportation at various existing points on Southern's contiguous pipeline system in St. Mary Parish, Louisiana, and Marion County, Mississippi. Southern states that it would redeliver to Cullman-Jefferson for Bishop's account at the Cullman-Jefferson Counties gas district meter station located in Jefferson County, Alabama, an equivalent quantity of gas less 3.25 percent of such amount which shall be deemed to be as compressor fuel and company-use gas (including system unaccounted-for gas losses), less any and all shrinkage, fuel or loss resulting from or consumed in the processing of gas, and less Bishop's pro-rata share of any gas delivered for Bishop's account which is lost or vented for any reason.

Southern states that Bishop has agreed to pay Southern each month, the following transportation rates:

(a) Where the aggregate of the volumes transported and redelivered by Southern on any day to Cullman-Jefferson under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to Cullman-Jefferson does not exceed the daily contract demand of Cullman-Jefferson, the transportation rate shall be 39.9 cents per MMBtu; and

(b) Where the aggregate of the volumes transported and redelivered by Southern on any day to Cullman-Jefferson under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to Cullman-Jefferson exceeds the daily contract

demand of Cullman-Jefferson, the transportation rate for the excess volumes shall be 64.9 cents per MMBtu.

Southern states that the transportation arrangement would enable Nicholson to diversify its natural gas supply sources and to obtain gas at competitive prices. Additionally, Southern advises that it would obtain take-or-pay relief on the gas Nicholson may obtain from its suppliers.

Comment date: September 21, 1987, in accordance with Standard Paragraph F at the end of this notice

14. Southern Natural Gas Company and) South Georiga Natural Gas Company)

August 31, 1987.

[Docket No. CP87-498-000]

August 31, 1987.

Take notice that on August 18, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202, and South Georgia Natural Gas Company (South Georgia), P.O. Box 1279, Thomasville, Georgia 31792, filed as co-applicant's in Docket No. Natural Gas Act for a limited-term certificate of public convenience and necessity authorizing Southern to transport gas on behalf of South Georiga as agent in arranging for the transportation of natural gas supplies for Florida Power Corporation (Florida Power) for use at its plant in Live Oak, Florida, and authorizing South Georgia to transport gas for Florida Power, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

South Georgia proposes to transport up to 35,000 MMBtu of natural gas on an interruptible basis for Florida Power in accordance with the terms and conditions of a transportation agreement dated July 24, 1987, wherein South Georgia has agreed to transport the gas and to act as agent in arranging for the transportation of the gas through Southern's pipeline system. Southern states that under contract dated July 24, 1987, it has agreed with South Georgia to transport on an interruptible basis up to 35,000 MMBtu equivalent of gas per day purchased by Florida Power from SNG Trading Inc. (SNG) and request authorization therefor. Southern and South Georgia request that the Commission issue a limited-term certificate authorizing such services for a term expiring on October 31, 1988.

Southern states that its transportation agreement provides for South Georgia to cause natural gas to be delivered to Southern for transportation at various existing points on Southern's contiguous pipeline system in the Breton Sound, Chandeleur Sound, Main Pass and Mississippi Canyon Areas, offshore Louisiana; Charles, Lincoln, Ouachita, Plaquemines, St. Martin and St. Mary Parishes, Louisiana; Lawrence County, Mississippi; and Pickens and Tuscaloosa Counties, Alabama. Southern states that it would redeliver to South Georgia at the existing point of interconnection between the pipeline facilities of Southern and those of South Georgia located in Lee County, Alabama, an equivalent quantity of gas less 3.25 percent of such amount which shall be deemed to be used as compressor fuel and company-use gas (including system unaccounted-for gas losses), less any and all shrinkage, fuel or loss resulting from or consumed in the processing of gas for the account of Florida Power, SNG or Southern, and less South Georgia's pro-rate share of any gas delivered for South Georgia's account which is lost or vented for any reason. South Georgia states that it would transport and deliver equivalent volumes of the gas, less 0.5 percent attributed to fuel use, to Florida Power at the existing interconnection facilities with Florida Power in Suwannee, Florida.

Southern states that its agreement with South Georgia provides for South Georgia to pay Southern each month, the following transportation rates:

(a) Where the aggregate of the volumes transported and redelivered by Southern on any day to South Georgia under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to South Georgia does not exceed the daily contract demand of South Georiga, the transportation rate shall be 39.9 cents per MMBtu; and

(b) Where the aggregate of the volumes transported and redelivered by Southern on any day to South Georgia under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's OCD Rate Schedule on such day to South Georgia exceeds the daily contract demand of South Georgia, the transportation rate for the excess volumes shall be 64.9 cents per MMBtu.

Additionally, Southern states it would collect the 1.52 cent per Mcf GRI surcharge, or such other amount as the Commission may from time to time prescribe or approve.

It is stated that the South Georgia agreement with Florida Power provides for Florida Power to pay South Georgia each month a transportation rate of 28.33 cents per MMBtu redelivered by South Georgia and to reimburse South Georgia for all transportation and fuel charges, and other charges and costs South Georgia pays Southern pursuant to the Southern-South Georgia agreement.

Southern states that the transportation arrangement would enable Florida Power to diversify its natural gas supply sources and to obtain gas at competitive prices. Additionally, Southern advises that it would obtain take-or-pay relief on the gas Florida Power may obtain from its suppliers.

Comment date: September 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

15. Williams Natural Gas Company

August 31, 1987.

[Docket No. CP87-496-000]

Take notice that on August 17, 1987, Williams Natural Gas Company (Williams), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP87-496-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to abandon by sale approximately 1.99 miles of 8-inch and 10-inch pipeline and appurtenant facilities located in Jasper County, Missouri, and to abandon the transportation of gas through said facilities, under the authorization issued in Docket No. CP82-479-000 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.

Williams requests abandonment authorization for the facilities, which were installed pursuant to Commission authorization in Docket No. G-298 (Williams' grandfather certificate). Williams indicates that the Kansas Power and Light Company (KPL) has made a request to purchase said facilities. It is stated that Williams has no customers on the section of pipeline proposed for abandonment and that there would be no denial of service as a result of the abandonment. It is further stated that KPL seeks to purchase the facilities to use as part of its distribution system. It is explained that Williams filed in Docket No. CP85-668-000 to abandon the facilities, but before they were abandoned, KPL made its request to purchase them. It is estimated that the cost to reclaim the facilities would be $2,800, the salvage value $300 and the sale price $300.

Comment date: October 15, 1987, in accordance with Standard Paragraph G 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 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-20485 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA87-2-27-000]

Applications; Proposed Changes In Gas Tariff; North Penn Gas Co.

August 28, 1987.

Take notice that North Penn Gas Company (North Penn) on August 20, 1987, tendered for filing proposed changes to its FERC Gas Tariff, First Revised Volume No. 1 pursuant to its PGA Clause for rates to be effective September 1, 1987.

Specifically, North Penn has included in its semiannual PGA, to be effective September 1, 1987, the following:

1. A change in rates to reflect changes in Cost of Gas Purchased.

2. A surcharge credit of 34.048¢ per Mcf resulting from amounts accumulated in the Unrecovered Purchased Gas Cost Account for the period January, 1987 through June 30, 1987; the jurisdictional portion of supplier refunds received by North Penn for the same six-month period; carrying charges computed in accordance with the regulations of the Federal Energy Regulatory Commission's (Commission); a carry-over balance from the surcharge credit effective for the period September 1, 1986 through February 28, 1987; and a credit to reflect the average pipeline commodity cost of gas for the period September, 1986 to February, 1987 pursuant to Article XIII of the Stipulation and Agreement in Docket No. RP85-193.

3. A TOP surcharge credit of 0.355¢ to repay customers of North Penn for the overrecovery of Take-Or-Pay payments made to Tennessee Gas Pipeline Company under procedures approved by the Commission in Docket No. RP83-8 et al, issued April 6, 1985.

As part of this filing, North Penn has also included Sixteenth Revised Sheet No. 15H which reflects no incremental pricing surcharges under section 15 of the General Terms and Conditions of its tariff, and a revised index page to reflect its current tariff.

North Penn respectfully requests waiver of any of the Commission's Rules and Regulations as may be required to permit this filing to become effective September 1, 1987, as proposed.

Copies of this letter of transmittal and all enclosures are being mailed to each of North Penn's jurisdictional customers 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 Energy 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). All such motions or protests should be filed on or before September 4, 1987. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-20486 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

Western Area Power Administration

Proposed Navajo Power Marketing Plan

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of proposed Navajo Power Marketing Plan and request for comments.

SUMMARY: By letter dated August, 5, 1987, the Commissioner of the Bureau of Reclamation (Reclamation) requested that the Western Area Power Administration (Western) initiate and administer a public process to obtain comments on the proposed Navajo Power Marketing Plan (Plan). This notice initiates that public process.

The proposed Plan was developed in consultation with representatives of Reclamation, Western, the Central Arizona Water Conservation District (CAWCD), the Governor of Arizona, and Arizona utility and water agencies pursuant to section 107 of the Hoover Power Plant Act of 1984 (98 Stat. 1333) (Act).

Section 107(a) of the Act provides that the capacity and energy associated with the United States interest in the Navajo Generating Station (Navajo), which is in excess of the pumping requirements of the Central Arizona Project (CAP), and certain needs for desalting and protective pumping facilities (Navajo Surplus) shall be marketed and exchanged by the Secretary of Energy. Furthermore, section 107(c) of the Act provides that in the marketing and exchanging of Navajo Surplus, the Secretary of the Interior shall adopt the plan deemed most acceptable, after consultation with the Secretary of Energy, the Governor of Arizona, and CAWCD (or its successor in the interest of the repayment obligation for the CAP), for the purposes of optimizing the availability of Navajo Surplus and providing financial assistance in the timely construction and repayment of

construction costs of authorized features of the CAP. The Act also provides that rates for Navajo surplus shall not exceed levels that allow for an appropriate saving for the contractor.

The proposed Plan provides the criteria for the sale and exchange of capacity and energy from Navajo determined to be surplus to the needs of CAP after the completion of the New Waddell Dam, a feature of CAP. The New Waddell Dam is a regulatory storage feature of CAP that would allow for operating flexibility to increase winter season pumping and reduce summer season pumping, thereby providing an enhanced power resource during the peak load season of the Southwest.

All interested parties are invited to submit comments concerning the proposed Plan to Western. After conclusion of the public comment process, Western will deliver the comments and all other relevant documents to Reclamation for its review, response to comments, and for adoption of the final Plan in accordance with the Act.

DATES: Interested parties may submit written comments on the proposed Plan on or before October 5, 1987. A public information forum on this subject will be held on September 21, 1987, at the Phoenix Hilton Hotel, Central and Adams, Phoenix, Arizona, beginning at 9 a.m. An opportunity will be given all interested parties to present written and oral comments at a public comment forum to be held on September 28, 1987, at the Phoenix Hilton Hotel, Central and Adams, Phoenix, Arizona, beginning at 9 a.m.

ADDRESSES: The public information forum and the public comment forum will be held at the Phoenix Hilton Hotel, Central and Adams, Phoenix, Arizona, on the dates cited above. Written comments concerning the proposed Plan should be sent to: Mr. Thomas A. Hine, Area Manager, Boulder City Area Office, Western Area Power Administration, P.O. Box 200, Boulder City, NV 89005.

FOR FURTHER INFORMATION: Mr. Earl W. Hodge, Acting Assistant Area Manager for Power Marketing, Boulder City Area Office, Western Area Power Administration, P.O. Box 200, Boulder City, NV 89005, (702) 477-3255.

SUPPLEMENTARY INFORMATION: The United States has acquired an entitlement to 24.3 percent of generation available at Navajo for use by CAP pursuant to the Colorado River Basin Project Act (32 U.S.C. 1501, *et seq.*) The CAP is a Reclamation multipurpose water resource development and management project in Arizona. During initial years of construction of CAP, the United States entitlement to Navajo power was sold on an interim basis to various public and private utilities (Layoff). The Layoff contracts were subject to withdrawal of power as needed by the United States. Notice of final withdrawal was given to all Layoff contractors, and the Layoff contracts terminated on May 31, 1987.

Section 107(c) of the Act provides that a power marketing plan be adopted by the Secretary of the Interior to provide for the marketing and exchange of Navajo Surplus. In order to provide for the interim marketing of the Navajo Surplus during the intial delivery and pump testing of the CAP and during the pre-New Waddell Dam period, an Interim Navajo Power Marketing Plan (Interim Plan) was developed and adopted by the Commissioner of Reclamation on March 17, 1986.

The proposed Plan provides that the Interim Plan will terminate upon expiration of all contracts entered into pursuant to the Interim Plan. Contracts entered into under the Interim Plan will expire upon 1 year notice given by Western subsequent to September 30, 1989; but no later than the date of initial operation of regulatory storage at New Waddell Dam.

This proposed Plan contains the criteria for the sale and exchange of Navajo Surplus, including a description of the power to be marketed, eligibility criteria, contact provisions, ratesetting procedures, and revenue collection and distribution criteria, after termination of the contracts under the Interim Plan. The ratesetting procedures in the proposed Plan were developed in order to accomplish the requirements of the Act to market and exchange Navajo Surplus "for the purposes of optimizing the availability of Navajo surplus and providing financial assistance in the timely construction and repayment of construction costs of authorized features of the Central Arizona project," to provide "That rates shall not exceed levels that allow for an appropriate saving for the contractor." The rates in the proposed Plan will provide annual revenues for repayment of costs associated with the marketing and exchange of Navajo Surplus. An additional rate component is included pursuant to section 107(d) of the Act to provide for repayment of funds advanced by CAWCD for authorized features of CAP. The timetable for the completion of the Plan is contained in the letter from the Commissioner of Reclamation included in this notice. The final Plan will be effective 30 days after publication in the **Federal Register.**

National Environmental Policy Act

In compliance with the National Environmental Policy Act of 1969 (NEPA), Council on Environmental Quality regulations, and the Department of the Interior regulations for compliance with NEPA, Reclamation completed an Environmental Impact Statement on the Regulatory Storage Division, Central Arizona Project, Statement No. INT FES 84-4, February 10, 1984. The environmental impact statement describes six alternatives for the proposed construction and operation of the Regulatory Storage Division of the CAP. The alternatives described provide for CAP regulatory storage, flood control for the Salt and Gila Rivers through the Phoenix metropolitan area, and concurrent and coincident aspects of the Safety of Dams program. A No Action alternative is also described. The environmental impact statement fulfills the requirements of Executive Order 11988 (Floodplain Management) and Executive Order 11990 (Protection of Wetlands), and the requirements of the Nationwide Permit in accordance with the provisons of section 404 of the Clean Water Act. Western is evaluating the EIS as to its relevancy to this marketing proposal and will determine if additional analysis is needed. Copies of the environmental impact statement will be made available to interested persons upon request.

Executive Order 12291

The Department of the Interior has determined that this Plan is not a major rule because the Plan does not meet the criteria of section 1(b) of Executive Order 12291 (46 FR 13193) dated February 17, 1981.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*), each agency, when required to publish a general notice of proposed rule, shall prepare for public comment an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities. In this instance, the Department of the Interior has determined that this proposed Navajo Power Marketing Plan relates to electric services. Under section 601(b) of the Regulatory Flexibility Act of 1980, services are not considered "rules" within the meaning of the Act; therefore, Reclamation believes that no flexibility analysis is required.

Paperwork Reduction Act of 1980

The Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3520) requires that certain information collection

requirements be approved by the Office of Management and Budget (OMB) before information is demanded of the public. OMB has issued a final rule on the Paperwork Burdens on the Public (48 FR 13666) dated March 31, 1983. Ample opportunity is provided for the interested public to participate in the development of the Navajo Power Marketing Plan. However, there is no requirement that members of the public participating in the development of the Navajo Power Marketing Plan supply information about themselves to the Government. It follows that the proposed Navajo Power Marketing Plan is exempt from the Paperwork Reduction Act.

Issued in Golden, Colorado, August 27, 1987.

William H. Clagett,

Administrator.

It is proposed that the Navajo Power Marketing Plan be adopted prior to December 31, 1987, as specified in the following letter from the Commissioner of Reclamation to the Administrator of Western.

August 5, 1987.

Mr. William H. Clagett, Administrator, *Western Area Power Administration, P.O. Box 3402, Golden, Colorado 80401.*

Dear Mr. Clagett: Section 107 of the Hoover Power Plant Act of 1984 (Act) provides that power associated with the United States' entitlement in the Navajo Generating Station, which is in excess of the pumping requirements of the Central Arizona Project, shall be marketed and exchanged pursuant to a plan adopted by the Secretary of the Interior (Secretary). We request that the Western Area Power Administration (Western) initiate and administer a public process to obtain comments on the proposed Navajo Power Marketing Plan (copy enclosed) in accordance with Department of Energy procedures. Western is further requested to deliver the comments and all other relevant documents to Reclamation for review, response to comments, and decision after the conclusion of the public comment process.

Our staff will continue to work very closely with your staff, the Arizona Department of Water Resources, and the Central Arizona Water Conservation District to complete the plan in a timely manner. The following schedule is our collective goal for completion of the plan:

Action	On or before
FEDERAL REGISTER Notice	Sept. 1, 1987.
Deadline for Public Comments	Oct. 1, 1987.
Recommend Plan with Responses to Comments.	Nov. 2, 1987.
Adoption of Plan	Dec. 31, 1987.

Environmental documentation in accordance with the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality regulations, and the Department of the Interior guidelines for compliance with NEPA is included in the *Final Environmental Impact Statement, Regulatory Storage Division, Central Arizona Project,* Document No. INT FES 84-4, dated February 10, 1984.

Upon receipt and review of public comments, upon making such changes as may be appropriate in response to such comments, and after consultation with the Secretary of Energy, the Governor of Arizona and the Central Arizona Water Conservation District (CAWCD), Reclamation will then proceed with the adoption of the final Navajo Marketing Plan in accordance with the Act. A notice of the adoption of the plan including the text of the plan and responses to comments will be published in the **Federal Register.**

I am pleased with the high level of cooperation between Reclamation, Western, the Arizona Governor's office, and the CAWCD which has thus far characterized the efforts to resolve this complex and difficult matter. I am confident that continuation of these efforts will result in a plan which will be fair to all involved.

Sincerely yours,

C. Dale Duvall,

Commissioner.

Enclosure.

cc: Thomas A. Hine, Area Manager, Boulder City Area Office, Western Area Power Administration, P.O. Box 200, Boulder City, Nevada 89005; Ronald K. Greenhalgh, Assistant Administrator for Washington Liaison, Western Area Power Administration, Room 8G061, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585.

Proposed Navajo Power Marketing Plan

I. Purpose and Scope

Section 107 of the Hoover Power Plant Act requires that a power marketing plan be developed to provide for marketing and exchanging of Navajo Surplus to provide financial assistance in the timely construction and repayment of construction costs of authorized features of the Central Arizona Project.

A. This Plan has been developed based upon data contained in the report by Reclamation entitled "Central Arizona Project Power Marketing and Water Supply Study-October 1985" to meet the requirements of the Hoover Power Plant Act and provide for the sale and Exchange of Navajo Surplus for the benefit of the Central Arizona Project as provided in section 107 of the Hoover Power Plant Act.

B. This Plan recognizes the obligation of the United States to use its entitlement to electrical capacity and energy from Navajo to provide necessary power for the pumping requirements of the Central Arizona Project and any such needs for desalting and protective pumping facilities as may be required under section 101(b)(2)(B) of the Colorado River Basin Salinity Control Act. For the purposes of this Plan, Reclamation has determined that the Navajo Surplus peaking resource identified in section V.A. and V.B. of this Plan is not required to meet the needs for desalting and protective pumping facilities as may be required under section 101(b)(2)(B) of the Colorado River Basin Salinity Control Act; however, the Navajo Surplus identified in section V.C. will be considered in meeting these needs.

C. The Plan provides that Western, working closely with Reclamation and CAWCD, will be the primary marketing entity responsible for the sale and Exchange of Navajo Surplus in accordance with applicable Federal law and regulations. Western may utilize exchange, banking, purchase agreements, or integration with other resources to fulfill any purpose of this Plan. CAWCD will act as a marketing entity solely for the purpose of establishing and causing to be collected the Additional Rate Component.

D. This Plan sets rates and parameters for the establishment of rates, not exceeding levels that allow for an appropriate saving for the contractor, that will provide revenues from the sale and Exchange of Navajo Surplus for the purposes of: payment of the operation and maintenance costs associated with Navajo Surplus; utilization and assignment of the revenues derived from the Additional Rate Component at least sufficient to make repayment and establish reserves for repayment of $175,000,000 (or more) of funds advanced by CAWCD to Reclamation for construction of authorized features of the CAP pursuant to the Plan Six Cost Sharing Agreement; recovery of capital costs, including interest, of authorized features of the Central Arizona Project allocated to power; and recovery of capital costs of authorized features of the Central Arizona Project allocated to power; and recovery of capital costs of authorized features of the Central Arizona Project allocated to irrigation that are determined to be beyond the irrigators' ability to repay.

II. Authorities

The authorities under which this Plan is developed are:

A. Federal Reclamation laws (43 U.S.C. 372, *et seq.*), and all Acts amendatory thereof or supplementary thereto); in particular, the Colorado River Basin Project Act (Pub. L. 90-537); and the Hoover Power Plant Act of 1984 (Pub. L. 98-381).

B. Rules, regulations, and agency agreements of Western and Reclamation issued or made pursuant to applicable law.

III. Definitions

The following terms wherever used herein shall have the following meanings:

A. "Additional Rate Component" shall mean the rate component(s) established, charged, and caused to be collected by CAWCD to recover the CAWCD Advance to Reclamation, plus interst thereon, pursuant to section 107 of the Act and to Chapter 21, Laws of the State of Arizona, Thirty-Seventh Legislature, Second Regular Session, 1986.

B. "Authority" shall mean the Arizona Power Authority.

C. "Authority's Final Hoover Power Marketing Plan" shall mean the Arizona Power Authority's marketing plan entitled "Final Hoover Power Mareketing, Post-1987," dated June 7, 1985.

D. "CAP" or "Central Arizona Project" shall mean the Reclamation multipurpose water resource development and management project in Arizona authorized by the Colorado River Basin Project Act, as amended (43 U.S.C. 1501, *et seq.*).

E. "CAWCD" shall mean the Central Arizona Water Conservation District.

F. "CAWCD Advance to Reclamation" shall mean the advance of $175,000,000 (or more) to Reclamation by CAWCD for authorized features of the Central Arizona Project in accordance with the Plan Six Cost Sharing Agreement.

G. "Colorado River Basin Salinity Control Act" shall mean the Colorado River Basin Salinity Control Act of 1974, as amended (43 U.S.C. 1591, *et seq.*).

H. "Conformed Criteria" shall mean the Conformed General Consolidated Power Marketing Criteria or Regulations for Boulder City Area Projects published in the **Federal Register** (49 FR 50583) on December 29, 1984.

I. "Date of Initial Operation" shall mean the date of initial test pumping into regulatory storage at New Waddell Dam, as determined by Reclamation.

J. "Exchange" shall mean any arrangements providing for delivery of capacity and energy to Western by an Exchange Contractor during an Operating Year and the return of such capacity and energy to the Exchange Contractor by Western from Navajo in the same Operating Year.

K. "Exchange Contractor" shall mean a contractor which enters into a Long-Term Exchange Contract.

L. "Exchange Energy Account" shall mean the record of Exchanges between Western and an Exchange Contractor.

M. "Hoover Power Plant Act" or "Act" shall mean the Hoover Power Plant Act of 1984 (Pub. L. 98-381.).

N. "Hoover Schedule B Capacity and Energy" shall mean the capacity and energy from the Boulder Canyon Project described in section 105(a)(1)(B) of the Act which is available to the Authority.

O. "Hoover Schedule C Excess Energy" shall mean the energy from the Boulder Canyon Project described in section 105(a)(1)(C) of the Act which is available to the Authority.

P. "Interim Plan" shall mean the Interim Navajo Power Marketing Plan adopted by the Commissioner of Reclamation on March 17, 1986.

Q. "Layoff Contract" shall mean the contract(s) entered into as of September 30, 1969, between certain non-Federal entities and Western for the sale of the Navajo Entitlement.

R. "Long-Term Contracts" shall mean the Long-Term Peaking Sales Contracts and the Long-Term Exchange Contracts.

S. "Long-Term Peaking Sales Contract" shall mean a contract between Western and a contractor for sale of Navajo Surplus for a period of years ending September 30, 2011.

T. "Long-Term Exchange Contract" shall mean a contract between Western and an Exchange Contractor for Exchange of Navajo Surplus for a period of years ending September 30, 2011.

U. "Navajo" shall mean the Navajo Generating Station, the thermal generating power plant located near Page, Arizona, and associated transmission facilities.

V. "Navajo Entitlement" shall mean the United States entitlement of 24.3 percent of the generation from Navajo.

W. "Navajo Surplus" shall mean capacity and energy associated with the Navajo Entitlement which is in excess of the pumping requirements of the Central Arizona Project and any such needs for desalting and protective pumping facilities as may be required under section 101(b)(2)(B) of the Colorado River Basin Salinity Control Act.

X. "New Waddell Dam" or "New Waddell Reservoir" shall mean the regulatory storage facilities constructed on the Agua Fria River as a feature of the CAP.

Y. "Offpeak" shall mean those hours during a day that are not considered Onpeak.

Z. "Onpeak" shall mean the hours during a day, except Sunday, that are between 9:00 a.m. to 9:00 p.m. mountain standard time during the Summer Season.

AA. "Operating Year" shall mean the period beginning October 1 and ending September 30 of the next succeeding year.

BB. "Plan" shall mean this Navajo Power Marketing Plan.

CC. "Plan Six Cost Sharing Agreement" shall mean the agreement among the United States, the Central Arizona Water Conservation District, the Flood Control District of Maricopa County, the Salt River Project Agricultural Improvement and Power District and Salt River Valley Water Users' Association, the Arizona cities of Chandler, Glendale, Mesa, Phoenix, Scottsdale, and Tempe, the State of Arizona, and the city of Tucson for funding of Plan Six facilities of the Central Arizona Project, Arizona, and for other purposes, dated April 15, 1986, and any amendments or supplements thereto.

DD. "Reclamation" shall mean the Bureau of Reclamation, Department of the Interior.

EE. "Summer Season" shall mean the period from May 1 through September 30 of any year.

FF. "Western" shall mean the Western Area Power Administration, Department of Energy.

GG. "Winter Season" shall mean the period from October 1 through April 30 of the next succeeding year.

IV. Elements

This Plan includes the following elements:

A. The estimated amounts of Navajo Surplus used in developing this Plan were obtained from data contained in a report by Reclamation, entitled "Central Arizona Project Power Marketing and Water Supply Study—October 1985," and the "Central Arizona Project, Surplus/Shortage Pumping Power Profile (Revision No. 1)," dated October 1986, prepared by CAWCD/Arizona Department of Water Resources.

B. Optimization of Navajo Surplus will be achieved through several means: (1) Delivering maximum amounts of water from the Colorado River in the Winter Season for storage in the New Waddell Reservoir and then serving CAP water demands in the Summer Season from water previously placed in storage, and on a daily basis, delivering maximum amounts of CAP water Onpeak from the limited aqueduct storage and recharging that storage to the extent possible Offpeak, thereby making Navajo Surplus available when electrical loads in the marketing area are at their peak and thus enhancing the value of the Navajo resource; (2) CAWCD contracting with the Authority for Hoover schedule B

Capacity and Energy and CAWCD receiving Hoover Schedule B Capacity and Energy pursuant to paragraph E of this section and using it to meet CAP pumping requirements in part; (3) CAWCD contracting with the Authority for Hoover Schedule C Excess Energy and CAWCD receiving the Hoover Schedule C Excess Energy pursuant to paragraph F of this section and using it to meet CAP pumping requirements in part; and (4) using CAP and Western operating flexibility.

C. In order to enhance the value of Navajo Surplus to maximize financial assistance to CAP, the proposed CAP operation will utilize daily energy management, weekly energy management, and seasonal power management as described in paragraph B of this section. Except for scheduling adjustments to achieve operating flexibility, to the extent possible CAP pumping will be Offpeak to optimize Onpeak availability of Navajo Surplus.

D. CAP pumping will be maximized during the Winter Season, to the extent possible, within the physical and legal limitations of moving CAP water through the CAP aqueduct. Any Winter Season energy deficiencies are intended to be met through exchanges or through a combination of exchange, banking, purchase agreements, or integration with other resources.

E. This Plan includes, for purposes of the Authority's Final Hoover Power Marketing Plan, the recapture of Hoover Schedule B Capacity and Energy pursuant to the Authority's Final Hoover Power Marketing Plan, as further provided for in a resolution of the Board of Directors of CAWCD which is attached hereto as appendix A and incorporated by reference herein, for the benefit of CAWCD (1) after October 1, 1991, if requested by CAWCD pursuant to the provisions of appendix A, or (2) upon the Date of Initial Operation, but (3) not later than December 31, 1994.

F. The Authority's Final Hoover Power Marketing Plan states that "the Authority intends to allocate and sell" Hoover Schedule C Excess Energy "in a manner which is consistent with such adopted [Navajo Marketing] Plan". In order to accomplish the goals of this Plan, this Plan assumes that all Hoover Schedule C Excess Energy available to the Authority will be marketed by the Authority in accordance with the Hoover C energy sales contracts dated as of April 15, 1987, as follows:

1. From June 1, 1987, until recapture of Hoover Schedule B Capacity and Energy for CAWCD is completed, to Authority contractors taking capacity and energy in a manner calculated to equalize load factors between Hoover Schedule A capacity and Hoover Schedule B capacity. (This provision contemplates that increasing amounts of Hoover Schedule C Excess Energy will be marketed with Hoover Schedule B capacity as increased amounts of that capacity become available.)

2. After recapture of Hoover Schedule B Capacity and Energy has been completed, pursuant to the Authority's power sales contracts with its contractors, dated as of September 15, 1986, on the basis of a first right of refusal to Authority contractors which are then utilizing Hoover Schedule B Capacity and Energy, pro rata to the amount of capacity being taken.

3. To CAWCD, on the basis of a first right of refusal, at any time after June 1, 1987, until recapture of Hoover Schedule B Capacity and Energy has been completed, to the extent that the amount of Hoover Schedule C Excess Energy, if made available under contract with the United States to be marketed by the Authority in the current contract year (October through September), shall exceed 400 GWh, but not exceed 800 GWh. During the same period, Hoover Schedule C Excess Energy over 800 GWh shall be marketed, if available, on the basis of first right of refusal, 50 percent to CAWCD and 50 percent to other Authority contractors. Delivery pursuant to this section shall be made only at a time and to the extent that the capacity of the Authority's contractors is not being utilized to generate Hoover Schedule A energy or Hoover Schedule B energy, or if other capacity is made available by Western for said delivery.

G. Termination of the Long-Term Contracts on September 30, 2011, will not terminate this Plan. So long as Navajo operates and there is Navajo Surplus, Western shall continue to market Navajo Surplus under this Plan with such amendments or revisions as may be adopted by the Secretary of the Interior, after consultation with the Secretary of Energy, CAWCD, and the Governor of Arizona and as provided by law, including the authorities set forth in section II. Contractors with Long-Term Peaking Sales Contracts and contractors with Long-Term Exchange Contracts whose contracts terminate in 2011 shall be given the first opportunity for new long-term sales contracts and new long-term exchange contracts for approximately the same amounts of power contained in the terminated contracts with available capacity and energy distribution pro rata among contractors. Such new contracts shall be entered into prior to October 1, 2007.

V. Power to be Marketed or Exchanged

Contracts entered into pursuant to the Interim Plan shall expire as follows: (1) After consultation by Western with Reclamation and CAWCD, upon 1 year notice given by Western subsequent to September 30, 1989; but in any event, (2) after such notice as Western deems appropriate, upon the Date of Initial Operation. The Interim Plan shall terminate upon expiration of all contracts entered into pursuant to the Interim Plan. Navajo Surplus to be sold or Exchanged under this Plan consists of the following:

A. Capacity and energy will be availalbe for sale on a long-term basis generally during the Summer Season. Capacity and energy will be available for delivery during the Summer Season and the Winter Season Onpeak and Offpeak. Capacity available for sale will be 400 MW, less the capacity used for Exchange purposes under paragraph B of this section. There will be 760 kWh of energy per year available for sale to a contractor for each kW of contract capacity.

B. A maximum of 150 MW of the 400 MW available under paragraph A of this section may be used for Exchanges on a long-term basis. Energy scheduled from an Exchange Contractor will be returned to such Exchange Contractor on a one-kWh-for-one-kWh basis under terms provided in a Long-Term Exchange Contract. There will be 760 kWh of energy per year available to an Exchange Contractor for each kW of contract capacity exchanged.

C. Any capacity or energy not sold or exchanged in accordance with paragraphs A and B of this section may, as determined by Western, in cooperation with CAWCD and Reclamation, be sold under appropriate long-term or short-term arrangements or integrated with the Federal system and sold by Western under arrangements developed in cooperation with CAWCD and Reclamation.

D. Any capacity or energy determined to be available under paragraph C of this section, up to 30 MW, will be made available first to Reclamation for the purposes of the Colorado River Basin Salinity Control Act.

E. Delivery of capacity and energy provided in paragraphs A and B of this seciton is subject to the following:

1. In the event of an outage, curtailment, or derating (or any combination thereof) of the generating capabilities at Navajo, each contractor's right to receive capacity and energy shall be as follows:

a. Capacity shall be reduced on a pro rata basis among all contractors and CAWCD.

b. Energy will be affected as follows:

(i) If the energy produced by the Navajo Entitlement is equal to or greater than an average of 3,500 GWh per year in the current and immediately prior Operating Year, then the contractor is entitled to the full 760 kWh per kW per year.

(ii) If the total energy produced by the Navajo Entitlement is less than an average of 3,500 GWh per year in the current and immediately prior Operating Year, then either (1) each contractor's right to receive energy may be reduced by Western, and if reduced, the reduction shall be on a pro rata basis among all contractors and CAWCD, or (2) at the contractor's option, energy may be scheduled to Western, on a one-for-one basis at times and amounts mutually acceptable to Western and the contractor, to replace the energy which would have otherwise been lost by pro rata reduction.

2. If in the Operating Year in which the Date of Initial Operation occurs, contract entitlements cannot be delivered, such entitlements shall be reduced among all contractors pro rata.

3. In September of each Operating Year, each Exchange Contractor shall supply Western with a schedule of proposed deliveries of energy during the Winter Season equal to the amount to which the Exchange Contractor will be entitled during the following Operating Year. Western may upon 24 hours notice cancel a day's delivery in the event that Western finds that the energy is not needed for pumping and could not be sold at a rate higher than the Navajo Surplus energy rates described in section VIII.A.2. In the event that the Exchange Contractor, because of emergency conditions, would have to supply Exchange energy from oil-fired or gas-fired resources, the contractor may notify Western and be relieved of its obligation under the schedule for the period of time until it is able to supply such Exchange energy without using oil-fired or gas-fired generation.

4. In the event of an outage, curtailment, or derating (or any combination thereof) of the Navajo transmission system, Western will use its best efforts to deliver Navajo Surplus to the contractors, in amounts as close to each contractor's Navajo Surplus entitlement or pro rata share of such entitlement as possible, using the available Navajo transmission system. Upon appropriate arrangements, Western may assist the contractors in the event of such outage, curtailment, or derating of the Navajo transmission system by arranging alternative emergency transmission service with third parties or on Western's transmission system as determined to be available in the sole judgment of Western.

5. Each long-Term Exchange Contract will provide for an Exchange Energy Account. It is generally intended that the account will contain a balance of energy owed to the Exchange Contractor. Under some circumstances, the balance of the Exchange Energy account may be reversed whereby the Exchange Contractor will owe energy to Western. Under either circumstance, energy can be scheduled by the Exchange Contractor at any time for credit to his Exchange Energy Account provided Western has adequate pumping loads or sales opportunities to use the energy. It is not intended that Western would accept energy for resale when such resale would be at rates less than Navajo Surplus energy rates described in section VIII.A.2. Energy deliveries by an Exchange Contractor to balance its Exchange Energy Account must be at times and amounts mutually acceptable to Western and to the Exchange Contractor.

6. Except as provided in paragraph 7 of this section, energy deliveries by Western under Long-Term Contracts will be scheduled at least 24 hours in advance, as mutually agreed between the contractor and Western, and such deliveries will be contingent only on the output of Navajo.

7. Capacity and energy, not scheduled at least 24 hours in advance, may be ordered by a contractor under a Long-Term Contract through appropriate dispatch channels. Such requested capacity and energy may be supplied, at Western's discretion, after coordinating with CAWCD, either through rapid pump unloading (estimated 100 percent loaded to 0 percent within 10 minutes) or from other resources available to Western. Such delivery not scheduled at least 24 hours in advance may be limited to 8 hours per day. A charge shall be assessed to a contractor as a start-up cost for each occurrence of a request for an increase in delivery not scheduled at least 24 hours in advance. The accounting for energy delivered under the provisions of this paragraph shall be identical to accounting for energy scheduled 24 hours in advance.

VI. Eligibility

Navajo Surplus will be offered for sale and Exchange in accordance with the requirements of this section.

A. Capacity and energy will be offered for sale in the following order of priority, in accordance with part IV, section A of the Conformed Criteria:

1. Federal preference entities within Arizona.

2. Federal preference entities within the Boulder City marketing area.

3. Federal preference entities in adjacent Federal marketing areas.

4. Nonpreference entities in the Boulder City marketing area.

B. In the event that a potential contractor fails to place capacity and energy under contract within a reasonable period, as specified by Western and in accordance with the terms and conditions offered by Western, the amounts of capacity and energy not placed under contract will be reoffered in accordance with the order of priority specified in paragraph A of this section.

C. Arizona entities, regardless of preference status, shall have first opportunity for electrical capacity and energy Exchange rights as necessary to implement this Plan. Western, in consultation with CAWCD and Reclamacation, may determine that any capacity and energy not subscribed to by Arizona entities for Exchange may be offered for long-term sale in the order of priority stated in paragraph A of this section or may be offered to non-Arizona entities for Exchange.

VII. Contract Provisions

Western, after consultation with Reclamation and CAWCD, shall enter into all power sales and Exchange contracts necessary to carry out the provisions of this Plan in selling and exchanging capacity and energy pursuant to section V. Navajo Surplus shall be marketed, and Exchange rights granted by Western on behalf of the Secretary of the Interior, under contracts consistent with this Plan and the Conformed Criteria. Contracts for sale or Exchange of Navajo Surplus made pursuant to this Plan shall include, but not be limited to, the following provisions:

A. Each Long-Term Peaking Sales Contract shall become effective upon its execution, the implementation of which, including all terms, covenants, and conditions related to delivery of capacity and energy and all appropriate payments therefore, shall begin on the first day within the Summer Season following the Date of Initial Operation. Contractors shall be given at least 60 days written notice prior to the Date of Initial Operation. If contract entitlements are reduced pursuant to section V.E.2, each contractor shall be charged only for the amount of capacity and the energy made available to the

contractor in that Operating Year. Each Long-Term Peaking Sales Contract shall terminate on September 30, 2011.

B. Each Long-Term Exchange Contract shall become effective upon its execution, the implementation of which, including all terms, covenants, and conditions related to the exchange of capacity and energy and all appropriate payments therefore, shall begin upon the Date of Initial Operation. Contractors shall be given at least 60 days written notice prior to the Date of Initial Operation. Each Long-Term Exchange Contract shall provide for an Exchange Energy Account. It is the intent of this Plan that the Exchange Energy Account will be balanced to zero annually. However, in the event that such balance owed Western is not reduced to zero, the Long-Term Exchange Contract shall include provisions for a carryover of such balance to the subsequent Operating Year or for payment to Western. In the event that such balance owed the Exchange Contractor is not reduced to zero, the Long-Term Exchange Contract shall include provisions for a carryover of such balance to the subsequent Operating Year to be credited against the Exchange Contractor's scheduled delivery. Prior to the Date of Initial Operation, each Exchange Contractor shall receive an estimate of the amount of capacity and energy which will be available to it during the first Operating Year, and the Exchange Contractor shall propose a schedule of Winter Season energy delivery to Western in the same amount as Reclamation's estimate of the available return of energy. If contract entitlements are reduced pursuant to section V.E.2, each Exchange Contractor shall be charged only for the amount of capacity made available to the Exchange Contractor in that Operating Year. Each Long-Term Exchange Contract shall terminate on September 30, 2011.

C. Any Long-Term Contract may, at the contractor's request, contain a provision that if the New Waddell Dam is not scheduled to be completed by a certain date the contractor may terminate the Long-Term Contract on or before a date established in the contract.

D. Contract entitlements will be measured or calculated at the 500 kV bus at the Navajo Generating Station. Capacity and energy, less losses, will be scheduled and delivered at a voltage of 500 kV to contractors at either Westwing Switchyard or McCullough Switchyard or at such other points and voltages on the Navajo system as Western and the contractor shall agree. Any necessary trasmission service beyond the contractor's point(s)-of-delivery will be the responsibility of the contractor.

E. CAWCD shall be a party to contracts for the sale or Exchange of Navajo Surplus for the limited purpose of establishing and collecting the Additional Rate Component.

F. Written metering and scheduling instructions shall be agreed upon between Western and the contractor, in consultation with CAWCD and Reclamation, prior to any deliveries under this Plan. The metering and scheduling instructions shall provide the operating and accounting procedures for such deliveries. Metering and scheduling instructions are intended to implement terms of the contract, not to modify or amend it, and therefore are subordinate to the contract. The implementation shall be the responsibility of Western and the contractor. After consultation with Reclamation and CAWCD, Western and the contractor may modify these instructions, as necessary, to reflect changing power system conditions. In the event the contractor fails or refuses to execute the initial metering and scheduling instructions or any revised instructions Western determines to be necessary, Western shall develop and implement temporary instructions until initially acceptable instructions have been developed and executed by Western and the contractor.

VIII. Ratesetting Procedures

In order to accomplish the requirements of the Act to market and Exchange Navajo Surplus "for the purposes of optimizing the availability of Navajo surplus and providing financial assistance in the timely construction and repayment of construction costs of authorized features of the Central Arizona project," and the provision, "That rates shall not exceed levels that allow for an appropriate saving for the contractor," rates for Navajo Surplus sales and Exchanges shall be established and modified in accordance with the following provisions:

A. Long-term capacity and energy described in section V.A shall be sold at rates which will provide financial assistance in the timely repayment of the CAWCD Advance to Reclamation, plus interest thereon, and repayment of costs of other authorized features of CAP to be repaid by power revenues. The following rates do not exceed a level that will allow for an appropriate saving for the contractor. The rates shall be composed of a capacity rate and an energy rate calculated in the following manner:

1. The capacity rate will be fixed for the term of the Long-Term Peaking Sales Contract at (a) the Additional Rate Component established by CAWCD, plus (b) an amount which when added to the Additional Rate Component shall total $72 per kW-year. The annual rate of $72 per kW-year shall be billed to each contractor in a monthly amount of $6 per kW based on the amount of each contractor's capacity entitlement.

2. The energy rate will be based on the actual annual operating costs associated with the Navajo Entitlement in the prior Operating Year plus a charge for Western's costs associated with Navajo. The Western charge will be based on Western's actual cost of services performed under this Plan, including appropriate administrative expenses. The annual operating costs will be determined in a similar manner as the generation operating charge, generation energy charge, and transmission operating charge in the Layoff Contracts. The energy rate will be a mills per kWh rate calculated by dividing the total costs described above by the total annual kWh available to the United States in the same Operating Year. The energy rate will be applied monthly to each kWh delivered.

B. Long-term Exchanges described in section V.B. shall be Exchanged at a one-for-one energy Exchange rate plus the following charges, which do not exceed a level that will allow for an appropriate saving for the contractor.

1. The capacity rate described in paragraph A.1 of this section.

2. A charge for Western's cost associated with Navajo as described in paragraph A.2 of this section.

3. If a balance remains in favor of Western in the Exchange Energy Account at the close of any Operating Year, Western may require a settlement of the account in cash at 115 percent of the Navajo Surplus energy rate described in paragraph A.2 of this section.

C. For capacity and energy not scheduled at least 24 hours in advance as described in section V.E.7, the charge shall be $4,000 each occurrence of a request for an increase in delivery. This charge shall be in addition to the charges for capacity and energy described in paragraphs A and B of this section.

D. Capacity and energy described in sections V.C. and V.D. shall be sold at rates established by Western, after consultation with CAWCD and Reclamation. Such rates may include an Additional Rate Component.

E. Because the Act's requirements for noncost-based rates, the rates established pursuant to this Plan are not suitable to the required review of Western's rates by the Federal Energy Regulatory Commission. All rates promulgated by the Administrator of Western under this Plan shall be a final act of the Secretary of Energy and shall be subject to review pursuant to the judicial review provided by the Administrative Procedure Act (5 U.S.C. 553, *et seq.*).

IX. Revenue Collection and Distribution

Western will bill and collect in accordance with the rates and charges for the sale or Exchange of Navajo Surplus, including the Additional Rate Component for CAWCD.

A. Western shall distribute all revenues collected from the application of the rates and charges in the following manner:

1. First, revenues will be deposited into the Lower Colorado River Basin Development Fund to pay all costs of operation and maintenance determined to be associated with the sale and Exchange of Navajo Surplus, including Western's costs.

2. Second, revenues derived from the collection of the Additional Rate Component by Western for CAWCD will be paid directly to CAWCD or its nominee for repayment and establishment of reserves for repayment of the CAWCD Advance to Reclamation plus interest thereon.

3. Third, any revenues remaining will be deposited into the Lower Colorado River Basin Development Fund to repay other CAP obligations.

B. In the event that the revenues and resulting funds available to make the repayments referenced in this Plan are insufficient for that purpose, the United States shall be under no obligation, by reason of this Plan, to supply funds to make up such insufficiency or to reduce any repayment obligations referenced in this Plan.

X. Effective Date

This Plan will become effective 30 days after publication in the **Federal Register** following adoption by the Secretary of the Interior.

XI. Consultation

This Plan is deemed most acceptable in accordance with section 107(c) of the Hoover Power Plant Act as evidenced by concurrences from Western (Secretary of Energy), the Governor of Arizona, and CAWCD, attached as Appendices to this Plan.

Appendix A—Resolution of the Board of Directors of the Central Arizona Water Conservation District

August 6, 1987.

Whereas, the proposed Navajo Power Marketing Plan includes, for purposes of the Arizona Power Authority's Final Hoover Power Marketing Plan of June 7, 1985, the recapture of Hoover Schedule B Capacity and Energy pursuant to the Authority's Final Hoover Power Marketing Plan for the benefit of the Central Arizona Water Conservation District ("CAWCD") (1) after October 1, 1991, if requested by CAWCD pursuant to the provisions of this Resolution, or (2) upon the Date of Initial Operation, but (3) not later than December 31, 1994; and

Whereas, in order to obtain Hoover Schedule B Capacity and Energy pursuant to the Authority's Final Hoover Power Marketing Plan, CAWCD must, among other requirements, deliver a written request to the Arizona Power Authority ("Authority") to recapture Hoover Schedule B Capacity and Energy after the Secretary of the Interior adopts the Navajo Power Marketing Plan; and

Whereas, the Authority's Final Hoover Power Marketing Plan provides that, upon compliance by CAWCD with the conditions of paragraph 5 of the Summary contained in the Authority's Final Hoover Power Marketing Plan and not later than 90 days after receipt of the written request for recapture from CAWCD, the Authority will issue the notice of recapture and it is assumed that the Authority will use its best efforts to issue such notice prior to the next quarterly advance, if any, required of CAWCD by the Plan Six Cost Sharing Agreement; and

Whereas, it is necessary and desirable to further define and clarify the circumstances under which CAWCD will request and the Authority will recapture Hoover Schedule B Capacity and Energy pursuant to the Authority's Final Hoover Power Marketing Plan for the benefit of CAWCD in order to promote wide support for the final Navajo Power Marketing Plan; and

Whereas, the proposed Navajo Power Marketing Plan prepared for the consideration of the Secretary of the Interior has been presented to the Board of Directors of the CAWCD for its approval, including Appendix A which contains this Resolution; and

Whereas, to the best of the knowledge of the Board of Directors of CAWCD, this Resolution is consistent with the obligations of CAWCD's Hoover Power Sales Contract with the Authority;

Now, therefore, be it resolved that, subject to the adoption by the Secretary of the Interior of the Navajo Power Marketing Plan ("Plan") in substantially the form presented to the Board of Directors for its consideration on this date, the Board of Directors approves the terms and conditions thereof, including but not limited to the following resolutions.

Be it further resolved that terms used in this Resolution which are defined in the Plan shall have the meanings ascribed to them in the Plan.

Be it further resolved that CAWCD agrees that, except as provided in the next resolved clause herein, any written request for recapture delivered to the Authority by CAWCD prior to October 1, 1992, will be delivered only after Reclamation has determined that construction of New Waddell Dam has sufficiently advanced that the Date of Initial Operation is scheduled to occur within 27 months.

Be it further resolved that CAWCD agrees that it will not, prior to October 1, 1989, deliver a written request for recapture to the Authority. CAWCD further agrees that any written request for recapture, not occasioned by a determination by Reclamation that construction of New Waddell Dam has sufficiently advanced that the Date of Initial Operation is scheduled to occur within 27 months, will be delivered to the Authority prior to October 1, 1992 only upon the occurrence of the events described in subsections a and b as follows:

a. CAWCD has advanced to the escrow account or subaccount for New Waddell Dam called for in the Plan Six Cost Sharing Agreement, and Congress has appropriated, funds collectively equivalent to seventy-two percent (72%) or more of the current estimated construction costs of $452.6 million for New Waddell Dam or CAWCD has advanced $110 million. Funds shall be considered appropriated by Congress for New Waddell Dam if actually spent, contractually obligated, or specifically designated in a Department of the Interior request that has resulted in appropriations legislation or continuing resolution passed by Congress and signed by the President. Funds shall be considered advanced by CAWCD when deposited in the escrow account or subaccount.

b. The CAWCD Board of Directors has formally determined in its sole discretion that, in order to continue to make the payments required of CAWCD by the Plan Six Cost Sharing Agreement it is required that the CAWCD issue or cause to be issued revenue bonds. In making this determination, the CAWCD Board will take into account revenues from Interim Plan sales and Plan sales of Navajo Surplus prior to recapture, effects of any renegotiation of the CAWCD contribution schedule in the Plan Six Cost Sharing Agreement, and the oral and written comments of interested parties delivered to CAWCD at and after a public meeting called for receiving such comments. The CAWCD Board will also take into account a reasonable reserve level and not more than the $17 million currently forecast for underground storage and recovery projects. Such dollar limit is not intended to limit the CAWCD Board from considering additional expenditures for such projects from other revenue resources.

Be it further resolved that, in the event that CAWCD fails to advance at least $110 million of the $175 million required by the Plan Six Cost Sharing Agreement by the end of the schedule defined therein, or any extension thereof under the current terms of that Agreement, or any extension thereof hereafter negotiated, or Congress and CAWCD fail to appropriate and advance funds collectively equivalent to seventy-two percent (72%) or more of the current

estimated construction costs of $452.6 million for New Waddell Dam, then CAWCD agrees that its amount of recapturable Hoover Schedule B Capacity and Energy shall be reduced in each Operating Year thereafter to an amount determined by multiplying (1) the total amount of Hoover Schedule B Capacity and Energy available to the Authority in that Operating Year under the Authority's contract with Western for electric service by (2) a fraction in which the numerator is the amount of total funds of the $175 million, exclusive of interest penalties and additional contributions, actually advanced by CAWCD and withdrawn by the United States, and the denominator is $175 million. The resulting reduced amount of recapturable Hoover Schedule B Capacity and Energy is hereinafter referred to as the "Reduced Recapturable Amount." In the event of such failure after recapture has been completed or partially completed, CAWCD shall, within 20 days, tender in each Operating Year thereafter a relinquishment to the Authority of such amounts of Hoover Schedule B Capacity and Energy as are being delivered and are determined by the above formula to be in excess of the Reduced Recapturable Amount. Each such relinquishment shall take effect and remain in effect when and so long as (1) CAWCD is relieved of its financial obligations to the Authority with respect to such relinquished Hoover Schedule B Capacity and Energy as provided in CAWCD's Hoover Power Sales Contract with the Authority, dated as of September 15, 1986 (including any amendments thereof), or (2) CAWCD is satisfactorily indemnified against such financial obligations. It is the intent of this Resolution that the "Eligible Entities," as defined in CAWCD's Hoover Power Sales Contract with the Authority, shall receive such amounts of Hoover Schedule B Capacity and Energy pursuant to Section 30 of CAWCD's Hoover Power Sales Contract with the Authority as to total 14.04 percent (14.04%) of the Hoover Schedule B Capacity and Energy available to CAWCD under this Resolution and CAWCD's Hoover Power Sales Contract with the Authority.

I, the undersigned, as Secretary of the Central Arizona Water Conservation District, hereby certify that the foregoing is a true and correct copy of the resolutions duly adopted by the Board of Directors of the Central Arizona Water Conservation District at a meeting thereof, duly called and held on August 6, 1987, at which a quorum was present and acting throughout. I further certify that said resolutions have not been modified or revoked since their adoption and are still in full force and effect.

Signed this 8th day of August, 1987.

Marilyn H. Ronstadt,

Secretary.

[FR Doc. 87-20535 Filed 9-3-87; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-3256-9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared August 17, 1987 through August 21, 1987 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act (CAA) and section 102(2)(c) of the National Environmental Policy Act (NEPA) as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 382-5076/73. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 24, 1987 (52 FR 13749).

Draft EISs

ERP No. D-AFS-L70008-AK, Rating EC2, Woewodski Island Area Analysis, Site-Specific Mgmt. Standards and Guidelines, Stikine Area, Tongass Nat'l Forest, AK. Summary: EPA is concerned that the lack of a water quality monitoring plan will make it difficult to ensure that Alaska Water Quality Standards (WQS) will be met and requests additional information on compliance with WQS, water quality and fish habitat monitoring, mitigation measures, and baseline data. EPA is also concerned as to how this area analysis fits into the overall Tongass Land Management Plan which will be updated in the next few years and that the range of alternatives for the area analysis may need to be expanded.

ERP No. D-NPS-K70003-CA, Rating LO, Decker Canyon Mgmt. and Development Concept Plan, Santa Monica Mtns. Nat'l Recreation Area, CA. SUMMARY: EPA expressed its lack of objections to the development concept plan proposed in the draft EIS.

ERP No. D-UAF-J10008-MT, Rating EC2, Malmstrom 341st Strategic Missile Wing, Air Force Base, Intercontinental Ballistic Missiles (ICBM) Program, Development, MT. Summary: EPA believes the draft EIS adequately identifies the environmental issues associated with the proposed program, however, discussion of the environmental consequences did not adequately represent the range of environmental conditions throughout the deployment area and possible cumulative impacts under varying launch site configurations. Specific information and greater detail needs to be provided concerning monitoring plans, mitigation techniques, and rationale for application of various mitigation techniques or spill contingency plans.

Final EISs

ERP No. FS-CDB-K89061-CA, Santa Maria Town Center Expansion and Development, CDBG, CA. Summary: EPA made no formal comments. EPA's prior concerns, mostly air issues, were found to be satisfactorily addressed in the final supplemental EIS.

ERP No. F-COE-G36114-TX, Cypress Creek Flood Control Plan, San Jacinto River and Tributaries, TX. Summary: The final EIS adequately responded to EPA comments issued on the draft EIS. EPA has no objections to the proposed action with proper implementation of the mitigation measures as described.

ERP No. F-FHW-E40088-TN, TN-34 Bypass Construction, TN-34 Southwest of Johnson City to TN-137 Northwest of Johnson City, TN. Summary: EPA's primary remaining concern was the final EIS uncertainty regarding a potential 500-foot channel relocation of Knob Creek (understanding from TN Department of Transportation that such a relocation is likely, but not finalized). Other concerns included noise and karst geologic impacts. Coordination with EPA and the State regarding the potential channel relocation, further consideration of mitigation, and additional documentation were requested.

ERP No. F-FHW-K40119-HI, Moanalua Road Improvement, Pali Momi Street to AIEA Interchange, 404 Permit, HI. Summary: EPA's review found that the final EIS adequately addressed the concerns EPA raised on the draft EIS.

Regulations

ERP No. R-NRC-A22110-00, 10 CFR Parts 30, 40 and 70, Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees (52 FR 12921). Summary: EPA recommended some modifications to NRC's proposed rule to reflect EPA's authority under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).

Amended Notice

The following review should have appeared in the FR Notice published on August 28, 1987.

ERP No. F-COE-H40130-IA, IA-415 Highway Modifications, Segment C, IA-415 and NW 78th Street to Barrier Dam Roadway, Saylorville Lake Recreation Areas, Access Roadway Improvement Under Section III of the Water Resource Act 1976, IA. Summary: EPA comments concerning the adequacy of the draft EIS

have been addressed in the final EIS. However, EPA believes that the selected alternative is the most environmentally damaging of those evaluated. EPA believes that another alternative is available that will both satisfy the public needs and avoid adverse impacts on the habitat in question. EPA urges the Corps to reevaluate its position prior to issuing the Record of Decision.

Dated: September 1, 1987.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 87-20466 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-3256-8]

Environmental Impact Statements; Notice of Availability

Responsible agency: Office of Federal Activities, General Information (202) 382-5073 or (202) 382-5075. Availability of Environmental Impact Statements Filed August 24, 1987 Through August 28, 1987 Pursuant to 40 CFR 1506.9.

EIS No. 870296, Final, FHW, CA, CA-85 Transportation Corridor Construction, CA-101 to I-280/Stevens Creek Boulevard, Santa Clara County, Due: October 5, 1987, Contact: Dave Eyres (916) 551-1314.

EIS No. 870297, Draft, AFS, CO, Rock Creek Reservoir, Routt National Forest or Muddy Creek Reservoir, Kremmling Resource Area Construction, Special Use Permit, Routt and Grand Counties, Due: October 26, 1987, Contact: Ed Ryberg (303) 879-1722.

EIS No. 870298, Final, AFS, CA, Angeles Pipeline Project, Construction, Operation Maintenance and Abandonment, Emidio Pump Station and Tank Farm to Los Angeles Basin Refineries, Approval, Angeles National Forest Kern and Los Angeles Counties, Due: October 5, 1987, Contact: Richard Simon (213) 620-4038.

EIS No. 870299, Final, AFS, NM, Santa Fe National Forest, Land and Resource Management Plan, Due: October 5, 1987, Contact: Maynard Rost (505) 988-6940.

EIS No. 870300, Final, FHW, GA, GA-400/North Atlanta Freeway Extension, I-85 to I-285, Construction, Fulton County, Due: October 5, 1987, Contact: Louis Papet (404) 347-4751.

Amended Notice

EIS No. 870257, Draft, USN, NJ, Naval Weapons Station Earle, Family Housing Development, Construction, Colts Neck, Due: September 14, 1987, Published FR 7-31-87—Review period extended.

Dated: September 1, 1987.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 87-20467 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPP-00245; FRL 3258-1]

FIFRA Scientific Advisory Panel; Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 1-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) to review a set of scientific issues being considered by the Agency in connection with the peer review classification of DDVP as a Class B-2 oncogen and as a neurotoxin; a set of issues being considered by the Agency in connection with the peer review classification of Assert as a Class D oncogen; a set of issues being considered by the Agency in connection with the peer review classification of Assert as a Class D oncogen; a set of issues being considered by the Agency in connection with the peer review classification of Chlorothalonil as a Class B-2 oncogen; a set of issues being considered by the Agency in connection with the peer review classification of Linuron as a Class C oncogen; a set of scientific issues being considered by the Agency in connection with the peer review classification of Isoxaben as a Class C oncogen; and an information briefing on ETU, Tributyltin and Part 158—Toxicology Data Requirements for Food Use Pesticides.

DATES: The meeting will be held on Wednesday, September 23, 1987, from 8:30 a.m. to 4 p.m.

ADDRESS: The meeting will be held at: Environmental Protection Agency, Rm. 1112, Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen L. Johnson, Executive Secretary, FIFRA Scientific Advisory Panel, Office of Pesticide Programs (TS-769C), 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1121, Crystal Mall Building No. 2, Arlington, VA, (703-557-7695).

SUPPLEMENTARY INFORMATION: The agenda for the meeting is:

1. Review of a set of scientific issues in connection with the Agency's classification of the peer review of DDVP as a Class B/2 oncogen and as a neurotoxin.
2. Review of a set of scientific issues in connection with the Agency's classification of the peer review of Assert as a Class D oncogen.
3. Review of a set of scientific issues in connection with the Agency's classification of the peer review of Chlorothalonil as a Class C oncogen.
4. Review of a set of scientific issues being considered by the Agency's classification of Linuron as a Class C oncogen.
5. Review of a set of scientific issues being considered by the Agency's classification of Isoxaben as a Class C oncogen.
6. An information briefing on Ethylthiourea (ETU).
7. An information briefing on Tributyltin (TBT).
8. An Information briefing on Part 158—Toxicology Data Requirements for Food Use Pesticides.
9. Completion of any unfinished business from previous Panel meetings.
10. In addition, the Agency may present status reports on other ongoing programs of the Office of Pesticide Programs.

Copies of documents relating to items 1-5 may be obtained by contacting: By mail: Information Services Branch, 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. 1006, Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, VA., (703-557-2605).

Any member of the public wishing to submit written comments should contact Stephen L. Johnson at the address or telephone number given above to be sure that the meeting is still scheduled and to confirm the Panel's agenda. Interested persons are permitted to file such statements before the meeting. To the extent that time permits and upon advance-notice to the Executive Secretary, interested persons may be permitted by the chairman of the Scientific Advisory Panel to present oral statements at the meeting. There is no limit on written comments for consideration by the Panel, but oral statements before the Panel are limited to approximately 5 minutes. Since oral statements will be permitted only as time permits, the Agency urges the public to submit written comments in lieu of oral presentations. Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment

that does not contain CBI must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket without prior notice. The public docket will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. All statements will be made part of the record and will be taken into consideration by the Panel. Persons wishing to make oral and /or written statements should notify the Executive Secretary and submit ten copies of a summary no later than September 16, 1987, in order to ensure appropriate consideration by the Panel.

Dated: September 1, 1987.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 87-20512 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPP-36147; FRL-3257-2]

Availability of Pesticide Chemical Fact Sheets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of Pesticide Chemical Fact Sheets. It also supersedes all other availability information in earlier **Federal Register** notices regarding Pesticide Chemical Fact Sheets. EPA has made arrangements with the National Technical Information Service (NTIS) to process and distribute the Pesticide Chemical Fact Sheets. EPA will provide NTIS with the Pesticide Chemical Fact Sheets, previously issued and future ones, as they are issued.

ADDRESS: Published Pesticide Fact Sheets may be purchased from NTIS at the following address: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650).

Orders may be placed by telephone to the NTIS order desk and charged against a deposit account or American Express, VISA, or MasterCard, or sent by mail with check, money order, or deposit account number.

FOR FURTHER INFORMATION CONTACT: By mail:

Summer Gardner, Registration Support and Emergency Response Branch, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 718, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-2126).

SUPPLEMENTARY INFORMATION: The Pesticide Chemical Fact Sheets include a description of the chemical use patterns and formulations, scientific findings, a summary of the Agency's regulatory position/rationale, and a summary of major data gaps. They are issued if one of the following regulatory actions occurs:

1. A Registration Standard has been issued.
2. A significantly different use pattern has been registered.
3. A new chemical is registered.
4. A Special Review determination document has been issued.

Facts Sheets have been prepared for Registration Standards issued since June 1982 and for new chemicals and for chemicals with significantly changed use patterns registered since January 1984. Fact Sheets have also been issued for Special Review final determinations since June 1983.

For each Pesticide Chemical Fact Sheet desired, provide NTIS with the title of the document, the corresponding NTIS Order Number, and whether hard copy or microfiche is desired. The NTIS Order Number is the same for hard copies and microfiche, but the price differs. All microfiche copies are $6.50 and the hard copies are $9.95.

The following Pesticide Chemical Fact Sheets are available to this date from NTIS:

Chemical name	EPA No.	NTIS Order No.
1,3-Dichloropropene	95	PB87-116547
2,4-Dichlorophenoxyacetic Acid	94.1	PB87-192712
3,5-Dibromo	67	PB87-108841
Actellic	59	PB87-108858
Aldicarb	19	PB87-108866
Aldoxycarb	115	PB87-155230
Aldrin	108	PB87-155164
Aliette	1	PB87-114179
Amitrole	20	PB87-108874
Anilazine	12	PB87-108882
Arosurf	17	PB87-108890
Arsenal	63	PB87-108908
Arsenic Acid	91	PB87-108916
Arsenic Trioxide	110	PB87-155180
Avermectin	89	PB87-114153
Azinphos-Methyl	100	PB87-116489
Bentazon	64	PB87-108924
Bronopol	32	PB87-108932
Butylate	7	PB87-108940
Cadmium	103	PB87-108957
Calcium Arsenate	111	PB87-155198
Captafol	35	PB87-131199
Captan	75	PB87-108965
Carbaryl	21	PB87-108973
Carbofuran	24	PB87-108981
Carbon Tetrachloride	102	PB87-155123
Carbophenothion	25	PB87-116596
Chlordane	109	PB87-155172
Chlorimuron Ethyl	82	PB87-114773
Chlorobenzilate	15	PB87-113981
Chlorothalonil	36	PB87-113296
Chlorpyrifos	37	PB87-114781
Chlorpyrifos Methyl	57	PB87-111993
Clipper	62	PB87-111928
Command	90	PB87-124764
Copper Sulfate	87	PB87-116570
Cryolite	2	PB87-116109
Cyanazine	41	PB87-117461
Cyhexatin	56	PB87-111969
Cyromazine	105	PB87-155131
Daminozide	26	PB87-112025
Dantochlor	33	PB87-112017
DCNA	13	PB87-112033
Demeton	45	PB87-112009
Diazinon	96	PB87-116505
Dicamba	8	PB87-111944
Dichlobenil	122	PB87-192522
Dicofol	16	PB87-111936
Diflubenzuron	68.1	PB87-193058
Dinocap	65.1	PB87-193066
Dipropetryn	55	PB87-114245
Disulfoton	43	PB87-115051
Diuron	9	PB87-115168
EPN	127	PB87-192753
EPTC	6	PB87-115150
Ethalfluralin	58	PB87-115143
Ethoprop	3.1	PB87-111498
Fenaminosulf	10	PB87-115069
Fenbutatin-Oxide	119	PB87-193041
Fenoxycarb	78	PB87-115614
Fensulfothion	14.1	PB87-111506
Fluchloralin	52	PB87-113494
Fluometuron	88	PB87-111514
Fluridone	81	PB87-111985
Fluvalinate	86	PB87-124756
Fonofos	22.1	PB87-124749
Formetanate Hydrochloride	11	PB87-112264
Glycoserve	47	PB87-112272
Heliothis NPV	27	PB87-112280
Heptachlor	107	PB87-155156
Hybrex	85	PB87-113049
Imazaquin	83	PB87-125522
Isomate-M	126	PB87-192746
Lactofen	128	PB87-201893
Lead Arsenate	112	PB87-155206
Linalool	77.1	PB87-111522
Lindane	73	PB87-111795
Linuron	28	PB87-116588
Mancozeb	125	PB87-192738
Methiocarb	120	PB87-191920
Methyl Bromide	98	PB87-116513
Methyl Parathion	117	PB87-155255
Metolachlor	106	PB87-155149
Metribuzin	53	PB87-116604
Metsulfuron Methyl	71	PB87-124731
Monocrotophos	72	PB87-116612
Nabam	124	PB87-192720
Naled	4	PB87-118485
Naptalam	49	PB87-118915
Nitrapyrin	54	PB87-118022
Norflurazon	60	PB87-118477
Parathion	116	PB87-155248
Pendimethalin	50	PB87-117578
Perfluidone	74	PB87-117560
Phorate	34.1	PB87-111530
Phosmet	101	PB87-117198
Picloram	48	PB87-117586
Potassium Bromide	38	PB87-118923
Potassium Permanganate	80	PB87-124772
Prometryn	121	PB87-191912
Pronamide	70	PB87-124723
Propachlor	44	PB87-116083
Propargite	99	PB87-116497
Propham	123	PB87-191938
Simazine	23	PB87-112256
Sodium & Calcium Hypochlorites	79	PB87-125530
Sodium Arsenate	114	PB87-155222
Sodium Arsenite	113	PB87-155214
Sodium Omadine	61	PB87-124384
Sulfuryl Fluonde	51	PB87-124392
Terbufos	5.1	PB87-125548
Terbutryn	104	PB87-121877
Thiodicarb	18	PB87-111811
Thiophanate Ethyl	84	PB87-111548
Thiophanate Methyl	92	PB87-111555
Thiram	29	PB87-111563
TPTH	39	PB87-111803
Trimethacarb	76	PB87-111571
Vitamin D-3	43	PB87-115622
Wood Preservatives	31	PB87-115630

The following Pesticide Chemical Fact Sheets have been recently issued and will be made available through NTIS. Please see the next quarterly issue for

the appropriate NTIS PB order number before ordering.

Brominated Salicylanilide
Dodine
Dinoseb
Diphenamid
Ethylenethiourea (ETU)
Isazophos
Oxamyl
Paraquat
Sodium & Calcium Hypochlorite
Sodium Salt of Fomesafen
Sulfurytl Fluoride
Tebuthiuron

Availability of additional Pesticide Chemical Fact Sheets through NTIS will be published quarterly in the **Federal Register**.

Dated: August 21, 1987.

Susan H. Wayland,

Acting Director, Office of Pesticide Programs.

[FR Doc. 87-20421 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59249; FRL-3254-8]

Acrylic Acid, 2-Allylphenol Polymer, Sodium Salt; Test Market Exemption Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5 (a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice, issued under section 5(h)(6) of TSCA, announces receipt of one application for exemption, provides a summary, and requests comments on the appropriateness of granting the exemption.

DATE: Written comments by September 2, 1987.

ADDRESS: Written comments, identified by the document control number "[OPTS-59249]" and the specific TME number should be sent to: Document Control Officer (TS-794), Confidential Data Branch, Information Management Division, Office of Toxic Substances, Environmental Protection Agency, Rm. L-100, 401 M Street, SW., Washington, DC 20460, (202) 554-1305.

FOR FURTHER INFORMATION CONTACT: Stephanie Roan, Premanufacture Notice Management Branch, Chemical Control Division (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street, SW., Washington, DC 20460, (202) 382-3725.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the TME received by EPA. The complete non-confidential document is available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

T 87-29

Close of Review Period. October 2, 1987.

Importer. Colloids, Incorporated.

Chemical. (G) Acrylic acid, 2-allylphenol polymer, sodium salt.

Use/Import. (G) Antiscalant for water treatment. Import range: Confidential.

Date: August 26, 1987.

Denise Devoe,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 87-20136 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51690; FRL-3255-1]

Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice announces receipt of forty-two such PMNs and provides a summary of each.

DATES: Close of Review Period:

P 87-1572, 87-1573, 87-1574, 87-1575, 87-1576 and 87-1577; November 11, 1987.
P 87-1578, 87-1579, 87-1580 and 87-1581; November 14, 1987.
P 87-1582, 87-1583, 87-1584, 87-1585, 87-1586, 87-1587, 87-1588, 87-1589, 87-1590, 87-1591, 87-1592, 87-1593, 87-1594 and 87-1595; November 15, 1987.
P 87-1596, 87-1597, 87-1598, 87-1599, 87-1600, 87-1601, 87-1602, 87-1603, 87-1604, 87-1605, 87-1606, 87-1607, 87-1608 and 87-1609; November 16, 1987.
P 87-1610, 87-1611, 87-1612 and 87-1613; November 17, 1987.

Written comments by:

P 87-1572, 87-1573, 87-1574, 87-1575, 87-1576 and 87-1577; October 10, 1987.
P 87-1578, 87-1579, 87-1580 and 87-1581; October 13, 1987.
P 87-1582, 87-1583, 87-1584, 87-1585, 87-1586, 87-1587, 87-1588, 87-1589, 87-1590, 87-1591, 87-1592, 87-1593, 87-1594 and 87-1595; October 16, 1987.
P 87-1596, 87-1597, 87-1598, 87-1599, 87-1600, 87-1601, 87-1602, 87-1603, 87-1604, 87-1605, 87-1606, 87-1607, 87-1608 and 87-1609; October 17, 1987.
P 87-1610, 87-1611, 87-1612 and 87-1613; October 18, 1987.

ADDRESS: Written comments, identified by the document control number "[OPTS-51690]" and the specific PMN number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. L-100, 401 M Street, SW., Washington, DC 20460, (202) 554-1305.

FOR FURTHER INFORMATION CONTACT: Stephanie Roan, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street SW., Washington, DC 20460, (202) 382-3725.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the PMNs received by EPA. The complete non-confidential PMNs are available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

P 87-1572

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Fiber reactive monoazo dyestuff.

Use/Production. (G) Fiber reactive dye for fibers. Prod. range: 18,000 to 54,000 kg/yr.

Toxicity Data. Acute oral: 5,000 mg/kg; Acute dermal: >2,000 mg/kg; Irritation: Skin—Non-irritant, Eye—Non-irritant; Ames test: Non-mutagenic; Skin sensitization: Non-sensitizing; LC_{50} 48 hr. (Zebra-fish): 500 mg/1, EC_{50} 24 hr. (Daphnia magna): >1,000 mg/1.

P 87-1573

Importer. Hoechst Celanese Corporation.

Chemical. (G) Perfluoralkyl group containing toluene—bisurethane.

Use/Import. (G) Fluorochemical to improve soil-, oil-, and water repellency. Import range: Confidential.

Toxicity Data. Acute oral: 2000 mg/kg; Irritation: Skin—Non-irritant; Eye—Non-irritant; LC_{50} 96 hr. (Zebra-fish): 500 mg/1.

P 87-1574

Importer. Confidential.
Chemical. (G) Diurea crystals.
Use/Import. (G) Site-limited and industrial coatings. Import range: Confidential.

P 87-1575

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Amino modified organopolysiloxane.
Use/Import. (S) Industrial textile finishing agent additive for resins or plastics and for waxes. Import range: 8,000 to 12,000 kg/yr.

P 87-1576

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Amino modified organosiloxane.
Use/Import. (S) Industrial textile finishing agent; additive for resins or plastics; and additive for waxes. Import range: 5,000 to 20,000 kg/yr.

P 87-1577

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Alkoxy modified organopolysiloxane.
Use/Import. (S) Industrial wax and lubricant. Import range: 500 to 1,500 kg/yr.

P 87-1578

Importer. Confidential.
Chemical. (G) Thiazoline derivative of para phenylinediamine.
Use/Import. (G) Additive for imaging products. Import range: Confidential.
Toxicity Data. Acute dermal: >2,000 mg/kg; Irritation: Eye—Non-irritant.

P 87-1579

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Amino modified organopolysiloxane.
Use/Import. (S) Industrial textile finishing agents, additive for resin or plastics and for waxes. Import range: 10,000 to 40,000 kg/yr.

P 87-1580

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Organoploysiloxane containing amino and hydroxy groups.
Use/Import. (S) Industrial textile finishing agent and additive for paints or rubber compounds. Import range: 1,000 to 3,000 kg/yr.

P 87-1581

Importer. Confidential.
Chemical. (G) Isophthalic alkyd resin.
Use/Import. (S) Priting ink. Import range: Confidential.

P 87-1582

Manufacturer. E.I. du Pont de Nemours and Company, Inc.
Chemical. (G) Styrene acrylic copolymer.
Use/Production. (G) Site-limited and industrial highly dispersive use. Prod. range: Confidential.

P 87-1583

Manufacturer. E.I. du Pont de Nemours and Company, Ind.
Chemical. (G) Acrylic copolymer.
Use/Production. (G) Site-limited and industrial open, non-dispersive use. Prod. range: Confidential.

P 87-1584

Manufacturer. Confidential.
Chemical. (G) Acrylic acid, 2-allyl phenol polymer, sodium salt.
Use/Production. (G) Antiscalant—industrial process water treatment. Prod. range: Confidential.

P 87-1585

Manufacturer. E.I. du Pont de Nemours and Company, Inc.
Chemical. (G) Styrene acrylic copolymer.
Use/Production. (G) Site-limited and industrial highly dispersive use. Prod. range: Confidential.

P 87-1586

Manufacturer. Finetex, Incorporated.
Chemical (G) N'-alky'-N,N,N",N"-tetra alkyl"-dipropylene-quarternary ammonium trialkyl' "-sulfate.
Use/Production. (S) Industrial anti-static agent for synthetic textiles; substantive lubricant and processing aid for fibrous materials; and pigment dispersing aid for use in cationic and substantive paints. Prod. range: 10,000 to 20,000 kg/yr.
Toxicity Data. Irritation: Skin-Irritant, Eye-Mild.

P 87-1587

Manufacturer. Confidential.
Chemical. (G) Neo-alcohol.
Use/Production. (S)Chemical intermediate for manufacture of oil additives. Prod. range: Confidential.
Toxicity Data. Acute oral: 3.2 ml/kg; Irritation: Skin-Mild; Ames test: Non-mutagenic.

P 87-1588

Manufacturer. Confidential.
Chemical. (G) Carboxyl-functional uralkyd.
Use/Production. (G) Varnish for printing inks. Prod. range: Confidential.

P 87-1589

Manufacturer. Confidential.
Chemical. (G) Polyamine phosphonate, amine salt.
Use/Production. (G) Dispersive use. Prod. range: Confidential.

P 87-1590

Manufacturer. Confidential.
Chemical. (G) Polyaminephosphonate, polyamine salt.
Use/Production. (G) Dispersive use. Prod. range: Confidential.

P 87-1591

Manufacturer. The Dow Chemical Company.
Chemical. (G) Modified styrene, butadiene polymer.
Use/Production. (S) Industrial polymer component of industrial adhesive formula. Prod. range: Confidential.
Toxicity Data. Acute oral: - 5,000 mg/kg; Irritation: Skin-Non-irritant, Eye-Slight.

P 87-1592

Manufacturer. Confidential.
Chemical. (G) Substituted thiadiazole.
Use/Production. (G) Industrial lubricant and engine oil additive. Prod. range: Confidential.
Toxicity Data. Acute oral: 5 g/kg; Acute dermal: 2 g/kg; Irriation: Skin-Moderate, Eye-Moderate; Ames test: Non-mutagenic.

P 87-1593

Manufacturer. Confidential.
Chemical. (G) Potassium alcoholates.
Use/Production. (S) Chemical intermediate for manufacture of polymers. Prod. range: Confidential.

P 87-1594

Manufacturer. The Dow Chemical Company.
Chemical. (G) Alkyl pyrimidine.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.
Toxicity Data. Acute oral: 800 mg/kg.

P 87-1595

Importer. Confidential.
Chemical. (G) Dibasic acid/glycol ester.
Use/Import. (S) Industrial stamping enamels-exterior can coating. Import range: Confidential.

P 87-1596

Manufacturer. The Dow Chemical Company.
Chemical. (G) Alkyl pyrimidine, methyl ether.

Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1597

Manufacturer. Confidential.
Chemical. (G) Amine salt of a styrene-acrylic copolymer.
Use/Production. (G) Site-limited and industrial contained use as an emulsifier for the production of an emulsion polymer. Prod. range: 15,000 to 60,000 kg/yr.

P 87-1598

Importer. Hodogaya Chemical (U.S.A.), Incorporated.
Chemical. (S) 1-Hexadecanaminium, N,N,N-trimethyl-, hexa-.mu.-oxotetra-.mu. 3-oxodi-.mu. 5-oxotetradecaoxooctamolybdate(4-) (4:1).
Use/Production. (G) Ingredient in toner for plain paper copy. Import range: 1,000 to 5,000 kg/yr.
Toxicity Data. Acute oral: 5 g/kg; Irritation: Skin—Slight, Eye—Irritant; Ames test: Non-mutagenic.

P 87-1599

Manufacturer. Alco Chemical Corporation.
Chemical. (G) Sodium polyacrylate; acrylate copolymer salt; and vinylic copolymer.
Use/Production. (G) Thickening compound for aqueous system. Prod. range: Confidential.

P 87-1600

Importer. Confidential.
Chemical. (S) Benzene, ethenyl-.2-propenoic acid, 2-methyl ester.2-propenoic acid, butylester. butanedioic acid, mono[2-[(1-oxo-2-propenyl)oxy]ethyl]ester polymer.
Use/Import. (G) Toner. Import range: 120,000 to 240,000 kg/yr.
Toxicity Data. Ames test: Non-mutagenic.

P 87-1601

Manufacturer. Interez Incorporated.
Chemical. (G) Modified polymeric amine.
Use/Production. (G) Industrial and commercial epoxy resin curing (crosslinking) agent. Prod. range: Confidential.

P 87-1602

Manufacturer. Confidential.
Chemical. (G) Polyurethane polymer.
Use/Production. (G) Coatings/adhesives for open, non-dispersive use. Prod. range: Confidential.

P 87-1603

Manufacturer. Confidential.
Chemical. (G) Alkyl phosphenic acid.
Use/Production. (G) Site-limited intermediate (destructive use). Prod. range: Confidential.

P 87-1604

Manufacturer. Confidential.
Chemical. (G) Alkyl phosphonic anhydride.
Use/Production. (G) Site-limited intermediate (destructive use). Prod. range: Confidential.

P 87-1605

Manufacturer. Confidential.
Chemical. (G) Alkyl phosphonic anhydride, homopolymer.
Use/Production. (G) Site-limited intermediate (destructive use). Prod. Range: Confidential.

P 87-1606

Manufacturer. Confidential.
Chemical. (G) Alkyl phosphonic acid, homopolymer.
Use/Production. (G) Site-limited intermediate. Prod. Range: Confidential.

P 87-1607

Manufacturer. Confidential.
Chemical. (G) Alkyl phosphonic acid, homopolymer, alkaline metal salt.
Use/Production. (G) Industrial boiler water dispersant (dispersive use). Prod. Range: Confidential.

P 87-1608

Manufacturer. E.I. du Pont de Nemours and Company, Inc.
Chemical. (G) Substituted indole.
Use/Production. (S) Industrial intermediate for manufacture of spectral sensitizer of photographic materials. Prod. range: 6 to 18 kg/yr.

P 87-1609

Manufacturer. E.I. du Pont de Nemours and Company, Inc.
Chemical. (G) Indole carbocyanine dye.
Use/Production. (G) Industrial and commercial photographic emulsion additive. Prod. range: 12 to 36 kg/yr.

P 87-1610

Importer. Confidential.
Chemical. (G) Polyamide resin.
Use/Import. (S) Printing ink component (used to disperse pigment and to provide gloss, adhesion and resistance properties when printed on paper, plastic and metal substrates. Import range: Confidential.

P 87-1611

Importer. The Aqualon Company.
Chemical. (G) Hydrophobically-modified hydroxyethylcellulose.
Use/Import. (S) A thickner for joint compounding tile cements and plasters, a protective colloid for emulsion polymerization and for suspension polymerization. Import range: Confidential.

P 87-1612

Manufacturer. Hoechst Celanese Corporation.
Chemical. (G) Polyester from aromatic dicarboxylic acid ester, aliphatic diols and oxirane polymer.
Use/Production. (G) Soil release additive, anti static agent, dye bath additive. Prod. range: Confidential.
Toxicity Data. Acute oral: >5,000 mg/kg; Irritation: Skin—Non-irritant, Eye—Non-irritant.

P 87-1613

Manufacturer. Peltz Rowley Chemical Company.
Chemical. (G) Epoxy—amine adduct.
Use/Production. (S) Curing agent for expoxy resin coating. Prod. range: Confidential.

Date: August 25, 1987.

Denise Devoe,

Acting Director, Information Management Division, Office of Toxic Substance.

[FR Doc. 87-20137 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59829; FRL-3254-9]

Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) permanufacture notices are discussed in EPA statements of the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. Notices for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of three such PMNs and provides the summary of each.

DATES: Close of Review Period:

Y 87-219	Sept. 3, 1987
Y 87-220	Sept. 8, 1987
Y 87-221	Sept. 9, 1987

FOR FURTHER INFORMATION CONTACT: Stephanie Roan, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street, SW., Washington, DC 20460, (202) 382-3725.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission by the manufacturer on the exemptions received by EPA. The complete non-confidential document is available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

Y 87-219

Importer. Unitika America Corporation.
Chemical. (G) Co-polyester.
Use/Import. (G) Resin for powder coating. Import range: 30,000 to 50,000 kg/yr.

Y 87-220

Importer. Nippon Gohsei U.S.A. Company, Ltd.
Chemical. (G) High molecular weight linear staturated polyester.
Use/Import. (S) Commercial and consumer flexibility modified for hard resins. Import range: 10,000 to 50,000 kg/yr.

Y 87-221

Importer. Confidential.
Chemical. (G) Isophthalic alkyd resin.
Use/Import. (G) Coatings.

Date: August 25, 1987.

Denise Devoe,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 87-20138 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51691; FRL-3257-6]

Toxic and Hazardous Substances Control; Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice announces receipt of forty-four such PMNs and provides a summary of each.

DATES: Close of Review Period:

P 87-1614, 87-1615 and 87-1616—November 18, 1987.
P 87-1617—November 15, 1987.
P 87-1618, 87-1619, 87-1620, 87-1621, 87-1622, 87-1623, 87-1624, 87-1625, 87-1626, 87-1627 and 87-1628—November 21, 1987.
P 87-1629, 87-1630, 87-1631, 87-1632, 87-1633, 87-1634, 87-1635, 87-1636, 87-1637, 87-1638 and 87-1639—November 22, 1987.
P 87-1640, 87-1641, 87-1642, 87-1643, 87-1644, 87-1645, 87-1646, 87-1647, 87-1648, 87-1649, 87-1650 and 87-1651—November 23, 1987.
P 87-1652, 87-1653, 87-1654, 87-1655, 87-1656 and 87-1657—November 24, 1987.

Written comments by:

P 87-1614, 87-1615 and 87-1616—October 19, 1987.
P 87-1617—October 16, 1987.
P 87-1618, 87-1619, 87-1620, 87-1621, 87-1622, 87-1623, 87-1624, 87-1625, 87-1626, 87-1627 and 87-1628—October 22, 1987.
P 87-1629, 87-1630, 87-1631 87-1632, 87-1633, 87-1634, 87-1635, 87-1636, 87-1637, 87-1638 and 87-1639—October 23, 1987.
P 87-1640, 87-1641, 87-1642, 87-1643, 87-1644, 87-1645, 87-1646, 87-1647, 87-1648, 87-1649, 87-1650 and 87-1651—October 24, 1987.
P 87-1652, 87-1653, 87-1654, 87-1655, 87-1656 and 87-1657—October 25, 1987.

ADDRESS: Written comments, identified by the document control number "[OPTS-51691]" and the specific PMN number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. L-100, 401 M Street, SW., Washington, DC 20460, (202) 554-1305.

FOR FURTHER INFORMATION CONTACT: Stephanie Roan, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street, SW., Washington, DC 20460, (202) 382-3725.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the PMNs received by EPA. The complete non-confidental PMNs are available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

P 87-1614

Manufacturer. Reichhold Chemicals, Incorporated.
Chemical. (G) Limonene—hydrocarbon resin.
Use/Production. (S) Industrial tackifier component in the production of various adhesives. Prod. range: Confidential.

P 87-1615

Manufacturer. Confidential.
Chemical. (G) Polyester.
Use/Production. (S) Coating. Prod. range: Confidential.

P 87-1616

Manufacturer. Confidential.
Chemical. (G) Alkyd copolymer.
Use/Production. (G) Resin for coating. Prod. range: Confidential.

P 87-1617

Manufacturer. Confidential.
Chemical. (G) Basic dyetone sm.
Use/Production. (G) Industrial and commercial open- non-dispersive. Prod. range: Confidential.

P 87-1618

Manufacturer. The Dow Chemical Company.
Chemical. (G) Alkyl amide.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1619

Manufacturer. The Dow Chemical Company.
Chemical. (G) Halogenated alkyl pyrimidine.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1620

Manufacturer. The Dow Chemical Company.
Chemical. (G) Alkyl diamide.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P-87-1621

Manufacturer. Hack Company.
Chemical. (S) N-decyl-tri-N-dodecylammonium bromide.
Use/Production. (S) Industrial and commercial part of formulation used in ion-specific nitrate electrode. Prod. range: 1 to 5 kg/yr.

P 87-1622

Manufacturer. The DOW Chemical Company.
Chemical. (G) Alkyl tetrahydropyrimidine.

Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1623

Importer. Marubeni America Corporation.

Chemical. (S) 4-[4-[4-(4-Butyl phenylazo)phenyl azo]-1-naphthyl azo]-N,N-diethyl aniline.

Use/Import. (S) Industrial coloring matter for liquid crystal. Import range: 0.1 to 1.0 kg/yr.

P 87-1624

Importer. Marubeni America Corporation.

Chemical. (S) 1-(4-n-Butoxybenzylideneamino)-4-[4-(4-n-butoxy benzylideneamino)phenylazo]naphthalene.

Use/Import. (S) Industrial coloring matter for liquid crystal. Import range: 0.1 to 1.0 kg/yr.

P 87-1625

Importer. Marubeni America Corporation.

Chemical. (S) 4-[4-(4-Butyl phenylazo)-1-naphthylazo]-N,N-dimethyl aniline.

Use/Import. (S) Industrial coloring matter for liquid crystal. Import range: 0.1 to 1.0 kg/yr.

P 87-1626

Manufacturer. Confidential.

Chemical. (G) Aliphathic aromatic poly(ester thioether urethane).

Use/Production. (G) Industrial paint product with open, dispersive uses. Prod. range: 50,000 to 398,000 kg/yr.

P 87-1627

Manufacturer. Confidential.

Chemical. (G) Mixed dibasic acid esters of monohydric alcohol and polyols mixed esters of monophydric alcohol and polyols.

Use/Production. (G) Metal working lubricant additive. Prod. range: Confidential.

P 87-1628

Manufacturer. Confidential.

Chemical. (G) Alkenyl substituted succinic anhydride product with substituted ethanol.

Use/Production. (G) Contained use. Prod. range: 40,000 to 150,000 ky/yr.

P 87-1629

Manufacturer. Confidential.

Chemical. (G) Alkaline water soluble polyester.

Use/Production. (G) Coating for paper and other cellulosics. Prod. range: Confidential.

P 87-1630

Manufacturer. Confidential.

Chemical. (G) Aliphatic aromatic acrylic resin.

Use/Production. (G) Industrial dispersively used coating. Prod. range: 120,000 to 240,000 kg/yr.

P 87-1631

Manufacturer. Confidential.

Chemical. (G) Alkenes, long chain alkyl.

Use/Production. (S) Intermediate for preparation of alkylated aromatic hydrocarbons from aromatic hydrocarbons; and intermediate for general synthetic usage. Prod. range: Confidential.

P 87-1632

Manufacturer. Confidential.

Chemical. (G) Alkylbenzene for manufacture of lubricant additives—destructive use.

Use/Production. (G) Intermediate for manufacture of lubricant additives—destructive use. Prod. range: Confidential.

Toxicity Data. Acute oral: 5 g/kg; Acute dermal: 2 g/kg; Irritation: Skin—Non-irritant, Eye—Non-irritant; Ames test: Non-mutagenic.

P 87-1633

Manufacturer. Confidential.

Chemical. (G) Metal salt of alkaryl sulfonate.

Use/Production. (G) Lubricating oil additive—contained use. Prod. range: Confidential.

Toxicity Data. Acute oral: 2,310 mg/kg; Acute dermal: >1,580 mg/kg; Irritation: Skin—Slight, Eye—Mild; Inhalation: Non-toxic.

P 87-1634

Manufacturer. Confidential.

Chemical. (G) Metal salt of alkaryl sulfonate.

Use/Production. (G) Petroleum lubricant additive—contained use. Prod. range: Confidential.

Toxicity Data. Acute oral: >5 g/kg; Acute dermal: >5 g/kg; Irritation: Skin—Moderate, Eye—Mild.

P 87-1635

Manufacturer. Confidential.

Chemical. (G) Metal salt of alkaryl sulfonate.

Use/Production. (G) Lubricating oil additive-contained use. Prod. range: Confidential.

Toxicity Data. Acute oral: 25,100 mg/kg; Acute dermal: 10,000 mg/kg; Irritation: Skin—Slight, Eye—Moderate; Inhalation: Non-toxic.

P 87-1636

Importer. Confidential.

Chemical. (G) Polyfluorinated copolymers.

Use/Import. (G) Oil and water repellent for paper. Import range: Confidential.

Toxicity Data. Acute oral: 22 ml/kg; Irritation: Skin—Slight, Eye—Moderate.

P 87-1637

Importer. Confidential.

Chemical. (S) Chloroethene.2-propenoic acid monoester with 1,2-propandiol.2-butenedioic acid polymer.

Use/Import. (S) Industrial paint vehicle. Import range: 24,000 to 36,000 kg/yr.

Toxicity Data. Ames test: Non-mutagenic.

P 87-1638

Importer. Shin-Etsu Silicones of America, Incorporated.

Chemical. (S) Polymer of dimethyl cyclosiloxane; methyl vinyl cyclosiloxane; and octaphenyl cyclotetrasiloxane.

Use/Import. (S) Industrial ingredient for silicone rubber compounds or adhesives. Import range: 3,000 to 5,000 kg/yr.

P 87-1639

Manufacturer. Confidential.

Chemical. (G) Alkaryl sulfonic acid.

Use/Production. (G) Intermediate for manufacture of lubricant additives and destructive use. Prod. range: Confidential.

Toxicity Data. Acute oral: >10.003 g/kg; Acute dermal: >7.94 g/kg; Irritation: Skin—Irritant, Eye—Irritant.

P 87-1640

Manufacturer. The Dow Chemical Company.

Chemical. (G) Alkylpyrimidinol

Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1641

Manufacturer. The Dow Chemical Company.

Chemical. (G) Vinylidene chloride/butadiene polymer with alkaneoic and alkanedioic acids.

Use/Production. (G) Industrial adhesive. Prod. range; Confidential.

P 87-1642

Manufacturer. The Dow Chemical Company.

Chemical. (G) Vinylidene chloride, butadiene, polymer with alkane dioic acid.

Use/Production. (G) Industrial adhesive. Prod. range: Confidential.

P 87-1643

Manufacturer. The Dow Chemical Company.

Chemical. (G)Alkyl pyrimide, alkali salt.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1644

Manufacturer. General Electric Company.
Chemical. (G) Aryl alkylarylpolyamide resin.
Use/Production. (S) Industrial thermoplastic resin for sheet and film blend resin for themoplastic blends. Prod. range: Confidential.

P 87-1645

Manufacturer. General Electric Company.
Chemical. (G) Aryl alkylpolyamide resin.
Use/Production. (S) Industrial thermoplastic resin for sheet and film and blend resin for thermoplastic blends. Prod. range; Confidential.

P 87-1646

Manufacturer. Milliken and Company.
Chemical. (G) Substituted polyoxyethylene aniline diacetylester.
Use/Production. (G) Open, non-dispersive use. Prod. range: Confidential.

P 87-1647

Manufacturer. Milliken and Company.
Chemical. (G) Substituted polyoxyethylene aniline.
Use/Production. (G) Dispersive use. Prod. range: Confidential.

P 87-1648

Manufacturer. Confidential.
Chemical. (G) Substituted phthalic anhydride.
Use/Production. (S) Chemical intermediate. Prod. range: Confidential.

P 87-1649

Importer. Confidential.
Chemical. (G) Soya alkyd resin.
Use/Import. (G) Coatings. Import range: Confidential.

P 87-1650

Importer. Confidential.
Chemical. (G) Soya alkyd resin.
Use/Import. (G) Coatings. Import range: Confidential.

P 87-1651

Manufacturer. General Electric Company.
Chemical. (G) Aryl alkylarylcopolyamide resin.
Use/Production. (S) Thermoplastic resin for sheet and film and blend resin for thermoplastic blends. Prod. range: Confidential.

P 87-1652

Importer. Shin-Etsu Silicones of America, Incorporated.
Chemical. (G) Methyl hydrogen methoxy polysiloxane.
Use/Import. (S) Industrial cross linking agent for liquid silicone rubber compound. Import range: 60 to 150 kg/yr.

P 87-1653

Manufacturer. Confidential.
Chemical. (G) Azoxy bis[(substituted phenyl) axo]bis[substituted naphthalenesulfonic acid, salt.
Use/Production. (G) Open, non-dispersive use. Prod. range: Confidential.

P 87-1654

Importer. Confidential.
Chemical. (G) Blocked aliphatic urethane.
Use/Import. (S) Textile finish. Import range; Confidential.

P 87-1655

Manufacturer. Confidential.
Chemical. (G) Azoxybis[(substituted phenyl)azo]bis[substituted naphthalenesulfonic acid, and salt.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 87-1656

Manufacturer. Confidential.
Chemical. (G) Modified maleated metal resinate.
Use/Production. (S) Industrial publication gravure printing inks. Prod. range: Confidential.

P 87-1657

Manufacturer. Confidential.
Chemical. (G) Cyclic halophosphite.
Use/Production. (G) Hydrocarbon, resin and polymer additive—contained use. Prod. range: Confidential.
Toxicity Data. Acute oral: >5,000 mg/kg; Acute dermal: >2,000 mg/kg; Irritation: Skin—Non-irritant, Eye—Non-irritant, Ames test: Non-mutagenic.

Date: August 28, 1987.

Linda K. Smith,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 87-20422 filed 9-3-87; 8:45 am]
BILLING CODE 6560-50-M

[OW-FRL-3258-5]

Water Quality Act of 1987 Implementation; Draft Guidance Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability for public comment of five draft guidance documents for implementation of several sections of the Water Quality Act of 1987. These five documents are: "Final Draft: Nonpoint Source Guidance," "Final Draft: Clean Lakes Program Guidance," "Draft: State Water Quality-based Toxics Control Program Review Guidance," "Draft: Initial Guidance—State Water Pollution Control Revolving Fund," and "State Clean Water Strategies: Meeting The Challenges of The Future."

DATE: Copies of these documents will be available for public comment from EPA Headquarters Office of Water for a period of 30 days, beginning September 4, 1987.

ADDRESSES: Copies of these documents can be obtained by writing Mario Hegewald, Office of Water, WH-556, U. S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. All comments should be forwarded to Mr. Hegewald at the same address.

FOR FURTHER INFORMATION CONTACT: Mr. Hegewald, (202) 382-5700.

SUPPLEMENTARY INFORMATION: The Water Quality Act of 1987 (WQA) expands and strengthens the Clean Water Act through a number of changes designed to enhance water quality and improve programs. The WQA builds on the progress made in water quality management, and focuses on remaining problems. The new law reinforces the national commitment to the goal of restoring and maintaining our waters; presents new challenges to EPA and States; and revises and expands the agenda for State and EPA water programs.

The EPA Office of Water intends to work closely with the States, municipalities and the public to structure implementation activities. In some areas, that will mean renewed vigor in implementing traditional base programs and priorities. In other areas, it will mean structuring new programs to improve their capability to achieve beneficial environmental results. To the extent possible, EPA will encourage States to integrate requirements across programs to avoid redundant efforts and to make efficient and effective use of resources. Final draft guidance on EPA's overall approach to State WQA implementation, entitled "State Clean Water Strategies: Meeting The Challenges of The Future," is available now from EPA at the above address.

As the first comprehensive revision of the Clean Water Act in a decade, the WQA establishes many new

requirements for EPA and the States from information gathering, assessments, strategies, control requirements, grants, and conferences, to management plans, studies and reports. Although they relate to dozens of different program activities, the cumulative burden of the requirements for EPA and the States is substantial.

A summary of the major provisions gives a flavor for the scope of the task.

Surface Water Toxics Control

The WQA establishes a program for identification of waters affected by toxic pollutants and implementation of specific controls, section 304(1) individual control strategies, to reduce those toxics.

This program requires States to assess and list their waters to determine where there are impairments of water quality due to point source discharges and to identify the discharges. By February 1989, States are to set effluent limitations in § 402 National Pollutant Discharge Elimination system (NPDES) permits ("individual control strategies") for these discharges to assure that water quality standards are attained. States are also to revise and expand their water quality standards to include all section 307(a) toxic pollutants where EPA has promulgated criteria and where their discharge could reasonably be expected to interfere with designated uses. Guidance on implementation of requirements under section 304(1) is nearing completion and will soon be available from EPA at the above address. EPA will publish a notice of availability when this draft guidance is available for comment.

An additional guidance document which is available now, is the "Draft State Water Quality-based Toxics Control Program Review Guidance." The purpose of this document is to provide guidance to EPA Regional offices in conducting comprehensive assessments of State toxics control programs on a State-by-State basis, and in developing detailed State action plans to strengthen State toxics control programs, including monitoring, water quality standards, and NPDES permitting.

Nonpoint Source Pollution

The legislation authorizes funding for State implementation of nonpoint source management programs. States must assess their waters to determine where there are impairments of water quality due to nonpoint sources and to identify the sources. By August 1988, States are to develop programs to implement best management practices and other controls including an implementation schedule, an Attorney General's statement of legal authorities, an identification of funding sources and a list of related Federal projects that conflict with a State's nonpoint source policies. The "Final Draft: Nonpoint Source Guidance" is available now from EPA at the above address.

State Revolving Loan Fund (SRF)

By authorizing Federal funds to capitalize State revolving fund programs, WQA provides for a transition from the current Federal Construction Grant Program to a new approach for assisting communities in construction of publicly owned treatment works (POTWs). From the SRF, States can provide loans and other types of financial assistance, but not grants, to local communities and intermunicipal and interstate agencies, for the construction of POTWs and for the implementation of projects and programs established under the nonpoint source pollution control program (sectiion 319) and the national estuaries program (section 320). The "Draft: Initial Guidance—State Water Pollution Control Revolving Fund" is available now from EPA at the above address.

Sewage Sludge

The WQA establishes a more aggressive program by EPA and States for the control of toxic pollutants in sewage sludge which may adversely affect public health or the environment. EPA is to promulgate standards for sludge use and disposal to control those pollutants and to implement those standards through permits. These standards will be proposed in a separate **Federal Register** notice of proposed rulemaking.

In the interim before promulgation of the standards for sewage sludge use and disposal, the WQA directs EPA to include sludge requirements in NPDES permits issues to publicly owned treatment works (POTWs) or to take other measures to protect public health and the environment. EPA is developing guidance for permit writers for including interim sludge requirements in POTWs' permits. The guidance currently is scheduled to be available in early FY 1988.

The WQA also directs EPA to promulgate regulations for approval of State sewage sludge management programs. EPA expects to propose these regulations, as well as regulations governing sludge permits, in December 1987.

Estuaries

The new law sets up a national estuary program. EPA and States are to convene management conferences for estuaries of national significance. These conferences will assess water quality and trends, and collect and assess data on problems and causes. States will develop and implement comprehensive management plans in expeditious fashion. Development of national estuary program guidance is presently underway, and assessment of the six existing estuary protection programs is underway to see if these programs will become established as management conferences. EPA will publish a notice of availability in the **Federal Register** when the draft guidance is available for comment.

Clean Lakes

The Clean Lakes provision of the WQA provides for a comprehensive analysis of the quality of lakes nationally through expanded monitoring and reporting. Completion of the lake water quality assessment is required in order for States and Indian Tribes to be eligible for Clean Lakes grants. States must assess all lakes to determine where there are impairments in water quality, to classify them by eutrophic condition and to discuss lake water quality trends. States must also identify the means planned to control pollution in lakes and restore lake quality, as well as methods planned to mitigate acidity. Several types of lake restoration and protection grants are authorized. The "Final Draft: Clean Lakes Program Guidance" is available now from EPA at the above address.

Storm Water

The legislation significantly alters the CWA approach to the control of storm water runoff pollution by adopting a phased and tiered approach.

EPA will promulgate regulations governing permit application requirements for storm water discharges associated with industrial activity and for discharges from large municipal storm sewer systems by February 4, 1989. Permit application requirements for discharges from medium municipal storm systems are to be developed by February 4, 1991. EPA, in consultation with the States, is required to study and submit reports to Congress on certain other storm water discharges for which permits are not required prior to October 1, 1992. A storm water discharge which EPA or a State with an approved NPDES program determines contributes to a violation of a water quality standard or is a significant contributor of pollutants to waters of the United States can be required to obtain a permit prior to October 1, 1992. EPA

will publish a notice of proposed rulemaking in the **Federal Register** when the proposed rule is available for comment.

Great Lakes

The bill formally establishes the Great Lakes National Program Office in EPA to carry out this Country's commitments in the Great Lakes Water Quality Agreement. The program office, in conjunction with the States, will develop and implement "action plans" for control of toxic pollutants. In addition, they will create a monitoring network, establish a five year nutrient control program, and undertake a five year toxic demonstration study.

There are dozens of additional implementation activities stemming from the WQA Amendments. They include policies, guidance documents and regulation changes. All will influence water pollution control efforts over the next several years and will require coordination with interested parties. We actively solicit your comments on the documents that are available today, as well as other guidances and regulations as they become available.

Dated: September 2, 1987.

Lawrence J. Jensen,

Assistant Administrator for Water.

[FR Doc. 87-20536 Filed 9-3-87; 8:45 am]

BILLING CODE 6560-50-M

EXPORT-IMPORT BANK OF THE UNITED STATES

Open Meeting of the Advisory Committee of the Export-Import Bank of the United States

SUMMARY: The Advisory Committee was established by Pub. L. 98-181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank to the United States Congress.

Time and Place: Tuesday, September 22, 1987 from 9:30 a.m. to 12 noon. The meeting will be held in Room 1143, 811 Vermont Avenue NW., Washington, DC 20571.

Agenda: The meeting agenda will include a discussion of the following topics: Trade Issues Update, Financial Report, Program Update, Legislative Update, Report of State/City/Municipal Task Force, Report of the FCIA Task Force, Report of LDC Debt Task Force, and other topics.

Public Participation: The meeting will be open to public participation; and the last 20 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. In order to permit the Export-Import Bank to arrange suitable accommodations, members of the public who plan to attend the meeting should notify Joan P. Harris, Room 935, 811 Vermont Avenue NW., Washington, DC 20571, (202) 566-8871, not later than September 21, 1987. If any person wishes auxiliary aids (such as a language interpreter) or other special accommodations, please contact prior to September 15, 1987 the Office of the Secretary, Room 935, 811 Vermont Avenue NW., Washington, DC 20571, Voice: (202) 566-8871 or TDD: (202) 535-3913.

Further Information: For further information, contact Joan P. Harris, Room 935, 811 Vermont Avenue NW., Washington, DC 20571, (202) 566-8871.

Hart Fessenden,

General Counsel.

[FR Doc. 87-20534 Filed 9-3-87; 8:45 am]

BILLING CODE 6690-01-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

August 26, 1987.

The Federal Communications Commission has submitted the following information collection requirements to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Copies of the submissions may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. For further information on these submissions contact Jerry Cowden, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on these information collections should contact J. Timothy Sprehe, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0329
Title: Equipment Authorization—Verification (Sections 2.955, 15.69(b), 15.814(b), 15.834(b)(c), 18.203(b))
Action: Revision
Respondents: Businesses (including small businesses)
Frequency of Response: On occasion recordkeeping
Estimated Annual Burden: 5,675 Recordkeepers; 102,150 Hours

Needs and Uses: Equipment testing is performed and data is gathered to provide information to aid in controlling interference to radio communications. Data collected verifies compliance of equipment to the FCC Rules. The information is retained by the equipment manufacturer and made available only at the request of the Commission.

OMB Number: 3060-0209
Title: Section 73.1920, Personal attacks
Action: Extension
Respondents: Businesses (including small businesses)
Frequency of Response: On occasion
Estimated Annual Burden: 1,189 Responses; 595 Hours

Needs and Uses: If an attack is made on the honesty, character, integrity, or like personal qualities of an identified person or group during the presentation of views on a controversial issue of public importance on a television or radio station, the licensee of the station must notify the person or group of the attack and offer a reasonable opportunity to respond over the licensee's facilities. The notification permits the person or group to respond to the attack.

Federal Communications Commission

William J. Tricarico,

Secretary.

[FR Doc. 87-20440 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

August 27, 1987.

The Federal Communications Commission has submitted the following information collection requirements to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Copies of the submissions may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. For further information on these submissions contact Jerry Cowden, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on these information collections should contact J. Timothy Sprehe, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0309
Title: Section 74.1281, Station Records
Action: Extension

Respondents: State or local governments, business (including small businesses), non-profit institutions
Frequency of Response: On occasion recordkeeping
Estimated Annual Burden: 1,900 Recordkeepers; 1,900 Hours

Needs and Uses: This rule requires licensees of FM translator or booster stations to maintain adequate records. These records include the current instrument of authorization, official correspondence with the FCC, maintenance records, contracts, permission for rebroadcasts, and information concerning antenna tower lights. The records are used by FCC staff in investigations to ensure that licensees are operating in accordance with FCC rules and the station authorizations.

OMB Number: 3060–0310
Title: Section 76.12, Registration statement required
Action: Revision
Respondents: State or local governments, businesses (including small businesses), non-profit institutions
Frequency of Response: On occasion
Estimated Annual Burden: 1,500 Responses; 375 Hours

Needs and Uses: This rule requires that a registration statement be filed with the FCC before a system community unit (a cable television system or portion of a cable television system) is authorized to commence operation. The data is used by FCC staff to maintain complete records regarding cable systems and to ensure compliance with FCC rules.

Federal Communications Commission
William J. Tricarico,
Secretary.

[FR Doc. 87–20441 Filed 9–3–87; 8:45 am]
BILLING CODE 6712-01-M

Special Radio Services; Lottery Rankings of 900 MHz SMRs Applicants

August 21, 1987.

On July 24, 1987, the Federal Communications Commission conducted its fourth round of lotteries to select applicants to provide 900 MHz Specialized Mobile Radio (SMR) Service. These lotteries were used to rank applications in each of the following Designated Filing Areas (DFAs):

#17 Minneapolis-St. Paul
#18 Seattle
#19 San Diego
#20 Tampa-St. Petersburg
#21 Denver
#22 Phoenix
#23 Cincinnati-Dayton
#25 Kansas City
#26 Portland
#28 Columbus
#47 Orlando

Lists of the forty top-ranked applications in each of these Designated Filing Areas are attached to this public notice. The top 20 selectees in each DFA will be granted authorizations to provide SMR service. The next 20 ranked applicants will be alternate selectees should it be determined that any of the winners are not qualified to be licensees, or if any of the winners fail to provide the Commission with required transmitter site information within the specified time period. Within 30 days of the publication of this public notice in the **Federal Register**, interested parties may advise the Commission of any matter that may reflect on an applicant's qualifications to be a licensee. A copy of any such pleading must be served on the applicant in question on or before the day on which the document is filed with the Commission. *See* § 1.47(b) of the Commission's rules, 47 CFR 1.47(b). Service can be accomplished pursuant to § 1.47(d) of the Commission's rules, 47 CFR 1.47(d). Matters raised in such pleadings will be resolved prior to issuance of any license to the applicant. Individual applications may be examined at the Private Radio Bureau's Public Reference Room in Gettysburg, PA. Copies of individual applications may be ordered from the Commission's copy contractor, International Transcription Services, at (717) 337–1433.

All applications ranked below number 40 are hereby dismissed and will not be returned to the applicants. There will be no individual notices of dismissal mailed to applicants. The Lottery Notice of July 9, 1987 contains the names and addresses of lottery participants.

For further information regarding the selection procedures, consult the November 4, 1986 public notice (1 FCC Rcd 543 (1986), 52 FR 1302 (January 12, 1987)) or contact Betty Woolford of the Land Mobile and Microwave Division at (202) 632–7125.

900 MHz SMR Applications in the Minneapolis-St. Paul DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Schmidt, Terry L	775	044634
2. Weidlein, Mimi C	920	049393
3. Johnson Communications	429	049919
4. Allison, Kenneth	027	046689
5. Perkins, Robert H	679	041997
6. Cohen, Deborah A	175	049803
7. Blasucci, Peter	095	050844

900 MHz SMR Applications in the Minneapolis-St. Paul DFA—Continued

Rank and applicant name	Lottery code	File No.
8. Dechert, Glen	235	049086
9. Pettey, Donald: Herzog	685	047697
10. Gifford Engineering, Inc	340	035445
11. General Communications Co	334	040624
12. M&M Communications	537	051075
13. Thomas, Jayne M	874	044365
14. Beck, Harold I	073	049800
15. Communications Sales & Service Inc	186	041914
16. Shults, William O	807	041414
17. Brown, Katherine	117	046229
18. Atlantic Coast Communications, Inc	043	049771
19. Cook, Tommy L	193	035872
20. D&L Communications, Inc	217	035940
Alternates		
21. Sundbland, C. William	860	039846
22. King, Tom	461	037339
23. Atlantic Excavating	044	050348
24. Cline, Richard H	167	042492
25. Via Net Companies	903	045255
26. Loesch, Paul C	521	047525
27. Compass Communications, Inc	190	046702
28. Ewens, James L	280	046292
29. Kramps, Walter H	476	038539
30. Kravetz Media Corp	477	038818
31. Klugerman, Gerald	468	038193
32. Foster, Kent S	307	040000
33. Hauschildt, Paula	375	035404
34. Simpson, Michael G	813	037346
35. Kramps, Karl	476	038278
36. Citrone, Joseph	161	044181
37. Smith, Norman	825	049080
38. Folta, Edmund V. Jr.	301	047777
39. Capobianchi, Joseph D	140	041296
40. Timm, B.F.J	878	047847

900 MHz SMR Applications in the Seattle DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Powell, Charles A	0727	039944
2. Parrott, Billy J	0697	048327
3. California Mobile Communications	0136	035050
4. Wilbur, Waymon D	0977	043357
5. Lofland, Douglas S	0545	050514
6. Roth, Alan	0785	036857
7. Gavin, Thomas	0341	037123
8. Farrar, David W	0294	040561
9. Barnes, Ronald E	0067	049848
10. Baker, David R	0058	040404
11. Ipekdjian, Michael H.S	0428	049740
12. Ross, Michael P	0784	045926
13. Professional Communicatons	0733	036294
14. McDonnell, Tim	0597	044896
15. Takaya, Cheri	0905	044526
16. Long, Ronald W	0547	043440
17. Radio Systems Inc	0746	037054
18. Crump, Donald T	0213	045672
19. Zeff, A Robert	1001	046448
20. BRL Industries	0119	040014
Alternates		
21. Johnson Communications	0447	049920
22. Metrolink Mobile Telephone Inc	0614	039564
23. Yeager, John J	0996	046449
24. M & M Communications Inc	0564	051074
25. Loesch, Paul C	0544	047524
26. Wang, Robert Y.: Wang, Jennifer W	0958	039983
27. Steinbrink, William H	0881	040599
28. Corsoro, Gloria	0205	050308
29. Stoffer, Gary	0888	046331
30. Lyon, Juliette J	0563	045723
31. Santos, Eliseus R	0797	051315
32. Woodrow, Barry	0988	046442
33. Lugbill, Ralph W	0560	038291
34. Kansas City Communications Ltd	0464	050280
35. Lesser, David	0592	041323
36. Sims, Joe	0846	040184
37. Perkins, Robert H	0708	048611
38. Alphatronics Inc	0027	036413
39. Feiler, Michael H	0295	046440

900 MHz SMR Applications in the Seattle DFA—Continued

Rank and applicant name	Lottery code	File No.
40. Stonnington, Nicholas H	0892	050476

900 MHz SMR Applications in the San Diego DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Rossi, Anthony	0917	048670
2. Super Trucking Co	1053	046704
3. Custom Radio, Inc	0262	047754
4. Legal Com Services, Inc	0621	048582
5. BCI Corporation	0085	036530
6. Rich, Paula C	0895	038507
7. Matinzii, David	0687	039743
8. Huffman Communications Sales Inc	0506	035339
9. Parrott, Billy J	0820	048326
10. Smiley, C. Philip	0997	044130
11. Holman, William H	0492	037584
12. Travel Paging Corporation of America	1080	051033
13. Fulton, James G	0394	042643
14. Heninger, Randall D	0472	047611
15. Progressive Mobile Communication Service	0860	036936
16. Abadie, Leon W	0005	041167
17. Jordan, Clifford D	0544	050269
18. Mitchell, Michael A	0741	036014
19. Kenney, Gerald	0561	046720
20. Parton, James D	0822	047263
Alternates		
21. DuCap Electronics Inc	0306	037779
22. Burlew, Randall T	0158	043403
23. Munch, David	0765	046723
24. Murphy, Jennifer	0767	039844
25. Manobar, Apte	0672	049487
26. Orosz, Keith S	0799	047623
27. Russ Miller Communications Inc	0921	036890
28. McGaw, John E	0707	040882
29. Crump, Donald T	0256	045674
30. Pounds, Gary S	0849	037355
31. Singleman, Amy	0993	044610
32. U S West Paging, Inc	1092	044048
33. XW Corporation	1162	038854
34. O'Connell, Barbara	0788	048173
35. Reese, Wayne Stewart	0888	038874
36. Young, Christopher W	1167	044943
37. Burdett Communications	0154	051274
38. Patton, William R	0827	046771
39. Wolfram, Duane E	1156	045501
40. BRL Industries	0140	040015

900 MHz SMR Applications in the Tampa/St. Petersburg DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Badar, Talat	0068	049538
2. Sells, Mark	1152	037755
3. Manobar, Apte	0790	049486
4. Morris, Peter L	0887	044444
5. Marsh, Fred C	0799	042478
6. Vader, Stephen L	1322	047543
7. Kyle Jones Enterprises Inc	0703	039733
8. Kasper, Adam	0647	049164
9. Dune Corporation	0349	036005
10. General Communications Inc	0471	039352
11. Shifler, Lois	1137	048362
12. Springall, Art R	1222	043562
13. Newell, Robert C	0912	040788
14. Gem Electronics of Monmouth Inc	0468	050931
15. Schempp, Albert H	1131	050764
16. Jenkins, C. David	0616	050286
17. Ryder, William A	1107	041810
18. Hopper, Richard	0578	038772
19. G. Witt and Sons	0454	047535
20. Malloy, Gerald M	0788	046868
Alternates		
21. Trixler, Dennis	1305	048420
22. Biarnesen, Keith R	0113	045411

900 MHz SMR Applications in the Tampa/St. Petersburg DFA—Continued

Rank and applicant name	Lottery code	File No.
23. D & R Radio	0296	040135
24. Parton, James D	0965	047265
25. Rinehart, Donald D	1068	043740
26. Eichberg, Robert H	0359	047135
27. Advanced Communications Service Co	0013	039792
28. Hornberger, Deborah L	0580	050212
29. B & L Communications, Inc	0053	049863
30. Jason, Day	0612	037290
31. Richardson, James G	1063	043737
32. Rankin, Joan W	1037	039293
33. Ginsberg, Richardi	0480	049127
34. Autophone Comm & Electronics Inc	0060	043417
35. Associated Technologies Inc	0053	047047
36. Ybarra, Susan Jane	1404	046899
37. Kramps, Karl	0695	038354
38. Hyder, Ronald H	0593	037889
39. Rick, Neil	1064	051054
40. Hern, Samuel L	0551	042182

900 MHz SMR Applications in the Phoenix DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Johnson Radio Communications Co., Inc	545	041912
2. Coates, Dawn	209	048775
3. Smiley, C. Philip	1033	044134
4. Mobile Radio Communications Inc	763	037709
5. B&L Communications, Inc	056	049861
6. King James Partnership	580	042934
7. Arcorp	040	039653
8. Vader, Stephen L	1135	047253
9. Kall, Kenneth E	560	050861
10. Shaw, David C	1003	042835
11. Salyers, Douglas D	961	043502
12. Swade, George, Jr	1089	045509
13. American Mobilphone Paging Inc	031	049997
14. Manobar Apte	689	049489
15. Gay, John	410	035127
16. Pounds, Gary S	875	037359
17. Stetter, John	1069	046527
18. Millicom Radio Telephone Company Inc	754	045445
19. Johnson Communications	543	049925
20. Stangel, Barry	1056	050729
Alternates		
21. Webre, John C	1161	042747
22. Cecil, Karen Kennedy	180	049305
23. O'Hara, James T	810	047444
24. Interphone Co	522	040627
25. Friedland, Albert	388	043287
26. Estep, Robert L	338	040592
27. Patel, Nilkanth	849	040779
28. Mussman, Kyle W	790	051135
29. Amesbury, Marilyn	033	045969
30. Allison, Kenneth	026	046885
31. American 3001 Telecommunications Inc	029	045519
32. Eby, Peter Jr	314	050712
33. Ewens, James L	345	048425
34. EM Associates	329	045549
35. Communications Service Co	225	050943
36. Cooper, Ellaree P	236	041581
37. Bowker, Eleanor L	122	041274
38. E.F. Johnson Co	311	037022
39. Simon, Harold	1022	045238
40. Jabbour, C. Eugene	530	041148

900 MHz SMR Applications in the Denver DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. DePhillips, Andrew J	0293	049568
2. Davidson, Carl	0277	047509
3. Gladysz, Larry	0423	040490

900 MHz SMR Applications in the Denver DFA—Continued

Rank and applicant name	Lottery code	File No.
4. Kinzler, Gerard P	0572	043926
5. Betterton, Floyd	0101	036229
6. Young, Christopher W	1187	044944
7. Burdett Communications	0153	051276
8. A & E Electronics Corp	0002	035541
9. X W Corporation	1180	038858
10. Wolfram, Duane E	1174	045504
11. Garofalo, Anita M	0406	044724
12. Gordon, Gloria	0430	047590
13. Boulais, Marcel J	0122	036607
14. Select Communications and Data Acquisition	0972	039299
15. Munch, David	0771	046833
16. Bearden, Ned S	0084	040058
17. Fife, Georgiann	0363	035098
18. Heubner, Sandra J	0477	049104
19. Mims, Annalisa S	0741	041224
20. Zolkos Communications	1196	049062
Alternates		
21. Howe, Delores M	0503	041614
22. Paoli, Richard D	0820	043105
23. Deking, Chad A	0288	039461
24. KKK Repeater Inc	0578	045525
25. Novastar Corporation	0791	047309
26. Francis Communications Corporation	0384	050915
27. Ramer, Donald J	0886	035946
28. Shapiro, Greg M	0985	037090
29. Swider, Robert A	1073	044545
30. Appell, James T	0041	049867
31. Gustlin, Golob & Bragin	0441	047870
32. Clinton, Joseph	0206	038242
33. Talbot, Roger W	1078	040675
34. Amesbury, Marilyn	0034	045968
35. Trixler, Dennis	1105	048418
36. Gati Associates Inc	0410	047336
37. White, William B	1158	040850
38. Atlantic Excavating	0051	050344
39. Mobile Radio Service Co	0748	039306
40. Hamblin Jr., Gordon S	0447	038514

900 MHz SMR Applications in the Cincinnati-Dayton DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Cutter Investments, Inc	219	050257
2. Bowles, William G., Jr	104	050121
3. Barak, Andrew P	060	039952
4. Simon, Harold	798	045248
5. Buff, Jonathan A	126	039488
6. Russ Miller Communications, Inc	742	036894
7. Carter, Richard M	145	042503
8. Sibits, David J	793	038070
9. Mariano, Ralph	549	048950
10. Haggerty, Robert C	354	035952
11. Schnedl, John S	764	035362
12. Meyer, Stephen C	595	043103
13. Hansen, Sumner M	363	045423
14. McGee Communications Electronics, Inc	577	035670
15. Morris, Peter L	615	044448
16. MDI Systems, Inc	585	039370
17. Longoria, Salvador Gonzalez	525	040737
18. Channel One Communications, Inc	151	050437
19. Bradford, Donald F	107	038549
20. Risingsun, Richard E	726	036267
Alternates		
21. Erekson, R. Crisman	276	037975
22. Riley, Michael W	724	038030
23. Cook, Richard B	192	045037
24. Fritz, Norman	318	046303
25. S & R Communications	745	036193
26. Ritchie, Donald A	727	037920
27. Ronney, Martin	735	045465
28. Alfieri, Edward V	017	038914
29. Rankin, Joan W	711	039433
30. Lachesky, Hilda E	485	036487
31. Singleman, Amy	801	044616
32. Friz, Edward	319	043972
33. Millicom Radio Telephone Co., Inc	599	045446
34. Wiztronics, Inc	925	030476
35. Mester, John	591	041358

900 MHz SMR Applications in the Cincinnati-Dayton DFA—Continued

Rank and applicant name	Lottery code	File No.
36. Rothstein, Elliot B	741	039443
37. Communications Service Co	182	050944
38. Jay M. Eshbach II & Associates	422	036705
39. McNamara, Kim E	583	046798
40. Sheahan, Dennis P	785	040306

900 MHz SMR Applications in the Kansas City DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Peters, Arthur	561	046545
2. Lee, Bruce V	415	037209
3. Kramps, Karl	369	038353
4. Certified Systems, Inc	125	036543
5. Henderson, Henry B	309	048893
6. Johnson, Edward M	357	038577
7. Cliatt Communications	141	047654
8. Chicago Communications Service, Inc	131	049045
9. Palmer Communications of Florida	543	038964
10. Rajala, A.I	590	044598
11. Abadie, Cynthia Y	004	043580
12. Olivett International Inc	533	035027
13. Cieslak, Terrance C	134	036803
14. Krell, Steven	393	048121
15. Landsberger III, John	403	038829
16. Steil, Jack E	686	048230
17. Coughlin, Michael J	177	048541
18. Progressive Communications Inc	578	041883
19. DePhillips, Andrew Joseph	207	049477
20. Brown & Schwaninger	099	035241
Alternates		
21. Parkinson Electronics Co	550	038416
22. Wiley, Byron N	762	039661
23. Domencich, Thomas A	214	040468
24. Berman, Gordon	071	046034
25. McCormick, Rhonda G	468	038737
26. D & R Radio	190	039903
27. Morris Communications, Inc	504	044082
28. Francis Communications Corp	263	050912
29. Dabrusin, Sheri L	191	048705
30. Rosenzweig, Saul	613	048015
31. Scott, Margaret A	638	041255
32. Baird, Robert	050	048377
33. Miloro, Jesse	494	051042
34. Denault Jr., Herbert M	205	040428
35. Sinelli, Paul R	665	046810
36. BCI Corporation	059	036523
37. United States Sugar Corp	731	039138
38. King James Partnership	379	042926
39. Rogers, Sharon	612	044472
40. Le Riche David E	419	043064

900 MHz SMR Applications in The Portland DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Ponce, Anna	637	037226
2. Dawson, John F	225	037792
3. Asmus, Richard V	036	049674
4. Bobrowsky, Charles	090	050688
5. Kramps, Walter	444	038356
6. Wall Enterprises	837	040046
7. Bryant, John	116	048480
8. Clear Channel Communications Corp	155	050650
9. Waxman, Marvin N	844	048034
10. Matthews Radio Service, Inc	521	051212
11. Sonnenschein, Irving	758	045378

900 MHz SMR Applications in The Portland DFA—Continued

Rank and applicant name	Lottery code	File No.
12. Super Trucking Co	784	046485
13. Motor Carrier Radio Network, Inc	577	050744
14. Gordon, Gloria	327	047586
15. Unitel Corp	821	037407
16. Johnson Radio Communications Co., Inc	401	041927
17. Stonnington, Nicholas H	780	050483
18. Snow, Terrance	756	039503
19. Channel One Communications, Inc	144	050434
20. Cohen, Murray	169	042386
Alternates		
21. Ramsey, Kenneth L	663	049827
22. Ross, Richard T	688	038594
23. Harris, Stanley W	345	040705
24. Dannehower, James K	219	042768
25. Holohan, William J	370	044843
26. Huffman Communications Sales, Inc	378	035347
27. Andes, Maureen	032	046253
28. Baird, Robert	052	048378
29. Burdick, Rita A	121	038150
30. Stark, Richard L	766	036899
31. Kimball, Robert M	428	039806
32. Sherwood, Stephen	734	045663
33. DePhillips, Andrew J	233	049478
34. Eichberg, Robert H	252	047130
35. Blatt, A. Jacqueline	088	045215
36. Palmer Communications of Florida	610	038963
37. Polokoff, John G	636	046157
38. Chicago Communication Service, Inc	149	049044
39. Barak, Andrew P	055	040854
40. Upwardly Mobile Communications Corp	822	051295

900 MHz SMR Applications in the Columbus DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Parkerson Electronics, Inc	590	036318
2. Atlantic Coast Communications	037	050092
3. BCI Corporation	063	036524
4. Doleba, Ivymarie	231	046654
5. Ross, Michael P	657	045935
6. Berson, Brian	078	042758
7. Franklin, John P	288	044212
8. Cooper, Charles B	179	047680
9. Metz, Forrest L	529	039932
10. Deking, Chad A	221	039464
11. Glassman, Steven B	313	035468
12. Central Communications & Electronics, Inc	138	036777
13. Evans, Charles J	259	038695
14. Lee, Bernard D	450	045799
15. Klowden, Arthur J	416	040085
16. Bittman, JoAnne	083	049499
17. Berryman, Gene C	077	048268
18. Kall, Kenneth E	397	050863
19. Hershkowitz, Joan	347	044661
20. Chi Shing Chan, Arthur	144	041058
Alternates		
21. Ditsky, Stuart	230	048968
22. Corsoro, Gloria	186	050297
23. Electronic Communications	244	036625
24. Forster, Robert W	263	047096
25. Ramer, Donald J	634	036715
26. Bell, Carl E	073	038269
27. Sanborn, JoAnn	667	045440
28. First Telecommunications Group, Inc	274	036574
29. Chatco Communications, Inc	142	039406
30. LMR International, Inc	465	043864
31. MacCutcheon, Chryssa	481	045200
32. Carlson, Kathleen G	133	046175

900 MHz SMR Applications in the Columbus DFA—Continued

Rank and applicant name	Lottery code	File No.
33. Telecommunications Network Inc	759	045332
34. Radio Communications Co	627	035703
35. McGregor, William A	513	043512
36. Elliot, David	250	044271
37. Bunten, Arthur H	118	039677
38. Communications Sales and Service, Inc	167	041901
39. Forkish, Joseph	282	047112
40. Kohler, Alan C	418	043695

900 MHz SMR Applications in the Orlando DFA

Rank and applicant name	Lottery code	File No.
Winners		
1. Global Communications, Inc	0465	048610
2. Blasucci, Peter	0116	050847
3. Tower Site Communications, Inc	1246	036939
4. Dawson Associates	0304	047364
5. Browne, Douglas V	0155	042684
6. Young, Christopher W	1360	044945
7. Teesdale, Susan	1223	043296
8. Metzkow, Parsons M	0817	043639
9. Norcom Communications Corp	0879	051333
10. Gale, Bruce	0440	047079
11. Shapiro, Greg M	1121	037088
12. Pogue, Richard W	0954	046968
13. Mounger, Robert G	0857	041536
14. Rothstein, Elliot B	1056	039440
15. Smith, Clifford G	1158	046957
16. Mims, Robert B	0831	042125
17. Baird, Robert	0069	048388
18. Ewens, James L	0377	046434
19. Salinas, Aroldo	1072	036331
20. Zolkos Communications	1371	049067
Alternates		
21. Kearns, David	0626	043002
22. Cutter Investments Inc	0287	050264
23. Bradway, W. Jean	0136	049257
24. Degrandis, Joseph	0311	050849
25. Oliver, James T	0892	043328
26. Ketzel, Raymond W	0634	045711
27. Moody, Karen A	0841	049204
28. Clutterbuck, Gretchen R	0226	038261
29. American Mobilphone Inc	0032	040353
30. Carr, Charles	0193	043485
31. Rynkewicz, John T	1066	043187
32. Cucci, Rick	0282	041123
33. Russo, Frederick	1063	045587
34. Ross, Michael P	1050	045939
35. Hall, J. Michael	0492	037329
36. Argyrides, Anthony	0047	047166
37. Communications Repeater Corp & Telauto	0242	047564
38. O'Neill, Dennis	0887	042021
39. Wawcomm Partnership	1307	038294
40. Salkind, Sandy	1073	047876

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-20442 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; John Strelitz, et al.

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant, City and State	File No.	MM Docket No.
A. John Strelitz; Karns, TN	BPH-860730MC	87-343
B. Piedmont Partnership; Karns, TN	BPH-860730ME	
C. Karns Broadcasters, Ltd.; Karns, TN	BPH-860730MF	
D. Beaver Ridge Communications, Ltd.; Karns, TN	BPH-860730MI	
E. Jacob Broadcasting Company, Inc.; Karns; TN	BPH-860730MK	
F. George S. Flinn, Jr.; Karns, TN	BPH-860730ML	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Comparative, A-F
2. Ultimate, A-F

3. A copy of the complete HDO in this proceeding 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 may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037. (Telephone (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 87-20443 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; Mehl D. Tafoya, et al.

1. The Commission has before it the following mutually exclusive applications for a new FM station.

Applicant, City and State	File No.	MM Docket No.
A. Mehl D. Tafoya; Bloomfield, NM	BPH-850710ML	87-340
B. James M. Taber *et al.*, d/b/a The Taber Broadcasting Company of New Mexico; Bloomfield, NM	BPH-850712RM	
C. Jose C. Olivarez; Bloomfield, NM	BPH-850712VB	

2. Pursuant to section 309(c) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Environmental, A
2. Air Hazard, B,C
3. Comparative, A,B,C
4. Ultimate, A,B,C

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding 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 may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037 (Telephone No. (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 87-20444 Filed 9-3-87; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL HOME LOAN BANK BOARD

[No. 87-942]

Pilot Program to Improve Liquidity and Reduce Cost of Funds of Institutions Under Supervisory Control

Date: August 28, 1987.

AGENCY: Federal Home Loan Bank Board.

ACTION: Advance notice of proposed policy.

SUMMARY: The Federal Home Loan Bank Board ("Bank Board" or "Board") is currently considering establishing a pilot program to alleviate certain difficulties facing a number of thrift institutions. The Board is exploring whether certain incentives might both attract deposits to these institutions and lower the cost of funds of these institutions. Ideas currently under consideration include certain undertakings by the Board and the Federal Savings and Loan Insurance Corporation ("FSLIC") in the event that any of the institutions within the program are declared in default and liquidated pursuant to section 406 of the National Housing Act ("NHA"), 12 U.S.C. 1729, and the FSLIC incurs the obligation to pay insurance on the insured accounts of the institution pursuant to section 405(b) of the NHA, 12 U.S.C. 1728(b). As part of its consideration of the advisability of such a pilot program, the Board is today soliciting public comment on such a program.

DATE: Comments must be received on or before September 21, 1987.

ADDRESS: Send comments to Director, Information Services Section, Office of the Secretariat, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552. Comments will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Henry R. F. Griffin, Associate General Counsel for FSLIC-Red Division, (202) 377-6442; or Deborah Dakin, Assistant Director, Regulations and Legislation Division, (202) 377-6445; Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Background

In recent months, a number of FSLIC-insured institutions operting under the supervisory control of the Bank Board ("supervisory institutions") have been facing two related significant—albeit temporary—problems. First, information presented to the Bank Board indicates that some supervisory institutions may have been finding it difficult to attract sufficient funds through usual channels at market rates to meet their operating needs. When these supervisory institutions have offered market rates of interest, they have experienced some run-off of wholesale deposits. Many do not have adequate collateral to allow them to secure advances from their respective Federal Home Loan Banks in order to replace these lost funds. As a result, to attract or retain deposits these supervisory institutions often must offer higher interest rates than those available from other insured institutions. These higher operating costs may adversely affect these institutions' net worth. This could eventually cause increased risks and costs to the FSLIC.

The Board believes that with the recent passage of the Competitive Equality Banking Act of 1987, Pub. L. No. 100-86, 101 Stat. 552, public confidence in the thrift industry will rise, eventually resulting in increased deposits in all thrift institutions. It may take some time, however, before this will be reflected in deposits at these supervisory institutions. In the interim, while the public becomes more educated about the effects of the new statute, the Bank Board is considering various methods to attract funds at lower rates to certain supervisory institutions. One method would be for the Bank Board to offer guarantees to, or enter into agreements with, certain securities firms or deposit brokers to induce them to place insured funds in these institutions. Many of these companies may have avoided supervisory institutions in the past, deeming certain consequences of potential liquidation unacceptable.

The Bank Board staff has had informal discussions with certain potential large-scale brokers about ways to minimize the risks that have deterred them from depositing funds on behalf of their customers in supervisory institutions. One such risk is that an insured depositor may not recover the full return on its investment at maturity because of an intervening liquidation of the institution by the FSLIC. Such liquidations result in the payment of insurance on both principal and interest, up to the date of default only, up to the statutory limit of $100,000.

Certain methods of paying insurance used by the FSLIC may result in an insured depositor's receiving no interest or a lower rate or return on insured funds for the period between the date of default and the maturity of the investment. Concerns have also been expressed about delays in access to funds beyond the maturity of the investment while the insured status of the funds is under review by the FSLIC pursuant to 12 U.S.C. 1728. Some companies have indicated that appropriate guarantees and agreements by the Bank Board and the FSLIC would counterbalance the perceived risks of placing funds in supervisory institutions and would encourage these investors to open accounts at lower interest rates. If supervisory institutions can attract sufficient funds to meet their needs at lower rates as higher cost funds mature and are withdrawn, not only these institutions but all thrift institutions would benefit. This benefit would accrue industry-wide because the high rates currently offered by many supervisory institutions appear to inflate the rates other thrift institutions, both in their geographic market and nationwide, must pay for deposits. This higher cost of funds increases the operating costs of all thrift institutions.

The Bank Board is in the process of collecting information to determine whether offering such guarantees or entering into such agreements will in fact result in the anticipated benefits, *i.e.*, lower cost of funds and alleviation of the liquidity problems. The Board believes that a one-year, experimental, carefully monitored pilot program incorporating some of the proposed agreements and commitments on a limited scale is the best way to determine if such benefits in fact result. The Bank Board is currently planning to limit this pilot program in two ways. First, it would cover only selected troubled institutions that are operating under supervisory control. Second, the Board currently plans to limit the number of brokers participating in the pilot program until it can determine if the contemplated agreements and guarantees are both workable and effective. The Board has not yet determined the exact scope of such agreements or guarantees or the number of thrift institutions or brokers who should participate in such a pilot program. Furthermore, the Board has not yet determined what criteria should distinguish participating brokers beyond the ability to raise sufficient low cost funds to help alleviate the problems discussed above.

II. Proposed Structure of the Pilot Program

At present, the Board is focussing on two ways of addressing some of the concerns brokers may have about investing on behalf of their customers in supervisory institutions. The first would be a Board statement of policy providing that if a receiver is appointed for liquidation of a designated supervisory institution, the FSLIC's insurance obligation to the insured members of such an institution would be fulfilled by the transfer of the insured accounts to another insured institution with the new accounts, maintaining the original rates and terms. The second is adopting certain expedited insurance verification procedures that the FSLIC would use in making insurance determinations on funds deposited pursuant to the pilot program in designated institutions.

A. Terms and Conditions

The first component of the proposed pilot program would be a commitment by the Bank Board on how it, as operating head of the FSLIC, would authorize the FSLIC to pay insurance on insured accounts at participating supervisory institutions pursuant to 12 U.S.C. 1728(b). The Board would undertake to pay insurance on such accounts only by transferring those accounts on the same terms and conditions to another insured institution. Such an undertaking in a published policy statement would address the concerns of some securities firms, brokers, and other investors that they might forfeit bargained-for income if an insurance action took the form of a cash payout or transfer of insured accounts at "passbook" rates. In either case, the investor would lose the benefit of its former contractual rate of return from the date of liquidation of the insured institution to what would have been the maturity of the investor's certificate of deposit.

Under 12 U.S.C. 1728(b), in paying insurance claims upon the default of an insured institution, the FSLIC may either pay cash or provide each insured member with an insured account in another insured institution. In either event, there are two caps on the amount that can be paid: (1) The withdrawable value of the insured account as of the date of the insured institution's default; and (2) the statutory insurance limit of $100,000. Subject to these limits, the FSLIC has paid insurance in the past in three ways: (1) A cash payment of the withdrawable value of the account, including both principal and interest accrued as of the date of default, which

the insured member may then invest however it wishes at whatever rate of return is then available; (2) a transfer of the insured accounts to another insured institution at the same terms and conditions (including rate, maturity, and penalty for early withdrawal) as the insured accounts carried at the defaulted institution; and (3) a transfer of insured accounts to another insured institution at "passbook" terms, thereby enabling the acquiring institution to reprice some or all acquired accounts, but also allowing the insured member to withdraw funds from the new institution without being subject to an early-withdrawal penalty. In the past year, in order to avoid a cash payout and its accompanying disruption to all depositors, the FSLIC has transferred accounts under Option 3 (allowing "repricing") when it could not find an acquirer willing to accept the accounts under Option 2 (same terms and conditions). Since July 1986 the FSLIC has found it necessary to effect a cash payout in only four instances out of twenty-one insurance actions where an acquirer of the insured accounts of a thrift institution could not be found under either of the other options.

Some potential large-scale brokers have informed the Board and the FSLIC that they would normally be unwilling to deposit on behalf of their customers large amounts of funds into institutions that they perceive as more likely to be liquidated when liquidation could mean an insurance action altering the original terms and conditions of their accounts. They would rather place funds at somewhat lower rates into thrift institutions where they are more confident that the terms and conditions originally negotiated will be honored until maturity of the certificate of deposit. To the extent, therefore, that the Board can provide these brokers with greater confidence that their customers will receive at maturity the return on their deposits that they originally negotiated (subject to the $100,000 insurance limit) even if they invest in supervisory institutions, these firms may be more willing to invest their customers' funds in those institutions. Moreover, it is anticipated that, because of the lower risks incurred, such deposits might be made in larger quantities at lower rates than these institutions would otherwise be able to attract. It is anticipated that this might significantly relieve the liquidity difficulties and lower the cost of funds of supervisory institutions designated to come within the pilot program. To the extent that a lower cost of funds decreases an institution's operating costs and losses and increases its net worth, the FSLIC would be the true beneficiary of such infusions of funds, since the reduced accumulated losses would reduce the FSLIC's eventual costs of assistance to an acquirer or of liquidation.

Therefore the Board is considering adopting a policy statement whereby only Option 2 (transfer of accounts) would be elected in the event that designated supervisory institutions participating in the pilot program are found in default and placed into a liquidating receivership. By making the designated institutions more attractive to depositors and thus alleviating those institution's liquidity and cost of funds difficulties, such a commitment may in fact significantly reduce the risk that a number of such institutions may have to be liquidated at all. This would result in lowered costs to the FSLIC. On the other hand, the pilot program may show that such commitments prove significantly more costly to the FSLIC than transfers whereby the acquiring institution is permitted to reprice the acquired insured accounts. For example, a requirement that accounts be maintained at existing terms could be expected to lower the attractiveness of such deposits to potential acquirers and reduce or eliminate any discount that they might otherwise be willing to pay for assuming such deposits. Furthermore, if no existing insured institution were willing to assume the insured accounts, under the suggested policy the FSLIC would have no alternative but to form a *de novo* federal association to take the accounts, which can involve significant ongoing administrative and supervisory costs.

The Board must also decide how broad any such commitment should be. The first question is the number of, and characteristics distinguishing, institutions that should be covered by such a commitment. The Board believes that program institutions must be subject to some degree of supervisory control in order to ensure to the greatest extent possible that new deposits are used to replace higher cost funds. The selection of participating institutions by the Director of the FSLIC must therefore be based primarily on supervisory information, often of a highly confidential nature. The second question is whether a distinction should be made in determining which accounts in an institution should be covered by such a commitment. Options under consideration include that any such commitment: Should cover all insured accounts in a participating supervisory institution as of the date of its default; should only apply to funds brought into such an institution under the direction of the Board or its agents; should apply to funds of only a certain range of maturities, not to the remainder of the institution's deposit base; or should cover not only funds brought into the institution under the direction of the Bank Board, but also any other "new" deposits (*i.e.*, those made after the institution was designated as a participant in the pilot program, including rollovers of existing deposits). Finally, the exact form such a commitment should take has not yet been determined.

In the past, decisions as to the appropriate method for meeting the FSLIC's insurance obligation have been made on an institution-by-institution basis. The Bank Board has generally treated the cash payout option as the least desirable method and the transfer of accounts on the same terms and conditions as the most desirable, because it is the least disruptive to the depositors. A choice among the options was made at the time of liquidation. The proposed commitments would limit that flexibility with respect to supervisory institutions designated to participate in the pilot program.

Before determining to make any such commitment, the Bank Board requests public comment about the authority for such commitment, the accompanying costs and benefits, and the appropriateness, based upon both authority and costs and benefits, of any distinctions with respect to either the targeted supervisory institutions or the types or maturities of insured accounts within an institution.

B. Insurance Verification

The second component of the pilot program would address the other concern expressed by some brokers: the perceived potential for delay accompanying insurance determinations in the event an institution is liquidated, regardless of the method used for paying insurance. In the past, the vast majority of accountholders, who hold funds under $100,000, have received immediate access to their insured funds. Other depositors with more than $100,000 in an insured institution do not have access to accounts in the acquiring institution until their funds have been determined to be insured, a process that generally takes a few days. In limited circumstances, however, due to the complexity of certain accounts, insurance determinations on some funds, including but not limited to those placed by some brokers, have been delayed for a longer time period,

occasionally past the maturity of the original account.

Some brokers and securities firms have indicated that access at maturity to the funds they have invested on behalf of their customers is critical to their willingness to invest in supervisory institutions. Additionally, some acquiring institutions have paid a lower interest rate on transferred funds during the period between maturity of the transferred account and the FSLIC's insurance determination and release of funds.

Under the NHA, the FSLIC has the obligation to make payment of insurance promptly to insured members. 12 U.S.C. 1728(b). It also has the obligation to pay only the insured members and to pay no more than the statutory $100,000 to each insured member. In that regard, the NHA provides that the FSLIC may require proof of claim before paying claims for insurance. *Id.* Since 1934, the FSLIC has had recordkeeping requirements to assist in making insurance determinations on accounts.

The Bank Board has long recognized the need to reduce delays in paying claims for insurance. In 1985, it proposed increased disclosure on the records of the insured institution for complex accounts. *See* 50 FR 19185, 19188–89 (1985). In commenting upon this proposed regulation, a number of brokers indicated that the new requirement would be unduly burdensome and was unnecessary because the brokers could provide information quickly to the FSLIC in the event of a default. Although the Bank Board ultimately withdrew the proposed regulation, *see* 52 FR 8611 (1987), the underlying problem remains: Large denomination accounts with multiple levels of complex relationships and numerous undisclosed principals are time-consuming for the FSLIC to analyze in making its insurance determinations, resulting in delays.

As part of the pilot program, the FSLIC is considering means of guaranteeing more expeditious insurance processing of some accounts, where the brokers have undertaken to provide the FSLIC with information and documentation on an expedited basis. As currently contemplated, qualified brokers placing funds into institutions under the pilot program would take steps internally to (1) limit the complexity of the accounts by avoiding multiple levels of agents, nominees, custodians, and trustees, (2) limit the size of deposits made in any institution for any principal to amounts under $100,000 so as to result in full insurance for both principal and interest, and (3) maintain business records containing the information about the identities and interests of its principals in a format compatible with the information drawn from the records of the insured institution. A qualified broker would provide this information to the FSLIC on a highly expedited basis after the default of the insured institution. The FSLIC would in turn guarantee that it would process the insurance determinations on such accounts on an expedited timetable so that insured accounts could be released before, at, or immediately after the original maturity. If such documentation is, in fact, maintained and provided quickly, in the FSLIC's experience, such expedited insurance determinations should be quite feasible.

Pursuant to its statutory obligation to process all insured accounts promptly, the FSLIC will of course make all interested brokers and depositors, whether or not qualified to participate in the pilot program, aware of its documentation requirements and expeditiously process the accounts of all accountholders. If any accountholder establishes less complex accounts, and quickly provides information that shows accounts that can readily be determined to be insured as held for principals who hold less than $100,000 in all accounts at the insured institution, the FSLIC has an easier, and more quickly completed, task in making insurance determinations. The FSLIC cannot bind itself to process accounts in all institutions according to a particular preset timetable. As part of a limited pilot program, however, it is willing to consider setting up timetables for release of funds, conditioned upon an expedited receipt of all necessary information about their principals from qualified brokers. If such timetables prove workable, the FSLIC would consider expanding them to all accountholders.

Accordingly, the Bank Board requests public comment about whether such expedited insurance processing is likely to assist in attracting funds to supervisory institutions, what criteria should be used to qualify investors for the benefit of such expedited timetables, and what timetables might be reasonable.

III. Summary

The Bank Board is today seeking comments about (1) whether a pilot program as described in this Notice should be established; (2) what should be the scope of such a program in terms of (a) participating supervisory institutions, (b) participating securities firms and brokers, (c) duration, and (d) commitments that could reasonably be expected to result in lowered costs of funds to both supervisory institutions and non-troubled thrifts that must compete with them at higher than market rates; (3) what criteria should be used to determine whether the pilot program should be expanded, modified, or terminated in terms of costs and benefits; (4) possible additional or alternative methods to address the liquidity and cost-of-funds problems; and (5) any other matter reasonably pertinent to the above-described proposal. The Bank Board currently anticipates that its staff will continue to have informal discussions with experts in this area in order to determine the details of any pilot program. The substance of any such discussions will be summarized and inserted in the administrative record.

Although the Administrative Procedure Act exempts general policy statements and internal agency procedures from notice and comment requirements, 5 U.S.C. 553(b)(3)(a), the Board is nevertheless requesting public comments on this proposed pilot program. However, because of the need for prompt action by the Bank Board, the Board is only seeking comment for a fifteen day period and contemplates implementing the pilot program shortly thereafter. Since the pilot program is designed as a short-term experiment (currently anticipated to last for one year) that in and of itself will be likely to demonstrate whether it is workable and effective, the Board does not believe that a longer notice and comment period is necessary or in the public interest before initiating the program. Comments received after the close of the comment period will be taken into account in evaluating the pilot program.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 87-20488 Filed 9-3-87; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants; Nadia B. Cardenas

Notice is hereby given that the following persons have filed applications for licenses as ocean freight forwarders with the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and 46 CFR Part 510.

Persons knowing of any reason why any of the following persons should not receive a license are requested to contact the Office of Freight Forwarder

and Passenger Vessel Operations, Federal Maritime Commission, Washington, DC 20573.

Nydia B. Cardenas, 48 Willia Avenue, Staten Island, NY 10301; Officer: Frank Vasta, Sole Officer

Durlar, Inc., 7257 N.W. 12th Street, Miami, FL 33126; Officers: Victor Larco, President/Director, Tusi Bruce Cottle, Secretary, Mario Mimbella

Transcontinental Cargo, Inc. dba Freight Forwarding Service, 7389 N.W. 54th Street, Miami, FL 33166; Officers: Carlos S. Estrada, President, Carlos R. Estrada, Vice President, Ana Pinero, Treasurer, Nubia Estraca, Secretary

The Camelot Company, 9865 West Leland, Schiller Park, IL 60176; Officers: Thomas C. Case, President, Sharon C. Case, Secretary/Treasurer, Julia L. Ertler, Assistant Secretary

Alphamain (U.S.A.) Inc., 1201 Corbin Street, Port Elizabeth Plaza, Elizabeth, NJ 07201; Officers: Frank E. Olschewski, President, Capt. C. M. Karnaker, Director, Franz J. Fassbener, Vice President

Gloria Ann Price dba Price Professional Services, 3111 North Alameda Street, Compton, CA 90222

Shu-Hwa Chen, 260 West 5th Street, San Pedro, CA 90731

Cargo Import Brokers, Inc., 2423 Greens Road, Suite 9B, Houston, TX 77032; Officers: Rodrigo Ulloa, President, Jose V. Torres, Secretary/Treasurer.

Dated: September 1, 1987.

Joseph C. Polking,
Secretary.

[FR Doc. 87-20454 Filed 9-3-87; 8:45 am]

BILLING CODE 6730-01-M

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.: 203-011145.

Title: Eastern Mediterranean Cooperation Agreement.

Parties: The United States Atlantic and Gulf Ports/Eastern Mediterranean and North African Freight Conference Nordana Lines.

Synopsis: The proposed agreement would permit the parties to discuss and agree upon rates, charges, service contracts and other matters in the trade from U.S. Atlantic, Gulf and Great Lakes ports, and U.S. points via such ports, to certain Eastern Mediterranean and North African ports and certain inland points via such ports.

Dated: September 1, 1987.

By Order of the Federal Maritime Commission.

Joseph C. Polking,
Secretary.

[FR Doc. 87-20453 Filed 9-3-87; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Agency Forms Under Review

August 28, 1987.

Background

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act of 1980, as per 5 CFR 1320.9, "to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320.9." Board-approved collections of information will be incorporated into the official OMB inventory of currently approved collections of information. A copy of the SF 83 and supporting statement and the approved collection of information instrument(s) will be placed into OMB's public docket files. The following forms, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority.

DATE: Comments must be received within fifteen working days of the date of publication in the **Federal Register**.

ADDRESS: Comments, which should refer to the OMB Docket number (or Agency form number in the case of a new information collection that has not yet been assigned an OMB number), should be addressed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551, or delivered to room B-2223 between 8:45 a.m. and 5:15 p.m. comments received may be inspected in room B-1122 between 8:45 a.m. and 5:15 p.m., except as provided in § 261.6(a) of the Board's Rules Regarding Availability of Information, 12 CFR 261.6(a).

A copy of the comments may also be submitted to the OMB desk officer for the Board: Robert Fishman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

A copy of the proposed form, the request for clearance (SF 83), supporting statement, instructions, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below:

Federal Reserve Board Clearance Officer, Nancy Steele, Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3822)

Proposed to approve under OMB delegated authority the extension, without revision, of the following reports:

1. *Report Title:* Officer's Questionnaire
Agency Form Number: FR 2410
OMB Docket Number: 7100-0050
Frequency: On occasion
Reporters: State member banks
Annual Reporting Hours: 70
Small businesses are affected.
General Description of Report:
This information collection is mandatory [12 U.S.C. 325] and is given confidential treatment [5 U.S.C. 552(b)(8)].
As part of its full-scale consumer affairs examination of a state member bank, the Federal Reserve requests a senior bank officer to complete this questionnaire, which provides information regarding past, present, and potential lawsuits in which the bank has been or may become involved concerning consumer credit compliance.

2. *Report Title:* Community Reinvestment Act Questionnaire
Agency Form Number: FR 1283
OMB Docket Number: 7100-0052
Frequency: On occasion
Reporters: State member banks
Annual Reporting Hours:
Small businesses are affected.
General Description of Report:
This information collection is mandatory [12 U.S.C. 325 and 12 U.S.C.

2901(b) and is given confidential treatment [5 U.S.C. 552(b)(8)].

Each state member bank that undergoes a comprehensive compliance examination is requested to complete this form, which is called the CRA Questionnaire. After it is completed by a senior bank officer, the questionnaire provides information regarding the bank's effort to serve the credit needs of its local community.

3. *Report Title:* Consumer Satisfaction Questionnaire
Agency Form Number: FR 1379
OMB Docket Number: 7100-0135
Frequency: On occasion
Reporters: Consumers who have filed consumer complaints concerning state member banks
Annual Reporting Hours: 9
Small businesses are affected.
General Description of Report:
This information collection is voluntary [15 U.S.C. 57(a)(f)(1)] and is not given confidential treatment.

This questionnaire is sent by the Federal Reserve System to people who have filed a consumer complaint with a Federal Reserve Bank concerning a state member bank. Complainants are requested to answer questions voluntarily about the effectiveness of the Reserve Bank's effort in handling the consumer complaint.

Board of Governors of the Federal Reserve System, August 28, 1987.

William W. Wiles,

Secretary of the Board.

[FR Doc. 87-20369 Filed 9-3-87; 8:45 am]

BILLING CODE 6210-01-M

Agency Forms Under Review

August 28, 1987.

Background

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act of 1980, as per 5 CFR 1320.9, "to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320.9." Board-approved collections of information will be incorporated into the official OMB inventory of currently approved collections of information. A copy of the SF 83 and supporting statement and the approved collection of information instrument(s) will be placed into OMB's public docket files. The following forms, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority.

DATE: Comments must be received within fifteen working days of the date of publication in the **Federal Register.**

ADDRESS: Comments, which should refer to the OMB Docket number (or Agency form number in the case of a new information collection that has not yet been assigned an OMB number), should be addressed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551, or delivered to room B-2223 between 8:45 a.m. and 5:15 p.m. Comments received may be inspected in room B-1122 between 8:45 a.m. and 5:15 p.m., except as provied n § 261.6(a) of the Board's Rules Regarding Availability of Information, 12 CFR 261.6(a).

A copy of the comments may also be submitted to the OMB desk officer for the Board: Robert Fishman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

A copy of the proposed form, the request for clearance (SF 83), supporting statement, instruction, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below:

Federal Reserve Board Clearance Officer Nancy Steele, Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3822)

Proposal to approve under OMB delegated authority the extension, with revision, of the following reports:

1. *Report Title:* Report of Selected Deposits in Foreign Branches Held by U.S. Addressees
Agency Form Number: FR 2050
OMB Docket Number: 7100-0068
Frequency: Weekly
Reporters: Foreign branches of U.S. banks and of Edge and Agreement corporations
Annual Reporting Hours: 9009
Small businesses are not affected.
General Description of Report:
This information collection is authorized by law [12 U.S.C. 248(a), 355, 461]. Individual respondent data are exempt from disclosure under the Freedom of Information Act [5 U.S.C. 552(b)(4), (b)(8)].

This report collects data from a selection of foreign branches of U.S. banks on overnight Eurodollar deposits held by U.S. nonbank residents. Data are used in construction of the monetary aggregates and analysis of liability management. A revision in the panel selection criteria is proposed which would reduce the size of the panel by approximately 18 percent.

2. *Report Title:* Monthly Report of Large International Banking Facility Accounts
Agency Form Number: FR 2072
OMB Docket Number: 7100-0158
Frequency: Monthly
Reporters: International Banking Facilities (IBFs) of large U.S.-chartered banks and large U.S. branches and agencies of foreign banks
Reporting Hours: 1187
Small businesses are not affected.
General Description of Report:
This information collection is required by law [12 U.S.C. 248(a), 602, 625, and 3105(b)]. Individual respondent data is given confidential treatment [5 U.S.C. 552(b)(4)].

This report collects data on assets and liabilities of International Banking Facility (IBF) accounts. Data are used to assist in interpreting the monetary aggregates and to monitor IBF activities. The proposed revisions include an increase in the reporting threshold which would reduce the panel; minor changes in report items; and a change in report date to the last day of the month.

3. *Report Title:* Monthly Report of Foreign Branch Assets and Liabilities
Agency Form Number: FR 2502
OMB Docket Number: 7100-0078
Frequency: Monthly
Reporters: Foreign branches of U.S. banks and of Edge and Agreement corporations
Reporting hours: 15,756
Small businesses are not affected.
General description of report:
This report is required by law [12 U.S.C. 248(a)(2), 353 et seq., 602 and 625]. Individual respondent data are given confidential treatment [5 U.S.C. 552(b)(8)].

This report provides a breakdown of foreign branch assets and liabilities by category of customer and between dollars and foreign currencies. Data are used for supervisory purposes, in construction of the monetary aggregates, and to monitor U.S. banks' foreign activities. The proposed revisions

include minor changes in reporting instructions and in form items.

4. *Report Title:* Quarterly Report of Foreign Branch Assets and Liabilities
Agency Form Number: FR 2502S
OMB Docket Number: 7100-0079
Frequency: Quarterly
Reporting: Foreign branches of U.S. banks and Edge and Agreement corporations
Reporting Hours: 7070
Small businesses are not affected.
General description of report:
This report is required by law [12 U.S.C. 248(a)(2), 353 et seq., 602 and 625]. Individual respondent data are given confidential treatment [5 U.S.C. 552(b)(8)].

This report provides a breakdown of assets and liabilities of foreign branch offices of U.S. banks geographically for all countries. It is used to monitor U.S. banks' claims on and liabilities to individual foreign countries by particular branch offices and to monitor countries' indebtedness to U.S. banks. The revisions include minor changes in instructions and country names on the form.

Board of Governors of the Federal Reserve System, August 28, 1987.
William W. Wiles,
Secretary of the Board.
[FR Doc. 87-20370 Filed 9-3-87; 8:45 am]
BILLING CODE 6210-01-M

Formations of; Acquisitions by; and Mergers of Bank Holding Companies; BMR Bancorp, Inc., et al.

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 available for inspection at the office 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 September 25, 1986.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *BMR Bancorp, Inc.,* Atlanta, Georgia; to acquire 100 percent of the voting shares of Citizens Bank of Americus, Americus, Georgia.

B. **Federal Reserve Bank of Chicago** (David S. Epstein, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *F&M Financial Services Corporation,* Menomonee Falls, Wisconsin; to acquire 100 percent of the voting shares of Citizens Community Bankshares, Inc., Wittenberg, Wisconsin, and thereby indirectly acquire Citizens State Bank of Wittenberg, Wittenberg, Wisconsin; Crandon National Bank, Crandon, Wisconsin; Iron Exchange Bank, Hurley, Wisconsin; and Farmers State Bank, Stetsonville, Wisconsin. Comments on this application must be received by September 21, 1987.

C. **Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Bradford Bancshares, Inc.,* Bradford, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Bradford, Bradford, Tennessee.

D. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Farmers Bancshares, Inc.* and Farmers National Bank Employees Stock Ownership Plan, both of Lincoln, Kansas; to become bank holding companies by acquiring 50.37 percent of the voting shares of Farmers Bancshares, Inc., Lincoln, Kansas, and thereby indirectly acquire The Farmers National Bank, Lincoln, Kansas.

Board of Governors of the Federal Reserve System, August 31, 1987.
William W. Wiles,
Secretary of the Board.
[FR Doc. 87-20371 Filed 9-3-87; 8:45 am]
BILLING CODE 6210-01-M

Formations of; Acquisitions by; and Mergers of Bank Holding Companies; Hartford National Corp. et al.

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 September 28, 1987.

A. **Federal Reserve Bank of Boston** (Richard E. Randall, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. *Hartford National Corporation,* Hartford, Connecticut; to acquire 100 percent of the voting shares of Massachusetts National Bank, Boston, Massachusetts.

B. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Home Bancorp, Inc.,* Sutton, West Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of The Home National Bank of Sutton, Sutton, West Virginia.

2. *Riggs National Corporation,* Washington, DC; to acquire 100 percent of the voting shares of The Riggs National Bank of Maryland, successor by merger to First Fidelity Bank, Rockville, Maryland.

C. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Rihord Bank Holding Company,* Lake Butler, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Farmers and Dealers Bank Lake Butler, Florida.

D. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Plains Capital Corporation,* Lubbock, Texas; to become a bank holding company by acquiring 84.6 percent of the voting shares of The Plains Corporation, Lubbock, Texas; and

thereby indirectly acquire The Plains National Bank of Lubbock, Lubbock, Texas.

Board of Governors of the Federal Reserve System, August 31, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-20372 Filed 9-3-87; 8:45 am]

BILLING CODE 6210-01-M

Acquisitions of Shares of Banks or Bank Holding Companies; Kenneth A. Jewell 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 express 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 September 25, 1987.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street NW., Atlanta, Georgia 30303:

1. *Kenneth A. Jewell,* Lake Worth, Florida; to acquire 20.07 percent of the voting shares of Gold Coast Bancshares, Inc., Hypoluxo, Florida; thereby indirectly acquire The Bank of South Palm Beaches, Hypoluxo, Florida.

B. **Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Peter J. and Margery J. Bollman,* Lena, Illinois; to acquire an additional 4 percent of the voting shares of Lena Bancorp, Lena, Illinois.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Glen Lau,* Clearwater, Nebraska; to acquire 6.35 percent of the voting shares of Clearwater Development Company, Inc., Clearwater, Nebraska; thereby indirectly acquire Citizens State Bank, Clearwater, Nebraska.

2. *Janet Newell,* Clearwater, Nebraska; to acquire 6.35 percent of the voting shares of Clearwater Development Company, Inc., Clearwater, Nebraska; thereby indirectly acquire Citizens State Bank, Clearwater, Nebraska.

3. *Marilyn Goetowski,* Clearwater, Nebraska, to acquire 6.35 percent of the voting shares of Clearwater Development Company, Inc., Clearwater, Nebraska; thereby indirectly acquire Citizens State Bank, Clearwater, Nebraska.

4. *Alan Domina,* Clearwater, Nebraska; to acquire 3.18 percent of the voting shares of Clearwater Development Company, Inc., Clearwater, Nebraska; thereby indirectly acquire Citizens State Bank, Clearwater, Nebraska.

Board of Governors of the Federal Reserve System, August 31, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-20373 Filed 9-3-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Meeting; Advisory Committee for Elimination of Tuberculosis

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), the Centers for Disease Control (CDC) announces the following committee meeting.

Name: Advisory Committee for Elimination of Tuberculosis (ACET).

Time and Date: 8:30 am—5:00 pm—September 22, 1987. 8:30 am—3:00 pm—September 23, 1987.

Place: Conference Room 207, Building 1, 1600 Clifton Road, N.E., Atlanta, Georgia 30333.

Status: Open.

Purpose: This Committee advises and makes recommendations to the Secretary, Department of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding feasible goals for eliminating tuberculosis. Specifically, the Committee makes recommendations regarding policies, strategies, objectives, and priorities, addresses the development of new technologies and their subsequent application, and reviews progress toward elimination.

Matters to be Discussed: The Committee will discuss the tuberculosis problem it the United States and current CDC activities for its prevention and control. The Committee will begin deliberations of a plan and priorities for achieving elimination of tuberculosis in the United States. The Committee will also discuss the impact of the acquired immunodeficiency syndrome (AIDS) on the tuberculosis problem and current CDC recommendations regarding BCG vaccine. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Dixie E. Snider, Jr., M.D., Director, Division of Tuberculosis Control, and Executive Secretary, ACET, Center for Prevention Services, CDC, 1600 Clifton Road, NE., Atlanta, Georgia 30333, Telephones: FTS: 236-2501; Commercial: 404/329-2501.

Elvin Hilyer,

Associate Director for Policy Coordination Centers for Disease Control.

[FR Doc. 87-20489 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

Advisory Committee Meetings; Amendment of Notice

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending an advisory committee meeting notice of the Blood Products Advisory Committee to reflect changes in location for the second day and in the open committee discussion agenda, and to add a closed committee discussion to the agenda. Notice of the meeting was published in the **Federal Register** of August 17, 1987 (52 FR 30738). The location and agenda are revised as follows:

Blood Products Advisory Committee

Date, Time, and Place

September 17, 1987, 9 a.m., Rm. 121, Office of Biologics Research and Review, 8800 Rockville Pike, Bethesda, Maryland, and September 18, 1987, conference rooms G and H, third floor, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland.

Type of Meeting and Contact Person

Open public hearing, September 17, 1987, 9 a.m. to 10 a.m. unless public participation does not last that long; open committee discussion, 10 a.m. to 11 a.m.; closed preparation of data, 11 a.m. to 5 p.m.; open committee discussion, 8 a.m. to 11 a.m.; September 18, 1987, closed committee discussion, 11 a.m. to 1 p.m., Clay Sisk, Center for Drugs and Biologics (HFN-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

Open Committee Discussion

For a brief period on September 17, 1987, the committee will discuss

methods for reevaluation of persons who are currently deferred from donating blood because of reactive hepatitis B surface antigen (HBsAg) tests, but which upon further, more specific testing again may be acceptable as donors. On September 18, testing for human immunodeficiency virus antigen will be discussed.

Closed Committee Discussion

The committee will discuss trade secret or confidential commercial information relevant to pending investigational new biological products and a license application for alpha-1-proteinase inhibitor. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Dated: Aug. 28, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-20378 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

Health Professional Organizations; Notice of Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming meeting of health professional organizations to be chaired by Frank E. Young, Commissioner of Food and Drugs. The agenda will include discussions on: acquired immune deficiency syndrome (AIDS) progress, the new drug approval process, treatment investigational new drugs (IND's), health messages on foods, cholesterol education messages, import concerns, anabolic steroids, and Talk About Prescriptions Month—1987.

DATE: The meeting will be held from 2 to 4 p.m. on Monday, September 21, 1987.

ADDRESS: The meeting will be held in Conference Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Robert Veiga, Office of Health Affairs (HFY-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5470.

Dated: August 28, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-20379 Filed 9-3-87; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

[IOA-014-N]

Final Report of the Task Force on Long-Term Health Care Policies

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of release of final report.

SUMMARY: Under section 10(a)(3) of the Federal Advisory Committee Act (Pub. L. 92-463 as amended), we are annoucing the release of the Report of the Task Force on Long-Term Health Care Policies.

DATE: The report will be available on September 21, 1987.

ADDRESS: Task Force on Long-Term Health Care Policies, Department of Health and Human Services, Attention: Dennis DeWitt, Executive Director, Room 4406, North Building, 300 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dennis DeWitt, (202) 245-0063.

SUPPLEMENTARY INFORMATION:

Purpose

The Task Force on Long-Term Health Care Policies, established under section 9601 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272), has evaluated current issues relating to private long-term care insurance. To ensure the evolution of sound private long-term care insurance policies and to help foster consumer confidence in them, the Task Force has developed recommendations that can be used by State regulators, persons involved in the insurance industry, and consumers who may wish to purchase such policies.

The term "long-term health care policy" means an insurance policy, or similar health benefits plan, that is designed for or marketed as providing (or making payment for) health care services (such as nursing home care and home health care) or related services (which may include home or community-base services), or both, over an extended period of time.

On September 21, 1987, the Task Force on Long-Term Health Care Policies will submit its Report to the Secretary of Health and Human Services and the Congress concerning the development of insurance policies for long-term care that are privately marketed to individuals or groups. The Task Force has developed recommendations for long-term health care policies, including recommendations designed to—

- Limit marketing and agent abuse of those policies;
- Assure the dissemination of information to consumers necessary to permit informed choice in purchasing the policies and to reduce the purchase of unnecessary or duplicative coverage;
- Assure that benefits provided under the policies are reasonable in relationship to premiums charged; and
- Promote the development and availability of long-term health care policies that meet these recommendations.

Release of Report

The Task Force will present its Report to the Secretary of Health and Human Services, Otis R. Bowen, M.D., at a Press Conference on Monday, September 21, 1987, at 10:30 am in the Small Theater on the Ground Floor of the Hubert H. Humphrey Building at 200 Independence Avenue, SW., Washington, DC. The press conference will be open to the public. The report also will be transmitted to the Congress on September 21. The Report will be available as of September 21, 1987, from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(Sec. 10(a)(3) of Pub. L. 92-463, as amended (5 U.S.C. App. I Sec. 1-15))

Dated: August 27, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

[FR Doc. 87-20483 Filed 9-3-87; 8:45 am]

BILLING CODE 4120-01-M

Public Health Service

National Toxicology Program; Announcement of Completed Short-Term Toxicology Studies on Fifteen Chemicals; Request for Comments

As part of an effort to inform the public and allow interested parties to comment and provide information on chemicals prior to designing of studies for long-term toxicology and carcinogenesis studies, the National Toxicology Program (NTP) will routinely announce in the **Federal Register** the list of chemicals for which short-term toxicology studies have been completed.

Short-term toxicology studies on the chemicals listed in this announcement have been completed and the National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP) is in the process of evaluating the results. A decision on whether additional studies, including long-term toxicology and carcinogenicity studies, are needed will soon be made by the NTP. If you have relevant

information (such as current production, use pattern, exposure levels, toxicological data) to share with the NTP on any of these chemicals, please contact the responsible NTP Scientist within 30 days of the appearance of this announcement by telephone or by mail to: NIEHS/NTP, P.O. Box 12233, Research Triangle Park, North Carolina 27709. The information provided will be considered by the NTP in determining which chemicals require additional studies and in designing these studies.

2-(4-Aminophenyl)-6-methyl-7-benzothiazole sulfonic acid (130-17-6)—14-day and 90-day dosed feed studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. Elmer Rauckman, telephone (919) 541-7981.

Azodicarbonamide (123-77-3)—14-day and 90-day inhalation studies in Fischer 344 rats and B6C3F$_1$ mice; 4-week inhalation study on airway hypersensitivity in guinea pigs. Dr. Linda Birnbaum, telephone (919) 541-3583.

n-Hexane (110-54-3)—14-day and 90-day inhalation studies in Fischer 344 rats and B6C3$_1$ mice. Dr. June Dunnick, telephone (919) 541-4811.

6-Methoxy-2-benzothiazolamine (1747-60-0)—14-day and 90-day dosed feed study in Fischer 344 rats and B6C3$_1$ mice. Dr. Elmer Rauckman, telephone (919) 541-7981.

4-(6-Methyl-2-benzothiazolyl)-benzenamine (92-36-4)—14-day and 90-day dosed feed study in Fischer 344 rats and B6C3F$_1$ mice. Dr. Elmer Rauckman, telephone (919) 541-7981.

Nickel Oxide (1313-99-1)—14-day and 90-day inhalation studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. June Dunnick, telephone (919) 541-4811.

Nickel Sulfate (10101-97-0)—14-day and 90-day inhalation studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. June Dunnick, telephone (919) 541-4811.

Crotonaldehyde (4170-30-3)—14-day and 90-day gavage study in Fischer 344 rats and B6C3F$_1$ mice. Dr. John French, telephone (919) 541-7990.

5,6-Dichloro-2-benzothiazolamine (24072-75-1)—14-day and 90-day dosed feed study in Fischer 344 rats and B6C3F$_1$ mice. Dr. Elmer Rauckman, telephone (919) 541-7981.

1,2-Dihydro-2,2,4-trimethylquinoline (147-47-7) (monomer)—14-day and 90-day dermal studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. John French, telephone (919) 541-7790.

1,2-Dihydro-2,2,4-trimethylquinoline (26780-96-1) (polymer)—14-day and 90-day dermal studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. John French, telephone (919) 541-7790.

Isobutyraldehyde (78-84-2)—14-day and 90-day inhalation studies in Fischer 344 rats and B6C3F$_1$ mice. Dr. John French, telephone (919) 541-7790.

Butyraldehyde (123-72-8)—14-day and 90-day gavage study in Fischer 344 rats and B6C3F$_1$ mice. Dr. John French, telephone (919) 541-7790.

Triethanolamine (102-71-6)—14-day and 90-day skin paint study in Fischer 344 rats and B6C3F$_1$ mice. Dr. Ronald Melnick, telephone (919) 541-4142.

Salicylazosulfapyridine (599-79-1)—14-day and 90-day gavage study in Fischer 344 rats and B6C3F$_1$ mice. Dr. Frank Kari, telephone (919) 541-2926.

Date: August 21, 1987.

David P. Rall,

Director, National Toxicology Program.

[FR Doc. 87-20423 Filed 9-3-87; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR-943-07-4220-11: GP-07-280; OR-37365]

Realty Action; Conveyance of Public Land; Order Providing for Opening of Land; Oregon; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice corrects the last sentence in the summary in the Conveyance of Public Land; Order Providing for Opening of Public Lands published in the **Federal Register** on August 12, 1987.

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Champ Vaughan, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503-231-6905.

SUPPLEMENTARY INFORMATION: In FR Doc. 87-18289, published at page 29895 in the issue of August 12, 1987, make the following correction:

The last sentence in the summary is hereby corrected to read: "The reconveyed land will not be opened to mining in order to protect existing Federal improvements."

Champ C. Vaughan, Jr.,

Acting Chief, Branch of Lands and Minerals Operations.

Dated: August 26, 1987.

[FR Doc. 87-20361 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-33-M

[OR-943-07-4220-11: GP-07-281; OR-39468]

Realty Action; Conveyance of Public Land; Order Providing for Opening of Land; Oregon; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice corrects the summary by adding an additional sentence in the Conveyance of Public Land: Order Providing for Opening of Land published in the **Federal Register** on August 13, 1987.

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Champ Vaughan, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503-231-6905.

SUPPLEMENTARY INFORMATION: 1. In FR Doc. 87-18459, published at page 30259 in the issue of August 13, 1987, make the following correction:

Add the following sentence to the summary: "The reconveyed land will not be opened to mining in order to protect the New River Area of Critical Environmental Concern.

Dated: August 26, 1987.

Champ C. Vaughan, Jr.,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 87-20362 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-33-M

[MT-920-07-4520-11]

Filing of Plat Survey; Land Resource Management; Montana

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: Plat of survey of the lands described below accepted August 12, 1987, was officially filed in the Montana State Office effective 10 a.m. on August 24, 1987.

Principal Meridian, Montana

T. 7 N., R. 47 E.

This plat represents the dependent resurvey of portions of the subdivision lines and Tracts No. 2 and S, and the survey of Tract Y. The area described is in Custer County.

This survey was executed at the request of the Deputy State Director, Division of Lands and Renewable Resources for the administrative needs of the Bureau.

EFFECTIVE DATE: August 24, 1987.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 222 North 32nd Street, P.O. Box 36800, Billings, Montana 59107.

Eugene D. Russell,
Acting State Director.

Dated: August 27, 1987.

[FR Doc. 87-20363 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-DN-M

National Park Service

Intention to Negotiate Concession Permit; Cherokee Boys Club

Pursuant to the provisions of section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that sixty (60) days after the date of publication of this notice, the Department of the Interior, through the Director of the National Park Service, proposes to negotiate a concession permit with Cherokee Boys Club authorizing it to continue to provide firewood sales for the public within Great Smoky Mountains National Park for a period of four (4) years from January 1, 1988, through December 31, 1991.

This permit renewal has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and an environmental document will be prepared.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under the existing permit which expires by limitation of time on December 31, 1987, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the permit and in the negotiation of a new permit as defined in 36 CFR 51.5.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be postmarked or hand-delivered on or before the sixtieth (60th) day following publication of this notice to be considered and evaluated. Interested parties should contact the Regional Director, Southeast Region, 75 Spring Street, SW., Atlanta Georgia 30303, for information as to the requirements of the proposed permit.

Robert M. Baker,
Regional Director, Southeast Region.

[FR Doc. 87-20470 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-70-M

Meeting; Statue of Liberty-Ellis Island Centennial Commission History Committee

AGENCY: National Park Service, Interior

ACTION: Notice of meeting.

SUMMARY: This notice announced a forthcoming meeting of the History Committee of the Statue of Liberty-Ellis Island Centennial Commission. The Committee will review its purpose in relation to the Statute of Liberty-Ellis Island restoration project and will discuss the committee's suggestions and initiatives that will commemorate the hundredth anniversaries of the Statue of Liberty (1986) and Ellis Island (1992).

DATE: September 28, 1987, 9 a.m. to 5 p.m.

ADDRESS: 52 Vanderbilt Avenue (at 45th Street), 4th floor, New York, New York 10017-3808.

FOR FURTHER INFORMATION CONTACT: Herbert S. Cables, Jr., Regional Director, National Park Service, 15 State Street, Boston, MA 02109-3572.

Date: August 26, 1987.

Herbert S. Cables, Jr.,
Regional Director, North Atlantic Region.

[FR Doc. 87-20468 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-70-M

Meeting; Sleeping Bear Dunes National Lakeshore Advisory Commission

Notice is hereby given, in accordance with the Federal Advisory Committee Act, 86 Stat. 770, 5 U.S.C. App. 1, as amended by the Act of September 13, 1976, 90 Stat. 1247, that a meeting of the Sleeping Bear Dunes National Lakeshore Advisory Commission will be held at 9:30 a.m. (EDT), October 9, 1987, at the Sleeping Bear Dunes National Lakeshore Visitor Center Auditorium at M-22 and M-72, Empire, Michigan.

The Commission was established by the Act of October 21, 1970, 84 Stat. 1076, 16 U.S.C. 460x-3, to meet and consult with the Secretary of the Interior on matters relating to the administration and development of the Sleeping Bear Dunes National Lakeshore and with respect to the provisions of Sections 9 (zoning bylaws), 12 (scenic roads), and 13 (commercial properties) of this Act.

The members of the Commission are as follows:

Mr. John B. Daugherty (Chairman)
Ms. Uledene Merrill
Mr. George T. Schilling
Mr. Lawrence J. Verdier
Mr. Charles Rubner
Ms. Cathlene Search
Ms. Evangeline J. Stanchik
Dr. Michael Chubb
Mr. George Weeks
Mr. Gary Jones

The agenda for the meeting will include updates on recent park development projects and future projects, development concept plans for North Manitou Island, the Glen Haven Village, and the Platte River Management Plan.

The meeting will be open to the public. Any member of the public may file with the Commission prior to the meeting a written statement concerning the matters to be discussed. Persons wishing further information concerning the meeting, or who wish to submit written statements, may contact Richard R. Peterson, Superintendent, Sleeping Bear Dunes National Lakeshore, P.O. Box 277, Empire, Michigan 49630, telephone (616) 326-5134.

Minutes of the meeting will be available for public inspection 4 weeks after the meeting at the Office of Sleeping Bear Dunes National Lakeshore, Empire, Michigan.

Date: August 27, 1987.

Don H. Castleberry,
Regional Director, Midwest Region.

[FR Doc. 87-20469 Filed 9-3-87; 8:45am]

BILLING CODE 4310-70-M

Office Surface Mining Reclamation and Enforcement

[OSM-EIS-23]

Availability of Final Petition Evaluation Document/Environmental Impact Statement on the North Chickamauga Creek Watershed, TN

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of availability of final petition evaluation document/environmental impact statement.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) is making available a final petition evaluation document/environmental impact statement (PED/EIS) on the North Chickamauga Creek watershed in Tennessee. The PED/EIS has been prepared to assist the Director of OSMRE in making a decision on the petition to designate certain lands as unsuitable for surface coal mining operations in the North Chickamauga Creek watershed in Tennessee.

ADDRESSES: Copies of the Final EIS may be obtained from Willis Gainer, Chief, Southern Branch, Division of Tennessee Permitting, OSMRE, 530 Gay Street SW., Suite 500, Knoxville, Tennessee 37902.

FOR FURTHER INFORMATION CONTACT: Willis Gainer, at the location given

under "**ADDRESSES**", telephone: (615) 673-4348.

SUPPLEMENTARY INFORMATION: On April 30, 1986, the Guardians of North Chickamauga Creek, Inc., and the Sierra Club filed a petition to designate certain lands as unsuitable for surface coal mining operations in the North Chickamauga Creek watershed in Tennessee. OSMRE determined the petition to be administratively complete on June 27, 1986. On March 27, 1987, OSMRE made available the draft PED/EIS for a 60-day public review and comment period.

The Final PED/EIS was prepared by OSMRE in accordance with section 522(d) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA). It analyzes five alternatives which range from designation of the entire petition area as unsuitable for all surface coal mining operations to not designating any of the petition area as unsuitable for surface coal mining operations.

In preparing the final PED/EIS, OSMRE has revised the draft PED/EIS in response to comments received during the public comment period. These comments and OSMRE's responses to them are included in the final PED/EIS.

No decision will be made on the petition by the Director of OSMRE until at least 30 days from the time that the Environmental Protection Agency announces that the PED/EIS is available to the public. Notice of such a decision by the Director will be made available to the public at that time.

Date: September 1, 1987.

Brent Walquist,

Assistant Director, Program Policy.

[FR Doc. 87-20425 Filed 9-3-87; 8:45 am]

BILLING CODE 4310-05-M

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 751-TA-12 and 751-TA-13]

Bicycle Tires and Tubes From Taiwan and the Republic of Korea

Determinations

On the basis of the record [1] developed in the subject investigations, the Commission determines, pursuant to section 751(b) of the Tariff Act of 1930 (19 U.S.C. 1675(b)), that an industry in the United States would not be materially injured or threatened with material injury, nor would the establishment of an industry in the United States be materially retarded, by reason of imports from Taiwan and the Republic of Korea (Korea) of bicycle tires and tubes if the antidumping orders covering such imports were to be revoked.[2] [3]

Background

On April 4, 1979, the Commission published in the **Federal Register** (44 FR 20308) its determination that an industry in the United States was being or was likely to be injured by reason of the importation of bicycle tires and tubes from Korea which the Department of the Treasury had determined were being, or were likely to be sold at less than fair value (LTFV) within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). Accordingly, on April 13, 1979, a dumping finding with respect to bicycle tires and tubes from Korea was published in the **Federal Register** as Treasury Decision 79-115 (44 FR 22051).

On May 31, 1984, the Commission published in the **Federal Register** (49 FR 22720) its determination that an industry in the United States was materially injured by reason of imports of bicycle tires and tubes from Taiwan which the Department of Commerce had determined to be sold or likely to be sold at LTFV. Accordingly, the Department of Commerce ordered that dumping duties be imposed on such imports (49 FR 24157, June 12, 1984).

On April 2, 1987, the Commission received a request, pursuant to section 751(b) of the Tariff Act of 1930, to review its affirmative determination in investigation No. 731-TA-166, Bicycle Tires and Tubes from Taiwan. This request was filed by counsel on behalf of the Taiwan producers of bicycle tires and tubes. On April 28, 1987, the Commission received a second request, pursuant to section 751(b) of the Act, to review its affirmative determination in investigation No. AA1921-193, Bicycle Tires and Tubes from the Republic of Korea. This request was filed by counsel on behalf of Korea Inoue Kasai Co., Ltd. (KIK), a Korean manufacturer and exporter of bicycle tires and tubes. Both requests provided similar alleged changed circumstances, the termination of production of bicycle tires and tubes by the sole U.S. producer, as of February 27, 1987.

On April 23, 1987, the Commission published a request for comments concerning the institution of a section 751(b) review investigation on bicycle tires and tubes from Taiwan (52 FR 13532). On May 6, 1987, a similar request concerning bicycle tires and tubes from Korea was published (52 FR 16923). In response to the Commission's request for comments, statements were filed by counsel for petitioners in the Taiwan case, counsel for the Bicycle Manufacturers Association of America, Inc., Midway Sales, Inc., an importer of bicycle tires and tubes from Taiwan, and Hedstrom Corporation, a manufacturer of children's bicycles. None of the respondents opposed the requests to institute review investigations. In addition to these comments, staff counsel for Carlisle Corporation, the original domestic petitioner in both the Taiwan and Korean case, submitted a letter advising the Commission that Carlisle Tire & Rubber Co. would interpose no objection to the revocation of the injury determination and dumping finding with respect to bicycle tires and tubes from Korea. In subsequent telephone conversations with Commission staff,[1] counsel extended his comments to include bicycle tires and tubes from Taiwan.

On the basis of the comments filed, the Commission instituted investigations Nos. 751-TA-12 and 751-TA-13 (effective July 1, 1987) and, at the same time, announced its tentative determinations that an industry in the United States would not be materially injured or threatened with material injury nor would the establishment of an industry in the United States be materially retarded, by reason of imports from Taiwan and Korea of bicycle tires and tubes if the antidumping orders covering such imports were to be revoked. Notice of the institution of the Commission's investigations and its tentative determinations was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade

[1] The record is defined in § 207.2(i) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(i).

[2] Bicycle tires and tubes are provided for in items 772.48 and 772.57, respectively, of the Tariff Schedules of the United States.

[3] Counsel for petitioners in the Taiwan case requested that the Commission revoke the antidumping order retroactively to March 1, 1987. It is the position of the Commission that section 751(b) does not empower us to recommend retroactive revocation to the Administering Authority (the Department of Commerce). Nonetheless, we have notified the Department of Commerce that domestic production of bicycle tires and tubes terminated as of February 27, 1987.

[1] Telephone conversations between Mr. Timothy P. O'Reilly, staff counsel for Carlisle Corp. and Daniel Leahy, Office of Investigations, May 12, 1987 and July 9, 1987.

Commission, Washington, DC, and by publishing the notice in the **Federal Register** of July 1, 1987 (52 FR 24539). The notice provided for a 30-day comment period. None of the parties requested that a public hearing be held and the Commission has waived rule 207.21 concerning preparation of a staff report.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: August 14, 1987.

[FR Doc. 87-20464 Filed 9-3-87; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

Motor Carriers; Agricultural Cooperative Filings; Intent To Perform Interstate Transportation For Certain Nonmembers; Western Agricultural Lines, Inc.

Date: August 31, 1987.

The following Notices were filed in accordance with section 10526 (a)(5) of the Interstate Commerce Act. These rules provide that agricultural cooperatives intending to perform nonmember, nonexempt, interstate transportation must file the Notice, Form BOP 102, with the Commission within 30 days, of its annual meetings each year. Any subsequent change concerning officers, directors, and location of transportation records shall require the filing of a supplemental Notice within 30 days of such change.

The name and address of the agricultural cooperative (1) and (2), the location of the records (3), and the name and address of the person to whom inquiries and correspondence should be addressed (4), are published here for interested persons. Submission of information which could have bearing upon the propriety of a filing should be directed to the Commission's Office of Compliance and Consumer Assistance, Washington, DC 20423. The Notices are in a central file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, DC.

(1) Western Agricultural Lines, Inc. 4734 N. Cornelia, Fresno, CA 93722.

(2) 4734 N. Cornelia, Fresno, CA 93722.

(3) John Hays, 4737 N. Cornelia, Fresno, CA 93722.

Noreta R. McGee,

Secretary.

[FR Doc. 87-20303 Filed 9-3-87; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Intent To Engage in Compensated Intercorporate Hauling Operations; Gifford Hill & Co., Inc., et al

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

A. 1. Parent corporation and address of principal office: Gifford-Hill & Company, Inc., P.O. Box 47127, Dallas, Texas 75247; Physical Address: 300 E. John Carpenter Freeway, Irving, Texas 75062. Incorporated—Delaware.

2. Wolly-Owned subsidiaries which will participate in the operations and address of their respective principal offices:

(i) ConAgg Transportation, Inc., P.O. Box 47127, Dallas, Texas 75247; Physical Address: 300 E. John Carpenter Freeway, Irving, Texas 75062. Incorporated—Texas.

(ii) Gifford-Hill Concrete Company, P.O. Box 47127, Dallas, Texas 75247; Physical Address: 300 E. John Carpenter Freeway, Irving, Texas 75062. Incorporated—Texas.

(iii) Gifford-Hill Materials Company, P.O. Box 47127, Dallas, Texas 75247; Physical Address: 300 E. John Carpenter Freeway, Irving, Texas 75062. Incorporated—Texas.

B. 1. *Parent Corporation and Address of Principal Office:* USG Corp., 101 South Wacker Drie, Chicago, IL 60606.

2. *Wholly Owned Subsidiaries Which Will Participate in the Operations and States of Incorporation:*

Corporation and principal office address	Incorporated in
I. United States Gypsum Co., 101 South Wacker Drive, Chicago, IL 60606.	Delaware.
II. Masonite Corp., 1 South Wacker Drive, Chicago, IL 60606.	Do.
(a) Wood Fiber Industries, Inc. 1 South Wacker Drive, Chicago, IL 60606.	Do.
III. USG Industries, Inc., 101 South Wacker Drive, Chicago, IL 60606.	Do.
IV. USG Interiors, Inc., 101 South Wacker Drive, Chicago, IL 60606.	Do.
(a) Integrated Ceilings Inc., 1601 Iowa Avenue, Riverside, CA 92507.	California.
V. L&W Supply Corp., 1 South Wacker Drive, Chicago, IL 60606.	Delaware.
(a) C-S-W Drywall Supply Co., 1 South Wacker Drive, Chicago, IL 60606.	Do.
(b) Stocking Specialists, Inc., 1 South Wacker Drive, Chicago, IL 60606.	Do.
VI. A. P. Green Refractories Co. Green Boulevard, Mexico, MO 65265.	Do.
(a) A. Lynn Thomas Co., Inc., 10 East Belt Boulevard, Richmond, VA 23225.	Virginia.
(b) A. P. Green Services, Inc. 1250 Maplelawn Drive, Troy, MI 48007-7000.	Michigan.
(c) A. P. Green Refractories (Canada) Ltd., 234 Rosemont Avenue, Weston, Ontario, Canada M9N 3C4.	Canada.
(d) Empire Firebrick Co., 219 Murray Street, Fort Wayne, IN 46803-2348.	Indiana.

Noreta R. McGee,
Secretary.

[FR Doc. 87-20304 Filed 9-3-87; 8:45 am]
BILLING CODE 7035-01-M

[Finance Docket No. 31095]

Rail Carriers; Exemption; Southern Railway Co. and Carolina and Northwestern Railway Co.; Control and Acquisition; Blue Ridge Railway Co.

Southern Railway Company (Southern) and Carolina and Northwestern Railway Company (C&NW) have filed a notice of exemption for (a) the acquisition by C&NW from Southern of 100 percent of the capital stock of Blue Ridge Railway Company (Blue Ridge) and (b) the subsequent acquisition by C&NW of the assets and properties of Blue Ridge pursuant to the liquidation and dissolution of Blue Ridge. C&NW and Blue Ridge are wholly owned subsidiaries of Southern. The transfer of common stock and dissolution were to occur on or about August 15, 1987. The proposed transaction is intended to simplify Southern's corporate structure, and results in various efficiencies and economies.

The control and acquisition involve a transaction within a corporate family of the type specifically exempted from prior approval under 49 CFR 1180.2(d)(3). This transaction will not result in any adverse changes in the level of services to shippers, or significant operational changes. Nor will it have any impact on the competitive balance with carriers outside the corporate family.

To ensure that all employees who may be affected by the transaction are given the minimum protection afforded under sections 10505(g)(2) and 11347, the labor conditions set forth in *New York Dock Ry.—Control—Brooklyn Eastern Dist.*, 360 I.C.C. 60 (1979), wil be imposed.[1]

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: J. Gary Lane, Norfolk Southern Corporation, One Commercial Place, Norfolk, VA 23510.

Decided: August 13, 1987.

By the Commision, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Noreta R. McGee,
Secretary.

[FR Doc. 87-20305 Filed 9-3-87; 8:45 am]
BILLING CODE 7035-01-M

[1] The Railway Labor Executives' Association (RLEA) filed a request for labor protection. Since this transaction involves an exemption from 49 U.S.C. 11343, the imposition of the labor protective condition is mandatory and it has been imposed above.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 87-19]

Hearing; James Beale, M.D., Southfield, MI

Notice is hereby given that on January 30, 1987, the Drug Enforcement Administration, Department of Justice, issued to James Beale, M.D., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your certificate of registration AB8737009 and deny any pending applications for registration.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, September 29, 1987, commencing at 10:00 a.m. in the U.S. Claims Court, 717 Madison Place NW., Washington, DC, Courtroom No. 10, Room 309.

Dated: August 28, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-20381 Filed 9-3-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 86-90]

Hearing; Wilfredo Fernandez-Vila, M.D., South Houston, TX

Notice is hereby given that on November 4, 1986, the Drug Enforcement Administration, Department of Justice, issued to Wilfredo Fernandez-Vila, M.D., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, AF0912798, and deny any pending applications for registration.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on Wednesday, September 16, 1987, at the Harris County Courthouse, LaPort Annex, 117 East Avenue-A, LaPort, Texas.

Dated: August 28, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-20382 Filed 9-3-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 86-93]

Hearing; Leo R. Miller, M.D., New York, NY

Notice is hereby given that on December 10, 1986, the Drug Enforcement Administration, Department of Justice, issued to Leo R. Miller, M.D., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your certificate of registration AM1852474 and deny any pending applications for registration.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Wednesday, September 9, 1987, commencing at 10:00 a.m. in the U.S. Claims Court, 717 Madison Place NW., Washington, DC, Courtroom No. 10, Room 309.

Dated: August 28, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-20383 Filed 09-3-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 86-86]

Gil E. Padlo, M.D., Jenkintown, PA Hearing;

Notice is hereby given that on October 16, 1986, the Drug Enforcement Administration, Department of Justice, issued to Gil E. Pablo, M.D. an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, AP2427993, and deny any pending applications for registration.

Thirty days having elasped since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on Thursday, September 10, 1987, at the U.S. Claims Court, 717 Madison Place NW., Courtroom No. 10, Washington, DC.

Dated: August 28, 1987.

John C. Lawn,

Administrator Drug Enforcement Administration.

[FR Doc. 87-20384 Filed 9-3-87; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 87-28]

Hearing; Richard T. Robinson, M.D., Detroit, MI

Notice is hereby given that on February 5, 1987, the Drug Enforcement Administration, Department of Justice, issued to Richard T. Robinson, M.D., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your certificate of registration AR8810461 and deny any pending applications for registration.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, September 29, 1987, commencing at 10:00 a.m. in the U.S. Claims Court, 717 Madison Place NW., Washington, DC, Courtroom No. 10, Room 309.

Dated: August 28, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-20385 Filed 9-3-87; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

[Unemployment Insurance Program Letter No. 35-87]

Determining Eligibility and Amounts Payable to Unemployed Self-Employed Individuals Under the Disaster Unemployment Assistance (DUA) Program

As previously applied, our Disaster Unemployment Assistance (DUA) position denied DUA eligibility to unemployed self-employed individuals if they could render *any* of their customary services in self-employment. A recent review of this matter has led the Department of Labor to modify this position to address the special circumstances of the self-employed, and to issue guidance to all States for their use in determining eligibility and amounts payable to unemployed self-employed individuals under this revised position. This change applies to all self-employed persons and is effective for all major presidentially declared disasters occurring on or after September 10, 1986. The Department has issued this modification to all State employment security agencies in Unemployment

Insurance Program Letter No. 35–87. Unemployment Insurance Program Letter No. 35–87 is published below.

Dated: August 31, 1987.

Roger D. Semerad,

Assistant Secretary of Labor.

August 25, 1987.

Directive: Unemployment Insurance Program Letter No. 35–87.

To: All state employment security agencies.

From: Donald J. Kulick, Administrator for Regional Management.

Subject: Disaster Unemployment Assistance (DUA), Eligibility for Partially Unemployed Self-Employed Individuals.

1. *Purposes.* To provide guidance to SESAs in determining eligibility and amounts payable to unemployed self-employed individuals under the DUA program.

2. *References.* Section 407(a) of the Disaster Relief Act of 1974 (42 U.S.C. 5177(a)); 20 CFR Part 625; and ET Handbook No. 356.

3. *Background.* Questions have been raised concerning the Department of Labor's policy (based on 20 CFR 625.5 and amplified in the DUA Handbook) that self-employed individuals, such as diversified farmers, were not eligible to receive DUA if they could render *any* of their customary services in self-employment. A recent review of this issue has led the Department to conclude that a modification of this policy is appropriate to address the special circumstances of the self-employed.

4. *Policy Reinterpretation.* This review has concluded that in some cases self-employed individuals can be substantially impacted by a major disaster even though they are still able to perform some of their customary services in self-employment. In accordance with 20 CFR 625.1(b), 625.2(w), and 625.6(d) such individuals, including diversified farmers, can be eligible for partial DUA payments even if they are still able to render some of their customary services in self-employment, provided their services performed in self-employment activity have been *substantially reduced* as a direct result of a major disaster. This policy change applies to all self-employed persons and is effective for all major presidentially declared disasters occurring on or after September 10, 1986.

5. *Procedures.* Eligibility for DUA initially and on a continuing basis depends on a finding that the individual's partial or total unemployment has been caused directly by the disaster. In order for any self-employed individual to establish eligibility for full or partial DUA, it is first necessary to determine that 1) the individual, as a direct result of the disaster, is unable to perform any customary services in self-employment or that the individual's services have been substantially reduced; and 2) the individual's potential self-employment income has been adversely affected. As soon as such individuals fully resume their customary services in self-employment they are no longer eligible for DUA. Each individual's situation needs to be evaluated case by case taking these factors into account.

Once such an individual is determined eligible for DUA the individual's weekly benefit amount (WBA) will be determined based upon the self-employed individual's net earnings as shown on the Federal income tax return (usually 1040, schedules F or C and SE) for the year preceding the beginning date of the disaster. The net earnings shown would be used to determine the DUA/WBA in accordance with § 625.6 of the DUA regulations. If it is determined that the individual suffered a loss or had zero net earnings, the applicant will be entitled to the State's minimum UI/WBA, as provided in § 625.6(a)(4). Since the WBA must be reduced by any net earnings in the case of partial or part-total unemployment, as provided in § 625.6(d) of the regulations, the applicant for DUA must file an affidavit, together with a reasonable explanation therefor, stating what the individual's anticipated net earnings will be for the taxable year in which the disaster occurs. The individual who projects no net earnings or a net loss for the current tax year will be eligible for the full DUA/WBA as determined under § 625.6 of the regulations. If the individual projects net self-employment earnings for the current tax year, that amount will be prorated to a fixed weekly amount and deducted from the WBA for each week claimed. If the prorated net earnings equal or exceed the weekly DUA/WBA payable (plus the earnings allowance applicable under State law) the individual will not be eligible for any DUA payments. If the individual projects net earnings which, when prorated to a weekly amount, are less than the weekly DUA/WBA (plus the State earnings allowance) the individual's weekly DUA payable will be reduced in accordance with State law as prescribed in § 625.6(d) of the regulations.

If a claimant claims DUA into a second tax year, a projection of net earnings for that tax year will also be necessary. The above procedures will then be followed.

All projections of net earnings/loss are subject to verification as soon as the individual's Federal income tax return for the year has been filed with the Internal Revenue Service. For all cases in which the claimant is still in active benefit status when the tax return is filed, the State agency must require the individual to furnish a copy of the return and make any necessary adjustments in the individual's DUA payable. Overpayments or underpayments shall be established. For cases in which the individual is no longer in active benefit status when the tax return is field, the State may use its discretion as to whether to require that a copy of the tax return be provided. The State should be guided in its judgment as to whether or not substantial adjustments are likely to be required.

Sources of information which might affect DUA farm claim eleigibility, such as customary seasonal activities and area farming operations, are the Agricultural Stabilization and Conservation Service (ASCS offices) and the country extension agents. These sources should be particularly helpful in determining those weeks of the year when farmers (or other seasonally self-employed) normally are not engaged in any of their customary self-employment activity and may not, therefore, be eligible for DUA.

Also, from time to time Congress passes special disaster assistance legislation for farmers. Such legislation may occur well after the occurrence of the disaster and could significantly affect a DUA applicant's earnings in the year of or the year following the disaster. To keep informed SESAs should stay in contact with county ASCS officials. In the event special legislation is enacted, active DUA recipients should be required to make a new projection of earnings and SESAs should make any appropriate adjustments to the DUA amount payable. Sources of information on other self-employment activities which might affect DUA claim eligibility are trade associations, business groups, the local Chamber of Commerce and the Small Business Administration (SBA).

When more than one family member claims DUA based on the same self-employment business, each individual's self-employment income must be supported by the last year's Federal income tax return(s) showing separate SE (self-employment) schedules. The fact that a husband and wife simply filed a joint tax return would not be sufficient for these purposes. In these instances where more than one family member files DUA claims, the separate

SE schedules should be used to determine the weekly DUA payable under Section 625.6. When a husband and wife have a loss or no net earnings there should still be documentary evidence that the individuals operated as a partnership for both to be eligible for DUA based on the same business. If a bona fide partnership exists a form 1065 should have been filed with IRS and the scheduled K-1 will show how the partnership income or loss is to be allocated.

Individuals cease to be eligible for DUA when their partial or total unemployment is no longer caused by the declared disaster or when they fully resume their customary services in self-employment or otherwise are no longer partically or part-totally unemployed as provided in § 625.2(w).

Earlier instructions to the Regional Offices conveying this policy reinterpretation were limited to diversified farmers. Under the circumstances, it is possible that certain partially self-employed persons, who were not diversified farmers, filed claims for DUA and were denied. If that occurred, SESAs should review those claims and make redeterminations in accordance with State law.

6. *Action Required.* SESA Administrators should communicate the contents of this UIPL to appropriate staff.

7. *Inquiries.* Direct questions to the appropriate Regional Office.

Expiration Date: August 31, 1988.

[FR Doc. 87-20461 Filed 9-3-87; 8:45 am]

BILLING CODE 4510-30-M

Labor Surplus Area Classifications; Additions to List

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

DATE: The additions to the labor surplus area list are effective September 1, 1987.

SUMMARY: The purpose of this notice is to announce additions to the list of labor surplus areas.

FOR FURTHER INFORMATION CONTACT: William J. McGarrity, Labor Economist, Employment and Training Administration, 200 Constitution Avenue, NW., Room N4470, Attention: TEESS, Washington, DC 20210. Telephone: 202-535-0185.

SUPPLEMENTARY INFORMATION: Executive Order 12073 requires executive agencies to emphasize procurement set-asides in labor surplus areas. The Secretary of Labor is responsible under that Order for classifying and designating areas as labor surplus areas.

Under Executive Order 10582 executive agencies may reject bids or offers of foreign materials in favor of the lowest offer by a domestic supplier, provided that the domestic supplier undertakes to produce substantially all of the materials in areas of substantial unemployment as defined by the Secretary of Labor. The preference given to domestic suppliers under Executive Order 10582 has been modified by Executive Order 12260. Federal Procurement Regulations Temporary Regulation 57 (41 CFR Chapter 1, Appendix), issued by the General Services Administration on January 15, 1981, (46 FR 3519), implements Executive Order 12260. Executive agencies should refer to Temporary Regulation 57 in procurements involving foreign businesses or products in order to assess its impact on the particular procurements.

The Department of Labor regulations implementing Executive Orders 12073 and 10582 are set forth at 20 CFR Part 654, Subparts A and B. Subpart A requires the Assistant Secretary of Labor to classify jurisdictions as labor surplus areas pursuant to the criteria specified in the regulations and to publish annually a list of labor surplus areas. Pursuant to those regulations the Assistant Secretary of Labor published the annual list of labor surplus areas on March 26, 1987 (52 FR 9727).

Subpart B of Part 654 states that an area of substantial unemployment for purposes of Executive Order 10582 is any area classified as a labor surplus area under Subpart A. Thus, labor surplus areas under Executive Order 12073 are also areas of substantial unemployment under Executive Order 10582.

The areas described below have been classified by the Assistant Secretary of Labor as labor surplus areas pursuant to 20 CFR 654.5(b) (48 FR 15615 April 12, 1983) and are added to the list of labor surplus areas, effective September 1, 1987.

The following additions to the list of labor surplus areas are published for the use of all Federal agencies in directing procurement activities and locating new plants or facilities.

Signed at Washington, DC, on August 31, 1987.

Roger D. Semerad,

Assistant Secretary of Labor.

Additions to the Annual List of Labor Surplus Areas

[September 1, 1987]

Labor surplus area	Civil jurisdiction included
New Mexico:	
Farmington City.	Farmington City in San Juan County.
Torrance County.	Torrance County.
Utah: Uintah County.	Uintah County.

[FR Doc. 87-20463 Filed 9-3-87; 8:45 am]

BILLING CODE 4510-30-M

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination; Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and

federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S-3504, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The numbers of the decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Alabama:
AL87-17 (January 2, 1987)—pp. 36-37
Connecticut:
CT87-1 (January 2, 1987)—pp. 70-71
Florida:
FL87-17 (January 2, 1987)—pp. 154-155
New Jersey:
NJ87-3 (January 2, 1987)—p. 640
New York:
NY87-3 (January 2, 1987)—pp. 704-707

Volume II

Indiana:
IN87-2 (January 2, 1987)—p. 251
IN87-3 (January 2, 1987)—pp. 268-269
IN87-4 (January 2, 1987)—p. 281
IN87-5 (January 2, 1987)—p. 292
IN87-6 (January 2, 1987)—p. 302
New Mexico:
NM87-1 (January 2, 1987)—p. 695
Ohio:
OH87-29 (January 2, 1987)—p. 846
Texas:
TX87-12 (January 2, 1987)—p. 952

Volume III

Alaska:
AK87-1 (January 2, 1987)—p. 2
California:
CA87-2 (January 2, 1987)—p. 46-62d.
Montana:
MT87-1 (January 2, 1987)—p. 165
North Dakota:
ND87-3 (January 2, 1987)—p. 230
Utah:
UT87-1 (January 2, 1987)—pp. 308-314
UT87-3 (January 2, 1987)—pp. 320-328

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the Country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783-3238

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, This 28th Day of August 1987.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 87-20218 Filed 9-3-87; 8:45 am]

BILLING CODE 4510-27-M

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 87-82; Exemption Application No. D-6725 et al.]

Grant of Individual Exemptions; Wichita Falls Clinic et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of pendency were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred

the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Wichita Falls Clinic Employees Profit Sharing Plan and Trust (the Plan), Located in Wichita Falls, TX

[Prohibited Transaction Exemption 87-82; Exemption Application No. D-6725]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale by the Plan of certain improved real property (the Real Property) to an acquiring partnershp, which is a party in interest with respect to the Plan, provided the sales price is the greater of the fair market value of the Real Property or the historical costs incurred by the Plan in its ownership of the Real Property.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 6, 1987 at 52 FR 25323.

For Further Information Contact: Ms. Jan D. Broady of the Department, telephone (202) 523-8883. (This is not a toll-free number.)

Steven Sohmer, Inc. Defined Benefit Pension Plan (the Plan), Located in Los Angeles, CA

[Prohibited Transaction Exemption 87-83; Exemption Application No. D-7027]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the contribution of a copyright interest by Steve Sohmer to the Plan.[1]

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 17, 1987 at 52 FR 27084.

For Further Information Contact: David Lurie of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Mortgage & Real Estate Class of John Hancock Separate Account No. 1 (the Fund), Located in Boston, Massachusetts

[Prohibited Transaction Exemption 87-84; Exemption Application No. D-7053]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4974(c)(1) (A) through (E) of the Code, shall not apply, effective March 31, 1987, to the sale of certain mortgage and real estate investments by the fund to the General Account of John Hancock Mutual Life Insurance Company, a party in interest with respect to plans participating in the Fund, provided that the terms of sale were not less favorable to the Fund than those terms obtainable in an arm's-length transaction with an unrelated party at the time of execution of the transaction.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 17, 1987 at 52 FR 27084.

Effective Date: March 31, 1987.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Iron Workers Local No. 25 Pension Fund (the Plan), Located in Birmingham, Michigan

[Prohibited Transaction Exemption 87-85; Exemption Application No. D-7090]

Exemption

The restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash purchase of a certain parcel of land (the Land) by the Plan from Local No. 25, International Association of Bridge, Structural and Ornamental Iron Workers, AFL-CIO (the Union), a party in interest with respect to the Plan, provided the terms of the transaction are at least as favorable to the Plan as those the Plan could obtain in a similar transaction with an unrelated party.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on June 5, 1987, at 52 FR 21394.

Written Comments Received

The Department has received four written comments regarding the proposed exemption. No requests for a hearing were received. Two of the comments were in favor of granting the proposed exemption, and two were opposed.

One of the comments in favor of granting the proposed exemption expresses the view that building a fringe benefit fund office building on the Land would benefit Plan participants, who now must drive from the union hall to the current offices of the fringe benefit funds.[2]

One of the comments opposed to granting the proposed exemption expressed the view that Union members were being misled because when land was purchased for the new union hall, this commentator had received the impression that the new union hall would also house the fringe benefit fund offices, credit union, and all Union-related functions. The other comment opposed to granting the proposed exemption expressed the opinion that the proposed purchase price was outrageously overpriced.

In response to the first adverse comment, the applicants represent that since the purchase of the Union property by the Union, there was never any serious consideration given to the construction of one main facility in which the Plan would lease space from the Union. The applicants point out that the Plan trustees have secured the expert advice of both a commercial real estate appraiser, as well as the auditors for the Plan, in an attempt to determine whether or not the purchase of the Land from the Union and the subsequent construction of the fringe benefit fund office building [2] would adversely affect

[1] Since Mr. Sohmer is the sole shareholder of Steve Sohmer, Inc. and is the sole participant in the Plan, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under title II of the Act pursuant to section 4975 of the Code.

[2] As mentioned in the notice of proposed exemption, this exemption does not cover the proposed construction of the fringe benefit office building on the Land.

the Plan's ability to meet its future obligations for vested participants.

The applicants assert that based upon the advice of the independent real estate appraiser, it is readily apparent that the proposed purchase of the Land will be a prudent investment of Plan assets. In addition, an exhaustive study by the Plan auditors has indicated that the purchase and the future construction will not have any negative impact upon the Plan's ability to pay present or future benefits. The applicants express the hope that the above commentators' apprehensions should be somewhat eased by the thoroughness of the investigation and preparation by the Plan concerning the proposed purchase, as well as the independent analysis of the independent fiduciary, Mr. Woodbeck, who is familiar with such transactions and has longstanding expertise in the fields of both construction and fiduciary investments under the Act.

In response to the second adverse comment, the applicants point out further that, notwithstanding the opinion of that commentator, the Plan trustees have secured an appraisal by an independent real estate appraiser who has attested to the fact that the market value of the Land far exceeds the purchase price which the Plan proposes to pay for the Land. The applicants anticipate that if the proposed exemption is granted, at the time of the closing on the Land, its market value will have appreciated even more than that indicated in the independent appraisal. However, the applicants represent that in no event will the Plan be required to pay any monies in excess of $35,595.00 or, if less, the fair market value of the Land on the purchase date, as determined by Mr. Woodbeck.

After considering the entire record, the Department has determined that the exemption should be granted as proposed.

For Further Information Contact: Mrs. Miriam Freund of the Department, telephone (202) 523-8194. (This is not a tool-free number.)

Emanuel Klimpl Pension Plan (the Plan), Located in New York, New York

[Prohibited Transaction Exemption 87-86; Exemption Application No. D-7162]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the contribution to the Plan of certain stock warrants (the Warrants) of Arlen Corporation (Arlen) by Emanuel Klimpl, a disqualified person with respect to the Plan, provided that: (1) The Warrants are valued at their fair market value at the time contributed, and (2) the Warrants, together with certain promissory notes of Arlen (the Arlen Notes), represent in the aggregate no more than 10% of the total assets of the Plan at the time of contribution of either the Warrants or the Arlen Notes.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 17, 1987 at 52 FR 27090.

For Further Information Contact: Mr. E.F. Williams of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 1st day of September 1987.

Elliot I. Daniel,

Associate Director for Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 87-20481 Filed 9-3-87; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (87-70)]

NASA Advisory Council (NAC), Space Applications Advisory Committee (SAAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Applications Advisory Committee.

DATE AND TIME: September 22, 1987, 9 a.m.-5 p.m.; September 23, 1987, 8:30 a.m.-2:30 p.m.; and September 24, 1987, 8:30 a.m.-10:30 a.m.

ADDRESS: NASA Headquarters, 600 Independence Avenue SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Ray J. Arnold, Code EE, National Aeronautics and Space Administration, Washington, DC 20546 (202/453-1707).

SUPPLEMENTARY INFORMATION: The NAC Space Applications Advisory Committee consults with and advises the Council and NASA on plans currently in progress and accomplishments for NASA's Space Applications programs. The Committee is chaired by Mr. Leonard Jaffe and is composed of 32 members. The Committee operates both through a number of informal subcommittees and as a whole. The agenda which follows include all Committee and Subcommittee sessions. The Full Committee meeting will be closed Wednesday, September 23, from 1 p.m. until 2:30 p.m., to discuss and evaluate the qualifications of candidates being considered for membership on the committee. Such discussions would invade the privacy of the individuals involved. Since these sessions will be concerned with matters listed in 5 U.S.C. 552b(c)(6), it has been determined that the meeting will be closed to the public for this period of time. The remainder of the meeting will be open to the public up

to the seating capacity of the rooms. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Type of Meeting: Open—except for closed session as noted in the agenda below.

Agenda

September 22, 1987.

Communications Subcommitte—Mars Room, Holiday Inn-Capitol
9 a.m.—Review status of Communication Division program and structure.
1 p.m.—Develop recommendations to NASA for future activities.
4:30 p.m.—Adjourn.

Information Systems Subcommittee—Room 770, Capitol Gallery East
9 a.m.—Introduction and Discussion of SAAC concerns.
9:30 a.m.—Proxmire Response Status Update.
10:30 a.m.—Space Station Information System.
1 p.m.—Technical and Management Information System.
2:30 p.m.—Space Station Software Support Environment.
3:45 p.m.—General Discussion.
4:30 p.m.—Adjourn.

Remote Sensing Subcommittee—Jupiter Room, Holiday Inn-Capitol
10 a.m.—Earth Science and Applications Division Management.
10:30 a.m.—Implementation of Applications Research Program.
11 a.m.—Update on Landsat Program Status.
1:30 p.m.—Discussions on the linkage between Earth System Science Program and Applications Research Program.
4 p.m.—Develop Recommendations for Chairman of SAAC.
5 p.m.—Adjourn.

September 23, 1987.

Full Committee—Room 226A, NASA Headquarters Building
8:30 a.m.—Introduction and Review of Agenda.
9 a.m.—Subcommittee Reports and Presentations of FY88 Workplans: Communications, Information Systems, Microgravity and Remote Sensing.
11 a.m.—Status of OSSA Programs.
1 p.m.—Closed Session.
2:30 p.m.—Adjourn.

September 24, 1987.

Remote Sensing Subcommittee—Jupiter Room, Holiday Inn-Capitol
8:30 a.m.—Development of a Constituency for the Applications Research Program.
9:30 a.m.—Development of Recommendations for Chairman of SAAC.
10:30 a.m.—Adjourn.

Richard L. Daniels,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

August 28, 1987.

[FR Doc. 87-20357 Filed 9-3-87; 8:45 am]

BILLING CODE 7510-01-M

[Notice (87-71)]

NASA Advisory Council (NAC), Space System, and Technology Advisory Committee (SSTAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Systems and Technology Advisory Committee, Ad Hoc Team on Photonics.

DATE AND TIME: September 30, 1987, 8:15 a.m. to 5 p.m.

ADDRESS: Room 625, Federal Office Building 10B, NASA Headquarters, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Anemarie DeYoung, Office of Aeronautics and Space Technology, National Aeronautics and Space Administration, Washington, DC 20546, 202/453-2969.

SUPPLEMENTARY INFORMATION: The NAC Space Systems and Technology Advisory Committee (SSTAC) was established to provide overall guidance and direction to the Office of Aeronautics and Space Technology (OAST). Special ad hoc teams were formed to address specific topics. The Ad Hoc Team on Photonics, chaired by Dr. Stanley Weiss, is comprised of ten members. The meeting will be open to the public up to the seating capacity of the room (approximately 30 persons including the team members and other participants).

Type of Meeting: Open.

AGENDA:

September 30, 1987

8:15 a.m.—Introduction.
8:30 a.m.—Review of NASA Photonics Program.
11 a.m.—Discussion of Photonics Program.
5 p.m.—Adjourn.

Richard L. Daniels,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

August 28, 1987.

[FR Doc. 87-20358 Filed 9-3-87; 8:45 am]

BILLING CODE 7510-01-M

[Notice (87-72)]

Intent To Grant a Partially Exclusive Patent License; BFGoodrich Co.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Intent to Grant a Patent License.

SUMMARY: NASA hereby gives notice of intent to grant to BFGoodrich Company, of Uniontown, Ohio, a combined partially exclusive and nonexclusive license to practice the invention described in United States Patent No. 4,690,353, Entitled "Electro-Expulsive Separation System," which issued on September 1, 1987; NASA Case No. ARC-11,613-1. This invention relates to a novel system for separating a solid body from the surface of a resilient member. It utilizes very high repulsive forces to impact rapid expulsive movements to a flexible elastomeric member. The forces are generated by overlapping conductive members that receive a very high instantaneous current pulse from a power storage unit. The forces distend the elastomeric member and separate the elastomeric member from a solid body thereon. The invention is useful for separating ice gathered on a substrate, and it is particularly useful for aircrafted deicing applications. It relates to an aircraft deicing system which does not require stretching of the aircraft structural members themselves in order to dislodge the accreted ice. Most especially, it relates to such a system that can be provided as a retrofit on existing aircraft.

The proposed partially exclusive license will contain a field of use limitation which will limit it to aeronautical deicing applications. Additionally, it will be for a limited number of years, royalty-bearing, revocable, and will contain appropriate terms and conditions to be negotiated in accordance with the NASA Patent Licensing Regulations, 14 CFR Part 1245, Subpart 2. The proposed nonexclusive license will be for all fields of use. However, the nonexclusive license may provide that after termination of a period specified in the license

agreement, NASA may restrict the license to the fields of use or geographic areas, or both, in which the licensee has brought the invention to practical application and continues to make the benefits of the invention reasonably accessible to the public. However, such restrictions shall be made only in order to grant an exclusive or partially exclusive license in accordance with the NASA Patent Licensing Regulations. The nonexclusive license will also be royalty-bearing, revocable, and will contain other appropriate terms and conditions to be negotiated.

NASA will negotiate the terms and conditions and grant the license unless, within 60 days of the date of this Notice, the Director of Patent Licensing receives written objections to the grant, together with supporting documentations. The Director of Patent Licensing will review all written responses to the Notice and then recommend to the Associate General Counsel (Intellectual Property) whether to grant the license.

DATE: Comments to the notice must be received by November 3, 1987.

ADDRESS: National Aeronautics and Space Administration, Code GP, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Harry Lupuloff, (202) 453-2430.

Date: August 28, 1987.

John E. O'Brien,

General Counsel.

[FR Doc. 87-20359 Filed 9-3-87; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Humanities, NFAH.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comment on this information collection must be submitted on or before October 5, 1987.

ADDRESSES: Send comments to Ms. Ingrid Foreman, Management Assistant, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, (202) 786-0233 and Ms. Elaina Norden, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., Room 3208, Washington, DC 20503, (202) 395-6880.

FOR FURTHER INFORMATION CONTACT: Ms. Ingrid Foreman, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 (202) 786-0233 from whom copies of forms and supporting documents are available.

SUPPLEMENTARY INFORMATION: All of the entries are grouped into new forms, revisions, or extensions. Each entry is issued by NEH and contains the following information: (1) The title of the form; (2) the agency form number, if applicable; (3) how often the form must be filed out; (4) who will be required or asked to report; (5) what form will be used for; (6) an estimate of the number of responses; (7) an estimate of the total number of hours needed to fill out the form. None of these entries is subject to 44 U.S.C. 3504(h).

Category Extension

Title: NEH—Division of Fellowships and Seminars—Guidelines and Application Instructions for Directors, Summer Seminars for College Teachers program

Form Number: 3136-0093

Frequency of collection: Collection occurs once yearly, according to individual program application deadline.

Respondents: University faculty

Use: The guidelines and application instructions provide direction for preparing narrative and budgetary parts of applications for grant funds and request additional information regarding grants recently received by applicants.

Estimated number of respondents: 780

Estimated hours for respondents to provide information: 1,794

Title: NEH—Division of Fellowships and Seminars—Guidelines and Application Instructions for Participants, Summer Seminars for College Teachers program

Form Number: 3136-0096

Frequency of collection: Collection occurs once yearly, according to individual program application deadline.

Respondents: College faculty and independent scholars

Use: The guidelines and application instructions provide direction for preparing narrative and budgetary parts of applications for grant funds and request additional information regarding grants recently received by applicants.

Estimated number of respondents: 5,935

Estimated hours for respondents to provide information: 17,805

Thomas Kingston,

Assistant Chairman for Programs.

[FR Doc. 87-20428 Filed 9-3-87; 8:45 am]

BILLING CODE 7536-01-M

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Humanities, NFAH.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this information collection must be submitted on or before October 5, 1987.

ADDRESSES: Send comments to Ms. Ingrid Foreman, Management Assistant, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 (202-786-0233) and Ms. Elaina Norden, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., Room 3208, Washington, DC 20503 (202-395-6880).

FOR FURTHER INFORMATION CONTACT: Ms. Ingrid Foreman, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 (202-786-0233) from whom copies of forms and supporting documents are available.

SUPPLEMENTARY INFORMATION: All of the entries are grouped into new forms, revisions, or extensions. Each entry is issued by NEH and contains the following information: (1) The title of the form; (2) the agency form number, if applicable; (3) how often the form must be filled out; (4) who will be required or asked to report; (5) what form will be used for; (6) an estimate of the number of responses; (7) an estimate of the total number of hours needed to fill out the form. None of these entries is subject to 44 U.S.C. 3504(h).

Category: Revision

Title I: NEH Challenge Grant Guidelines and Application Instructions Form Numbers Not Applicable

Frequency of Collection: Annually

Respondents: Applicants for Challenge Grants

Estimated number of respondents: 195 annually
Estimated hours for respondents to provide information: 45 hours per respondent annually

Thomas Kingston,
Assistant Chairman for Programs.

[FR Doc. 87-20429 Filed 9-3-87; 8:45 am]

BILLING CODE 7536-01-M

NATIONAL SCIENCE FOUNDATION

Task Force on Women, Minorities and the Handicapped in Science and Technology; Meeting and Public Hearing; Correction

September 2, 1987.

Correction of address of public hearing on page 32086 of August 25, 1987 edition of **Federal Register**:

Name: Task Force on Women, Minorities and the Handicapped in Science and Technology
Date and Time: September 22, 1987, 9:30 am—4:45 pm
Place: Conference Center, University of New Mexico, 1634 University Boulevard, NE., Albuquerque, New Mexico

Sue Kemnitzer,
Executive Director.

[FR Doc. 87-20521 Filed 9-3-87; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-08280; Licensee No. 52-14939-01]

Order Imposing Civil Monetary Penalty; Centro Oftamologico Metropolitano

In the matter of Centro Oftamologico Metropolitano, San Juan, PR 00922.

I

Centro Oftalmologico Metropolitano (licensee) is the holder of materials License No. 52-14939-01 (license) issued by the Nuclear Regulatory Commission (NRC/Commission) on August 16, 1982. The license authorizes the licensee to employ the use of a strontium-90 eye applicator for the superficial treatment of eye disease in accordance with the conditions specified therein.

II

A routine inspection of the licensee's activities was conducted on April 14, 1987. The results of this inspection indicated that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty was served upon the licensee by letter dated June 24, 1987. The notice states the nature of the violations, the provisions of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violations. The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalty by letter dated June 29, 1987.

III

After consideration of the licensee's response and the statement of fact, explanations, and argument for mitigation contained therein, the Deputy Executive Director for Regional Operations has determined, as set forth in the appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalty should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *It is hereby ordered* That:

The licensee pay a civil penalty in the amount of Seven Hundred Fifty Dollars ($750) within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Attn: Document Control Desk, Washington, DC 20555.

The licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Attn: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the licensee was in violation of the Commission's requirements as set forth in the Notice of Violation and Proposed Imposition of Civil Penalty referenced in Section II above, and

(b) Whether, on the basis of such violation, this Order should be sustained.

For the Nuclear Regulatory Commission.
Dated at Bethesda, Maryland this 31st day of August 1987.

James M. Taylor,
Deputy Executive Director for Regional Operations.

Appendix—Evaluations and Conclusions

On June 24, 1987 a Notice of Violation and Proposed Imposition of Civil Penalty (NOV) was issued for violations identified during a routine NRC inspection. Centro Oftalmologico Metropolitano (licensee) responded to the notice on June 29, 1987. The licensee admitted that the violations did occur and requested that the civil penalty be fully mitigated. The NRC's evaluation and conclusion regarding the licensee's arguments are as follows:

Restatement of Violation

I. Violation Assessed a Civil Penalty

License Condition 12 requires that licensed material be used by or under the supervision of the two named physicians.

Contrary to the above, five additional users have used licensed material on numerous occasions since 1982 without supervision.

This is a Severity Level III violation (Supplement VI). (Civil Penalty—$750)

II. Violations Not Assessed a Civil Penalty

A. License Condition 15 requires in part that licensed material be stored in a wall cabinet and kept locked at all times.

Contrary to the above, on April 14, 1987, licensed material was stored in an unlocked treatment room on open shelving.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 19.11 requires a licensee to post current copies of certain documents near or in a licensed activity location. These documents include 10 CFR Part 19, 10 CFR Part 20, the license complete with amendments, referenced documents, and operating procedures. If posting is not practicable, the licensee may post a notice that describes the documents and where they may be examined. The licensee is also required to post Form NRC-3, "Notice to Employees," to permit individuals who frequent any portion of a "restricted area" to observe the form.

Contrary to the above, on April 14, 1987, the licensee had not posted the documents, or the notice of where the documents might be examined, nor had the licensee posted Form NRC-3.

This is a Severity Level V violation (Supplement VI).

Summary of Licensee's Response

The licensee, while admitting that the violations occurred as stated, requested mitigation of the civil penalty due to the fact that the authorized users had trained and supervised the unauthorized users and felt that by reason of proximity, education, and experience they were qualified to independently use licensed material. The licensee also contended that the unauthorized users were under the supervision of authorized user.

NRC Evaluation of Licensee's Response

The NRC has considered your request for mitigation of the Civil penalty based on the fact that the authorized users had trained and supervised the unauthorized users, but mitigation was considered inappropriate because (1) your license does not authorize you to make a determination of the qualification of users, and (2) the unauthorized users did not meet the qualification criteria stated in 10 CFR 35.941 based on your letter of June 29, 1987. Under your current license, qualification of users is an NRC determination which is made following submittal of a license amendment. Furthermore, based upon the explanation set forth in your letter of June 29, 1987 and the results of the April 14, 1987 inspection, NRC does not believe that these unauthorized users were sufficiently supervised to meet the requirements of 10 CFR 35.25.

NRC Conclusion

The NRC concludes that the violations occurred as stated in the Notice of Violation and that no mitigation of the civil penalty is warranted. Therefore, the proposed Civil Penalty in the amount of $750 should be imposed.

[FR Doc. 87-20448 Filed 9-3-87; 8:45 am]
BILLING CODE 7590-01-M

[Docket No. 40-08027, License No. SUB-1010, EA 87-108]

Order To Show Cause; Sequoyah Fuels Corp.

In the matter of Sequoyah Fuels Corporation, P.O. Box 5801, Oklahoma City, OK 73125.

I

Sequoyah Fuels Corporation (the licensee) (SFC) is the holder of Source Material License No. SUB-1010 which authorizes the licensee to possess and use source material for the purpose of refining uranium from uranium ore concentrates and converting this uranium to uranium hexafluoride (UF_6) for use by enrichment facilities. The license was most recently renewed on September 20, 1985 and will expire on September 30, 1990.

II

On January 4, 1986 a cylinder containing in excess of 30,000 pounds of UF_6 ruptured while being heated in a steam chest at the Sequoyah Fuels facility in Gore, Oklahoma. The cylinder had been overfilled to the point that its contents exceeded the cylinder's maximum allowable shipping weight of 27,560 pounds. A process operator, with the consent of his supervisor, had placed the cylinder in a steam chest to heat the cylinder to facilitate removal of the excess UF_6. While the cylinder was being heated, the cylinder wall ruptured because of the expansion of UF_6 as it changed from the solid to the liquid phase. Heating of the overfilled cylinder was contrary to the requirements of the license and the licensee's operating procedures. The high pressure in the cylinder and the large size of the rupture resulted in the rapid release of much of the UF_6 into the atmosphere. One individual employed by the licensee died because of exposure to hydrogen fluoride (a hydrolysis product of UF_6). Other employees received exposures to uranium and hydrogen fluoride.

By letter dated January 9, 1986, the licensee committed not to restart the UF_6 conversion process at the Sequoyah facility without the concurrence of the NRC. In addition, the licensee made a number of commitments in meetings with the NRC Region IV staff. These commitments were confirmed in a Confirmation of Action Letter issued by Region IV to the licensee dated January 17, 1986.

Kerr-McGee Corporation promptly instituted an internal investigation of the event. (A letter from Sequoyah Fuels Corporation to the Director, Office of Inspection and Enforcement, dated September 24, 1986, summarizes the results of this investigation.) The NRC initiated a number of inspections, investigations, and reviews after the January 4 accident with the assistance of other State and Federal agencies to determine the cause and effects of the event and the efficiency and adequacy of the response of the licensee to the event. The NRC also has inspected and reviewed all of the requirements of the license.

As a result of these efforts, several violations of NRC requirements were identified. These violations were addressed in a Notice of Violation dated October 14, 1986 and an Order Imposing Civil Monetary Penalties issued February 5, 1987. These actions addressed procedural deficiencies in the management and operation of the Sequoyah facility, which were associated with the January 4, 1986 accident.

In an Order Modifying License issued October 2, 1986, the NRC specified certain actions required before restart of Sequoyah Fuels Facility would be authorized. These conditions included imposition of an independent oversight team (IOT) to maintain a 24-hour surveillance while the facility is in operation. The IOT was required to ensure full compliance with required procedures because of NRC concerns with the conduct of certain supervisors. The Director, Office of Inspection and Enforcement, was authorized to relax or rescind all or part of those requirements. On October 16, 1986 the Commission authorized restart and the facility has resumed operations. Reports of the IOT and NRC inspections have been reviewed by the staff. Based on NRC consideration of these reports and submittals from the licensee, in a letter accompanying this Order, the Deputy Executive Director for Regional Operations has reduced the required IOT coverage from 24-hours to 8-hours per day.

III

The NRC investigations of the accident and the management and operation of the facility sought information concerning possible overfilling and heating of UF_6 cylinders, including supervisory knowledge of and acquiescence in those practices which violated authorized procedures. An NRC Augmented Investigation Team (AIT) conducted its inquiry immediately following the accident. In addition, subsequent to the accident, Sequoyah Fuels Corporation formed an Internal Investigation Team (IIT) to investigate the cause of the accident. The IIT report concluded that the January 4, 1986 rupture was "most likely caused by heating of the overfilled cylinder" and also noted that overfilling regularly occurred. In March 1986, the Office of Investigations (OI) commenced an investigation which, in addition to the above areas of inquiry, also examined whether willful material false statements were made in the January 29, 1986 letter.

The NRC investigations revealed that several Sequoyah Fuels Corporation employees in supervisory positions apparently were aware that UF_6 cylinders were being filled beyond the authorized limit and were subsequently heated while in an overfilled condition. The licensee's September 24, 1986 response to a question from the Commission stated that: "Some supervisory personnel either acquiesced in or condoned this practice" (i.e., heating with more than the maximum net weight). In the course of responding to questions from the various investigators, Messrs. J. Brewer, L. McCoy, L. Reid, and J. Swimmer did not appear to fully disclose their knowledge of the overfilling and heating of the UF_6 cylinders. Information provided by other SFC employees, including the operators and the Facility Manager, indicated that these supervisors were more aware of the subject practices than they revealed. These supervisors were aware of the weight limitations for cylinders and the provisions of Operating Procedure N-280-1, Revision 6, which prohibited the heating of overfilled cylinders. They all signed cylinder status sheets reflecting excessive weights. Further, some of the statements of these individuals to the investigators were inconsistent.

IV

The holder of a license from the NRC has a clear obligation to be candid and forthcoming in dealing with the NRC and its staff. The effectiveness of the regulatory program is dependent on the ability of NRC investigators to obtain complete and accurate information in determining the causes of accidents in order to protect the public health and safety as well as workers in licensed facilities. The OI investigation revealed a lack of candor among supervisory personnel, specifically with regard to Messrs. Brewer, McCoy, Reid, and Swimmer. It appears that these supervisors knew about and acquiesced in practices that were contrary to authorized procedures. The NRC needs assurance that these supervisors will properly run plant operations, ensure that these operations will be conducted in accordance with authorized procedures, and in the future provide complete and accurate information to the NRC.

V

In view of the foregoing, pursuant to sections 63, 161 b, i, and o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and Part 40, *It is hereby ordered that the licensee:*

Show cause why an Order should not be issued suspending licensed activities while the following individuals are involved in licensed activities:

1. J. Brewer, Shift Supervisor
2. L. McCoy, Area Supervisor
3. L. Reid, Shift Supervisor
4. J. Swimmer, Shift Supervisor

The response should at a minimum address actions such as disciplinary action taken or to be taken, training conducted or scheduled to be conducted and management controls, including disciplinary policies, instituted which will provide assurance if these employees are allowed to perform licensed activities, that the licensee will have, and the NRC should have, confidence that each of these individuals will be candid with the NRC in the future. If the licensee should decide to remove these supervisors from licensed activities, the response should include information concerning their replacements, to provide assurance that the replacements are qualified and will be candid with the NRC so that they can be relied on to provide complete and accurate information.

VI

The licensee may show cause why this Order should not have been issued and should be vacated by filing a written answer under oath or affirmation within 30 days of the date of this Order which sets forth the matters of fact and law on which the licensee relies. If the licensee fails to file an answer within the specified time the Deputy Executive Director for Regional Operations may issue without further notice an Order described above.

The licensee or any other person who has an interest adversely affected by this Order may request a hearing on this Order within 30 days of the date of its issuance. Any answer to this Order or request for hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Attn: Document Control Desk, Washington, DC 20555, with copies to (1) the Assistant General Counsel for Enforcement, Office of the General Counsel, and (2) the Regional Administrator, Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011. If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which the person's interest is adversely affected by this Order and should address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at the hearing shall be whether this Order shall be sustained.

Dated at Bethesda, Maryland this 1st day of September 1987.

For the Nuclear Regulatory Commission.

James M. Taylor,

Deputy Executive for Regional Operations.

[FR Doc. 87-20447 Filed 9-3-87; 8:45 am]

BILLING CODE 7590-01-M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

AGENCY: Railroad Retirement Board.

ACTION: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) Collection title: Application and Claim for RUIA Benefits Unpaid at Death.

(2) Form(s) submitted: ID-28(a)(1), SI-62 and UI-63.

(3) Type of request: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

(4) Frequency of use: On occasion.

(5) Respondents: Individuals or households.

(6) Annual responses: 3,625.

(7) Annual reporting hours: 572.

(8) Collection description: The collection obtains the information needed by the Board to pay, under section 2(g) of the RUIA, benefits under that Act accrued but not paid because of the death of the employee.

Additional Information or Comments: Copies of the proposed forms and supporting documents can be obtained from Pauline Lohens, the agency clearance officer (312-751-4692). Comments regarding the information collection should be addressed to Pauline Lohens, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Elaina Norden (202-395-7316), Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503.

Pauline Lohens,

Director of Information and Data Management.

[FR Doc. 87-20364 Filed 9-3-87; 8:45 am]

BILLING CODE 7905-01-M

Agency Forms Submitted for OMB Review

AGENCY: Railroad Retirement Board.

ACTION: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) Collection title: Application for Reimbursement for Hospital Insurance Services in Canada.

(2) Form(s) submitted: AA-104.

(3) Type of request: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

(4) Frequency of use: On occasion.

(5) Respondents: Individuals or households.

(6) Annual responses: 123.

(7) Annual reporting hours: 21.

(8) Collection description: The Board administers the Medicare program for persons covered by the Railroad Retirement system. The collection obtains the information needed to determine eligibility for and amount due for covered hospital services received in Canada.

Additional Information or Comments: Copies of the proposed forms and supporting documents can be obtained from Pauline Lohens, the agency clearance officer (312-751-4692). Comments regarding the information collection should be addressed to Pauline Lohens, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Elaina Norden (202-395-7316), Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503.

Pauline Lohens,

Director of Information and Data Management.

[FR Doc. 87-20365 Filed 9-3-87; 8:45 am]

BILLING CODE 7905-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-24862; File No. SR-NASD-87-32]

Self-Regulatory Organizations; Proposed Rule Change; National Association of Securities Dealers, Inc.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on August 26, 1987, the National Association of Securities Dealers, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items, I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The National Association of Securities Dealers, Inc. ("NASD") hereby requests that the Securities and Exchange Commission ("SEC") extend the period of effectiveness of the Pilot Program with The International Stock Exchange of the United Kingdom and the Republic of Ireland, Ltd. ("Exchange"), formerly The Stock Exchange, London, England. This matter was the subject of five (5) previous filings made by the NASD: File Nos. SR-NASD-86-4, SR-NASD-86-26, SR-NASD-86-35, SR-NASD-87-15 and SR-NASD-87-24. Each of those filing was approved timely by the Commission to enable continous operation of the Pilot Program from April 22, 1986 through August 31, 1987. The NASD is seeking another extension of this approval until September 30, 1987. The proposed extention will permit continued operation of the Pilot Program while the Commission considers the disposition of File No. SR-NASD-87-20. In that filing the NASD requests Commission approval of the Pilot for a prospective two-year term as well as certain modifications in access terms.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purposes of and basis for the proposal and discussed any comments it received on the proposal. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this rule filing is to obtain an extension of the SEC's temporary approval of the Pilot Program through September 30, 1987. Absent such an extention, the NASD's link with the Exchange will terminate August 31, 1987.

The Pilot Program, the first transatlantic communication link of its kind between major domestic and foreign equities marketplaces, provides a unique opportunity to gather and analyze information leading to the efficient and effective development of international trading, related regulatory programs and potentially new systems designs. As currently structured, the Pilot Program provides for the exchange of market data, between the NASD and the Exchange, without charge, on a group of securities of international interest and the transmission of that data by the recipient (NASD or Exchange) to its current subscribers as part of either NASDAQ Level 2/3, TOPIC, or TOPICLINE service. When the Pilot Program was originally filed (*i.e.*, File No. SR-NASD-86-4), the NASD requested the SEC's approval of the Pilot for a two year period. At the SEC's request, however, the NASD has acquiesced in the Agency's approved of the Pilot for shorter, consecutive time periods.

The tentative approach is not traceable to any regulatory concern, actual or potential, arising from the linkage's daily operation. Rather, the SEC's reluctance to approve the Pilot Program for a two year term relates to the fact that the broker-dealers able to access quotes disseminated via the linkage are not assessed an additional fee for that access. This issue was raised by one vendor of securities market information (hereinafter referred to as the "Vendor") during the SEC's notice and comment process on the original rule filing (File No. SR-NASD-86-4).[1] Vendor claimed that this aspect of the Pilot Program was anticompetitive because Vendor could not obtain access to linkage data (particularly market makers' quotations) from the NASD or the Exchange on the same terms as participating brokers, *i.e.*, at no cost. Further, Vendor maintained that the NASD was utilizing its status as a self-regulatory organization to impede competition from Vendor by virtue of the NASD's receiving quotation information from the Exchange on a preferential basis.

The Association continues to believe that the legal and economic arguments that Vendor previously raised are lacking in merit. Moreover, those arguments suggest a misperception of the economic incentives that have

[1] *See* letter from Daniel T. Brooks, Cadwalader, Wickersham & Taft, Counsel for Instinet Corporation, to John Wheeler, Secretary, SEC, dated April 16, 1986. *See also* Securities Exchange Act Release No. 23158 (April 21, 1986), 51 FR 15989 (April 29, 1986).

prompted various market centers to initiate international linkages in recent years. Nonetheless, the NASD and the Exchange have re-examined the original access terms for the Pilot Program and proposed certain modifications in File No. SR-NASD-87-20.[2] Generally, the proposed modifications would narrow the universe of firms/terminals accessing linkage data at no cost. Such modifications were based in part upon the results of an Exchange survey to provide objective information respecting the breadth of dissemination of Pilot data among Exchange members. This information should also respond definitively to specific questions raised by the Commission staff.

The Commission staff has requested additional time to analyze that data, along with comment letters submitted by Vendor and the NASD, in formulating a recommendation to the Commission on File No. SR-NASD-87-20. Therefore, the Association has submitted the instant filing to sustain the operation of the Pilot Program until September 30, 1987 pursuant to temporary Commission approval. During the requested extension, only information on a limited group of securities of international interest will be exchanged on a like kind basis in lieu of separate and offsetting monetary transfers. Further, the NASD and the Exchange will refrain from introducing an automatic execution linkage during this temporary extension of the Pilot Program.

The statutory bases for the Pilot Program and the requested extension thereof, are found in section 11A(a)(1) (B) and (C), 15A(b)(6), and 17A(a)(1) (C) and (D) of the Act. Subsections (B) and (C) of section 11A(a)(1) set forth the Congressional goals of achieving more efficient and effective market operations, the availability of information with respect to quotations for securities and the execution of investor orders in the best market through new data processing and communications techniques. Section 15A(b)(6) requires that the rules of the Association be designed "to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market. . . ." Section 17A(a)(1) sets forth the Congessional goal of linking all clearance and settlement facilities and reducing costs involved in the clearance and settlement process through new data processing and communications techniques. The NASD believes that the requested extension of approval for the Pilot Program will foster significant progress toward these ends by providing the cooperative regulatory environment and operating experience necessary to realize these goals in the international marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

In its first release announcing temporary approval of the Pilot Program, the Commission articulated arguments made by Vendor regarding the competitive impact which Vendor believes the Program has upon it. These arguments were summarized in the preceding section. In response, the NASD and the Exchange have re-examined the existing access terms and proposed to narrow the universe of firms/terminals permitted access to linkage data at no cost. These changes are contained in File No. SR-NASD-87-20. Hence, the NASD and the Exchange have made a good faith effort to address the perceived, competitive concerns raised by Vendor and reiterated by the SEC in its original release. In light of these factors, the NASD believes that no additional competitive burden would be created by the SEC's extension of the Pilot Program until September 30, 1987.

During the period of such extension, no use will be made of the information exchanged for purposes of operation of an automatic execution system. Given the limited numbers of securities involved, the limited use to be made of the information exchanged, and the Association's efforts to address the competitive issues previously raised, the NASD submits that the benefits to be derived from the further extension of the Pilot Program significantly outweigh any perceived burden upon competition and materially advance the purposes to be served under the above-referenced sections of the Act.

C. Self-Regulatory Organization's Statement on Comment on the Proposed Rule Change Received from Members, Participants or Others

Not applicable.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests the Commission to find good cause for approving the proposed rule change prior to the 35th day after its publication in the **Federal Register**, and, in any event, by August 28, 1987, the last business day before the expiration date for the Pilot Program. The NASD believes that the continuation of the Pilot Program provides an opportunity to develop additional information leading to the efficient and effective development of international trading, related regulatory programs and the potential for new system designs. Accordingly, the NASD believes that good cause exists to accelerate the effectiveness of the rule change to no later than August 28, 1987.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of sections 11A(a)(1)(B) and (C), 15A(b)(6), and 17A(a)(1)(C) and (D) and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof. Specifically, accelerated approval and the continuation of the Pilot Program will benefit public investors and provide the opportunity to develop additional information leading to the efficient and effective development of international trading, related regulatory programs and the potential for new system designs. The Commission recognizes that without accelerated approval, authorization for the Pilot Program will expire on August 31, 1987. The Commission believes that the benefits of extending its approval of the Pilot Program on a temporary basis outweigh any potential adverse effects during the period of the rule change's effectiveness.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filings will also be available for inspection and copying at the principal office of the above-

[2] *See.* Release No. 34-24364 (April 17, 1987), 52 FR 13891 (April 27, 1987). In this filing, the NASD also seeks approval of the Pilot Program for a two-year term which would commence from the Commission's approval of File No. SR-NASD-87-20.

mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by September 25, 1987.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Jonathan G. Katz,

Secretary.

Dated: August 28, 1987.

[FR Doc. 87-20410 Filed 9-3-87; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Inc.

August 28, 1987.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

Hancock Fabrics, Inc.
Common Stock, $0.01 Par Value (File No. 7-0372)
KaiserTech Limited
Common Stock, $0.33 1/3 Par Value (File No. 7-0373)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before September 21, 1987, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 87-20409 Filed 9-3-87; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-15952; 811-3168]

Application: Bache/KILICO Variable Annuity Account

August 28, 1987.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application on Form N-8F under the Investment Company Act of 1940 (the "1940 Act").

Applicant: Bache/KILICO Variable Annuity Account.

Relevant 1940 Act Sections: Order requested under Section 8(f).

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company.

Filing Date: August 19, 1987.

Hearing or Notification of Hearing: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m., on September 28, 1987. Request a hearing in writing, giving the nature of your interest, the reason for the request, either personally or by mail, and also sent it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicant, 120 S. LaSalle Street, Chicago, Illinois 60603.

FOR FURTHER INFORMATION CONTACT: David S. Goldstein, Attorney (202) 272-2622 (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. It registered under the 1940 Act on April 9, 1981, and its depositor, Kemper Investors Life Insurance Company, filed a registration statement for variable annuity contracts on Form S-6 on April 9, 1981, but the registration statement never became effective and no public offering of securities was ever made.

2. It is an insurance company separate account created on March 6, 1981, under the laws of California, and the Board of Directors of Kemper Investors Life Insurance Company will rescind the resolution creating the Applicant at the next practicable opportunity.

3. It has no securityholders, no assets, and no outstanding debts or other liabilities.

4. It is not a party to any litigation or administrative proceeding and has made no sales of securities of which it is the issuer.

5. It is not now engaged and does not propose to engage in any business activities other than those necessary for winding up its affairs.

For the Commission, by the Division of Investment, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 87-20411 Filed 9-3-87; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[Public Notice CM-8/1109]

Meeting; Secretary of State's Advisory Committee on Private International Law, Study Group on the Law Applicable to Decedents' Estates

There will be a meeting of the subject Study Group at 10:00 a.m. to 4:00 p.m., on Thursday, September 17, 1987 in Room 413 of the Federal Mediation and Conciliation Service Building, 2100 K Street, NW., Washington, DC. Members of the general public may attend up to the capacity of the meeting room and participate in the discussion subject to instructions of the Chairman.

The meeting agenda will include a review of the progress of the Special Commission of experts of The Hague Conference on Private International Law in developing a proposed convention on the law applicable to decedents' estates. Comments will be sought on the appropriateness of a single applicable law for purposes of succession to all assets, the extent to which the decedent can appropriately choose the applicable law and on the identification of the controlling contact, i.e., domicile or nationality, in absence of testamentary direction. A preliminary draft of the proposed convention will be discussed.

Entry to the Federal Mediation and Conciliation Service Building is controlled. As entry will be facilitated by advance arrangements, members of the general public planning to attend should, prior to September 15, notify the Office of the Assistant Legal Adviser for Private International Law, Department of State, Washington, DC, 20520 (telephone: (202) 653-9851) of their

name, affiliation, address and telephone number.

Peter H. Pfund,

Assistant Legal Adviser for Private International Law and Vice-Chairman, Secretary of State's Advisory Committee on Private International Law.

[FR Doc. 87-20366 Filed 9-3-87; 8:45 am]

BILLING CODE 4710-08-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: August 28, 1987.

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 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.

Internal Revenue Service

OMB Number: New
Form Number: 8656
Type of Review: New Collection
Title: Alternative Minimum Tax—Fiduciaries
Description: This form was developed to assist fiduciaries in computing the alternative minimum tax under new Code sections 55 through 59. The minimum tax is determined by recomputing the distributable net income of the fiduciary on a minimum tax basis. The distributable net alternative minimum taxable income is then allocated to the beneficiaries
Respondents: Businesses or other for-profit
Estimated Burden: 161,454 hours
OMB Number: 1545-0915
Form Number: 8332
Type of Review: Extension
Title: Release of claim to Exemption for Child for Divorced or Separated Parents
Description: This form is used by the custodial parent to release claim to the dependency exemption for a child of divorced or separated parents. The data is used to verify that the noncustodial parent is entitled to claim the exemption
Respondents: Individuals or households
Estimated Burden: 20,715

Clearance Officer: Garrick Shear (202) 535-4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224

OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503

Dale A. Morgan,

Department Reports Management Officer.

[FR Doc. 87-20386 Filed 9-3-87; 8:45 am]

BILLING CODE 4810-25-M

Fiscal Service

[Dept. Circ. 570, 1987 Rev., Supp. No. 2]

Surety Companies Acceptable on Federal Bonds; Southeastern Casualty and Indemnity Insurance Co., Inc., and Southeastern Reinsurance Co., Inc.; Correction of Address

The business address for the above mentioned companies was listed at 52 FR 24625 (July 1, 1987) as: 499 NW. 79th Street, #200, Plantation, FL 33317. The companies' business address is hereby corrected to: 499 NW. 70th Avenue, Suite 200, Plantation, FL 33317.

Federal bond-approving officers should annotate their reference copies of Treasury Circular 570, 1987 Revision, at the appropriate pages to reflect this correction.

Questions concerning this correction notice may be directed to the Department of the Treasury, Financial Management Service, Finance Division, Surety Bond Branch, Washington, DC 20226, or by calling (202) 634-2295.

Dated: August 27, 1987.

Mitchell A. Levine,

Assistant Commissioner, Comptroller, Financial Management Service.

[FR Doc. 87-20360 Filed 9-3-87; 8:45 am]

BILLING CODE 4810-35-M

Sunshine Act Meetings

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

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).

FEDERAL ELECTION COMMISSION

DATE AND TIME, Wednesday, September 9, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C., 437g.
Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
International personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE AND TIME: Thursday, September 10, 1987, 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of Dates for Future Meetings.
Correction and Approval of Minutes.
Eligibility Report for Candidates to Receive Presidential Primary Matching Funds.
Draft Advisory Opinion 1987-24—John B. Simon on behalf of Hyatt Corporation.
Draft Advisory Opinion 1987-25—Ricardo A. Otaola.
Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Information Officer, Telephone: 202-376-3155.

Marjorie W. Emmons,
Secretary of the Commission.

[FR Doc. 87-20537 Filed 9-2-87; 8:45 am]
BILLING CODE 6715-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

August 27, 1987.

TIME AND DATE: 10:00 a.m., September 2, 1987.

PLACE: Room 600, 1730 K Street NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: Consideration of the matter below, previously announced in the agenda for September 2, 1987 is canceled. Consideration will be rescheduled at a future date. Consideration of the other matter previously announced in the agenda for September 2, 1987 remains in effect.

2. *Martha Perando v. Mettiki Coal Corporation,* Docket No. YORK 85-12-D.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, (202) 653-5629.

Jean H. Ellen,
Agenda Clerk.

[FR Doc. 87-20496 Filed 9-2-87; 8:45 am]
BILLING CODE 6735-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, September 9, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of their routine nature, no substantive discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed extension and revision of the Weekly Report of Assets and Liabilities (FR 2416) and the Weekly Report of Selected Assets (FR 2644).
2. Proposed extensions and revision of the Monthly Survey of Eligible Bankers Acceptances (FR 2006).
3. Proposed revision and extension of Senior Loan Officer Opinion Survey on Bank Lending Practices (FR 2018).
4. Proposed revision and extension of the Domestic Finance Company Reports of Consolidated Assets and Liabilities (FR 2248/2248a).

Discussion Agenda

5. Publication for comment of a proposed amendment to Regulation Z (Truth in Lending) to implement provisions of the Competitive Equality Banking Act of 1987 regarding adjustable rate mortgage caps.
6. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

James McAfee,
Associate Secretary of the Board.

[FR Doc. 87-20507 Filed 9-2-87; 11:11 am]
BILLING CODE 6219-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 10:30 a.m., Wednesday, September 9, 1987, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: September 2, 1987.

James McAfee,
Associate Secretary of the Board.

[FR Doc. 87-20508 Filed 9-2-87; 11:11 am]
BILLING CODE 6210-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

STATUS: Open.

TIME AND DATE: September 9-10, 1987, 9:00 p.m.

PLACE: City Council Chambers, the Electric Building, 140 South Capital, Idaho Falls, Idaho.

MATTERS TO BE CONSIDERED:

1. Public Hearing on General Model Conservation Standards.
2. Public Hearing on Umatilla Hatchery Amendment.

3. Public Comment on Yakima/Klickitat Outplanting Facility Master Plan Issue Paper.
4. Staff Presentation, Public Comment and Council Deliberation on Comments regarding the Bonneville Power Administration Partnership Program.
5. Public Comment on Heating Cost Comparison Study.
6. Council Decision on the Analysis of Conservation Measures as required by Section 4(k) of the Northwest Power Act.
7. Bonneville Presentation on the Status of the Residential Weatherization Program.
8. Staff Presentation of an Issue Paper on Current Resources in the West for the Western Electricity Study.
9. Staff Presentation of an Issue Paper on the Status of Commercial Model Conservation Standards.
10. Council Decision on Proposed Guidelines on Notice of Meetings.
11. Council Business.
12. Public Comment.

FOR FURTHER INFORMATION CONTACT: Ms. Bess Atkins at (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 87-20524 Filed 9-2-87; 12:17p.m.]

BILLING CODE 0000-00-M

UNITED STATES INSTITUTE OF PEACE

TIMES AND DATES:

9:00 a.m.-5:00 p.m., Thursday, September 10, 1987

9:00 a.m.-5:00 p.m., Friday, September 11, 1987

PLACE: National Trust for Historic Preservation, 1785 Massachusetts Avenue, NW., Washington, DC 20035.

STATUS: Open (portions may be closed pursuant to subsection (c) of section 552(b) of title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Pub. L. 98-525).

AGENDA (TENTATIVE): Meeting of Board of Directors convened. Chairman's Report. President's Report. Committee Reports. Consideration of minutes of the fifteenth meeting. Report on National Peace Essay Contest. Discussion of Jennings Randolph Program. Presentation on Chairman's Report to Congress and the President. Reports on Housing, TV Project, and Institute Seal. Consideration of grant applications.

CONTACT: Mrs. Olympia Diniak. Telephone: (202) 789-5700.

Dated: September 2, 1987.

Robert F. Turner,

President, United States Institute of Peace.

[FR Doc. 87-20526 Filed 9-2-87; 12:52 PM]

BILLING CODE 3155-01-M

Corrections

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

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.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Activities of Self-Regulatory Organization Governing Members Who Possess Material, Nonpublic Information

Correction

In proposed rule document 87-19688 beginning on page 32568 in the issue of Friday, August 28, 1987, make the following corrections on page 32572:

1. In the first column, in the paragraph under **Regulatory Flexibility Act**, in the 20th line, "§ 1.59 (a)(8) and (c)" should read "§ 1.59 (a)(9) and (c)".

2. In the second column, in the **Authority**, in the last line, "rated" should read "noted.".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Western Area Power Administration

Salt Lake City Area Integrated Projects; Rate Order; Utah

Correction

In notice document 87-18432 beginning on page 30245 in the issue of Thursday, August 13, 1987, make the following correction on page 30249:

In the second column, in the first complete paragraph, in the next to the last line, "would be expected" should read "would not be expected".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPTS-62053; FRL 3176-1]

Polychlorinated Biphenyls; Exclusions, Exemptions and Use Authorizations

Correction

In proposed rule document 87-15245 beginning on page 25838 in the issue of Wednesday, July 8, 1987, make the following corrections:

1. On page 25838, in the first column, in the **SUMMARY**, in the 23rd line, "elimination" should read "eliminate".

§ 761.20 [Corrected]

2. On page 25860, in the third column, in § 761.20(e)(4)(i), in the sixth line insert "required" after "records".

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Parts 203 and 234

[Docket No. R-87-1317; FR-2266]

Termination of Section 245(b) GPM Program

Correction

In rule document 87-19768 beginning on page 32754 in the issue of Friday, August 28, 1987, make the following correction:

On page 32755, in the third column, in the second complete paragraph, in the fourth line, "justify" should read "disqualify".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-AWP-21]

Amendment to Santa Maria, CA, Control Zone

Correction

In rule document 87-19028 beginning on page 31385 in the issue of Thursday, August 20, 1987, make the following correction:

§ 71.171 [Corrected]

On page 31385, in the third column, in § 71.171, in the description for the Santa Maria, CA control zone, in the third line, insert "during" after "effective".

BILLING CODE 1505-01-D

federal register

Friday
September 4, 1987

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 888

Orthopedic Devices; General Provisions and Classifications of 77 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 78N-3028]

Orthopedic Devices; General Provisions and Classifications of 77 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 77 orthopedic devices. In the preamble to this rule, FDA is responding to comments received on the proposed regulations classifying these devices. These actions are being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Carl Larson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7156.

SUPPLEMENTARY INFORMATION:

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A. Background.
B. FDA's Priorities for Establishing Performance Standards.
C. Changes in the Name of the Orthopedic Device Advisory Committee.
D. Devices Not Being Classified at This Time.
E. List of Orthopedic Devices.
F. Changes in Classifications in Final Rule.
G. Summary of Comments on Classification and FDA's Responses.
H. Exemptions for Class I Orthopedic Devices.
I. Classification Regulations Published To Date.
J. Minor Changes or Clarifications.
K. Transitional Devices.
L. Studies Submitted By Comments.
M. Environmental Impact.
N. Economic Impact.

A. Background

In the **Federal Register** of July 2, 1982 (47 FR 29052), FDA published a proposed rule containing general provisions applicable to the classification of orthopedic devices, and individual proposed regulations classifying 77 orthopedic devices into one or more of three regulatory classes: Class I (general controls), class II (performance standards), and class III (premarket approval).

FDA is postponing final classification of 2 of the 77 orthopedic devices subject to the proposed rule in order to review additional data on electrical safety. Thus, in this final rule FDA is classifying 75 orthopedic devices based on the proposed rule. Also, in this final rule FDA is codifying the statutory classification into class III of two transitional devices that were not subjects of the proposed classification rule. Accordingly, in this final rule FDA is classifying 77 generic types of orthopedic devices (77 minus 2 plus 2 equals 77). Of these 77 devices, FDA is classifying 15 devices into class I, 37 devices into class II, 24 devices into class III, and 1 device into class II or class III depending upon its intended use.

To reduce printing costs, FDA is publishing in one final rule, the general provisions and the classifications of 77 orthopedic devices. FDA previously published a separate final rule for each device.

Classification of medical devices in commercial distribution is required by section 513 (21 U.S.C. 360c) of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 through 392). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before March 30, 1990, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the proposed regulations described the development of the general provisions and the proposed regulations classifying orthopedic devices and the activities of the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of orthopedic devices. FDA provided a period of 90 days, later extended to 180 days (October 8, 1982; 47 FR 44475), for interested persons to submit written comments on the proposed regulations. The comments received and FDA's responses to the comments are discussed below.

In April 1985, H.R. 2177 (99th Cong. 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) made the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards required by section 514 of the act. If legislation comparable to this bill becomes law, there would be only two categories of devices: Class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because the proposed legislation contains transitional provisions that convert classifications under the current law to classifications under the proposed law, FDA is continuing to issue classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. FDA does not have the resources, however, to establish simultaneously performance standards for all the devices already classified (or being classified) in class II. In the October 23, 1985 notice, FDA announced that it will consider the following factors when setting priorities for establishing performance standards for class II devices:

a. The seriousness of questions concerning the safety or effectiveness of the devices; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device:

b. The recommendations of FDA's advisory committees:

c. The impact of an FDA guideline or recommendation;

d. The effect of a Federal standard or other regulatory controls under an authority other than the act;

e. The impact of voluntary standards;

f. The impact of activities authorized under the general controls provisions of the act;

g. The effect of dissemination of information and educational efforts;

h. The sufficiency of voluntary corrective actions;

i. Valid scientific evidence developed since classification;

j. The existence of a petition for reclassification;

k. The impact of any other factors that affect a devices's safety or effectiveness.

C. Changes in the Name of the Orthopedic Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Orthopedic and Rehabilitation Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to orthopedic devices as did its predecessors, the Orthopedic Device Classification Panel. (1976–1978) and the Surgical and Rehabilitation Devices Panel (1978–1984).

D. Devices Not Being Classified at This Time

FDA is postponing classification of the following two generic types of orthopedic devices in order to review additional data on electrical safety: AC-powered goniometer and AC-powered cast removal instrument.

E. List of Orthopedic Devices

The list below shows, for each orthopedic device, the section of the Code of Federal Regulations at which classification of that device is being codified (or will be codified), the docket number of the corresponding proposed classification regulation (where applicable), the final classification of the device, and an indication (yes or no) of whether public comments were received on the proposed regulation. The list includes the two AC-powered orthopedic devices for which classification is being postponed. For each of these two devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "[1]," and no classification of the device is provided (§§ 888.1500 and 888.5960). The two transitional devices included in this rule are identified with footnote "[2]," (§§ 888.3015 and 888.3027). (See "K. Transitional Devices" near the end of the preamble.)

Section and device	Docket No.	Class	Comments
Subpart B—Diagnostic Devices			
888.1100—Arthroscope	78N-3041	II	Yes.
888.1240—AC-powered dynamometer	78N-3300	II	No.
888.1250—Nonpowered dynamometer	78N-3042	I	No.
(888.1500)—AC-powered goniometer [1]	78N-3043		No.
888.1520—Nonpowered goniometer	78N-3044	I	Yes.
Subpart D—Prosthetic Devices			
888.3000—Bone cap	78N-3046	II	Yes.
888.3010—Bone fixation cerclage	78N-3051	II	Yes.
888.3015—Bone heterograft [2]	III		
888.3020—Intramedullary fixation rod	78N-3056	II	Yes.
888.3025—Passive tendon prosthesis	78N-3098	II	Yes.
888.3027—Polymethylmethacrylate (PMMA) bone cement [2]		III	
888.3030—Single/multiple component metallic bone fixation appliances and accessories	78N-3049	II	Yes.
888.3040—Smooth or threaded metallic bone fixation fastener	78N-3053	II	Yes.
888.3050—Spinal interlaminal fixation orthosis	78N-3047	II	Yes.
888.3060—Spinal intervertebral body fixation orthosis	78N-3048	II	Yes.
888.3100—Ankle joint metal/composite semi-constrained cemented prosthesis	78N-3059	II	Yes.
888.3110—Ankle joint metal/polymer semi-constrained cemented prosthesis	78N-3060	II	Yes.
888.3120—Ankle joint metal/polymer non-constrained cemented prosthesis	78N-3061	III	No.
888.3150—Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	78N-3062	III	Yes.
888.3160—Elbow joint metal/polymer semi-constrained cemented prosthesis	78N-3063	II	Yes.
888.3170—Elbow joint radial (hemi-elbow) polymer prosthesis	78N-3064	II	Yes.
888.3180—Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	78N-3065	III	No.
888.3200—Finger joint metal/metal constrained uncemented prosthesis	78N-3066	III	No.
888.3210—Finger joint metal/metal constrained cemented prosthesis	78N-3301	III	No.
888.3220—Finger joint metal/polymer constrained cemented prosthesis	78N-3067	III	No.
888.3230—Finger joint polymer constrained prosthesis	78N-3068	II	Yes.
888.3300—Hip joint metal constrained cemented or uncemented prosthesis	78N-3070	III	Yes.
888.3310—Hip joint metal/polymer constrained cemented or uncemented prosthesis	78N-3071	III	Yes.
888.3320—Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	78N-3072	III	No.
888.3330—Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.	78N-3073	III	No.
888.3340—Hip joint metal/composite semi-constrained cemented prosthesis	78N-3074	II	Yes.
888.3350—Hip joint metal/polymer semi-constrained cemented prosthesis	78N-3075	II	Yes.
888.3360—Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	78N-3077	II	Yes.
888.3370—Hip joint (hemi-hip) acetabular metal cemented prosthesis	78N-3076	III	No.
888.3380—Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	78N-3078	III	No.

[1] Classification postponed.

[2] Not proposed; statutory classification.

Section and device	Docket No.	Class	Comments
888.3390—Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	78N-3079	II	No.
888.3400—Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	78N-3080	II	Yes.
888.3410—Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis	78N-3081	III	Yes.
888.3480—Knee joint femorotibial metallic constrained cemented prosthesis	78N-3082	III	Yes.
888.3490—Knee joint femorotibial metal/composite non-constrained cemented prosthesis	78N-3083	II	Yes.
888.3500—Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	78N-3302	II	Yes.
888.3510—Knee joint femorotibial metal/polymer constrained cemented prosthesis	78N-3084	II	Yes.
888.3520—Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	78N-3085	II	No.
888.3530—Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	78N-3086	II	Yes.
888.3540—Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	78N-3087	III	Yes.
888.3550—Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	78N-3088	III	Yes.
888.3560—Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.	78N-3090	II	Yes.
888.3570—Knee joint femoral (hemi-knee) metallic uncemented prosthesis	78N-3091	III	No.
888.3580—Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	78N-3092	II, III	Yes.
888.3590—Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	78N-3093	II	No.
888.3640—Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	78N-3094	III	Yes.
888.3650—Shoulder joint metal/polymer non-constrained cemented prosthesis	78N-3095	III	Yes.
888.3660—Shoulder joint metal/polymer semi-constrained cemented prosthesis	78N-3096	III	Yes.
888.3680—Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	78N-3058	III	Yes.
888.3690—Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	78N-3097	II	Yes.
888.3720—Toe joint polymer constrained prosthesis	78N-3099	II	Yes.
888.3730—Toe joint phalangeal (hemi-toe) polymer prosthesis	78N-3100	II	Yes.
888.3750—Wrist joint carpal lunate polymer prosthesis	78N-3101	II	Yes.
888.3760—Wrist joint carpal scaphoid polymer prosthesis	78N-3102	II	Yes.
888.3770—Wrist joint carpal trapezium polymer prosthesis	78N-3304	II	Yes.
888.3780—Wrist joint polymer constrained prosthesis	78N-3103	II	Yes.
888.3790—Wrist joint metal constrained cemented prosthesis	78N-3305	III	No.
888.3800—Wrist joint metal/polymer semi-constrained cemented prosthesis	78N-3104	II	No.
888.3810—Wrist joint ulnar (hemi-wrist) polymer prosthesis	78N-3105	II	Yes.
Subpart E—Surgical Devices			
888.4150—Calipers for clinical use	78N-3106	I	Yes.
888.4200—Cement dispenser	78N-3107	I	Yes.
888.4210—Cement mixer for clinical use	78N-3108	I	Yes.
888.4200—Cement monomer vapor evacuator	78N-3109	I	No.
888.4230—Cement ventilation tube	78N-3110	I	Yes.
888.4300—Depth gauge for clinical use	78N-3111	I	Yes.
888.4540—Orthopedic manual surgical instrument	78N-3114	I	Yes.
888.4580—Sonic surgical instrument and accessories/attachments	78N-3116	II	No.
888.4600—Protractor for clinical use	78N-3117	I	Yes.
888.4800—Template for clinical use	78N-3118	I	Yes.
888.5850—Nonpowered orthopedic traction apparatus and accessories	78N-3120	I	No.
888.5890—Noninvasive traction component	78N-3122	I	Yes.
888.5940—Cast component	78N-3123	I	No.
(888.5960)—AC-powered cast removal instrument [1]	78N-3124		Yes.
888.5980—Manual cast application and removal instrument	78N-3125	I	No.

[1] Classification postponed.
[2] Not proposed; statutory classification.

F. Changes in Classifications in Final Rule

Based upon consideration of the comments received and on additional information before the agency, FDA has placed the six devices listed below in different classes from those originally proposed:

Section and Device	Proposed class	Final class
888.3100—Ankle joint metal/composite semi-constrained cemented prosthesis	III	II
888.3340—Hip joint metal/composite semi-constrained prosthesis	III	II
888.3480—Knee joint femorotibial metallic constrained prosthesis	II	III
888.3490—Knee joint femorotibial metal/composite non-constrained cemented prosthesis	III	II
888.3500—Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	III	II
888.3550—Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	II	III

FDA's reasons for changing the classifications of these six devices are provided in this preamble under the heading "G. Summary of Comments on Classification and FDA's Responses" in paragraphs 14, 20, 25, 26, 27, and 29.

FDA believes that it is unnecessary to issue a new proposed rule concerning these decisions. The purpose of publishing a proposed regulation and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposed regulation or upon reconsideration, the agency may be persuaded that its proposed classification was incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed regulation on orthopedic devices (see 47 FR 29052). Persons who disagree with the final classification of a device may petition for reclassification of the device under number Subpart C of Part 860 (21 CFR Part 860).

G. Summary of Comments on Classification and FDA's Responses

FDA notes that it is required by section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) to classify a device intended to be implanted into class III, unless the agency determines that such class is unnecessary. After determining that classification of such a device into class III is unnecessary, in determining whether it should classify a device intended to be implanted into class II or class I, FDA believes that it should classify such a device into class II, unless the agency determines such class is unnecessary. Because of the risks to health presented by devices intended to be implanted, such as loss or reduction of limb function, adverse tissue reaction, immediate risk of infection, and long-term potential for increased risk of infection from the presence of a foreign body discussed in the proposed rule (47 FR 29054 at 29055 (Refs. 4 and 5)); FDA believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of any device intended to be implanted. Thus, FDA believes that establishment of a performance standard is necessary for any device intended to be implanted that the agency believes need not be in class III.

1. One comment asked that FDA explain its rationale for proposing to classify into class II a number of orthopedic implants with failure rates in excess of 20 percent, while proposing to classify into class III other such devices for which insufficient data are available to estimate their failure rates and, consequently, whose failure rates may be less than 20 percent.

FDA agrees that further explanation is needed. In accordance with section 513 of the act (21 U.S.C. 360c), FDA is classifying into class II orthopedic devices intended to be implanted for which sufficient evidence is available to (a) identify and assess the risks to health presented by the devices, (b) weigh the probable benefits to health from use of the devices against the probable risks from such use, (c) establish performance standards to provide reasonable assurance of the safety and effectiveness of the devices, and (d) determine that the general controls of class I alone are insufficient to provide such assurance. Implants for which such evidence is unavailable are being placed in class III, as required by section 513 of the act. Accordingly, consistent with the statutory standard, FDA proposed to classify into class III many orthopedic devices intended to be implanted because important information concerning their safety and effectiveness is not currently available.

To provide reasonable assurance of the safety and effectiveness of devices intended to be implanted, clinical studies of the devices should include periodic followup examinations of patients over a number of years. These periodic examinations should include taking X-rays of the implant to help determine whether the device is biocompatible. If long-term followup of patients receiving an implant has not been documented in the results of the clinical studies, or if such data are unavailable, FDA believes that the safety and effectiveness of the device have not been established. Thus, when the failure rate of a device intended to be implanted is unknown because of lack of followup data, FDA is classifying the device into class III. When such data become available, and if the data establish that the device has an acceptable failure rate, the device may be reclassified.

2. Comments argued that, for several reasons, FDA should classify into class I many of the devices intended to be implanted that it proposed be in class II or class III. FDA's responses to each of these arguments follow.

2a. Comments recommended that many devices intended to be implanted be classified into class I because, for those devices, the existence of a performance standard or the requirement of premarket approval would not improve the outcome for a patient who develops an infection following implantation of a device.

FDA agrees that the existence of a performance standard or the requirement of premarket approval would not change the result for a patient who develops an infection following implantation of the device, but disagrees that that is a valid reason for classifying the device into class I. Although performance standard requirements and premarket approval requirements will not eliminate all possibility of infection, these requirements will reduce the risk of infection and, therefore, FDA believes that these requirements are necessary to provide reasonable assurance of the safety and effectiveness of these devices.

2b. Comments recommended that FDA classify many devices intended to be implanted into class I in order to ensure their continued commercial availability.

FDA disagrees with the comments. The continued commercial availability of a device is not the major criterion to be considered by FDA when classifying devices. Classification decisions are based on the degree of regulatory control necessary to ensure the safety and effectiveness of the device. In any event, classification of a preamendments device into class II or class III has no immediate impact on the commercial availability of the device. For each device classified into class II or class III, FDA must publish an additional proposed and final regulation allowing further public comment before the agency may establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact."

2c. Comments requested that many devices intended to be implanted be classified into class I instead of class II as proposed, arguing that the Panel recommended that standards be established, not for the finished devices themselves, but rather for the materials intended for use in such devices.

FDA disagrees with the comments. As stated in the "Summary of the Reasons for Recommendations" for each of the regulations proposing that devices intended to be implanted be classified into class II, the Panel recommended and FDA proposed that performance standards be established that would apply both to the materials intended for use in the devices and to the finished devices themselves.

2d. Comments requested that many orthopedic devices intended to be implanted be classified into class I, arguing that the literature cited in the proposed rule did not support classification of these devices into class II or class III.

FDA disagrees with the comments. FDA based its proposed classification of each device primarily on the Panel's recommendation. Section 513(c)(2)(A) of the act requires that a Panel summarize the data upon which its recommendation is based. The legislative history of the amendments provides that the term "data" as used in that section has a special meaning. As used in section 513(c)(2)(A), "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or the judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94–853, 94th Cong., 2d Sess. 40 (1976)). FDA's proposed classifications, therefore, are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited medical literature. Furthermore, FDA believes that a lack of data in the literature regarding a device intended to be implanted, or a lack of clinical experience with the device, supports classifying the device into class II or class III, rather than class I. Moreover, the little literature available shows that such devices present risks to health that can be controlled only by requiring performance standards or premarket approval.

2e. Several comments argued that many orthopedic devices intended to be implanted should be classified into class I because no major health problems have been identified in FDA's device experience network or in manufacturers' complaint files for either the devices or the materials used in them.

FDA disagrees with the comments. FDA believes that the data in complaint files of manufacturers or the voluntarily submitted adverse experience reports in FDA's device experience network are not necessarily an accurate reflection of the number of adverse experiences with devices. Although FDA has published in the**Federal Registera** final rule requiring manufacturers and importers to report to FDA adverse experiences with devices (49 FR 36326; September 14, 1984), the rule does not apply to physicians who implant orthopedic devices. Consequently, FDA may not be informed of all adverse experiences with these devices. Further, FDA has identified risks to health presented by orthopedic devices intended to be implanted that support classifying the devices into class II or class III. As stated earlier, a lack of information about, or a lack of clinical experience with, a device intended to be implanted also supports classification of the device into class II or class III.

2f. Comments argued that FDA should classify many joint prostheses intended to be implanted into class I because little data exist showing a correlation between in vitro wear and strength measurements of the devices or the materials intended for use in them, and performance of the devices after they are implanted.

FDA agrees that little data are available showing a correlation between in vitro measurements of wear or strength of devices intended to be implanted, or materials used in them, and in vivo performance of such devices. FDA is not classifying any device intended to be implanted solely on the basis of the amount of in vitro wear and strength data available. However, as shown by the available data summarized in the proposed rule (Ref. 7; 47 FR 29052 at 29055), when wear debris produced by an orthopedic implant was injected into rats, tumorigenesis was observed among a significant proportion of the rats. Further, the fact that little data exists supports the concept that the increased level of control provided by classification into class II or class III is necessary. The fact that little in vitro wear and strength data exists certainly does not support classifying devices intended to be implanted into class I. Thus, FDA believes that it is necessary to classify joint prostheses into class II or class III in order to ensure that the level of wear debris produced by an orthopedic joint prosthesis is kept to a minimum by requiring in vitro wear and strength measurements of the devices before they are implanted. FDA believes that sufficient information exists for manufacturers to develop standard methods for in vitro measurements of wear or strength of joint prostheses and of materials intended for use in these devices. Further, FDA believes that the results of such comparative measurements of wear or measurements of other critical device attributes using standard test methods should be included in the labeling of the devices to assist the physician in selecting an appropriate device for a patient.

2g. Comments noted that FDA did not include in the proposed regulations the acceptance criteria for materials intended for use in components of devices intended to be implanted and did not identify which of the materials used in such devices the agency believed resulted in a lack of biocompatibility. For these reasons, comments suggested that many devices intended to be implanted be classified into class I.

FDA disagrees with the comments. FDA believes that it was unnecessary to include in the proposed classification regulations specific criteria for acceptance of materials intended for use in devices intended to be implanted or to identify specific materials used in such devices thar may not be biocompatible. The appropriate time to identify the materials to be used in these devices and to establish acceptance criteria for these materials is when FDA establishes performance standards for the devices or when manufacturers prepare applications for premarket approval of the devices. Certainly, the absence of this information does not support classifying these devices into class I, as these devices are intended to be implanted to fix living bone or replace a joint, uses which are of substantial importance in preventing impairment of human health. Moreover, section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) requires that FDA classify all implants into class III unless the agency determines that, for a particular implant, premarket approval is unnecessary to provide reasonable assurance of its safety and effectiveness. FDA believes that orthopedic devices intended to be implanted have not been implanted in a sufficient number of patients by a sufficient number of medical practitioners to provide adequate evidence on the long-term biocompatibility of these devices to permit these devices to be classified into class I. Consequently, FDA believes that insufficient evidence of safety and effectiveness is available at this time to support classifying any orthopedic device intended to be implanted into class I. The considerations discussed in this paragraph are also relevant to the comments described below in paragraphs 10, 14, 16, 17, 20, 22, 23, 26, 27, 29, 32, 35, 36, 37, 38, and 39.

3. One comment complained that public involvement in the classification of orthopedic devices was limited and that, as a result, FDA proposed to classify too many orthopedic devices in class II or class III.

FDA disagrees with the comment. During its classification deliberations, the Panel held public meetings and provided the public numerous opportunities to make presentations and submit data. Additionally, when FDA published its proposed rule classifying orthopedic devices, the agency provided 180 days for interested persons to comment on the proposed rule and included in the proposed rule a list of

500 references supporting its proposed classifications.

4. Comments said that mandatory performance standards are unnecessary for the orthopedic devices that FDA proposed to classify into class II that are subject to voluntary standards, arguing that the voluntary standards are adequate to control the documented risks.

FDA disagrees with the comments. Section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)) requires that performance standards be established under section 514 of the act (21 U.S.C. 360d) for each device classified into class II. In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a final policy statement regarding class II devices in which it identified the factors the agency will take into account in setting priorities for initiating proceedings to establish performance standards under section 514 of the act. See "B. FDA's Priorities for Establishing Performance Standards" at the beginning of this preamble. Among the factors FDA will consider is the existence of an adequate, adhered to voluntary standard. In the notice of October 23, 1985 (50 FR 43065) FDA stated "[u]nder the final policy, FDA will not conclude that an adequate, adhered to voluntary standard makes a performance standard under section 514 of the act unnecessary for a class II device. FDA does not believe nor does the legislative history suggest, however, that Congress intended that FDA could not consider the existence of adequate adhered to, voluntary standards in setting priorities for the initiation of proceedings under section 514 of the act."

5. Comments recommended that the labeling for joint prostheses devices intended to be implanted should be improved by including in the package insert the kinematic description of the device. The comments also recommended that a kinematic description of the device be included in the codified identification of the device.

FDA agrees that the labeling of a joint prosthesis device intended to be implanted should contain the kinematic description of the device. FDA also agrees that the classification regulation for each such device should be clarified by including a general kinematic description of the device. In the preamble to the proposed rule, FDA defined several terms used in the proposed names or identifications of joint prostheses devices intended to be implanted. To clarify further the names of such devices and their identifications, FDA is codifying certain definitions, § 888.5 *Resurfacing technique*, and § 888.6 *Degree of constraint*. One of the terms defined, i.e., degree of constraint, is a general kinematic description of the device.

6. Comments noted that the proposed names of many, but not all, prosthetic devices included information regarding: (a) The general kinds of materials used in the construction of the device (e.g., "metallic" or "polymer"), and (b) whether or not bone cement (§ 888.3027) is to be used during implantation of the device (e.g., use in the name and identification of the device of the term "cemented" or "uncemented"). The comments suggested that, for the sake of consistency, the names of all prosthetic devices should include this information.

FDA agrees with the comments that the names of the devices should be clarified. For the sake of consistency, therefore, in the final rule FDA is including in the name of each prosthetic device intended to be implanted information regarding the general kinds of materials used in the construction of the device and, where appropriate, whether or not bone cement (§ 888.3027) is intended to be used to implant the device.

7. One comment said that where the only risk to health cited by the Panel concerning a device was electrical shock or leakage current, FDA should classify the device into class I.

FDA tentatively agrees with the comment. FDA believes that two electrically powered orthopedic devices present only the risk of electrical shock or leakage current: AC-powered goniometer (§ 888.1500) and AC-powered cast removal instrument (§ 888.5960). Accordingly, FDA is postponing classification of these two devices pending review of additional data regarding electrical safety of devices. See the discussion under "D. Devices Not Being Classified at This Time" located earlier in this preamble.

8. Section 888.1100; Arthroscope; proposed class II.

a. Comments on the proposed regulation classifying this device argued that the device should be classified into class I instead of class II as proposed, because performance standards are not necessary to control the risks of electrical shock or leakage current presented by this device.

The agency tentatively agrees that AC-powered devices that present only the risk of electrical shock or leakage current should be considered for classification into class I. However, the arthroscope presents risks to health in addition to the risks of electrical shock and leakage current, i.e., the risks of infection and tissue trauma. The agency believes that establishment of a performance standard for this device is necessary to control these risks.

b. One comment on the proposed regulation classifying the arthroscope argued that the device should be classified into class I because it has a record of safe use. The comment submitted published reports (Studies 1 through 18) showing results of clinical experience with the device.

FDA concludes that the studies provided by the comments contain insufficient data on long-term followup for FDA to evaluate fully the safety and effectiveness of the arthroscope. As noted above, the device presents risks to health of infection and tissue trauma, risks which general controls alone would be insufficient to control. A performance standard would control the design, optical characteristics, size, shape, rigidity/flexibility, surface finish, materials used, and construction of the device to assure that it is capable of being sterilized properly and that it has sufficient strength to prevent tissue trauma from breakage of the device when it is inserted into a patient's joint. Accordingly, the agency believes that establishment of a performance standard for this device is necessary.

c. One comment urging the agency to classify this device into class I said that the labeling requirements of class I are sufficient to ensure proper use of the device by surgeons.

FDA agrees that adequate directions for use in the labeling of the device would generally ensure that the device is used properly by surgeons. However, the device is required to comply with the labeling requirements of class I, whether the device is classified into class I, class II, or class III. (See discussion at "N. Economic Impact.") FDA disagrees that adequate labeling would ensure that the device performs properly. Therefore, for the reasons provided in paragraph 8b above, FDA believes that establishment of a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device, and that sufficient information is available to establish such a standard. Accordingly, in this final rule FDA is adopting the proposed regulation classifying the arthroscope into class II with minor clarifying changes.

9. Comments on the proposed regulations classifying the devices listed below argued that these devices should be classified into class I instead of class II or class III as proposed because the risks to health cited in the proposed regulations either were not identified by the Panel or are not supported by the cited literature.

Section and Device

888.1100—Arthroscope
888.3010—Bone fixation cerclage
888.3020—Intramedullary fixation rod
888.3030—Single/multiple component metallic bone fixation appliances and accessories
888.3040—Smooth or threaded metallic bone fixation fastener
888.3050—Spinal interlaminal fixation orthosis
888.3060—Spinal intervertebral body fixation orthosis
888.3530—Knee joint femorotibial metal/polymer semi-constrained prosthesis
888.3540—Knee joint patellofemoral polymer/metal semi-constrained prosthesis
888.3560—Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis

FDA disagrees with the comments. FDA has re-reviewed the supplemental data sheets on which the Panel recorded information concerning the classification of the devices named above and the transcript of the Panel meeting during which classification of these devices was discussed. The risks to health that were listed in the proposed regulations accurately reflect the risks to health identified by the Panel for these devices. In addition, as stated in the proposed regulations, clinical experience and judgment also qualify as valid scientific evidence to support classification of a device. Thus, while many of the risks to health identified in the proposed regulations are, in fact, supported by the cited literature, it is unnecessary that every risk to health cited by the Panel be supported by the medical literature. Accordingly, FDA is adopting the proposed regulations classifying the devices listed above into class II or class III as proposed because performance standards or requirements of premarket approval are necessary to control the risks to health presented by these devices that were identified in the proposed regulations.

10. Section 888.3000; Bone cap; proposed class II.

Comments requested that this device be classified into class I instead of class II as proposed. The comments cited three published reports of preclinical and clinical experience with the device to support their requests (Studies 19, 20, and 21).

FDA disagrees with the comments. One of the studies (Study 19) reports on the use of the device in surgical procedures involving dogs. The other two studies (Studies 20 and 21) describe experimental use of the device and surgical technique for its implantation at one clinic. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the bone cap. FDA still believes that the device should be classified into class II because a performance standard is necessary to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, in order to prevent loss or reduction of limb function, adverse tissue reaction, or infection. FDA believes that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such a standard. Accordingly, FDA is adopting the proposed regulation classifying the bone cap into class II with minor clarifying changes.

11. Section 888.3050; Spinal interlaminal fixation orthosis; proposed class II.

a. Comments requested that this device be classified into class I instead of class II as proposed. In support of the request, the comments cited one published study that they claimed showed a low incidence of infections following implantation of the device (Study 22), and two published studies that they claimed showed a low incidence of adverse tissue reactions or fracture of a component of the device (Studies 23 and 24). The comments argued that all of the complications resulting from use of the device are related to surgical technique, and not to the safety and effectiveness of the device itself.

FDA disagrees with the comments. FDA disagrees that the studies cited by the comments support classifying this device in class I. One of the studies involved implantation of a different type of device in a part of the body other than the spine. In another study, the rate of adverse results could not be determined because the total numbers of patients and implanted devices were unknown. In the remaining study, the authors determined that the device components that fractured showed characteristics of fatigue fracture. FDA believes that performance standards are necessary to control the risks to health listed in the proposed regulation, i.e., adverse tissue reaction, infection, and paralysis. As with all surgically implanted devices, the surgical risks attendant upon implantation of the device must be considered along with the risks presented by the device itself in determining the total risks to health from the intended uses of the device.

b. One comment on the proposed regulation classifying the spinal interlaminal fixation orthosis into class II objected that the proposed regulation did not identify what specific material in the device might cause an adverse tissue reaction or infection, two of the risks to health identified by the Panel.

FDA agrees that it did not identify a specific material used in the device that may cause an adverse tissue reaction or infection. However, the proposed regulations do contain information on the risks of adverse tissue reaction or infection that may be caused by orthopedic implants in general (47 FR 29054).

Therefore, for the reasons stated in the preamble to the proposed rule, FDA believes that the spinal interlaminal fixation orthosis should be classified into class II and that sufficient information exists to establish performance standards for the device, including the telemetered data on stress forces placed on the device (Study 25) and studies concerning stress analysis of the rod component of the device (Study 26). FDA believes that establishing performance standards for the device will provide reasonable assurance of its safety and effectiveness. Accordingly, FDA is adopting the proposed regulation classifying the spinal interlaminal fixation orthosis into class II with minor clarifying changes.

12. Section 888.3060; Spinal intervertebral body fixation orthosis; proposed class II.

a. One comment urged FDA to classify this device into class I instead of class II as proposed, citing a published study that the comment claimed showed a low incidence of infections following implantation of the device (Study 22).

FDA disagrees with the comment. The data in Study 22 cannot be used to evaluate the safety and effectiveness of the spinal intervertebral body fixation orthosis. The spinal intervertebral body fixation orthosis is implanted as treatment for "sway back," scoliosis (lateral curvature of the spine), or other conditions. Study 22 describes clinical treatment of deep wound infections following total hip arthroplasty. Study 22, therefore, involves implantation of a different device in a part of the body other than the spine.

b. One comment indicated that the major risk to health from use of this device is failed fusion of the vertebrae following implantation of the device. The comment argued that, because this problem is caused by improper surgical technique, establishing performance standards for the device would not reduce the incidence of failed fusion and, therefore, that the device should be classified into class I instead of class II as proposed.

FDA disagrees with the comment. Although performance standards may not reduce the risk of failed fusion, they would reduce the risks of adverse tissue reaction, infection, and paralysis by controlling the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in the final rule FDA is adopting the proposed regulation classifying the spinal intervertebral body fixation orthosis into class II with minor clarifying changes.

13. FDA received comments suggesting that, to simplify the regulations, the three devices listed below should be combined into one generic type of device, identified as the single/multiple component metallic bone fixation appliances and accessories: Bone fixation cerclage (§ 888.3010), intramedullary fixation rod (§ 888.3020), and smooth or threaded bone fixation fastener (§ 888.3040).

FDA disagrees with the comments. Each of the devices listed above has different indications for use, has different functions, or presents different risks to health. Accordingly, FDA is adopting the proposed regulations on the devices listed above, with minor clarifying changes.

14. Section 888.3100; Ankle joint metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 27 through 33) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3110) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the ankle joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of the safety and effectiveness of the device. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device. However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the ankle joint metal/composite semi-constrained prosthesis. In addition, FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the ankle joint metal/composite semi-constrained prosthesis into class II, with minor clarifying changes.

15. Section 888.3150; Elbow joint constrained prosthesis; proposed class III.

a. A comment agreed that class III is appropriate for the elbow joint constrained prosthesis because the device has an unacceptably high failure rate due to the interaction between the two implanted metallic parts.

FDA agrees with the comment and is classifying the elbow joint constrained prosthesis into class III as proposed.

b. A comment noted that the identification of this device excluded the ultra-high molecular weight polyethylene (UHMWPE) component often used as a bushing or liner between the metallic humeral and ulnar components of the device.

FDA agrees with the comment. FDA's proposed identification of the device inadvertently failed to include the UHMWPE bushing that often is used in the elbow joint constrained prosthesis. FDA is modifying the identification of the device in the final rule to include this component.

c. A comment noted that, while the original versions of the elbow joint constrained metallic rigid hinge device had unacceptably high failure rates, many of the original devices either are no longer marketed or have been modified to provide less rigid restraint, thereby reducing the incidence of device loosening. These later, modified versions of the device consist of constrained, loose hinge, elbow joint prostheses with an UHMWPE bushing. The comment submitted six published studies (Studies 34 through 39) that it claimed show that five more recent, modified versions of the device (Volz, Tri-Axial, Mayo, Pritchard-Walker, and Coonrad) are safe and effective and should be classified into class II instead of class III as proposed.

FDA has reviewed the studies supplied by the comment and has concluded that they do not show that the more recent loose hinge versions of the elbow joint constrained prosthesis with or without a UHMWPE bushing have a significantly reduced overall rate of loosening compared to the earlier rigid hinge versions of this device. Also, as stated in the proposed regulation, the biomechanics of the elbow joint are not well understood (Refs. 144 and 145) and the amount of varus-valgus laxity in elbow joint constrained devices necessary to reduce the rate of loosening is currently unknown. FDA believes that premarket approval is necessary to ensure the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the elbow joint constrained prosthesis into class III with minor clarifying changes.

16. Section 888.3170; Elbow joint radial (hemi-elbow) prosthesis; proposed class II.

Comments on the elbow joint radial (hemi-elbow) prosthesis requested that the device be in class I rather than class II as proposed. To support the request, the comments submitted three studies (Studies 40, 51, and 52). In these studies, the practitioners implanting the device reported that the results were predictable and satisfactory, that the risks to health identified in the proposed regulation (loss or reduction of joint function, adverse tissue reaction, and infection) were essentially nonexistent, or occurred at low frequency rates, and thus these risks were not unreasonable risks requiring controls of regulatory performance standards.

FDA disagrees with the comments. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the elbow joint radial (hemi-elbow) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed

to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the elbow joint radial (hemi-elbow) prosthesis into class II with minor clarifying changes.

17. Section 888.3230; Finger joint polymer constrained prosthesis; proposed class II.

a. Comments suggested that this proposed generic type of device be split into three generic types: (1) Finger joint plastic/elastomer constrained uncemented prosthesis, (2) finger joint elastomer/polyester fiber composite constrained porous ingrowth prosthesis, and (3) finger joint elastomer constrained uncemented prosthesis. The comments said that FDA had proposed to group dissimilar devices into one generic type of device.

FDA disagrees with the comments. FDA recognizes that this proposed generic type of device includes devices of various designs, materials, and fixation techniques. Despite these variations, however, the devices encompassed within the proposed generic type of device do not differ significantly in purpose, design, materials, or function, or any other feature relating to safety or effectiveness (see the definition of generic type of device in 21 CFR 860.3(i)). FDA believes that the same regulatory controls are required to provide reasonable assurance of the safety and effectiveness of all the devices encompassed within this proposed generic type of device.

b. Some comments requested that the finger joint polymer constrained prosthesis be classified into class II instead of class II as proposed. These comments submitted eight published studies (Studies 42 through 49) and a letter from a medical practitioner to support their requests.

FDA disagrees with the comments. FDA's review of the additional data submitted by the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the finger joint polymer constrained prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish.

c. One comment suggested that the device be classified in class III instead of class II as proposed, claiming that a high percentage of complications occur from use of the device. No additional data on complication rates were provided by the comment.

FDA disagrees with the comment. FDA has no knowledge of a high complication rate from use of the device. Although the finger joint polymer constrained prosthesis is an implanted device, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. In addition, FDA had identified and assessed the major risks to health associated with the use of this device. FDA believes that the major risks, i.e., fracture, loosening, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of this device. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by the device. Accordingly, FDA is adopting the proposed regulation classifying the finger joint polymer constrained prosthesis into class II with minor clarifying changes.

18. Section 888.3300; Hip joint metal constrained prosthesis; proposed class III.

A comment stated that the proposed name of this device and its proposed identification are inconsistent with respect to the materials used in the device.

FDA agrees with the comment. Accordingly, fn the final rule, FDA has revised the identification of the device to remove reference to a polyethylene component.

19. Section 888.3310; Hip joint metal/polymer constrained prosthesis; proposed class III.

A comment argued that this device should not be classified because it is no longer commercially distributed.

FDA agrees that the device is not currently commercially distributed. This device was commercially distributed before the enactment date of the amendments. Accordingly, in the final rule FDA is adopting the proposed regulation classifying the hip joint metal/polymer constrained prosthesis into class III with minor clarifying changes.

20. Section 888.3340; Hip joint metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 33 and 53 through 57) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3350) that FDA proposed to classify in class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the hip joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of the safety and effectiveness of the device. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA also believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint metal/

composite semi-constrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the hip joint metal/composite semi-constrained prosthesis into class II with minor clarifying changes.

21. Section 888.3360; Hip joint femoral (hemi-hip) metallic prosthesis; proposed class II—Section 888.3400; Hip joint femoral (hemi-hip) resurfacing prosthesis; proposed class II.

Comments requested that these devices be classified into class I instead of class II as proposed. The comments argued that the mechanical properties of the devices, such as their strength and the resistance to wear of the materials used in them, should not be used as a basis for classifying the devices into class II.

FDA disagrees with the comments. FDA believes that the mechanical properties of the materials intended for use in implanted joint prostheses are important criteria to be considered in determining whether performance standards are necessary to ensure the safety and effectiveness of the devices. For example, if a material used to construct a joint prosthesis lacked strength or resistance to wear, particles of the material could break or wear off of the contact surfaces of the joint prosthesis within the patient's joint and cause pain and inflammation. Further, as shown by the data summarized in the proposal (Ref. 7; 47 FR 29052 at 29055), when wear debris produced by an orthopedic implant was injected into rats, tumorigenesis was observed among a significant proportion of the rats. FDA believes that sufficient information exists to develop standard methods for measuring strength and resistance to wear of joint prostheses and the materials intended for use in such devices. FDA believes that results of comparative, standardized in vitro measurements of wear or other critical device parameters should be included in the labeling of joint prostheses to assist the user in selecting an appropriate device for a patient. See also paragraphs 2f and 2g earlier in this preamble. FDA believes that the general controls of class I are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) metallic prosthesis and the hip joint femoral (hemi-hip) resurfacing prosthesis. FDA believes that performance standards are necessary to control the risks to health presented by these two devices and that sufficient information is available to develop performance standards that would provide reasonable assurance of their safety and effectiveness. Accordingly, FDA is adopting the proposed regulations classifying the two devices above into class II with minor clarifying changes.

22. Section 888.3360; Hip joint femoral (hemi-hip) metallic prosthesis; proposed class II.

A comment argued that the literature cited in the proposed rule contained no evidence that the design of the device contributed to its failure and, therefore, suggested that the device be in class I.

FDA disagrees with the comment. As discussed in paragraph 2d above, FDA's proposed classifications are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited literature. It is unnecessary, therefore, that all risks to health presented by a device be described in the medical literature. Moreover, Ref. 236, cited in the proposed rule, contains data showing that faulty design of the stem of the device did, indeed, contribute to its failure. Also, a comparative study of various designs of the device showed that different stem designs resulted in variations in yield strength (Study 58). FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) metallic prosthesis.

FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the hip joint femoral (hemi-hip) metallic prosthesis into class II with minor clarifying changes.

23. Section 888.3400; Hip joint femoral (hemi-hip) resurfacing prosthesis; proposed class II.

A comment argued that this device should be classified into class I because there is no evidence showing that failure of the device due to lack of strength is related to improper design of the device.

FDA disagrees with the comment. As discussed in paragraph 2d above, FDA's proposed classifications are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited literature. It is unnecessary, therefore, that every reason why a device may fail be documented in the medical literature. FDA believes that the device presents the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) resurfacing prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the hip joint femoral (hemi-hip) resurfacing prosthesis into class II with minor clarifying changes.

24. Section 888.3410; Hip joint metal/polymer semi-constrained resurfacing prosthesis; proposed class III.

Comments recommended that FDA classify this device into class II instead of class III as proposed, arguing that one of the risks to health identified in the proposed regulation, adverse tissue reaction, is only a hypothetical risk that has not been documented. The comments submitted additional data to support the request (Studies 59 through 61).

FDA disagrees with the comments. The references cited in the proposed rule (Refs. 9, 89, 241, 242, 243, 299, 341, 342, and 345 through 359) do, in fact, discuss adverse tissue reactions resulting from implantation of this device. In addition, the data supplied in the comments. show that the device continues to present the other risks to health described in the proposed regulation, i.e., loss or reduction of joint function and infection. FDA believes that there is insufficient information from which to conclude that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of this device. FDA believes that premarket approval is necessary to provide such assurance. Accordingly, FDA is adopting the proposed regulation classifying the hip joint metal/polymer semi-constrained resurfacing prosthesis

into class III with minor clarifying changes.

25. Section 888.3480; Knee joint femorotibial metallic constrained prosthesis; proposed class II—Section 888.3550; Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis; proposed class II.

Comments suggested that these devices be classified into class III instead of class II as proposed, because the literature FDA cited in the proposed regulation shows that a large volume of metallic particles are generated within the joint after implantation due to metal-to-metal contact between articulating components of the devices. The comments said that these metallic particles cause adverse effects in patients. Some of the comments noted that FDA proposed to classify into class III several other prostheses that had similar metal-to-metal articulation.

FDA agrees with the comments. Because of their design, these devices present a potential unreasonable risk of illness or injury. In addition, the devices are purported or represented to be for a use (implantation to replace a major joint) that is of substantial importance in preventing impairment of human health. Furthermore, the agency has determined that premarket approval is necessary for the devices because general controls and performance standards are insufficient to provide reasonable assurance of their safety and effectiveness. FDA also believes that there is insufficient information to establish a standard to provide such assurance. Accordingly, in this final rule, FDA is classifying both the knee joint femorotibial metallic constrained prosthesis and the knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis into class III with minor clarifying changes.

26. Section 888.3490; Knee joint femorotibial metal/composite non-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 33, 53, and 62 through 65) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3520) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the knee joint metal/composite non-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of its safety and effectiveness. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint femorotibial metal/composite nonconstrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the knee joint femorotibial metal/composite nonconstrained prosthesis into class II, with minor clarifying changes in the regulation.

27. Section 888.3500; Knee joint femorotibial metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed and submitted published and unpublished additional data (Studies 53, 62, 63, 66, and 67) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees with the recommendations of the comments that the device be classified in class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3530) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the knee joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of its safety and effectiveness. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint femorotibial metal/composite semi-constrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is classifying the knee joint femorotibial metal/composite semi-constrained prosthesis into class II, with minor clarifying changes in the regulation.

28. Section 888.3540; Knee joint patellofemoral polymer/metal semi-constrained prosthesis; proposed class III.

Comments requested that this device be classified into class I instead of class III as proposed, arguing that the risks to health identified in the proposed rule classifying this device, i.e., loss or reduction of joint function, adverse tissue reaction, and infection, occur very infrequently. The comments submitted a published study supporting their request (Study 68).

FDA disagrees with the comments. FDA believes that the data provided by the comments (Study 68), particularly the failure rate of the device as reflected by the number of revisions performed, show that insufficient information exists to determine that the general controls of class I or the establishment of performance standards would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the knee joint patellofemoral

polymer/metal semi-constrained prosthesis into class III with minor clarifying changes.

29. Section 888.3560; Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis; proposed class II.

Comments requested that this device be classified into class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation classifying this device, i.e., loss or reduction of joint or limb function, adverse tissue reaction, and infection, occur very infrequently. The comments submitted six studies in support of their requests (Studies 63 and 69 through 73).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis into class II with minor clarifying changes.

30. Section 888.3580; Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis; proposed class II.

a. One comment recommended that this device be classified into class III instead of class II as proposed, arguing that the device has metal to metal articulation which generates harmful metallic particles within the joint after implantation.

FDA disagrees with the comment. The device does not have metal to metal articulation, but rather is intended to articulate with intact hyaline cartilage within the femoral sulcus (groove). It is unlikely, therefore, that metallic wear debris would be generated and increase the failure rate of the device.

b. A comment recommended that the identification of this device not limit its use to treatment of degenerative and posttraumatic patellar (osteo) arthritis. The comment also suggested that FDA classify the device into class II for all intended uses, but did not furnish any additional data.

FDA disagrees with the comment. FDA proposed to classify the device into class II, when intended for treatment of degenerative and posttraumatic patellar arthritis, based on the recommendation of the Panel and FDA's review of the literature cited and summarized in the proposed rule. By limiting the proposed class II intended uses of the device to treatment of degenerative and posttraumatic patellar arthritis, FDA effectively proposed to classify the device into class III, when intended for other uses. FDA still believes that when intended for uses other than the treatment of degenerative and posttraumatic patellar arthritis, the device should be classified into class III, because there is no valid scientific evidence supporting its safety and effectiveness for such uses and section 513 of the act requires that FDA classify the device into class III when no data exists for the intended uses of the device.

Accordingly, for the reasons provided in the proposed rule, FDA is classifying the knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis into class II when intended for treatment of degenerative and posttraumatic patellar arthritis, and into class III when intended for other uses. FDA also is making clarifying changes in the codified language for the device.

31. Section 888.3640; Shoulder joint constrained prosthesis; proposed class III.

a. Comments recommended that this device be classified into class I instead of class III as proposed, arguing that the device has a high level of success and that the references FDA cited in the proposed regulation show that the device is safe and effective with only minimal complications.

FDA disagrees with the comments. The information reviewed by the Panel and summarized by FDA in the proposed regulation consisted of published data concerning implantation of the device in about 35 patients. The data reviewed by the Panel and FDA showed that 8 of the 35 patients (about 23 percent) did not achieve successful results. FDA also summarized in the proposed regulation 4 additional published studies (Refs. 447 through 450; 47 FR 29106) concerning this device in which a significant percentage of patients had adverse experiences following implantation of the device. FDA disagrees, therefore, that the references FDA cited in the proposed regulation for the shoulder joint constrained prosthesis show that the device is safe and effective with only minimal complications.

b. Comments requesting that the device be classified into class I instead of class III as proposed also argued that the device loosenings and fractures that were reported in oral presentations at the Panel meetings held in March and October of 1981 were not device-related, but rather were due to unusual stress placed on the device by the patient, such as that occurring as a result of falls, accidents, or fights.

FDA disagrees with the comments. Although one investigator at the Panel meeting did report that device loosening and fractures were associated with unusual stress, other investigators at that meeting reported loosening of the device in cases where unusual stress had not occurred. The evidence consisted of "loosening lines" at the juncture of the device and bone, shown by radiographic examination of the implanted device. Because of limited data available on both use of the device and followup of patients following its implantation, the Panel recommended that the device be classified into class III.

For the reasons provided in the proposed rule, FDA believes that the shoulder joint contrained prosthesis presents an unreasonable risk of illness or injury. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint constrained prosthesis into class III with minor clarifying changes.

32. Section 888.3650; Shoulder joint metal/polymer non-constrained prosthesis; proposed class III.

Comments requested that FDA classify this device into class I or class II instead of class III as proposed, arguing that no adverse effects from implanting the device were described in the proposed regulation. The comments submitted additional data to support their requests (Studies 74 and 75).

FDA disagrees with the comments. In the proposed regulation, FDA cited available literature on the device (47 FR 29106; Refs. 451 and 452) and identified several adverse effects following implantation of the device in a small number of patients, such as infection and dislocation requiring reoperation. Moreover, as the author of Study 74 concluded, the 3-year followup period of patients involved in that study was

insufficient to assess either wear or loosening of the components of the device. Study 75 does not distinguish the results obtained from implanting the shoulder joint metal/polymer non-constrained prosthesis from those obtained from implanting other generic types of shoulder joint prostheses. As a result, the data in Study 75 cannot be used to assess the safety and effectiveness of the shoulder joint metal/polymer non-constrained prosthesis. Accordingly, FDA believes that the data submitted by the comments and other data considered by FDA are insufficient to support classification of the shoulder joint metal/polymer non-constrained prosthesis into class I or class II. FDA believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint metal/polymer non-constrained prosthesis into class III with minor clarifying changes.

33. Section 888.3660; Shoulder joint semi-constrained prosthesis; proposed class III.

a. Comments requested that FDA classify this device into class I or class II instead of class III as proposed, arguing that the reference that FDA cited in the proposed regulation (Ref. 453) did not identify infection and lack of biocompatibility as risks to health presented by the device.

FDA disagrees with the comments. Ref. 453, which contains the results of the only study available on this device, shows that, of the 28 patients in whom the device was implanted, one patient developed an infection and the device dislocated in two patients. FDA believes that the data from this one study is insufficient evidence upon which to conclude that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device. FDA believes that premarket approval is necessary to provide such assurance. Further, as stated earlier in this preamble, FDA bases its classification decisions as much on the Panel members' experience and expert judgments as on the information in the medical literature. It is not necessary, therefore, that all risks to health presented by a device be described in the literature in order for FDA to classify the device into class III.

b. A comment noted that FDA incorrectly stated in the proposed rule that the Panel recommended that the labeling of the device include information on the dimensions, kinematics, and the strength and wear characteristics of the device.

FDA agrees that the Panel did not make the recommendation described above for this device, although FDA inadvertently stated that it did. This error, however, had no effect on the agency's decision to propose that the device be classified into class III or to recommend that the labeling of the device include information on the dimensions, kinematics, and strength and wear characteristics of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint semi-constrained prosthesis into class III with minor clarifying changes.

34. Section 888.3680; Shoulder joint glenoid (hemi-shoulder) prosthesis; proposed class III.

a. Comments said that FDA's proposed identification of this device was incorrect in limiting the device to components made only of alloys. The comments suggested that the identification be changed to include ultra-high molecular weight polyethylene (UHMWPE) in addition to alloys, arguing that the device made of alloys with UHMWPE is as safe and effective as the device made only with alloys.

FDA agrees with the comments. FDA agrees that, when made of alloys with UHMWPE, the device is as safe and effective as it is when made of alloys alone. In the final rule, therefore, FDA is changing the identification of the device to state that the device may be composed of UHMWPE with alloys.

b. Comments recommended that FDA classify this device into class I instead of class III as proposed, arguing that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the comments. Because the device is intended to be implanted in the human body, the act requires that it be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness. On the basis of the information currently available, FDA cannot make this determination for this device. Insufficient information exists to support the conclusion that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of this device. FDA believes that premarket approval is necessary to provide such assurance. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint glenoid (hemi-shoulder) prosthesis into class III with clarifying changes in the identification of the device.

35. Section 888.3720; Toe joint constrained uncemented prosthesis; proposed class II.

a. Comments suggested that this proposed generic type of device be split into the following three generic types of devices: toe joint elastomer unconstrained uncemented prosthesis, toe joint elastomer/polyester fiber composite constrained porous ingrowth prosthesis, and toe joint polymer/elastomer constrained uncemented prosthesis.

FDA disagrees with the comments. FDA recognizes that the proposed generic type of device encompasses devices of various designs, materials, and fixation techniques. However, despite these variations, devices subject to the regulation do not differ significantly in purpose, design, materials, function, or any other feature relating to safety or effectiveness (see the definition of generic type of device in 21 CFR 860.3(i)). In addition, FDA believes that the same regulatory controls are required to provide reasonable assurance of the safety and effectiveness of all the devices encompassed within the proposed generic type of device.

b. Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health of adverse tissue reaction and infection occur very infrequently. These comments provided additional data to support their requests (Studies 76 through 79).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of intection, and also the long-term potential for infection from an implant. FDA believes that the general controls of Class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the toe joint constrained uncemented prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material

composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the toe joint constrained uncemented prosthesis into class II with minor clarifying changes.

36. Section 888.3730; Toe joint phalangeal (hemi-toe) prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health of adverse tissue reaction and infection occur very infrequently. These comments submitted additional data to support their requests (Studies 77 and 80).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the toe joint phalangeal (hemi-toe) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the toe joint phalangeal prosthesis into class II with minor clarifying changes.

37. Section 888.3770; Wrist joint carpal trapezium prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health cited in the proposed rule occur very infrequently. These comments provided additional data to support their requests (Study 81). One of the studies submitted by the comments (Study 82), was summarized by FDA in the proposal and identified as Ref. 486 (47 FR 29052 at 29113).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint carpal trapezium prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint carpal trapezium prosthesis into class II with minor clarifying changes.

38. Section 888.3780; Wrist joint polymer constrained uncemented prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation occur very infrequently. The comments provided additional data to support their requests (Studies 83 through 85).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint polymer constrained uncemented prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint polymer constrained uncemented prosthesis into class II with minor clarifying changes.

39. Section 888.3810; Wrist joint ulnar (hemi-wrist) prosthesis; proposed class II.

Comments requested that FDA classify this device in class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation occur very infrequently. The comments provided additional data to support their requests (Studies 87 and 88). One of the studies submitted by the comments (Study 86), was summarized by FDA in the proposal and identified as Ref. 500 (47 FR 29052 at 29117).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint ulnar (hemi-wrist) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device, and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint ulnar (hemi-wrist) prosthesis into class II with minor clarifying changes.

H. Exemptions for Class I Orthopedic Devices

Exemptions From Current Good Manufacturing Practices (CGMP) Requirements

Although FDA proposed to grant exemptions from most CGMP requirements for the nonpowered dynamometer (§ 888.1250) and the nonpowered goniometer (§ 888.1520), in this final rule FDA is classifying each of the two devices into class I without such

an exemption. FDA now believes that in order to control the risks to health that may result from incorrect measurement of a patient's muscle strength (§ 888.1250) or incorrect measurement of the range of motion of a patient's joints (§ 888.1520) due to device defects caused by inadequate manufacturing practices, each of the devices should be subject to all of the requirements of the CGMP regulations for noncritical devices.

Exemptions From Requirement of Premarket Notification

FDA proposed to exempt eight class I orthopedic devices from the requirement of premarket notification. In this final rule, FDA is exempting the eight devices from the premarket notification procedures; however, the exemption for the orthopedic manual surgical instrument (§ 888.4540) is limited and will apply only to those devices made of the same materials that were used in the device before May 28, 1976.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule proposing to exempt from the requirement of premarket notification, or exempt with limitations, seven orthopedic devices being classified into class I in this final rule.

I. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel name and Publication Date in "Federal Register"

Circulatory System Devices Panel—March 9, 1979, 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations)

Clinical Chemistry and Clinical Toxicology Devices Panel—February 2, 1982, 47 FR 4802–4929 (proposals)

Hematology and Pathology Devices Panel—September 11, 1979, 44 FR 53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations)

General Hospital and Personal Use Devices Panel—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations)

Gastroenterology-Urology Devices Panel—January 23, 1981, 46 FR 7562–7641 (proposals); November 23, 1983, 48 FR 53012–53029 (final regulations)

Immunology Devices Panel—April 22, 1980, 45 FR 27204–27359 (proposals); November 9, 1982, 47 FR 50814–50840 (final regulations)

Microbiology Devices Panel—April 22, 1980, 45 FR 27204–27359 (proposals); November 9, 1982, 47 FR 50814–50840 (final regulations)

Obstetrics-Gynecology Devices Panel—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations)

Radiologic Devices Panel—January 29, 1982, 47 FR 4406–4451 (proposals)

Ophthalmic Devices Panel—January 26, 1982, 47 FR 3694–3749 (proposals)

Ear, Nose, and Throat Devices Panel—January 22, 1982, 47 FR 3280–3325 (proposals); November 6, 1986, 51 FR 40378–40393 (final regulations)

Dental Devices Panel—December 30, 1980, 45 FR 85962–86168 (proposals)

Anesthesiology and Respiratory Therapy Devices Panel—November 2, 1979, 44 FR 63292–63426 (proposals); July 16, 1982, 47 FR 31130–31150 (final regulations)

Neurological Devices Panel—November 23, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations)

Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices)—August 28, 1979, 44 FR 50458–50537 (proposals); November 23, 1983, 48 FR 53032–53054 (final regulations)

Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices)—July 2, 1982, 47 FR 29052–29140 (proposals); September 4, 1987 (final regulations)

General and Plastic Surgery Devices Panel—January 19, 1982, 47 FR 2810–2853 (proposals)

J. Minor Changes or Clarifications

Occasionally the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Additionally, the agency is adding new sections in Subpart A to explain the various effective dates for premarket approval requirements for devices classified into class III and to define various terms used in the names and identifications of orthopedic devices. FDA also is adding new paragraph (c) in the classification regulation for devices classified into class III to declare, where applicable, the effective date of premarket approval requirements for the device.

K. Transitional Devices

The amendments include transitional provisions applicable to devices intended for human use that were declared to be drugs before enactment of the amendments. (See section 520(l)(1) of the act (21 U.S.C. 360j(l)(1).) The transitional provisions assure that devices formerly regarded as drugs continue to be subject to appropriate regulatory controls as the amendments are being implemented. Thus, a device previously considered a drug is classified into class III unless the agency in response to a petition has reclassified it into class I or class II.

FDA is including in this final rule sections codifying the statutory classification into class III of the following two commercially distributed, transitional orthopedic devices: bone heterograft (§ 888.3015) and polymethylmethacrylate (PMMA) bone cement (§ 888.3027).

L. Studies Submitted by Comments

Some comments submitted copies of clinical studies to support their requests for changes in the classification of certain devices. These studies are available in the Dockets Management Branch and may be seen by interested persons between 9:00 a.m. and 4:00 p.m., Monday through Friday.

1. Axon, A.T.R., et al., "Disinfection in Upper-digestive-tract Endoscopy in Britain," *Lancet*, pp. 1093–1094, 1981.

2. Dandy, D.J., and R.W. Jackson, "The Impact of Arthroscopy on the Management of Disorders of the Knee," *Journal of Bone and Joint Surgery* (British Volume), 57–B:346–348, 1975.

3. Fiddian, N.J., and H. Poirier, "The Morbidity of Arthroscopy of the Knee," *Journal of Bone and Joint Surgery* (British Volume), 63–B:630, 1981.

4. Fraider, C.T., "Arthroscopic Surgery of the Knee: History and State of the Art," *Journal of American Osteopathic Association*, 80:817–822, 1981.

5. Henderson, C.E., and C.N. Hopson, "Pneumoscrotum as a Complication of Arthroscopy," *Journal of Bone and Joint Surgery* (American Volume), 64–A:1238–1240, 1982.

6. Ikeuchi, H., "Arthroscopic Treatment of the Discoid Lateral Meniscus, Technique and Long-term Results," *Clinical Orthopaedics and Related Research*, 167:19–28, 1982.

7. Jackson, R.W., "Current Concepts Review, Arthroscopic Surgery," Accepted by: *Journal of Bone and Joint Surgery*.

8. Jackson, R.W., and I. Abe, "The Role of Arthroscopy in the Management of Disorders of the Knee. An Analysis of 2000 Consecutive Examinations," *Journal of Bone and Joint Surgery*, 54–B:310–322, 1972.

9. Johnson, L.L., "Diagnostic and Surgical Arthroscopy. The Knee and other Joints," 2d Ed., C.V. Mosby, St. Louis, 1981. (Sterilization and disinfection, pp. 22–24; care of instruments between patients, p. 41; complications, pp. 58–60; intra-articular shaver, pp. 217–221; surgical equipment and instruments, pp. 221–240.)

10. Johnson, L.L., et al., "A Cold Sterilization Method for Arthroscopes Using Activated Dialdehyde," *Orthopedic Review*, 6:75–77, 1977.

11. Johnson, L.L., et al., "Two Percent Glutaraldehyde: A Disinfectant in Arthroscopy and Arthroscopic Surgery," *Journal of Bone and Joint Surgery* (American Volume), 64–A:237–239, 1982.

12. Lindenbaum, B.L., "Complications of Knee Joint Arthroscopy," *Clinical Orthopaedics and Related Research*, 160:158, 1981.

13. Lysholm, J., et al., "Arthroscopy in the Early Diagnosis of Injuries to the Knee Joint," *Acta Orthopaedica Scandinavica*, 52:111–118, 1981.

14. Mulhollan, J.S., "Complications of Arthroscopic Surgery," Presentation, International Arthroscopy Association Course on Surgery of the Knee, Bermuda, 1981.

15. O'Connor, R.L., "Arthroscopy," J.B. Lippincott Co., Philadelphia, 1977. (Incandescent lamp, pp. 2, 4–5; cleaning and sterilization, pp. 10–13; indications, pp. 14–15; contraindications, p. 20; complications, pp. 20–22.)

16. Perry, G.B., and R.A. Moyer, "Arthroscopic Instrument Breakage. Expedient Method for Retrieving Metal Fragments," *Orthopedic Review*, 11:141–142, 1982.

17. Schonholtz, G.J., "Arthroscopy and Arthroscopic Surgery," *Maryland State Medical Journal*, 56–59, 1981.

18. Whipple, T.L., and F. Bassett, "Arthroscopic Examination of the Knee. Polypuncture Technique with Percutaneous Intra-articular Manipulation," *Journal of Bone and Joint Surgery*, 60–A:444–453, 1978.

19. Swanson, A.B., "Improving the End Bearing Characteristics of Lower Extremity Amputation Stumps—A Preliminary Report," *Inter-Clinic Information Bulletin*, 5(5):1–7, 1966.

20. Swanson, A.B., "Bone Overgrowth in the Juvenile Amputee and its Control by the Use of Silicone Rubber Implants," *Inter-Clinic Information Bulletin*, 8(5):9–18, 1969.

21. Swanson, A.B., "Silicone-Rubber Implants to Control the Overgrowth Phenomenon in the Juvenile Amputee," *Inter-Clinic Information Bulletin*, 11(9):5–8, 1972.

22. Murray, W.R., "Treatment of Deep Wound Infection After Total Hip Arthroplasty," *in* "American Academy of Orthopedic Surgeons Symposium on Osteoarthritis," C.V. Mosby Co., St. Louis, 1976.

23. MacEwen, C.D., W.P. Bunnell, and K. Sriram, "Acute Neurological Complications in the Treatment of Scoliosis. A Report of the Scoliosis Research Society," *Journal of Bone and Joint Surgery* (American Volume), 57–A:404–408, April 1975.

24. Erwin, W.D., J.H. Dickson, and P.R. Harrington, "Clinical Review of Patients with Broken HARRINGTON® Rods," *Journal of Bone and Joint Surgery* (American Volume), 62–A:1302–1307, December 1980.

25. Machemson, A., and C. Elfstroem, "Intravital Wireless Telemetry of Axial Forces in Harrington Distraction Rods in Patients with Idiopathic Scolisis," *Journal of Bone and Joint Surgery* (American Volume), 53–A:445–465, April 1971.

26. Sinclair, C.B., and C.A. Lubon, "Design of a Lifelong Harrington Rod," *Journal of Biomedical Engineering*, 4(2):133–136, April 1982.

27. Groth, H.E., "Oregon Total Ankle—A Clinical Report," unpublished report.

28. Groth, H.E., and J.M. Shilling, "Tissue Responses to Carbon-Reinforced Polyethylene," *Journal of Orthopedic Research*, 1:129–135, 1983.

29. Groth, H.E., et al., "Postmortem Analysis of Carbon-Fiber Reinforced UHMWPE Prostheses Retrieved from a Single Subject After a Service Life of 12 to 15 Months," Transactions of the Orthopedic Research Society, February 21–23, 1978.

30. Segal, N.M. and R.N. Stauffer, "Mayo Clinic Ankle Arthroplasty: Four Years Experience," Transactions of the Orthopedic Research Society, February 21–23, 1978.

31. Samuelson, K.M., "ICLW Ankle Arthroplasty," Transactions of the Orthopedic Research Society, February 21–23, 1978.

32. Groth, H.E., "The Oregon Ankle—A Review of Forty-one Cases," Transactions of the Orthopedic Research Society, February 21–23, 1978.

33. Farling, G.M. and K. Greer, "An Improved Bearing Material for Joint Replacement Prostheses: Carbon Fibre-reinforced Ultra High Molecular Weight Polyethylene," *in* "Mechanical Properties of Biomaterials," Edited by Hastings, G.W. and D.F. Williams, John Wiley and Sons, Ltd., pp. 53–64, 1980.

34. Coonrad, R.W., "History of Total Elbow Arthroplasty," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

35. Volz, R.G., "Development and Clinical Analysis of a New Semi-constrained Total Elbow Prosthesis," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

36. Inglis, A.E., "Tri-Axial Total Elbow Replacement: Indications, Surgical Technique, and Results," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

37. Morrey, B.F., et al., "Total Elbow Arthroplasty: A Five-Year Experience at the Mayo Clinic," *Journal of Bone and Joint Surgery*, 63–A:1050–1063, 1981.

38. Coonrad, R.W., "Seven-Year Follow-up of Coonrad Total Elbow Replacement," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

39. Dryer, R.F., J.A. Buckwalter, and R.L. Sprague, "Hinged Total Elbow Replacement," *Orthopedics*, 4(7):763–768, 1981.

40. Swanson, A.B., et al., "Comminuted Fractures of the Radial Head," *Journal of Bone and Joint Surgery*, 68(4):1039–1049, 1981.

41. Madden, J.W., letter to the Food and Drug Administration, December 28, 1982.

42. Swanson, J.W., and J.E. Lebeau, "The Effect of Implantation on the Physical Properties of Silicone Rubber," *Journal of Biomedical Materials Research*, 8:357–367, 1974.

43. Swanson, A.B., et al., "Durability of Silicone Implants—An In Vivo Study," *Orthopedic Clinics of North America*, 4(4):1097–1112, 1973.

44. Madden, J.W., et al., "A Rational Postoperative Management Program for Metacarpophalangeal Joint Implant Arthroplasty," *Journal of Hand Surgery*, 2(5):358–366, 1977.

45. Frisch, E.E., "Medical Grade High Performance Silicone Elastomer," First International Symposium, Frontiers of Biomedical Polymers, University of Akron, Akron, OH, June 2–3, 1981.

46. Swanson, A.B., "Implant Arthroplasty in the Hand and Upper Extremity and Its Future," *Surgical Clinics of North America*, 61(2):369–382, 1981.

47. Swanson, A.B., "Flexible Implant Arthroplasty for Arthritic Finger Joints," *Journal of Bone and Joint Surgery*, 54–A(3):435–456, 1972.

48. Swanson, A.B., and G. Swanson, "Joint Replacement in the Rheumatoid Metacarpophalangeal Joint," *in* "American Academy of Orthopedic Surgeons Symposium on Total Joint Replacement of the Upper Extremity," Edited by A.E. Inglis, The C.V. Mosby Company, St. Louis, pp. 238–254, 1982.

49. Swanson, A.B., et al., "Silicone Implants in Dogs—A Ten Year Histopathological Study," unpublished paper.

50. Swanson, A.B., et al., "Bone Remodeling Phenomena in Flexible (Silicone) Implant Arthroplasty in the Metacarpophalangeal Joints—Long Term Study," Kappa Delta Award Presentation, 49th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, January, 21, 1982.

51. Swanson, A.B., letter to the Food and Drug Administration, December 26, 1982.

52. Madden, J.W., letter to the Food and Drug Administration, December 28, 1982.

53. Rae, T. and M. Rushton, "The Biocompatibility of Carbon Fibers, High Density Polyethylene and the Resultant Composite Material," *in* "International Symposium on Biomaterials," Durham, England, pp. 23–28, 1982.

54. Hess, W.E., "Mueller-Type Hip with Poly-Two™ Acetabular Component: A Clinical Evaluation," unpublished report.

55. Dobbs, H.S., "Survivorship of Total Hip Replacements," *Journal of Bone and Joint Surgery*, 62–B(2):168, 1980.

56. Stauffer, R., "Ten-Year Follow-Up Study of Total Hip Replacement," *Journal of Bone and Joint Surgery*, 64–A(7):983, 1982.

57. Sutherland, C., "Ten-Year Follow-Up of One Hundred Consecutive Mueller Curved-Stem Total Hip Replacement Arthroplasties," *Journal of Bone and Joint Surgery*, 64–A(7):970, 1982.

58. Reuban, J.D., et al., "Comparative Mechanical Properties of Forty-Five Total Hip Stems," *Clinical Orthopaedics and Related Research*, 141:55–65, 1979.

59. Dutton, R.O., et al., "Tharies Surface Replacement for Osteonecrosis of the Femoral Head," *Journal of Bone and Joint Surgery*, 64–A:1225–1237, 1982.

60. Amstutz, H.C., "Recent Advances in Total Hip Resurfacing," unpublished manuscript.

61. Amstutz, H.C., "Total Hip Resurfacing: An Endangered Species with a Future," *Orthopedic Survey*, 5(2):123–127, 1981.

62. Wright, T.M., T. Fukubayashi, and A.H. Burstein, "The Effect of Carbon Fibre Reinforcement on Contact Area, Contact Pressure, and Time-Dependent Deformation in Polyethylene Tibial Components," *Journal of Biomedical Materials Research*, 15:719–730, 1981.

63. Salvati, E.A., et al., "Infection Rates After 3175 Total Hip and Total Knee Replacements Performed With and Without a Horizontal Unidirectional Filtered Air-Flow System," *Journal of Bone and Joint Surgery*, 64–A(4):525–535, 1982.

64. Shetly, H.R., "*In Vivo* Wear Performance of Poly-Two® Plateaus in Cloutier™ I Total Knee Tibial Components," unpublished technical report.
65. Cloutier, J., "Cloutier II Total Knee; A Clinical Evaluation," unpublished report.
66. Zimmer, USA, internal report.
67. Cracchiolo, A., et al., "A Prospective Comparative Clinical Analysis of the First Generation Knee Replacement: Polycentric vs. Geometric Knee Arthroplasty," *Clinical Orthopaedics and Related Research*, 145:37–46, 1979.
68. Blazina, M.E., et al., "Patellofemoral Replacement," *Clinical Orthopaedics and Related Research*, 0(144):98–102, 1979.
69. Mallory, T.H., D. Smalley, and J. Danyi, "Townley Anatomic Total Knee Arthroplasty Using Total Tibial Components with Crucial Release," *Clinical Orthopaedics and Related Research*, 0(169):197–201, 1982.
70. Kettelkamp, D.B., "Knee Implants: Review of Current Status," *Journal of Continuing Education in Orthopedics*, 21–29, 1978.
71. Flynn, L.M., "Experiences with U.C.I. Total Knee," *Clinical Orthopaedics and Related Research*, 0(135):188–191, 1978.
72. Lacey, J.A., "A Statistical Review of 100 Consecutive 'U.C.I.' Low Friction Knee Arthroplastics with Analysis of Results," *Clinical Orthopaedics and Related Research*, 0(132):163–166, 1978.
73. Accardo, N.J., et al., "Moiles Total Knee Replacement Procedure," *Orthopedics*, 2(1):37–45, 1979.
74. Neer, C.S., K.C. Watson, and F.J. Stanton, "Recent Experience in Total Shoulder Replacement," *Journal of Bone and Joint Surgery*, 64–A:310–337, 1982.
75. Clayton, M.L., D.C. Ferlic, and P.D. Jeffers, "Prosthetic Arthroplasties of the Shoulder," *Clinical Orthopedics*, 164:184–191, 1982.
76. Cracchiolo, A., A.B. Swanson, and G. Swanson, "The Arthritic Great Toe Metatarsophalangeal Joint: A Review of Flexible Silicone Implant Arthroplasy from Two Medical Centers," *Clinical Orthopaedics and Related Research*, 157:64–69, 1981.
77. Swanson, A.B., R.M. Lunsden, and G. Swanson, "Silicone Implant Arthroplasty of the Great Toe: A Review of Single Stem and Flexible Hinge Implants," *Clinical Orthopaedics and Related Research*, 142:30–43, 1979.
78. Kampner, S.L., "Total Joint Replacement in Bunion Surgery," *Orthopedic Surgery*, 2(4):215–216, 1979.
79. Gudmundsson, G., and K. Robertsson, "Silastic Arthroplasty of the First Metatarsophalangeal Joint," *Acta Orthopaedica Scandinavica*, 51:575–578, 1980.
80. Molster, A.O., O.D. Lunde, and M. Rait, "Hallux Rigidus Treated with the Swanson Silastic Hemi-Joint Prosthesis," unpublished paper.
81. Swanson, A.B., G. Swanson, and J.J. Watermeier, "Trapezium Implant Arthroplasty," *Journal of Hand Surgery*, 6(2):125–1414, 1981.
82. Swanson, A.B., "Disabling Arthritis at the Base of the Thumb," *Journal of Bone and Joint Surgery*, 54–A(3):456–471, 1972.
83. Goodman, M.J., et al., "Arthroplasty of the Rheumatoid Wrist with Silicone Rubber: An Early Education," *Journal of Hand Surgery*, 5(2):114–121, 1980.
84. Swanson, A.B., and G. Swanson, "Flexible Implant Arthroplasty of the Radiocarpal Joint: Surgical Technique and Long Term Results," American Academy of Orthopedic Surgeons Symposium on Total Joint Replacement of the Upper Extremities, Edited by A. Inglis, C.V. Mosby Co., St. Louis, 1982.
85. Swanson, A.B., "Flexible Implant Arthroplasty for Arthritic Disabilities of the Radiocarpal Joint," *Orthopedic Clinics of North America*, 4(2):383–394, 1973.
86. Swanson, A.B., "Implant Arthroplasty for Disabilities of the Distal Radioulnar Joint," *Orthopedic Clinics of North America*, 4(2):373–382, 1973.
87. Swanson, A.B., A. Pareinel, and J.H. Herndon, "Long Term Follow-up on Implant Arthroplasty of the Distal Radioulnar Joint—An X-Ray and Clinical Study," Orthopedic Transactions, *Journal of Bone and Joint Surgery*, 1(1):111–112, 1977.
88. Swanson, A.B., and G.R. Chambers, "Ulnar Head Implant Resection Arthroplasty for Disabilities of the Distal Radio-Ulnar Joint—Long Term Results," Orthopedic Transactions, *Journal of Bone and Joint Surgery*, 5(1):115, 1981.

M. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

N. Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into Class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. Similarly, devices classified into Class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into Class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into Class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects in 21 CFR Part 888

Orthopedic devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 888, to read as follows:

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.
888.1 Scope.
888.3 Effective dates of requirement for premarket approval.
888.5 Resurfacing technique.
888.6 Degree of constraint.

Subpart B—Diagnostic Devices

888.1100 Arthroscope.
888.1240 AC-powered dynamometer.
888.1250 Nonpowered dynamometer.
888.1520 Nonpowered goniometer.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3015 Bone heterograft.
888.3020 Intramedullary fixation rod.
888.3025 Passive tendon prosthesis.
888.3027 Polymethylmethacrylate (PMMA) bone cement.
888.3030 Single/multiple component metallic bone fixation appliances and accessories.
888.3040 Smooth or threaded metallic bone fixation fastener.
888.3050 Spinal interlaminal fixation orthosis.
888.3060 Spinal intervertebral body fixation orthosis.
888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.
888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.
888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.
888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.
888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.
888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.
888.3200 Finger joint metal/metal constrained uncemented prosthesis.
888.3210 Finger joint metal/metal constrained cemented prosthesis.
888.3220 Finger joint metal/polymer constrained cemented prosthesis.
888.3230 Finger joint polymer constrained prosthesis.
888.3300 Hip joint metal constrained cemented or uncemented prosthesis.
888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.
888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.
888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.
888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.
888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.
888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.
888.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis.
888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.
888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.
888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.
888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.
888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.
888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.
888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.
888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.
888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.
888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.
888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.
888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
888.3720 Toe joint polymer constrained prosthesis.
888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.
888.3750 Wrist joint carpal lunate polymer prosthesis.
888.3760 Wrist joint carpal scaphoid polymer prosthesis.
888.3770 Wrist joint carpal trapezium polymer prosthesis.
888.3780 Wrist joint polymer constrained prosthesis.
888.3790 Wrist joint metal constrained cemented prosthesis.
888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.
888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

Subpart E—Surgical Devices

Sec.
888.4150 Calipers for clinical use.
888.4200 Cement dispenser.
888.4210 Cement mixer for clinical use.
888.4220 Cement monomer vapor evacuator.
888.4230 Cement ventilation tube.
888.4300 Depth gauge for clinical use.
888.4540 Orthopedic manual surgical instrument.
888.4580 Sonic surgical instrument and accessories/attachments.
888.4600 Protractor for clinical use.
888.4800 Template for clinical use.
888.5850 Nonpowered orthopedic traction apparatus and accessories.
888.5890 Noninvasive traction component.
888.5940 Cast component.
888.5980 Manual cast application and removal instrument.

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgical device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 888.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket

approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 888.5 Resurfacing technique.

Because of resurfacing techniques, certain joint prostheses require far less bone resection than other devices intended to repair or replace the same joint. The amount of bone resection may or may not affect the safety and effectiveness of the implantation of the prosthesis. When a resurfacing technique is used, the name of the prosthesis includes this information.

§ 888.6 Degree of constraint.

Certain joint prostheses provide more constraint of joint movement than others. FDA believes that the degree of constraint is an important factor affecting the safety and effectiveness of orthopedic prostheses. FDA is defining the following standard terms for categorizing the degree of constraint.

(a) A "constrained" joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

(b) A "semi-constrained" joint prosthesis is used for partial or total joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

(c) A "non-constrained" joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

Subpart B—Diagnostic Devices

§ 888.1100 Arthroscope.

(a) *Identification.* An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

(b) *Classification.* Class II.

§ 888.1240 AC-powered dynamometer.

(a) *Identification.* An AC-powered dynamometer is an AC-powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

(b) *Classification.* Class II.

§ 888.1250 Nonpowered dynamometer.

(a) *Identification.* A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.1520 Nonpowered goniometer.

(a) *Identification.* A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

§ 888.3000 Bone cap.

(a) *Identification.* A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) *Classification.* Class II.

§ 888.3010 Bone fixation cerclage.

(a) *Identification.* A bone fixation cerclage is a device intended to be implanted that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. The device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

(b) *Classification.* Class II.

§ 888.3015 Bone heterograft.

(a) *Identification.* Bone heterograft is a device intended to be implanted that is made from mature (adult) bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 888.3.

§ 888.3020 Intramedullary fixation rod.

(a) *Identification.* An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

(b) *Classification.* Class II.

§ 888.3025 Passive tendon prosthesis.

(a) *Identification.* A passive tendon prosthesis is a device intended to be implanted made of silicon elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

(b) *Classification.* Class II.

§ 888.3027 Polymethylmethacrylate (PMMA) bone cement.

(a) *Identification.* Polymethylmethacrylate (PMMA) bone cement (luting agent) is a device intended to be implanted that is made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid or copolymers containing polymethylmethyacrylate and polystyrene. The device is intended

for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to the living bone.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 888.3.

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3050 Spinal interlaminal fixation orthosis.

(a) *Identification.* A spinal interlaminal fixation orthosis is a device intended to be implanted made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) *Classification.* Class II.

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification.* A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification.* Class II.

§ 888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation: in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys with a ultra-high molecular weight polyethylene bushing, and used to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt chromium-molybdenum, and a radial resurfacing component made of ultra-

high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

(a) *Identification.* An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.

(b) *Classification.* Class II.

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

(a) *Identification.* An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or protheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3210 Finger joint metal/metal constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3220 Finger joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3230 Finger joint polymer constrained prosthesis.

(a) *Identification.* A finger joint polymer constrained prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination pf polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve.

(b) *Classification.* Class II.

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have components made of alloys, such as cobalt-chromium-molybdenum, and is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and

an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene with carbon fibers composite. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with bone cement (§ 888.3027) as well as designs which have large window-like holes in the stem of the device and which are intended for use without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) *Classification.* Class II.

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

(a) *Identification.* A hip joint (hemi-hip) acetabular metal cemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis is intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with bone cement (§ 888.3027) or implanted by impaction.

(b) *Classification.* Class II.

§ 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic resurfacing prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

(b) *Classification.* Class II.

§ 888.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral cap component made of alloy, such as cobalt-chromium-molybdenum, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device

may be perforated, but are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon fibers composite and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. The generic class also includes devices whose upper and lower components are linked with a solid bolt passing through a journal bearing of greater radius, permitting some rotation in the transverse plane, a minimal arc of abduction/adduction. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for use with bone cement (§ 888.3027). The patellar component is designed to be implanted only with its femoral component.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar surfacing component may be attached to the resected patella either with a metallic

screw or bone cement. All stemmed metallic components within this generic type are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) *Identification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* (1) Class II when intended for treatment of degenerative and posttraumatic patellar arthritis.

(2) Class III when intended for uses other than treatment of degenerative and posttraumatic patellar arthritis.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device intended for uses described in paragraph (b)(2). See § 888.3.

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

(a) *Identification.* A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date

has been established of the requirement for premarket approval. See § 888.3.

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class II.

§ 888.3720 Toe joint polymer constrained prosthesis.

(a) *Identification.* A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II.

§ 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.

(a) *Identification.* A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.

(b) *Classification.* Class II.

§ 888.3750 Wrist joint carpal lunate polymer prosthesis.

(a) *Identification.* A wrist joint carpal lunate prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal lunate bone of the wrist.

(b) *Classification.* Class II.

§ 888.3760 Wrist joint carpal scaphoid polymer prosthesis.

(a) *Identification.* A wrist joint carpal scaphoid polymer prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal scaphoid bone of the wrist.

(b) *Classification.* Class II.

§ 888.3770 Wrist joint carpal trapezium polymer prosthesis.

(a) *Identification.* A wrist joint carpal trapezium polymer prosthesis is a one-piece device made of silicone elastomer or silicone elastomer/polyester material intended to be implanted to replace the carpal trapezium bone of the wrist.

(b) *Classification.* Class II.

§ 888.3780 Wrist joint polymer constrained prosthesis.

(a) *Identification.* A wrist joint polymer constrained prosthesis is a device made of polyester-reinforced silicone elastomer intended to be implanted to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II.

§ 888.3790 Wrist joint metal constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification.* Class II.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification.* A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4200 Cement dispenser.

(a) *Identification.* A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

(b) *Classification.* Class I.

§ 888.4210 Cement mixer for clinical use.

(a) *Identification.* A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a tube-like device usually made of plastic intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in Subpart E of Part 807.

§ 888.4540 Orthopedic manual surgical instrument.

(a) *Identification.* An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4580 Sonic surgical instrument and accessories/attachments.

(a) *Identification.* A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

(b) *Classification.* Class II.

§ 888.4600 Protractor for clinical use.

(a) *Identification.* A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on X-rays or in surgery.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4800 Template for clinical use.

(a) *Identification.* A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

(a) *Identification.* A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5890 Noninvasive traction component.

(a) *Identification.* A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5940 Cast component.

(a) *Identification.* A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5980 Manual cast application and removal instrument.

(a) *Identification.* A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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Friday
September 4, 1987

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 888

Orthopedic Devices; Proposed Exemptions From Premarket Notification; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 86N-0012]

Orthopedic Devices; Proposed Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exempt from the requirement of premarket notification, with limitations, seven class I orthopedic devices. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule classifying these and other orthopedic devices. These actions are being taken under the Medical Device Amendments of 1976 and are a step in implementing one of the goals in FDA's plan for action.

DATES: Comments by November 3, 1987. FDA is proposing that the final rule based on this proposed rule become effective 30 days after its date of publication in the **Federal Register.**

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

FOR FURTHER INFORMATION CONTACT: Carl A. Larson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7156.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR Part 807, Subpart E. Such an exemption allows manufacturers to introduce into commercial distribution devices of the generic type exempted without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendment devices, the agency did not routinely evaluate whether it should grant to manufacturers of such devices placed in class I an exemption from the requirement of premarket notification in section 510(k) of the act and 21 CFR Part 807, Subpart E. Generally, FDA considered such exemptions only when the advisory panels recommended the exemptions.

Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of premarket notifications on relatively innocuous devices while freeing agency resources for the review of more complex notifications.

The development of these criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification in section 510(k) of the act will help implement a goal in FDA's July 1985 "A Plan for Action" (Ref. 1).

Criteria for 510(K) Exemptions

FDA is proposing to exempt a generic type of class I device from the requirement of premarket notification with the limitations described below, if FDA determines that premarket notification is not necessary for the protection of the public health. FDA may propose to grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (1) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (2) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience with premarket notification and publicly available reports or studies on device performance. Based on the criteria above, FDA will place the exempted device into the same class as the class I device to which it would be substantially equivalent.

FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Application of the Criteria To Class I Orthopedic Devices

In the proposed rule of July 2, 1982 (47 FR 29052), FDA proposed to classify preamendments orthopedic devices in accordance with the amendments. When FDA proposed to classify the seven devices below, the agency did not propose exemptions from the requirement of premarket notification for these devices. The Panel did not recommend exemptions from the requirement of premarket notification for certain of these devices. FDA agrees that full exemption from premarket notification is unjustified for these devices; however, for the efficient enforcement of the act and consistent with its policy regarding exemptions from premarket notification, FDA now is proposing to exempt from the requirement of premarket notification, with limitations, the seven devices below.

Section	Device
888.4200	Cement dispenser.
888.4210	Cement mixer for clinical use.
888.4220	Cement monomer vapor evacuator.
888.4230	Cement ventilation tube.
888.5890	Noninvasive traction component.
888.5940	Cast component.
888.5980	Manual cast application/removal instrument.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the devices above in class I. FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above. However, the proposed exemptions for the cement dispenser (§ 888.4200), cement mixer for clinical use (§ 888.4210), cement ventilation tube (§ 888.4230), and the cast component (§ 888.5940) are limited and would apply only to those devices made of the same materials that were used in the devices before May 28, 1976.

Reference

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action," Public Health Service, Department of Health and Human Services, July 1985, p. 18.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order. The device subject to this proposed rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions. Under any final rule based on this proposal, the devices would remain subject to such controls, other than premarket notification.

Interested persons may, on or before November 3, 1987, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 888

Orthopedic devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

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

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Part 888 is amended by adding new § 888.9, to read as follows:

§ 888.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. In § 888.4200 by revising paragraph (b) to read as follows:

§ 888.4200 Cement dispenser.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

4. In § 888.4210 by revising paragraph (b) to read as follows:

§ 888.4210 Cement mixer for clinical use.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

5. In § 888.4220 by revising paragraph (b) to read as follows:

§ 888.4220 Cement monomer vapor evacuator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in Subpart E of Part 807.

6. In § 888.4230 by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

7. In § 888.5890 by revising paragraph (b) to read as follows:

§ 888.5890 Noninvasive traction component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

8. In § 888.5940 by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

9. In § 888.5980 by revising paragraph (b) to read as follows:

§ 888.5980 Manual cast application/removal instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-20195 Filed 9-3-87; 8:45 am]

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federal register

Friday
September 4, 1987

Part IV

Department of Defense

Department of the Navy

32 CFR Part 728

Medical and Dental Care for Eligible Persons at Navy Medical Department Facilities; Final Rule

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 728

Medical and Dental Care for Eligible Persons at Navy Medical Department Facilities

AGENCY: Naval Medical Command, Navy, DOD.

ACTION: Final rule.

SUMMARY: The Naval Medical Command has promulgated this regulation to describe and publish the policies and procedures for providing medical and dental care to eligible persons at Navy Medical Department facilities. This promulgation enumerates those persons eligible to receive medical and dental care at Navy Medical Department facilities and prescribes the extent and conditions under which medical and dental care may be provided such persons. It updates a Department of the Navy instruction for conformity with Department of Defense directives.

EFFECTIVE DATE: May 14, 1987.

FOR FURTHER INFORMATION CONTACT: Herbert L. Pelham, Program Analyst, Naval Medical Command, Washington, DC 20372-5120, (202) 653-1179.

SUPPLEMENTARY INFORMATION: This revision relates to internal naval management and personnel practices and largely reflects nonsubstantive changes adopted in NAVMEDCOMINST 6320.38. It was determined that invitation of public comment on these changes prior to adoption would be impracticable and is therefore not required under public rulemaking provisions of Parts 296 and 701 of 32 CFR.

List of Subjects in 32 CFR Part 728

Dental health, Government employees, Health care, Military personnel.

Jane M. Virga,

LT. JAGC, USNR, Federal Register Liaison Officer.

Date: August 20, 1987.

Accordingly, 32 CFR Part 728 is revised to read as follows:

PART 728—MEDICAL AND DENTAL CARE FOR ELIGIBLE PERSONS AT NAVY MEDICAL DEPARTMENT FACILITIES

Subpart A—General

Sec.
728.1 Mission of Navy Medical Department facilities.
728.2 Definitions.
728.3 General restrictions and priorities.
728.4 Policies.

Subpart B—Members of the Uniformed Services on Active Duty

Sec.
728.11 Eligible beneficiaries.
728.12 Extent of care.
728.13 Application for care.
728.14 Pay patients.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Programs, and National Guard Personnel

728.21 Navy and Marine Corps Reservists.
728.22 Members of other reserve components of the uniformed services.
728.23 Reserve Officers' Training Corps (ROTC).
728.24 Navy and Marine Corps Officer Candidate Programs.
728.25 Army and Air Force National Guard personnel.

Subpart D—Retired Members and Dependents of the Uniformed Services

728.31 Eligible beneficiaries and health benefits authorized.
728.32 Application for care.
728.33 Nonavailability statement (DD 1251).
728.34 Care beyond the capabilities of a naval MTF.
728.35 Coordination of benefits—third party payers.
728.36 Pay patients.

Subpart E—Members of Foreign Military Services and Their Dependents

728.41 General provisions.
728.42 NATO.
728.43 Members of other foreign military services and their dependents.
728.44 Members of security assistance training programs, foreign military sales, and their ITO authorized dependents.
728.45 Civilian components (employees of foreign military services) and their dependents.
728.46 Charges and collection.

Subpart F—Beneficiaries of Other Federal Agencies

728.51 General provisions—the "Economy Act".
728.52 Veterans Administration beneficiaries (VAB).
728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) beneficiaries.
728.54 U.S. Public Health Service (USPHS), other than members of the uniformed services.
728.55 Department of Justice beneficiaries.
728.56 Treasury Department beneficiaries.
728.57 Department of State and associated agencies.
728.58 Federal Aviation Agency (FAA) beneficiaries.
728.59 Peace Corps beneficiaries.
728.60 Job Corps and Volunteers in Service to America (VISTA) beneficiaries.
728.61 Medicare beneficiaries.

Subpart G—Other Persons

728.71 Ex-service maternity care.
728.72 Applicants for enrollment in the Senior Reserve Officers' Training Program.
728.73 Applicants for enlistment or reenlistment in the Armed Forces, and applicants for enlistment in the reserve components.
728.74 Applicants for appointment in the regular Navy or Marine Corps and reserve components, including members of the reserve components who apply for active duty.
728.75 Applicants for cadetship at service academies and applicants for the Uniformed Services University of Health Sciences (USUHS).
728.76 Naval Home residents.
728.77 Secretarial designees.
728.78 American Red Cross representative and their dependents.
728.79 Employees of Federal contractors and subcontractors.
728.80 U.S. Government employees.
728.81 Other civilians.
728.82 Individuals whose military records are being considered for correction.
728.83 Persons in military custody and nonmilitary Federal prisoners.

Subpart H—Adjuncts to Medical Care

728.91 General.
728.92 Policy.
728.93 Chart of Adjuncts.

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

728.101 General.
728.102 Care from other than Federal sources.

Subpart J—Initiating Collection Action on Pay Patients

728.111 General.
728.112 Responsibilities.
728.113 Categories of patients.

Authority: 5 U.S.C. 301 and 8101; 10 U.S.C. 1071-1095, 1201-1221, 2104, 2107, 2109, 2110, 5031, 5537, 6011, 6201-6203; 22 U.S.C. 1158, 2357, 2504, 2505, 2507, 2522; 24 U.S.C. 15, 34, 35; 31 U.S.C. 1535; 42 U.S.C. 249, 253; and 32 CFR 700.1202.

Subpart A—General

§ 728.1 Mission of Navy Medical Department facilities.

The primary mission of Navy Medical Department facilities is to provide medical and dental care for members of the Navy and Marine Corps and for members of the other uniformed services who may be sick, injured, or disabled. In addition, Navy Medical Department facilities may provide medical and dental care to dependents of military personnel, to members not on active duty, and to such other persons as authorized by law, U.S. Navy regulations, and Department of Defense directives. These authorizations also provide that Navy Medical Department facilities may be called upon to furnish medical and dental care, under laws of humanity or principles of international

courtesy, to civilians and to other persons not otherwise entitled to medical and dental care.

§ 728.2 Definitions.

Unless otherwise qualified in this part, the following terms, when used throughout, are defined as follows:

(a) *Active duty.* Full-time duty in the active military service of the United States. This includes full-time training duty; annual training duty; and attendance, while in the active military service, at a school designated as a service school by law or by the Secretary of the military department concerned. It does not include full-time National Guard duty.

(b) *Active duty for training.* A tour of active duty for reserves for training under orders that provide for automatic reversion to non-active status when the specified period of active duty is completed. It includes annual training, special tours, and the initial tour performed by enlistees without prior military service.

(c) *CHAMPUS.* Civilian Health and Medical Program of the Uniformed Services.

(d) *Catchment area.* A specified geographic area surrounding each Uniformed Services Medical Treatment Facility (USMTF) or designated Uniformed Services Treatment Facility (USTF). In the United States, catchment areas are defined by zip codes and are based on an area of approximately 40 miles in radius for inpatient care and 20 miles in radius for ambulatory care. Zip codes designating such areas in the United States are specified in Volumes I and II of the Military Health Services System (MHSS) Catchment Area Directory. Catchment areas for facilities outside the United States are defined in Volume III of the MHSS Catchment Area Directory. These directories exclude certain areas because of geographic barriers.

(e) *Chronic condition.* Any medical or surgical condition marked by long duration or frequent recurrence—or likely to be so marked—which, in light of medical information available, will ordinarily resist efforts to eradicate it completely; a condition which needs health benefits to achieve or maintain stability that can be provided safely only by, or under the supervision of, physicians, nurses, or persons authorized by physicians.

(f) *Civilian employee.* Under 5 U.S.C. 2105, a nonmilitary individual (1) appointed in the civil service, (2) engaged in the performance of a Federal function, or (3) engaged in the performance of his or her duties while subject to the supervision of The President, a Member or Members of Congress, or the Congress, a member of a uniformed service, an individual who is an employee under 5 U.S.C. 2105, the head of a Government controlled corporation, or an adjutant general designated by the Secretary concerned under section 709c of title 32. Included are justices and judges of the United States, appointed and engaging in the performance of duties per 5 U.S.C. 2104.

(g) *Cooperative care.* Medical services and supplies for which CHAMPUS will share in the cost under circumstances specified in § 728.4 (z), even though the patient remains under the primary control of a USMTF.

(h) *Cooperative care coordinator.* Designated individual in a CHAMPUS contractor's office who serves as the point of contact for health benefits advisors on all matters related to supplemental-cooperative care or services provided or ordered for CHAMPUS-eligible beneficiaries by USMTF providers.

(i) *Dental care.* Treatment which will prevent or remedy diseases, disabilities, and injuries to the teeth, jaws, and related structures and thereby contribute to maintenance or restoration of the dental health of an individual.

(j) *Dependent.* A spouse, an unremarried widow or widower, a child, or a parent who bears that legal relationship to his or her sponsor. For the purpose of rendering care under title 10, U.S.C., chapter 55, this category may also include an unremarried former spouse. However, each beneficiary must also meet the eligibility criteria in § 728.31(b) and § 728.31(c).

(k) *Designated USTFs.* The following former U.S. Public Health Service (USPHS) facilities operate as "designated USTFs" for the purpose of rendering medical and dental care to active duty members and to all CHAMPUS-eligible individuals.

(1) *Sisters of Charity of the Incarnate Word Health Care System,* 6400 Lawndale, Houston, TX 77058 (713) 928-2931 operates the following facilities:

(i) St. John Hospital, 2050 Space Park Drive, Nassau Bay, TX 77058, telephone (713) 333-5503. Inpatient and outpatient services.

(ii) St. Mary's Hospital Outpatient Clinic, 404 St. Mary's Boulevard, Galveston, TX 77550, telephone (409) 763-5301. Outpatient services only.

(iii) St. Joseph Hospital Ambulatory Care Center, 1919 La Branch, Houston, TX 77002, telephone (713) 757-1000. Outpatient services only.

(iv) St. Mary's Hospital Ambulatory Care Center, 3600 Gates Boulevard, Port Arthur, TX 77640 (409) 985-7431. Outpatient services only.

(2) *Inpatient and outpatient services.* (i) Wyman Park Health System, Inc., 3100 Wyman Park Drive, Baltimore, MD 21211, telephone (301) 338-3693.

(ii) Alston-Brighton Aid and Health Group, Inc., Brighton Marine Public Health Center, 77 Warren Street, Boston, MA 02135, telephone (617) 782-3400.

(iii) Bayley Seton Hospital, Bay Street and Vanderbilt Avenue, Staten Island, NY 10304, telephone (718) 390-5547 or 6007.

(iv) Pacific Medical Center, 1200 12th Avenue South, Seattle, WA 98144, telephone (206) 326-4100.

(3) *Outpatient services only.* (i) Coastal Health Service, 331 Veranda Street, Portland, ME 04103, telephone (207) 774-5805.

(ii) Lutheran Medical Center, Downtown Health Care Services, 1313 Superior Avenue, Cleveland, OH 44113, telephone (216) 363-2065.

(l) *Disability retirement or separation.* Temporary or permanent retirement or separation for physical disability as provided in title 10, U.S.C., 1201-1221.

(m) *Elective care.* Medical, surgical, or dental care desired or requested by the individual or recommended by the physician or dentist which, in the opinion of other cognizant professional authority, can be performed at another place or time without jeopardizing life, limb, health, or well-being of the patient, e.g., surgery for cosmetic purposes and nonessential dental prosthetic appliances.

(n) *Emergency care.* Medical treatment of patients with severe, life-threatening, or potentially disabling conditions that require immediate intervention to prevent undue suffering or loss of life or limb and dental treatment of painful or acute conditions.

(o) *Health benefits advisors (HBA).* Designated individuals at naval facilities who are responsible for advising and assisting beneficiaries covered in this part concerning medical and dental benefits in uniformed services facilities and under CHAMPUS. They also provide information regarding Veterans' Administration, Medicare, MEDICAID, and such other local health programs known to be available to beneficiaries (see § 728.4(n)).

(p) *Hospitalization.* Inpatient care in a medical treatment facility.

(q) *Inactive duty training.* Duty prescribed for Reserves by the Secretary concerned under section 206 of title 37, U.S.C. or any other provision of law. Also includes special additional duties authorized for Reserves by an authority designated by the Secretary concerned and performed on a voluntary basis in connection with the prescribed training

or maintenance activities of the units to which they are assigned. It includes those duties when performed by Reserves in their status as members of the National Guard.

(r) *Legitimate care.* Those medical and dental services under the cooperative/supplemental care program of CHAMPUS that are legally performed and not contrary to governing statutes.

(s) *Maximum hospital benefit.* That point during inpatient treatment when the patient's progress appears to have stabilized and it can be anticipated that additional hospitalization will not directly contribute to any further substantial recovery. A patient who will continue to improve slowly over a long period without specific therapy or medical supervision, or with only a moderate amount of treatment on an outpatient basis, may be considered as having attained maximum hospital benefit.

(t) *Medical care.* Treatment required to maintain or restore the health of an individual. Medical care may include, but is not limited to, the furnishing of inpatient treatment, outpatient treatment, nursing service, medical examinations, immunizations, drugs, subsistence, transportation, and other adjuncts such as prosthetic devices, spectacles, hearing aids, orthopedic footwear, and other medically indicated appliances or services.

(u) *Medically inappropriate.* A situation arising when denial of a Nonavailability Statement could result in significant risk to the health of a patient or significant limitation to the patient's reasonable access to needed health care.

(v) *Medically necessary.* The level of services and supplies (i.e., frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, including maternity care. Medically necessary, includes the concept of appropriate medical care.

(w) *Medical treatment facility (MTF).* Any duly authorized medical department center, hospital, clinic, or other facility that provides medical, surgical, or dental care.

(x) *Member or former member.* Includes:

(1) Members of the uniformed services ordered to active duty for more than 30 days.

(2) Retired members as defined in § 728.2(bb).

(3) Members of a uniformed service ordered to active duty for more than 30 days who died while on that duty.

(4) Deceased retired members.

(y) *Military patient.* A member of a United States uniformed service on active duty, active duty for training, or inactive duty training, or an active duty member of the armed forces of a foreign government who is receiving inpatient or outpatient care.

(z) *Occupational health services.* Includes medical examinations and tests related to preemployment, preplacement, periodic, and pretermination; tests required for protecting the health and safety of naval personnel; job-related immunizations and chemoprophylaxis; education and training related to occupational health; and other services provided to avoid lost time or to improve effectiveness of employees. The latter will include the furnishing of emergency treatment of illnesses or injuries occurring at work. Furnish such health services to both active duty military personnel and naval civilian employees per current directives.

(aa) *Retired member.* A member or former member of a uniformed service who is entitled to retired or retainer pay, or equivalent pay, as a result of service in a uniformed service. This includes a member or former member who is: (1) Retired for length of service; (2) permanently or temporarily retired for physical disability; (3) on the emergency officers' retired list and is entitled to retired pay for physical disability; or (4) otherwise in receipt of retired pay under chapter 67 of title 10.

(bb) *Routine care.* Medical and dental care necessary to maintain health or dental functions other than care of an emergency or elective nature.

(cc) *Supplemental care or services.* When medical or dental management is retained by a naval MTF and required care is not available at the facility retaining management, any additional material, professional diagnostic or consultative services, or other personal services ordered by qualified uniformed service providers, and obtained for the care of that patient are supplemental. See § 728.12 concerning the management of active duty member patients.

(dd) *Uniformed services.* The Navy, Marine Corps, Air Force, Army, Coast Guard, Commissioned Corps of the Public Health Service, and the Commissioned Corps of the National Oceanic and Atmospheric Administration.

(ee) *USMTF.* Uniformed services medical treatment facility.

(ff) *Visit, outpatient.* Appearance by an eligible beneficiary at a separate, organized clinic or specialty service for: Examination, diagnosis, treatment, evaluation, consultation, counseling, or medical advice; or treatment of an eligible beneficiary in quarters; and a signed and dated entry is made in the patient's health record. Specifically excluded are personnel in an inpatient status at the time of such a visit.

§ 728.3 General restrictions and priorities.

(a) *Restrictions.* (1) Naval MTFs provide care to all eligible beneficiaries subject to the capabilities of the professional staff and the availability of space and facilities.

(2) Hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to officers and employees of any department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to accompanying dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *Provided,* such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities. Hospitalization of such individuals in a naval MTF is limited to the treatment of acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Routine dental care, other than dental prosthesis or orthodontia, may be rendered on a space available basis outside the continental limits of the United States and in Alaska, *Provided,* such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(b) *Priorities.* When care cannot be rendered to all eligible beneficiaries, the priorities in the following chart will prevail. Make no distinction as to the sponsoring uniformed service when providing care or deciding priorities.

PRIORITIES FOR THE VARIOUS CATEGORIES OF PERSONNEL ELIGIBLE FOR CARE IN NAVY MEDICAL DEPARTMENT FACILITIES

Priority	Category	Degree of entitlement
1	A. Members of the uniformed services on active duty (including active duty for training and inactive duty training) and comparable personnel of the NATO nations meeting the conditions prescribed in this part.	See Subpart B.
	B. Members of a Reserve Component of the Armed Forces and National Guard personnel under orders.	See Subpart C.
2	Dependents of active duty members of the uniformed services, dependents of persons who died while in such a status, and the dependents of active duty members of NATO nations meeting the conditions prescribed in subpart E of this part.	See Subparts D and E.
3	Members ot the Senior Reserve Officers' Training Corps of the Armed Forces	See § 728.23.
4	Retired members of the uniformed services and their dependents and dependents of deceased retired members.	See Subpart D.
5	Civilian employees of the Federal Government under the limited circumstances covered by the Federal Employees' Health Service program.	See § 728.80.
6	All others, including ex-service maternity eligibles	See Subparts F and G.

§ 728.4 Policies.

(a) *Admissions to closed psychiatric wards.* Admit patients to closed psychiatric wards only when they have a psychiatric or emotional disorder which renders them dangerous to themselves or others, or when a period of careful closed psychiatric observation is necessary to determine whether such a condition exists. When a patient is admitted to a closed psychiatric ward, the reason for admission must be clearly stated in the patient's clinical record by the physician admitting the patient to the ward. These same policies apply equally in those instances when it becomes necessary to place a patient under constant surveillance while in an open ward.

(b) *Absence from the sick list.* See § 728.4 (d), (x), and (y).

(c) *Charges and collection.* Charges for services rendered vary and are set by the Office of the Assistant Secretary of Defense (Comptroller) and published in a yearly NAVMEDCOMNOTE 6320, (Cost elements of medical, dental, subsistence rates, and hospitalization bills). Billing and collection actions also vary according to entitlement or eligibility and are governed by the provisions of NAVMED P-5020, Resource Management Handbook. See subpart J on the initiation of collection action on pay patients.

(d) *Convalescent leave.* Convalescent leave, a period of authorized absence of active duty members under medical care when such persons are not yet fit for duty, may be granted by a member's commanding officer (CO) or the hospital's CO per the following:

(1) Unless otherwise indicated, grant such leave only when recommended by COMNAVMEDCOM through action taken upon a report by a medical board, or the recommended findings of a physical evaluation board or higher authority.

(2) Member's commanding officer (upon advice of attending physician); commanding officers of Navy, Army, or Air Force medical facilities; commanders of regional medical commands for persons hospitalized in designated USTFs or in civilian facilities within their respective areas of authority; and managers of Veterans Administration hospitals within the 50 United States or in puerto Rico may grant convalescent leave to active duty naval patients, with or without reference to a medical board, physical evaluation board, or higher authority provided the:

(i) Convalescent leave is being granted subsequent to a period of hospitalization.

(ii) Member is not awaiting disciplinary action or separation from the service for medical or administrative reasons.

(iii) Medical officer in charge:

(A) Considers the convalescent leave beneficial to the patient's health.

(B) Certifies that the patient is not fit for duty, will not need hospital treatment during the contemplated convalescent leave period, and that such leave will not delay final disposition of the patient.

(3) When considered necessary by the attending physician and approved on an individual basis by the commander of the respective geographic regional medical command, convalescent leave in excess of 30 days may be granted. The authority to grant convalescent leave in excess of 30 days may not be redelegated to hospital commanding officers. Member's permanent command must be notified of such extensions (see MILPERSMAN 3020360).

(4) Exercise care in granting convalescent leave to limit the duration of such leave to that which is essential in relation to diagnosis, prognosis, estimated duration of treatment, and patient's probable final disposition.

(5) Upon return from convalescent leave;

(i) Forward one copy of original orders of officers, bearing all endorsements, to the Commander, Naval Military Personnel Command (COMNAVMILPERSCOM) (NMPC-4) or the Commandant of the Marine Corps (CMC), as appropriate.

(ii) Make an entry on the administrative remarks page (page 13 for Navy personnel) of the service records of enlisted personnel indicating that convalescent leave was granted and the dates of departure and return.

(6) If considered beneficial to the patient's health, commanding officers of hospitals may grant convalescent leave as a delay in reporting back to the parent command.

(e) *Cosmetic surgery.* (1) Defined as that surgery which is done to revise or change the texture, configuration, or relationship of contiguous structures of any feature of the human body which would be considered by the average prudent observer to be within the broad range of "normal" and acceptable variation for age or ethnic origin, and in addition, is performed for a condition which is judged by competent medical opinion to be without potential for jeopardy to physical or mental health of an individual.

(2) Commanding officers will monitor, control, and assure compliance with the following cosmetic surgery policy:

(i) Certain cosmetic procedures are a necessary part of training and retention

of skills to meet the requirements of certification and recertification.

(ii) Insofar as they meet minimum requirements and serve to improve the skills and techniques needed for reconstructive surgery, the following cosmetic procedures may be performed as low priority surgery on active duty members only when time and space are available.

(A) Cosmetic facial rhytidectomies (face lifts) will be a part of all training programs required by certifying boards.

(B) Cosmetic augmentation mammaplasties will be done only by properly credentialed surgeons and residents within surgical training programs to meet requirements of certifying boards.

(f) *Cross-utilization of uniformed services facilities.* To provide effective cross-utilization of medical and dental facilities of the uniformed services, eligible persons, regardless of service affiliation, will be given equal opportunity for health benefits. Catchment areas have been established by the Department of Defense for each USMTF (see § 728.2(d)). Eligible beneficiaries residing within such a catchment area are expected to use that inpatient facility for care. Make provisions to assure that:

(1) Eligible beneficiaries residing in a catchment area served by a USMTF not of the sponsor's own service may obtain care at that facility or at a facility of the sponsor's service located in another catchment area.

(2) If the facility to which an eligible beneficiary applies cannot furnish needed care, the other facility or facilities in overlapping catchment areas are contacted to determine whether care can be provided thereat.

(g) *Disengagement.* Discontinuance of medical management by a naval MTF for only a specific episode of care.

(1) *General.* Disengagement is accomplished only after alternative sources of care (i.e., transfer to another USMTF, a USTF, or other Federal source via the aeromedical evacuation system, if appropriate) and attendant costs, if applicable, have been fully explained to patient or responsible family member. Counselors may arrange for counseling by other appropriate sources when the patient is or may be eligible for VA, Medicare, MEDICAID, etc. benefits. With the individual's permission, counselors may also contact State programs, local health organizations, or health foundations to determine if care is available for the condition upon which disengagement is based. After the disengagement decision is made, the patient to be disengaged or the responsible family member should be advised to return to the naval MTF for any care required subsequent to receiving the care that necessitated disengagement.

(2) *CHAMPUS-eligible individuals.* (i) Issue a Nonavailability Statement (DD 1251) per § 728.33, when appropriate, to patients released to civilian sources for total care (disengaged) under CHAMPUS. CHAMPUS-eligible patients disengaged for total care, who do not otherwise require a DD 1251 (released for outpatient care or those released whose residence is outside the inpatient catchment area of all USMTFs and USTFs) will be given the original of a properly completed DD 2161, Referral For Civilian Medical Care, which clearly indicates that the patient is released for total care under CHAMPUS. CHAMPUS-eligible beneficiaries will be disengaged for services under CHAMPUS when:

(A) Required services are beyond your capability and these services cannot be appropriately provided through one of the alternatives listed in § 728.4(z), or

(B) You cannot effectively provide required services or manage the overall course of care even if augmented by services procured from other Government or civilian sources using naval MTF operation and maintenance funds as authorized in subpart § 728.4(z).

(ii) When a decision is made to disengage a CHAMPUS-eligible individual, commanding officers (CO) or officers-in-charge (OIC) are responsible for assuring that counseling and documentation of counseling are appropriately accomplished. Complete a NAVMED 6320/30. Disengagement for Civilian Medical Care, to document that all appropriate disengagement procedures have been accomplished.

(iii) After obtaining the signature of the patient or responsible family member, the counselor will file a copy of the DD 2161 and the original of the NAVMED 6320/30 in the patient's Health Record.

(3) *Patients other than active duty or CHAMPUS-eligible individuals*— (i) *Categories of patients.* The following are categories of individuals who also may be disengaged:

(A) Medicare-eligible individuals.

(B) MEDICAID-eligible individuals.

(C) Civilians (U.S. and foreign) admitted or treated as civilian humanitarians.

(D) Secretarial designees.

(E) All other individuals, with or without private insurance, who are not eligible for care at the expense of the Government.

(ii) *Disengagement decision.* Disengage such individuals when:

(A) Required services are beyond the capability of the MTF, and services necessary for continued treatment in the MTF cannot be appropriately provided by another USMTF, a USTF, or another Federal source. (Explore alternative sources, for individuals eligible for care from these sources, before making the disengagement decision.)

(B) The MTF cannot, within the facility's capability, effectively provide required care or manage the overall course of treatment even if augmented by services procured from other Government sources or through procurement from civilian sources using supplemental care funding.

(iii) *Counseling.* The initial step in the disengagement process is appropriate counseling and documentation. In an emergency, or when the individual cannot be appropriately counseled prior to leaving the MTF, establish procedures to ensure counseling and documentation are accomplished during the next working day. Such "follow-up" counseling may be in person or via a witnessed telephone conversation. In either instance, the counselor will document counseling on a NAVMED 6320/30, Disengagement for Civilian Medical Care. The disengagement decision making authority must assure the accomplishment of counseling by personally initiating this service or by referring the patient or responsible family member to the HBA for counseling. As a minimum, counseling will consist of:

(A) Explaining that the patient is being disengaged from treatment at the facility and the reason therefor. Assure that the individual understands the meaning of "disengagement" by explaining that the MTF is unable to provide for the patient's present needs and must therefore relinquish medical management of the patient to a health care provider of the individual's choice.

(B) Assuring the individual that the disengagement action is taken to provide for the patient's immediate medical needs. Also assure that the individual understands that the disengagement is not indicative of whether care is or will be available in the MTF for other aspects of past, current, or future medical conditions.

(C) Explaining Medicare, MEDICAID, or other known programs as they relate to the particular circumstance of the patient, including cost-sharing, deductibles, allowable charges, participating and authorized providers, physicians accepting assignment, claim filing procedures, etc. Explain that once disengagement is accomplished, the Navy, is not responsible for any costs

for care received from a health care provider of the patient's or responsible family member's choice.

(iv) *Documentation.* Commanding officers are responsible for ensuring that proper documentation procedures are started and that providers and counselors under their commands are apprised of their individual responsibilities for counseling and documenting each disengagement. Failure to properly counsel and document counseling may result in the naval MTF having to absorb the cost of the entire episode of care. Document counseling on a NAVMED 6320/30. Disengagement for Civilian Medical Care. Completion of all items on the form assures documentation and written acknowledgement of appropriate disengagement and counseling. If the patient or responsible family member refuses to acknowledge receipt of counseling by signing the form, state this fact on the bottom of the form and have it witnessed by an officer. Give the patient or responsible family member a copy and immediately file the original in the patient's Health Record.

(4) *Active duty members.* When an active duty member seeks care at a USMTF, that USMTF retains some responsibility (e.g., notification, medical cognizance, supplemental care, etc.) for that member even when the member must be transferred to another facility for care. Therefore, relinquishment of total management of an active duty member (disengagement) cannot be accomplished.

(h) *Domiciliary/custodial care.* The type of care designed essentially to assist an individual in meeting the normal activities of daily living, i.e., services which constitute personal care such as help in walking and getting in or out of bed, help in bathing, dressing, feeding, preparation of special diets, and supervision over medications which can usually be self-administered and which does not entail or require the continuing attention of trained medical or paramedical personnel. The essential characteristics to be considered are the level of care and medical supervision that the patient requires, rather than such factors as diagnosis, type of condition, or the degree of functional limitation. Such care will not be provided in naval MTFs except when required for active duty members of the uniformed services.

(i) *Emergency care.* Treat patients authorized only emergency care and those admitted as civilian emergencies only during the period of the emergency. Initiate action to effect appropriate disposition of such patients as soon as the emergency period ends.

(j) *Evaluation after admission.* Evaluate each patient as soon as possible after admission and continue reevaluation until disposition is made. Anticipate each patient's probable type and date of disposition. Necessary processing by the various medical and administrative entities will take place concurrently with treatment of the patient. Make the medical disposition decision as early as possible for U.S. military patients inasmuch as immediate transfer to a specialized VA center or to a VA spinal cord injury center may be in their best interest (see NAVMEDCOMINST 6320.1.2). Make disposition decisions for military personnel of NATO nations in conformance with § 728.42(d).

(k) *Extent of care.* Subject to the restrictions and priorities in § 728.3, eligible persons will be provided medical and dental care to the extent authorized, required, and available. When an individual is accepted for care, all care and adjuncts thereto, such as nonstandard supplies, as determined by the CO to be necessary, will be provided from resources available to the CO unless specifically prohibited elsewhere in this part. When a patient has been accepted and required care is beyond the capability of the accepting MTF, the CO thereof will arrange for the required care by one of the means shown below. The method of choice will be based upon professional considerations and travel economy.

(1) Transfer the patient per § 728.4(bb).

(2) Procure from civilian sources the necessary material or professional personal services required for the patient's proper care and treatment.

(3) Care authorized in § 728.4(k)(2) will normally be accomplished in the naval MTF. However, when such action is not feasible, supplementation may be obtained outside the facility. Patients may be sent to other Federal or civilian facilities for specific treatment or services under § 728.4(k)(3) *provided* they remain under medical management of the CO of the sending facility during the entire period of care.

(l) *Family planning services.* Provide family planning services following the provisions of SECNAVINST 6300.2A.

(m) *Grouping of patients.* Group hospitalized patients according to their requirements for housing, medical, or dental care. Provide gender identified quarters, facilities, and professional supervision on that basis when appropriate. Individuals who must be retained under limited medical supervision (medical hold) solely for administrative reasons or for medical conditions which can be treated on a clinic basis will be provided quarters and messing facilities, where practicable, separately from those hospitalized. Provide medical care for such patients on a periodic clinic appointment basis (see § 728.4(p) for handling enlisted convalescent patients). Make maximum use of administrative versus medical personnel in the supervision of such patients.

(n) *Health benefits advising*—(1) *General.* A Health Benefits Advising program must be started at all shore commands having one or more medical officers. While health benefits advisors are not required aboard every ship with a medical officer, the medical department representative can usually provide services to personnel requiring help. The number of health benefits advisors (HBAs) of a command will be commensurate with counseling and assistance requirements. The program provides health benefits information and counseling to beneficiaries of the Uniformed Services Health Benefits Program (USHBP) and to others who may or may not qualify for care in USMTFs. Office location of HBAs, their names, and telephone numbers will be widely publicized locally. If additional help is required, contact MEDCOM-333 on AUTOVON 294-1127 or commercial (202) 653-1127. In addition to the duties described in § 728.4(n)(2), HBAs will:

(i) Maintain a depository of up-to-date officially supplied health benefits information for availability to all beneficiaries.

(ii) Provide information and guidance to beneficiaries and generally support the medical and dental staff by providing help to eligible beneficiaries seeking or obtaining services from USMTFs, civilian facilities, VA facilities, Medicare, MEDICAID, and other health programs.

(iii) Assure that when a referral or disengagement is required, patients or responsible family members are:

(A) Fully informed that such action is taken to provide for their immediate medical or dental requirements and that the disengagement or referral has no bearing on whether care may be available in the naval MTF for other aspects of current or other future medical conditions.

(B) Provided the services and counseling outlined in § 728.4(n)(2) or § 728.3(g)(3)(ii), as appropriate, *prior* to their departure from the facility when such beneficiaries are referred or disengaged because care required is beyond the naval MTF's capability. In an emergency, or when the patient or sponsor cannot be seen by the HBA

prior to leaving, provide these benefits as soon thereafter as possible.

(2) *Counseling and Assisting CHAMPUS-Eligible Individuals.* HBAs, as a minimum, will:

(i) Explain alternatives available to the patient.

(ii) If appropriate, explain CHAMPUS as it relates to the particular circumstance, including the cost-sharing provisions applicable to the patient, allowable charges, provider participation, and claim filing procedures. Fully inform the patient or responsible family member that when a patient is disengaged for care under CHAMPUS or when cooperative care is to be considered for payment under the provisions of § 728.4(z)(5) and (6), the naval MTF is not responsible for monetary amounts above the CHAMPUS-determined allowable charge or for charges CHAMPUS does not allow.

(iii) Explain why the naval MTF is paying for the supplemental care, if appropriate (see § 728.4(z)(3) and (4)), and how the bill will be handled. Then:

(A) Complete a DD 2161, Referral For Civilian Medical Care, marking the appropriate source of payment with the concurrence of the naval MTF commanding officer or CO's designee.

(B) If referred for a specified procedure with a consultation report to be returned to the naval MTF retaining medical management, annotate the DD 2161 in the consultation report section to state this requirement. Advise patient or responsible family member to arrange for a completed copy of the DD 2161 to be returned to the naval MTF for payment, if appropriate, and inclusion in patient's medical record.

(iv) Brief patient or responsible family member on the use of the DD 2161 in USMTF payment procedures and CHAMPUS claims processing, as appropriate. Provide sufficient copies of DD 2161 and explain that CHAMPUS contractors will return claims submitted without a required DD 2161. Obtain signature of patient or responsible family member on the form.

(v) Arrange for counseling from appropriate sources when the patient is eligible for VA, Medicare, or MEDICAID benefits.

(vi) Serve as liaison between civilian providers and naval MTF on administrative matters related to the referral and disengagement process.

(vii) Serve as liaison between naval MTF and cooperative care coordinators on matters relating to care provided or recommended by naval MTF providers, as appropriate.

(viii) Explain why the patient is being disengaged and, per § 728.4(g)(2), provide a DD 1251, Nonavailability Statement, or DD 2161, Referral For Civilian Medical Care, as appropriate.

(o) *Immunizations.* Administer immunizations per BUMED INST 6230.1H.

(p) *Medical holding companies.* Medical holding companies (MHC) have been established at certain activities to facilitate handling of enlisted convalescent patients whose medical conditions are such that, although they cannot be returned to full duty, they can perform light duty ashore commensurate with their condition while completing their medical care on an outpatient basis. Where feasible, process such patients for transfer.

(q) *Notifications.* The interests of the Navy, Marine Corps, and DOD have been adversely affected by past procedures which emphasized making notifications only when an active duty member's condition was classed as either seriously ill or injured or classed as very seriously ill or injured. However, even temporary disabilities which preclude communication with the next of kin have generated understandable concern and criticism, especially when emergency hospitalization has resulted. Accordingly, naval MTFs will effect procedures to make notifications required in § 728.4(q)(2), (3), and (4), upon admission or diagnosis of individuals specified. The provisions of § 728.4(q) supplement articles 1810520 and 4210100 of the Naval Military Personnel Manual and chapter 1 of Marine Corps Order P3040.4B, Marine Corps Casualty Procedures Manual; they do not supersede them.

(1) *Privacy Act.* The right to privacy of individuals for whom hospitalization reports and other notifications are made will be safeguarded as required by the Privacy Act, implemented in the Department of the Navy by SECNAVINST 5211.5C, U.S. Navy Regulations, the Manual of the Judge Advocate General, the Marine Corps Casualty Procedures Manual, and the Manual of the Medical Department.

(2) *Active duty flag or general officers and retired Marine Corps general officers.* Upon admission of subject officers, make telephonic contact with MEDCOM-33 on AUTOVON 294-1179 or commercial (202) 653-1179 (after duty hours, contact the command duty officer on AUTOVON 294-1327 or commercial (202) 653-1327) to provide the following information:

(i) *Initial.* Include in the initial report:

(A) Officer's name, grade, social security number, and designator.

(B) Duty assignment in ship or station, or other status.

(C) Date of admission.

(D) Present condition, stating if serious or very serious.

(E) Diagnosis, prognosis, and estimated period of hospitalization. To prevent possible invasion of privacy, report the diagnosis only in International Classification of Diseases—9th Edition (ICD-9-CM) code designator.

(ii) *Progress reports.* Call frequency and content will be at the discretion of the commanding officer. However, promptly report changes in condition or status.

(iii) *Termination report.* Make a termination of hospitalization report to provide appropriate details for informational purposes.

(iv) *Additional commands to apprise.* The geographic naval medical region serving the hospital and, if different, the one serving the officer's command will also be apprised of such admissions.

(3) *Active duty members*—(i) *Notification of member's command.* The commanding officer of naval medical treatment facilities has responsibility for notifying each member's commanding officer under the conditions listed below. Make COMNAVMILPERS.COM or CMC, as appropriate, information addressees on their respective personnel:

(A) *Direct admissions.* Upon direct admission of an active duty member, with or without orders regardless of expected length of stay. The patient administration department (administrative watch officer after hours) is responsible for preparation, per § 728.4(q)(4), and release of these messages. If the patient is attached to a local command (CO's determination), initial notification may be made telephonically. Record the name, grade or rate, and position of the person receiving the call at the member's command on the back of the NAVMED 6300/5, Inpatient Admission/Disposition Record and include the name and telephone number of the MTF's point of contact as given to the patient's command.

(B) *Change in medical condition.* Upon becoming aware of any medical condition, including pregnancy, which will now or in the foreseeable future result in the loss of a member's full duty services in excess of 72 hours. Transmit this information in a message, prepared per § 728.4(q)(4), marked "Commanding Officer's Eyes Only."

(ii) *Notification of Next of Kin (NOK)*—(A) *Admitted members.* As part of the admission procedure, encourage all patients to communicate expeditiously and regularly with their NOK. When an active duty member's

incapacity makes timely personal communication impractical, i.e., fractures, burns, eye pathology, psychiatric or emotional disorders, etc., MTF personnel will initiate the notification process. Do not start the process if the patient specifically declines such notification or it is clear that the NOK already has knowledge of the admission (commands should develop a local form for such patients to sign attesting their desire or refusal to have their NOK notified). Once notification has been made, the facility will make progress reports, at least weekly, until the patient is again able to communicate with the NOK.

(*1*) *Navy personnel.* Upon admission of Navy personnel, effect the following notification procedures.

(*i*) *In the contiguous 48 States.* Patient administration department personnel will notify the NOK in person, by telephone, telegraph, or by other expeditious means. Included are notifications of the NOK upon arrival of all Navy patients received in the medical air-evacuation system.

(*ii*) *Outside the contiguous 48 States.* If the next of kin has accompanied the patient on the tour of duty and is in the immediate area, hospital personnel will notify the next of kin in person, by telephone, telegraph, or by other expeditious means. If the next of kin is located in the 48 contiguous United States, use telegraphic means to notify COMNAVMILPERSCOM who will provide notification to the NOK.

(*2*) *Marine Corps personnel.* When Marine Corps personnel are admitted, effect the following notification procedures.

(*i*) *In the Contiguous 48 States.* The commander of the unit or activity to which the casualty member is assigned is responsible for initiating notification procedures to the NOK of seriously or very seriously ill or injured Marine Corps personnel. Patient administration department personnel will assure that liaison is established with the appropriate command or activity when such personnel are admitted. Patient administration personnel will notify the Marine's command by telephone and request that cognizance be assumed for in-person initial notification of the NOK of Marine Corps patients admitted with an incapacity that makes personal and timely communication impractical and for those arriving via the medical air-evacuation system. If a member's command is unknown or cannot be contacted, inform CMC (MHP-10) on AUTOVON 224-1787 or commercial (202) 694-1787.

(ii) Outside the contiguous 48 States. Make casualty notification for Marine Corps personnel hospitalized in naval MTFs outside the contiguous 48 States to the individual's command. If the command is unknown or not located in close proximity to the MTF, notify CMC (MHP-10). When initial notification to the individual's command is made via message, make CMC (MHP-10) an information addressee.

(iii) In and outside the United States. In life-threatening situations, the Commandant of the Marine Corps desires and encourages medical officers to communicate with the next of kin. In other circumstances, request that the Marine Corps member communicate with the NOK if able. If unable, the medical officer should communicate with the NOK *after* personal notification has been effected.

(B) *Terminally ill patients.* As soon as a diagnosis is made and confirmed (on inpatients or outpatients) that a Navy member is terminally ill, MILPERSMAN 4210100 requires notification of the primary and secondary next of kin. Accomplish notification the same as for Navy members admitted as seriously or very seriously ill or injured, i.e., by priority message to the Commander, Naval Military Personnel Command and to the Casualty Assistance Calls/ Funeral Honors Support Program Coordinator, as appropriate, who has cognizance over the geographical area in which the primary and secondary NOK resides (see OPNAVINST 1770.1). Submit followup reports when appropriate. See MILPERSMAN 4210100 for further amplification and for information addressees.

(1) In the contiguous 48 States. Notification responsibility is assigned to the USMTF making the diagnosis and to the member's duty station if diagnosed in a civilian facility.

(2) Outside the contiguous 48 States. Notification responsibility is assigned to the naval medical facility making the diagnosis. When diagnosed in nonnaval facilities or aboard deployed naval vessels, notification responsibility belongs to the Commander, Naval Military Personnel Command.

(C) *Other uniformed services patients.* Establish liaison with other uniformed services to assure proper notification upon admission or diagnosis of active duty members of other services.

(D) *Nonactive duty patients.* At the discretion of individual commanding officers, the provisions of § 728.4(q)(3)(ii) on providing notification to the NOK may be extended to admissions or diagnosis of nonactive duty patients; e.g., admission of dependents of members on duty overseas.

(4) *Messages*— (i) *Content.* Phrase contents of messages (and telephonic notifications) in lay terms and provide sufficient details concerning the patient's condition, prognosis, and diagnosis. Messages will also contain the name and telephone number of the facility's point of contact. When appropriate for addressal, psychiatric and other sensitive diagnoses will be related with discretion. When indicated, also include specific comment as to whether the presence of the next of kin is medically warranted. **Note:** In making notification to the NOK of patients diagnosed as having Acquired Immune Deficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV), use one of the symptoms of the disease as the diagnosis (e.g., pneumonia) rather than "HIV", "AIDS", or the diagnostic code for AIDS.

(ii) *Information addressees.* Make the commander of the geographic naval medical region servicing the member's command and the one servicing the hospital, if different, information addressees on all messages. For Marine Corps personnel, also include CMC (MHP-10) and the appropriate Marine Corps district headquarters as information addressees. COMNAVMEDCOM WASHINGTON DC requires information copies of messages *only* when a patient has been placed on the seriously ill or injured or very seriously ill or injured list or diagnosed as terminally ill.

(r) *Outpatient care.* Whenever possible, perform diagnostic procedures and provide preoperative and post operative care, surgical care, convalescence, and followup observations and treatment on an outpatient basis.

(s) *Performance of duties while in an inpatient status.* U.S. military patients may be assigned duties in and around naval MTFs when such duties will be, in the judgement of the attending physician, of a therapeutic value. Physical condition, past training, and other acquired skills must all be considered before assigning any patient a given task. Do not assign patients duties which are not within their capabilities or which require more than a very brief period of orientation.

(t) *Prolonged definitive medical care.* Prolonged definitive medical care in naval MTFs will not be provided for U.S. military patients who are unlikely to return to duty. The time at which a patient should be processed for disability separation must be determined on an individual basis, taking into consideration the interests of the patient as well as those of the Government. A long-term patient roster will be maintained and updated at least

once monthly to enable commanding officers and other appropriate staff members to monitor the progress of all patients with 30 or more continuous days of hospitalization. Include on the roster basic patient identification data (name, grade or rate, register number, ward or absent status, clinic service, and whether assigned to a medical holding company); projected disposition (date, type, and profile), diagnosis, and cumulative hospital days (present facility and total).

(u) *Remediable physical defects of active duty members.*—(1) *General.* When a medical evaluation reveals that a Navy or Marine Corps patient on active duty has developed a remediable defect while on active duty, the patient will be offered the opportunity of operative repair or other appropriate remediable treatment, if medically indicated.

(2) *Refusal of treatment.* Per MANMED art. 18–15, when a member refuses to submit to recommended therapeutic measures for a remediable defect or condition which has interfered with the member's performance of duty and following prescribed therapy, the member is expected to be fit for full duty, the following procedures will apply:

(i) Transfer the member to a naval MTF for further evaluation and appearance before a medical board. After counseling per MANMED art. 18–15, any member of the naval service who refuses to submit to recommended medical, surgical, dental, or diagnostic measures, other than routine treatment for minor or temporary disabilities, will be asked to sign a completed NAVMED 6100/4, Medical Board Certificate Relative to Counseling on Refusal of Surgery and/or Treatment, attesting to the counseling.

(ii) The board will study all pertinent information, inquire into the merits of the individual's refusal to submit to treatment, and report the facts with appropriate recommendations.

(iii) As a general rule, refusal of minor surgery should be considered unreasonable in the absence of substantial contraindications. Refusal of major surgical operations may be reasonable or unreasonable, according to the circumstances. The age of the patient, previous unsuccessful operations, existing physical or mental contraindications, and any special risks should all be taken into consideration.

(iv) Where surgical procedures are involved, the board's report will contain answers to the following questions:

(A) Is surgical treatment required to relieve the incapacity and restore the individual to a duty status, and may it be expected to do so?

(B) Is the proposed surgery an established procedure that qualified and experienced surgeons ordinarily would recommend and undertake?

(C) Considering the risks ordinarily associated with surgical treatment, the patient's age and general physical condition, and the member's reason for refusing treatment, is the refusal reasonable or unreasonable? (Fear of surgery or religious scruples may be considered, along with all the other evidence, for whatever weight may appear appropriate.)

(v) If a member needing surgery is mentally competent, do not perform surgery over the member's protestation.

(vi) In medical, dental, or diagnostic situations, the board should show the need and risk of the recommended procedure(s).

(vii) If a medical board decides that a diagnostic, medical, dental, or surgical procedure is indicated, these findings must be made known to the patient. The board's report will show that the patient was afforded an opportunity to submit a written statement explaining the grounds for refusal. Forward any statement with the board's report. Advise the patient that even if the disability originally arose in line of duty, its continuance may be attributable to the member's unreasonable refusal to cooperate in its correction, and that the continuance of the disability might, therefore, result in the member's separation without benefits.

(viii) Also advise the patient that:

(A) Title 10 U.S.C. 1207 precludes disposition under chapter 61 of 10 U.S.C. if such a member's disability is due to intentional misconduct, willful neglect, or if it was incurred during a period of unauthorized absence. A member's refusal to complete a recommended therapy regimen or diagnostic procedure may be interpreted as willful neglect.

(B) Benefits from the Veterans Administration will be dependent upon a finding that the disability was incurred in line of duty and is not due to the member's willful misconduct.

(ix) The Social Security Act contains special provisions relating to benefits for "disabled" persons and certain provisions relating to persons disabled "in line of duty" during service in the Armed Forces. In many instances persons deemed to have "remediable" disorders have been held not "disabled" within the meaning of that term as used in the statute, and Federal courts have upheld that interpretation. One who is deemed unreasonably to have refused to undergo available surgical procedures may be deemed both "not disabled" and to have incurred the condition "not in the line of duty."

(x) Forward the board's report directly to the Central Physical Evaluation Board with a copy to MEDCOM–25 except in those instances when the convening authority desires referral of the medical board report for Departmental review.

(xi) Per MANMED art. 18–15, a member who refuses medical, dental, or surgical treatment for a condition that existed prior to entry into the service (EPTE defect), not aggravated by a period of active service but which interferes with the performance of duties, should be processed for reason of physical disability, convenience to the Government, or enlisted in error rather than under the refusal of treatment provisions. Procedures are delineated in BUMEDINST 1910.2G and SECNAVINST 1910.4A.

(3) *Other uniformed services patients.* When a patient of another service is found to have a remediable physical defect developed in the military service, refer the matter to the nearest headquarters of the service concerned.

(v) *Responsibilities of the commanding officer.* In connection with the provisions of this part, commanding officers of naval MTFs will:

(1) Determine which persons within the various categories authorized care in a facility will receive treatment in, be admitted to, and be discharged from that specific facility.

(2) Supervise care and treatment, including the employment of recognized professional procedures.

(3) Provide each patient with the best possible care in keeping with accepted professional standards and the assigned primary mission of the facility.

(4) Provide for counseling patients and naval MTF providers when care required is beyond the naval MTF's capability. This includes:

(i) Establishing training programs to acquaint naval MTF providers and HBAs with the uniformed services' referral for supplemental/cooperative care or services policy outlined in § 728.4(z).

(ii) Implementing control measures to ensure that:

(A) Providers requesting care under the provisions § 728.4(z) are qualified to maintain physician case management when required.

(B) Care requested under the supplemental/cooperative care criteria is medically necessary, legitimate, and otherwise permissible under the terms of that part of the USHBP under which it will be considered for payment.

(C) Providers explain to patients the reason for a referral and the type of referral being made.

(D) Attending physicians properly refer beneficiaries to the HBA for counseling and services per § 728.4(n).

(E) Uniform criteria are applied in determining cooperative care situations without consideration of rate, grade, or uniformed service affiliation.

(F) All DD 2161's are properly completed and approved by the commanding officer or designee.

(G) A copy of the completed DD 2161 is returned to the naval MTF for inclusion in the medical record of the patient.

(w) *Sick call.* A regularly scheduled assembly of sick and injured military personnel established to provide routine medical care. Subsequent to examination, personnel medically unfit for duty will be admitted to an MTF or placed sick in quarters; personnel not admitted or placed sick in quarters will be given such treatment as is deemed necessary. When excused from duty for medical reasons which do not require hospitalization, military personnel may be authorized to remain in quarters, not to exceed 72 hours.

(x) *Sicklist—authorized absence from.* Commanding officers of naval MTFs may authorize absences of up to 72 hours for dependents and retired personnel without formal discharge from the sicklist. When absences are authorized in excess of 24 hours, subsistence charges or dependent's rate, as applicable, for that period will not be collected and the number of reportable occupied bed days will be appropriately reduced. Prior to authorizing such absences, the attending physician will advise patients of their physical limitations and of any necessary safety precautions, and will annotate the clinical record that patients have been so advised. For treatment under the Medical Care Recovery Act, make reporting consistent with § 728.4(aa).

(y) *Subsisting out.* A category in which officer and enlisted patients on the sicklist of a naval MTF may be placed when their daily presence is not required for treatment nor examination, but who are not yet ready for return to duty. As a general rule, patients placed in this category should reside in the area of the facility and should be examined by the attending physician at least weekly. Enlisted personnel in a subsisting out status should be granted commuted rations.

(1) Granting of subsisting out privileges is one of many disposition alternatives; however, recommend that other avenues (medical holding company, convalescent leave, limited duty, etc.) be considered before granting this privilege.

(2) Naval MTF patients in a subsisting out status should not be confused with those enlisted personnel in a rehabilitation program who are granted liberty and are drawing commuted rations, but are required to be present at the treating facility during normal working hours. These personnel are not subsisting out and must have a bed assigned at the naval MTF.

(3) Naval MTF patients who are required to report for examinations or treatment more often than every 48 hours should not be placed in a subsisting out status.

(z) *Supplemental/cooperative care or services*—(1) *General.* When such services as defined in § 728.2(cc) are rendered to other than CHAMPUS-eligible individuals, the cost thereof is chargeable to operation and maintenance funds available for operation of the facility requesting care or services. Cooperative care applies to CHAMPUS-eligible patients receiving inpatient or outpatient care in a USMTF who require care or services beyond the capability of that USMTF. The following general principles apply to such CHAMPUS-eligible patients:

(i) *Cooperation of uniformed services physicians.* USMTF physicians are required to cooperate in providing CHAMPUS contractors and OCHAMPUS additional medical information. SECNAVINST 5211.5C delineates policies, conditions, and procedures that govern safeguarding, using, accessing, and disseminating personal information kept in a system of records. Providing information to CHAMPUS contractors and OCHAMPUS will be governed thereby.

(ii) *Physician case management.* Where required by NAVMEDCOMINST 6320.18 (CHAMPUS Regulation; implementation of), uniformed services physicians are required to provide case management (oversight) as would an attending or supervising civilian physician.

(iii) *CHAMPUS-authorized providers.* CHAMPUS contractors are responsible for determining whether a civilian provider is CHAMPUS-authorized and for providing such information, upon request, to USMTFs.

(iv) *Phychiatric or psychotherapeutic services.* If psychiatric care is being rendered by a psychiatric or clinical social worker, a psychiatric nurse, or a marriage and family counselor, and the uniformed services facility has made a determination that it does not have the professional staff competent to provide required physician case management, the patient may be (partially) disengaged for the psychiatric or psychotherapeutic service, yet have the remainder of required medical care provided by the naval MTF.

(v) *Forms and documentation.* A DD 2161, Referral For Civilian Medical Care, will be provided to each patient who is to receive supplemental or cooperative care or services. When supplemental care is required under the provisions of § 728.4(z) (3) and (4), the provisions of § 728.4(z)(3)(iii) apply. When cooperative care or services are required under the provisions of § 728.4(z) (5) and (6), the provisions of § 728.4(z)(5)(iv) apply.

(vi) *Clarification of unusual circumstances.* Commanding officers of naval MTFs will submit requests for clarification of unusual circumstances to OCHAMPUS or CHAMPUS contractors via the Commander, Naval Medical Command (MEDCOM-33) for consideration.

(2) *Care beyond a naval MTF's capability.* When, either during initial evaluation or during the course of treatment of CHAMPUS-eligible beneficiaries, required services are beyond the capability of the naval MTF, the commanding officer will arrange for the services from an alternate source in the following order, subject to restrictions specified. The provisions of § 728.4(z)(2)(i) through (iii) must be followed before either supplemental care, authorized in § 728.4(z)(4), is considered for payment from Navy Operations and Maintenance funds, or cooperative care, authorized in § 728.4(z)(6), is to be considered for payment under the terms of CHAMPUS.

(i) Obtain from another USMTF or other Federal MTF the authorized care necessary for continued treatment of the patient within the naval MTF, when such action is medically feasible and economically advantageous to the Government.

(ii) When the patient is a retired member or dependent, transfer per § 728.4(bb)(3) (i), (ii), (iii), or (iv), in that order. When the patient is a dependent of a member of a NATO nation, transfer per § 728.4(bb)(4) (i), (ii), or (iii), in that order.

(iii) With the patient's permission, the naval MTF may contact State programs, local health agencies, or health foundations to determine if benefits are available.

(iv) Obtain such supplemental care or services as delineated in § 728.4(z)(4) from a civilian source using local operation and maintenance funds, or

(v) Obtain such cooperative care or services as delineated in § 728.4(z)(6)

from a civilian source under the terms of CHAMPUS.

(3) *Operation and maintenance funds.* When local operation and maintenance funds are to be used to obtain supplemental care or services, the following guidelines are applicable:

(i) Care or services must be legitimate, medically necessary, and ordered by a qualified USMTF provider.

(ii) The naval MTF must make the necessary arrangements for obtaining required care or services from a specific source of care.

(iii) Upon approval of the naval MTF commanding officer or designee, provide the patient or sponsor with a properly completed DD 2161, Referral For Civilian Medical Care. The DD 2161 will be marked by the health benefits advisor or other designated individual to show the naval MTF as the source of payment. Forward a copy to the MTF's contracting or supply officer who is the point of contact for coordinating obligations with the comptroller and thus is responsible for assuring proper processing for payment.

(iv) Authorize care on an inpatient or outpatient basis for the minimum period necessary for the civilian provider to perform the specific test, procedure, treatment, or consultation requested. Patients receiving inpatient services in civilian medical facilities will not be counted as an occupied bed in the naval MTF, but will be continued on the naval MTF's inpatient census. Continue to charge pay patients the USMTF inpatient rate appropriate for their patient category.

(v) Naval MTF physicians will maintain professional contact with civilian providers.

(4) *Care and services authorized.* Use local operation and maintenance funds to defray the cost of the following when CHAMPUS-eligible patients are referred to civilian sources for the following types of care or services;

(i) All specialty consultations for the purpose of establishing or confirming diagnoses or recommending a course of treatment.

(ii) All diagnostic tests, diagnostic examinations, and diagnostic procedures (including genetic tests and CAT scans), ordered by qualified USMTF providers.

(iii) Prescription drugs and medical supplies.

(iv) Civilian ambulance service ordered by USMTF personnel.

(5) *CHAMPUS funds.* When payment is to be considered under the terms of CHAMPUS for cooperative care, even though the beneficiary remains under naval MTF control, the following guidelines are applicable:

(i) Process charges for care under the terms of CHAMPUS.

(A) If the charge for a covered service or supply is above the CHAMPUS-determined reasonable charge, the direct care system will not assume any liability on behalf of the patient where a civilian provider is concerned, although a USMTF physician recommended or prescribed the service or supply.

(B) Payment consideration for all care or services meeting cooperative care criteria will be under the terms of CHAMPUS and payment for such care or services will not be made from naval MTF funds. Conversely, any care or services meeting naval MTF supplemental care or services payment criteria will not be considered under the terms of CHAMPUS.

(ii) Care must be legitimate and otherwise permissible under the terms of CHAMPUS and must be ordered by a qualified USMTF provider.

(iii) Provide assistance to beneficiaries referred or disengaged under CHAMPUS. Although USMTF personnel are not authorized to refer beneficiaries to a specific civilian provider for care under CHAMPUS, health benefits advisors are authorized to contact the cooperative care coordinator of the appropriate CHAMPUS contractor for aid in determining authorized providers with the capability of rendering required services. Such information may be given to beneficiaries. Also encourage beneficiaries to obtain required services only from providers willing to participate in CHAMPUS. Subject to the availability of space, facilities, and capabilities of the staff, USMTFs may provide consultative and such other ancillary aid as required by the civilian provider selected by the beneficiary.

(iv) Provide a properly completed DD 2161, Referral For Civilian Medical Care, to patients who are referred (versus disengaged) to civilian sources under the terms of CHAMPUS for cooperative care. (A Nonavailability Statement (DD 1251) may also be required. Provide this form when required under § 728.33.) The DD 2161 will be marked by the health benefits advisor, or other designated individual, to show CHAMPUS as the source of payment consideration. All such DD 2161's must be approved by the commanding officer or designee. Give the patient sufficient copies to ensure a copy of the DD 2161 accompanies each CHAMPUS claim. Advise patients that CHAMPUS contractors will return claims received without the DD 2161. Also advise patients to arrange for return of a completed copy of the DD 2161 to the naval MTF for inclusion in their medical record.

(v) Such patients receiving inpatient or outpatient care or services will pay the patient's share of the costs as specified under the terms of CHAMPUS for their beneficiary category. Patients receiving inpatient services will not be continued on the naval MTF's census and will not be charged the USMTF inpatient rate.

(vi) Certain ancillary services authorized under CHAMPUS require physician case management during the course of treatment. USMTF physicians will manage the provision of ancillary services by civilian providers when such services are obtained under the terms of CHAMPUS. Examples include physical therapy, private duty (special) nursing, rental or lease/purchase of durable medical equipment, and services under the CHAMPUS Program for the Handicapped. USMTF providers exercising physician case management responsibility for ancillary services under CHAMPUS are subject to the same benefit limitations and certification of need requirements applicable to civilian providers under the terms of CHAMPUS for the same types of care. USMTF physicians exercising physician case management responsibility will maintain professional contact with civilian providers of care.

(6) *Care and services authorized.* Refer CHAMPUS-eligible patients to civilian sources for the following under the terms of CHAMPUS:

(i) Authorized nondiagnostic medical services such as physical therapy, speech therapy, radiation therapy, and private duty (special) nursing.

(ii) Preauthorized (by OCHAMPUS) adjunctive dental care, including orthodontia related to surgical correction of cleft palate.

(iii) Durable medical equipment. (CHAMPUS payment will be considered only if the equipment is not available on a loan basis from the naval MTF.)

(iv) Prosthetic devices (limited benefit), orthopedic braces and appliances.

(v) Optical devices (limited benefit).

(vi) Civilian ambulance service to a USMTF when service is ordered by other than direct care personnel.

(vii) All CHAMPUS Program for the Handicapped care.

(viii) Psychotherapeutic or psychiatric care.

(ix) Except for those types of care or services delineated in § 728.4(z)(4), all other CHAMPUS authorized medical services not available in the naval MTF (for example, neonatal intensive care).

(aa) *Third party liability case.* Per chapter 24, section 2403, JAG Manual, use the following guidelines to complete

and submit a NAVJAG 5890/12, Hospital and Medical Care, 3rd Party Liability Case, when a third party may be liable for the injury or disease being treated:

(1) *Preparation.* All naval MTFs will use the front of NAVJAG 5890/12 to report the value of medical care furnished to any patient when (i) a third party may be legally liable for causing the injury or disease, or (ii) when a Government claim is possible under workmen's compensation, no-fault insurance (see responsibilities for apprising the insurance carrier in § 728.4(aa)(5)), uninsured motorist insurance, or under medical payments insurance (e.g., in all automobile accident cases). Block 4 of this form requires an appended statement of the patient or an accident report, if available. Prior to requesting such a statement from a patient, the person preparing the front side of NAVJAG 5890/12 will show the patient the Privacy Act statement printed at the bottom of the form and have the patient sign his or her name beneath the statement.

(2) *Submission*—(i) *Naval patients.* For naval patients, submit the completed front side of the NAVJAG 5890/12 to the appropriate action JAG designee listed in section 2401 of the JAG Manual at the following times:

(A) *Initial.* Make an initial submission as soon as practicable after a patient is admitted for any period of inpatient care, or if it appears that more than 7 outpatient treatments will be furnished. This submission should not be delayed pending the accumulation of all potential charges from the treating facility. This submission need not be based upon an extensive investigation of the cause of the injury or disease, but it should include all known facts. Statements by the patient, police reports, and similar information (if available), should be appended to the form.

(B) *Interim.* Make an interim submission every 4 months after the initial submission until the patient is transferred or released from the facility, or changed from an inpatient status to an outpatient status.

(C) *Final.* Make a final submission upon completion of treatment or upon transfer of the patient to another facility. The facility to which the patient is transferred should be noted on the form. Report control symbol NAVJAG 5890-1 is assigned to this report.

(ii) *Nonnaval patients.* When care is provided to personnel of another Federal agency or department, that agency or department generally will assert any claim in behalf of the United States. In such instances, submit the NAVJAG 5890/12's (initial, interim, and final) directly to the appropriate of the following:

(A) *U.S. Army.* Commanding general of the Army or comparable area commander in which the incident occurred.

(B) *U.S. Air Force.* Staff judge advocate of the Air Force installation nearest the location where the initial medical care was provided.

(C) *U.S. Coast Guard.* Commandant (G-K-2). U.S. Coast Guard, Washington, DC 20593-0001.

(D) *Department of Labor.* The appropriate Office of Workers' Compensation Programs (OWCP).

(E) *Veterans Administration.* Director of the Veterans Administration hospital responsible for medical care of the patient being provided treatment.

(F) *Department of Health and Human Services (DHHS).* Regional attorney's office in the area were the incident occurred.

(3) *Supplementary documents.* An SF 502 should accompany the final submission in all cases involving inpatient care. Additionally, when Government care exceeds $1,000, inpatient facilities should complete and submit the back side of NAVJAG 5890/12 to the action JAG designee. On this side of the form, the determination of "patient status" may be used on local hospital usage.

(4) *Health record entries.* Retain copies of all NAVJAG 5890/12's in the Health Record of the patient. Immediately notify action JAG designees when a patient receives additional treatment subsequent to the issuance of a final NAVJAG 5890/12 if the subsequent treatment is related to the condition which gave rise to the claim.

(5) *No-fault insurance.* When no-fault insurance is or may be involved, the naval legal service office at which the JAG designee is located is responsible for apprising the insurance carrier that the Federal payment for the benefits of this part is secondary to any no-fault insurance coverage available to the injured individual.

(6) *Additional guidance.* Chapter 24 of the JAG Manual and BUMEDINST 5890.1A contain supplemental information.

(bb) *Transfer of patients*—(1) *General.* Treat all patients at the lowest echelon equipped and staffed to provide necessary care; however, when transfer to another MTF is considered necessary, use Government transportation when available. Accomplish medical regulating per the provisions of OPNAVINST 4630.25B and BUMEDINST 6320.1D.

(2) *U.S. military patients.* Do not retain U.S. military patients in acute care MTFs longer than the minimum time necessary to attain the mental or physical state required for return to duty or separation from the service. When required care is not available at the facility providing area inpatient care, transfer patients to the most readily accessible USMTF or designated USTF possessing the required capability. Transportation of the patient and a medical attendant or attendants, if required, is authorized at Government expense. Since the VA is staffed and equipped to provide care in the most expeditious manner, follow the administrative procedures outlined in NAVMEDCOMINST 6320.12 when:

(i) A patient has received the maximum benefit of hospitalization in a naval MTF but requires a protracted period of nursing home type care. The VA can provide this type care or arrange for it from a civilian source for individuals so entitled.

(ii) Determined that there is or may be spinal cord injury necessitating immediate medical and psychological attention.

(iii) A patient has sustained an apparently severe head injury or has been blinded necessitating immediate intervention beyond the capabilities of naval MTFs.

(iv) A determination has been made by the Secretary concerned that a member on active duty has an alcohol or drug dependency or drug abuse disability.

(3) *Retired members and dependents.* When a retired member of a dependent requires care beyond the capabilities of a facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USTF located in an overlapping inpatient catchment area of the transferring facility if either has the required capability.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USTF with required capability, regardless of its location.

(iii) Arrange for transfer of retired members to the Veterans Administration MTF nearest the patient's residence.

(iv) Provide aid in releasing the patient to a civilian provider of the patient's choice under the terms of Medicare, if the patient is entitled. Beneficiaries entitled to Medicare, Part A, because they are 65 years of age or older or because of a disability or chronic renal disease, lose CHAMPUS

eligibility but remain eligible for care in USMTFs and designated USTFs.

(v) If the patient is authorized benefits under CHAMPUS, disengage from medical management and issue a Non-availability Statement (DD 1251) per the provisions of § 728.33, for care under CHAMPUS. This step should only be taken after due consideration is made of the supplemental/cooperative care policy addressed in § 728.4(z).

(4) *Dependents of members of NATO nations.* When a dependent, as defined in § 728.41, of a member of a NATO nation requires care beyond the capabilities of a facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USTF with required capability if either is located in an overlapping inpatient catchment area of the transferring facility.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USTF with required capability, regardless of its location.

(iii) Effect disposition per § 728.42(d).

(5) *Others*—(i) *Medical care.* Section 34 of title 24, United States Code, provides that hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to officers and employees of any department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *Provided,* such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities. Hospitalization of such persons in a naval MTF is further limited by 24 U.S.C. 35 to the treatment of acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care.

(ii) *Dental care.* Section 35 of title 24 provides for space available routine dental care, other than dental prosthesis and orthodontia, for the categories of individuals enumerated in § 728.4(bb)(5)(i): *Provided,* that such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(iii) *Transfer.* Accomplish transfer and subsequent treatment of individuals in § 728.4(bb)(5)(i) per the provisions of law enumerated in § 728.4(bb)(5) (i) and (ii).

(cc) *Verification of patient eligibility*—(1) *DEERS.* (i) The Defense Enrollment Eligibility Reporting System (DEERS) was implemented by OPNAVINST 1750.2. Where DEERS has been started at naval medical and dental treatment facilities, commanding officers will appoint, in writing, a DEERS project officer to perform at the base level. The project officer's responsibilities and functions include coordinating, executing, and maintaining base-level DEERS policies and procedures; providing liaison with line activities, base-level personnel project officers, and base-level public affairs project officers; meeting and helping the contractor field representative on site visits to each facility under the project officer's cognizance; and compiling and submitting reports required within the command and by higher authority.

(ii) Commanding officers of afloat and deployable units are encouraged to appoint a unit DEERS medical project officer as a liaison with the hospital project officer providing services to local medical and dental treatment facilities. Distribute notice of such appointments to all concerned facilities.

(iii) When a DEERS project officer has been appointed by a naval MTF or DTF, submit a message (report control symbol MED 6320–42) to COMNAVMEDCOM, with information copies to appropriate chain of command activities, no later than 10 October annually, and situationally when changes occur. As a minimum, the report will provide:

(A) Name of reporting facility. If the project officer is responsible for more than one facility, list all such facilities.

(B) Mailing address including complete zip code (zip + 4) and unit identification code (UIC). Include this information for all facilities listed in § 728.4(cc)(1)(iii)(A).

(C) Name, grade, and corps of the DEERS project officer designated.

(D) Position title within parent facility.

(E) AUTOVON and commercial telephone numbers.

(2) *DEERS and the identification card.* This subpart includes DEERS procedures for eligibility verification checks to be used in conjunction with the identification card system as a basis for verifying eligibility for medical and dental care in USMTFs and uniformed services dental treatment facilities (USDTFs). For other than emergency care, certain patients are required to have a valid ID card in their possession and, under the circumstances described in § 728.4(cc)(3), are also required to meet DEERS criteria before treatment or services are rendered. Although DEERS and the ID card system are interrelated, there will be instances where a beneficiary is in possession of an apparently valid ID card and the DEERS verification check shows that eligibility has terminated or vice versa. Eligibility verification via an ID card does not override an indication of ineligibility in DEERS without some other collateral documentation. Dependents (in possession of or without ID cards) who undergo DEERS checking will be considered ineligible for the reasons stated in § 728.4(cc)(4)(v) (A) through (G). For problem resolution, refer dependents of active duty members to the personnel support detachment (PSD) servicing the sponsor's command; refer retirees, their dependents, and survivors to the local PSD.

(3) *Identification cards and procedures.* All individuals, including members of uniformed services in uniform, must provide valid identification when requesting health benefits. Although the most widely recognized and acceptable forms of identification are DD 1173, DD 2, Form PHS–1866–1, and Form PHS–1866–3 (Ret), individuals presenting for care without such identification may be rendered care upon presentation of other identification as outlined in this part. Under the circumstances indicated, the following procedures will be followed when individuals present without the required ID card.

(i) *Children Under 10.* Although a DD 1173 (Uniformed Services Identification and Privilege Card) may be issued to children under 10 years of age, under normal circumstances they are not. Accordingly, certification and identification of children under 10 years of age are the responsibility of the member, retired member, accompanying parent, legal guardian, or acting guardian. Either the DD 1173 issued the spouse of a member or former member or the identification card of the member or former member (DD 2, DD 2 (Ret), Form PHS–1866–1, or Form PHS–1866–3 (Ret)) is acceptable for the purpose of verifying eligibility of a child under 10 years of age.

(ii) *Indefinite expiration.* The fact that the word "indefinite" may appear in the space for the expiration date on a *member's* card does not lessen its acceptability for identification of a child. See § 728.4(cc)(3)(iii) for dependent's cards with an indefinite expiration date.

(iii) *Expiration date.* To be valid, a dependent's DD 1173 *must* have an expiration date. Do not honor a dependent's DD 1173 with an expiration date of "indefinite". Furthermore, such a card should be confiscated, per NAVMILPERSCOMINST 1750.1A, and forwarded to the local PSD. The PSD may then forward it to the Commander, Naval Military Personnel Command,

(NMPC (641D)/Pers 7312), Department of the Navy, Washington, DC 20370-5000 for investigation and final disposition. Render necessary emergency treatment to such a person. The patient administration department must determine such a patient's beneficiary status within 30 calendar days and forward such determination to the fiscal department. If indicated, billing action for treatment will then proceed following NAVMED P-5020.

(iv) *Without cards or with expired cards.* (A) When parents or parents-in-law (including step-parents and step-parents-in-law) request care in naval MTFs or DTFs without a DD 1173 in their possession or with expired DD 1173's, render care if they or their sponsor sign a statement that the individual requiring care has a valid ID card or that an application has been submitted for a renewal DD 1173. In the latter instance, include in the statement the allegation that: (*1*) The beneficiary is dependent upon the service member for over one-half of his or her support, and (*2*) that there has been no material change in the beneficiary's circumstances since the previous determination of dependency and issuance of the expired card. Place the statement in the beneficiary's medical record. Inform the patient or sponsor that if eligibility is not verified by presentation of a valid ID card to the patient administration department within 30 calendar days, the facility will initiate action to recoup the cost of care. If indicated, billing action for the cost of treatment will then proceed following NAVMED P-5020.

(B) When recent accessions, National Guard, reservists, or Reserve units are called to active duty for a period greater than 30 days and neither the members nor their dependents are at yet in receipt of their identification cards, satisfactory collateral identification may be accepted in lieu thereof, i.e., official documents such as orders, along with a marriage license, or birth certificate which establish the individual's status as a dependent of a member called to duty for a period which is not specified as 30 days or less. For a child, the collateral documentation must include satisfactory evidence that the child is within the age limiting criteria outlined in § 728.31(b)(4). An eligible dependent's entitlement, under the provisions of this subpart, starts on the first day of the sponsor's active service and ends as of midnight on the last day of active service.

(4) *DEERS checking.* Unless otherwise indicated, all DEERS verification procedures will be accomplished in conjunction with possession of a valid ID card.

(i) *Prospective DEERS processing*—(A) *Appointments.* To minimize difficulties for MTFs, DTFs, and patients, DEERS checks are necessary for prospective patients with future appointments made through a central or clinic appointment desk. Without advance DEERS checking, patients could arrive at a facility with valid ID cards but may fail the DEERS check, or may arrive without ID cards but be identified by the DEERS check as eligible. Records, including full social security numbers, of central and clinic appointment systems will be passed daily to the DEERS representative for a prospective DEERS check. This enables appointment clerks to notify individuals with appointments of any apparent problem with the DEERS or ID card system and refer those with problems to appropriate authorities prior to the appointment.

(B) *Prescriptions.* Minimum checking requirements of the program require prospective DEERS checks on all individuals presenting prescriptions of civilian providers (see § 728.4(cc)(4)(iv)(D)).

(ii) *Retrospective DEERS processing.* Pass daily logs (for walk-in patients, patients presenting in emergencies, or patients replacing last minute appointment cancellations) to the DEERS representative for retrospective batch processing if necessary for the facility to meet the minimum checking requirements in § 728.4(cc)(4)(iv). For DEERS processing, the last four digits of a social security number are insufficient. Accordingly, when retrospective processing is necessary, the full social security number of each patient must be included on daily logs.

(iii) *Priorities.* With the following initial priorities, conduct DEERS eligibility checks using a CRT terminal, single-number dialer telephone, or 800 number access provided for the specific purpose of DEERS checking to:

(A) Determine whether a beneficiary is enrolled.

(B) Verify beneficiary eligibility. Eastablishment of eligibility is under the cognizance of personnel support activities and detachments.

(C) Identify any errors on the data base.

(iv) *Minimum checking requirements.* Process patients presenting at USMTFs and DTFs in the 50 States for DEERS eligibility verification per the following minimum checking requirements.

(A) Twenty five percent of all outpatient visits.

(B) One hundred percent of all admissions.

(C) One hundred percent of all dental visits at all DTFs for other than active duty members, retired members, and dependent.

(*1*) Active duty members are exempt from DEERS eligibility verification checking at DTFs.

(*2*) Retired members will receive a DEERS vertification check at the initial visit to any DTF and annually thereafter at time of treatment at the same facility. To qualify for care as a result of the annually performed verification check, the individual performing the eligibility check will make a notation to this effect on an SF 603, Health Record—Dental. Include in the notation the date and result of the check.

(*3*) Dependents will have a DEERS eligibility verification check upon initial presentation for evaluation or treatment. This check will be valid for up to 30 days if, when the check is conducted, the period of eligibility requested is 30 days. A 30-day eligibility check may be accomplished online or via telephone by filling in or requesting the operator to fill in a 30 day period in the requested treatment dates on the DEERS eligibility inquiry screen. Each service or clinic is expected to establish auditable procedures to trace the date of the last eligibility verification on a particular dependent.

(D) One hundred percent of pharmacy outpatients presenting new prescriptions written by a civilian provider. Prospective DEERS checks are required for all patients presenting prescriptions of civilian providers. A DEERS check is not required upon presentation of a request for refill of a prescription of a civilian provider if the original prescription was filled by a USMTF within the past 120 days.

(E) One hundred percent of all individuals requesting treatment without a valid ID card if they represent themselves as individuals who are eligible to be included in the DEERS data base.

(v) *Ineligibility determinations.* When a DEERS verification check is performed and eligibility cannot be verified for any of the following reasons, deny routine nonemergency care unless the beneficiary meets the criteria for a DEERS eligibility override as noted in § 728.4(cc)(4)(viii).

(A) Sponsor not enrolled in DEERS.

(B) Dependent not enrolled in DEERS.

(C) "End eligibility date" has passed. Each individual in the DEERS data base has a date assigned on which eligibility is scheduled to end.

(D) Sponsor has separated from active duty and is no longer entitled to benefits.

(E) Spouse has a final divorce decree from sponsor and is not entitled to continued eligibility as a former spouse.

(F) Dependent child is married.

(G) Dependent becomes an active duty member of a uniformed service. (Applies only to CHAMPUS benefits since the former dependent becomes entitled to direct care benefits in his or her own right as an active duty member and must enroll in DEERS.)

(vi) *Emergency situations.* When a physician determines that emergency care is necessary, initiate treatment. If admitted after emergency treatment has been provided, a retrospective DEERS check is required. If an emergency admission or emergency outpatient treatment is accomplished for an individual whose proof of eligibility is in question, the patient administration department must determine the individual's beneficiary status within 30 calendar days of treatment and forward such determination to the fiscal department. Eligibility verifications will normally consist of presentation of a valid ID card along with either a positive DEERS check or a DEERS override as noted in § 728.4(cc)(4)(viii). If indicated, billing action for treatment will then proceed per NAVMED P-5020.

(vii) *Eligibility verification for nonemergency care.* When a prospective patient presents without a valid ID card and:

(A) DEERS does not verify eligibility, deny nonemergency care. Care denial will only be accomplished by supervisory personnel designated by the commanding officer.

(B) The individual is on the DEERS data base, do not provide nonemergency care until a NAVMED 6320/9, Dependent's Eligibility for Medical Care, is signed by the member, patient, patient's parent, or patient's legal or acting guardian. This form attests the fact that eligibility has been established per appropriate directives and includes the reason a valid ID card is not in the prospective patient's possession. Apprise the aforementioned responsible individual of the provisions on the form NAVMED 6320/9 now requiring presentation of a valid ID card within 30 calendar days. Deny treatment or admission in physician determined nonemergency situations of persons refusing to sign the certification on the NAVMED 6320/9. For persons rendered treatment, patient administration department personnel must determine their eligibility status within 30 calendar days and forward such determination to the fiscal department. If indicated, billing action for treatment will then proceed following NAVMED P-5020.

(viii) *DEERS overrides.* Possession of an ID card alone does not constitute sufficient proof of eligibility when the DEERS check does not verify eligibility. What constitutes sufficient proof will be determined by the reason the patient failed the DEERS check. For example, groups most expected to fail DEERS eligibility checks are recent accession members and their dependents, Guard or Reserve members recently activated for training periods of greater than 30 days and their dependents, and parents and parents-in-law with expired ID cards. Upon presentation of a valid ID card, the following are reasons to "override" a DEERS check either showing the individual as ineligible or when an individual does not appear in the DEERS data base.

(A) *DD 1172.* Patient presents an original of a copy of a DD 1172, Application for Uniformed Services Identification and Privilege Card, which is also used to enroll beneficiaries in DEERS. If the original is used, the personnel support detachment (PSD) furnishing the original will list the telephone number of the verifying officer to aid in verification. Any copy presented must have an original signature in section III; printed name of verifying officer, his or her grade, title, and telephone number; and the date the copy was issued. For treatment purposes, this override expires 120 days from the date issued.

(B) *Recently issued identification cards—(1) DD 1173.* Patient presents a recently issued DD 1173, Uniformed Services Identification and Privilege Card. Examples are spouses recently married to sponsor, newly eligible stepchildren, family members of sponsors recently entering on active duty for a period greater than 30 days, parents or parents-in-law, and unremarried spouses recently determined eligible. For treatment purposes, this override expires 120 days from the date issued.

(2) *Other ID Cards.* Patient presents any of the following ID cards with a date of issue within the previous 120 days: DD 2, DD 2 (Ret), Form PHS 1866-1, or Form PHs 1866-3 (Ret). When these ID cards are used for the purpose of verifying eligibility for a child, collateral documentation is necessary to ensure the child is actually the alleged sponsor's dependent and in determining whether the child is within the age limiting criteria outlined in § 728.31(b)(4).

(C) *Active duty orders.* Patient or sponsor presents recently issued orders to active duty for a period greater than 30 days. Copies of such orders may be accepted up to 120 days of their issue date.

(D) *Newborn infants.* Newborn infants for a period of 1 year after birth provided the sponsor presents a valid ID card.

(E) *Recently expired ID cards.* If the DEERS data base shows an individual as ineligible due to an ID card that has expired within the previous 120 days (shown on the screen as "Elig with valid ID card"), care may be rendered when the patient has a new ID card issued within the previous 120 days.

(F) *Sponsor's duty station has an FPO or APO number or sponsor is stationed outside the 50 United States.* Do not deny care to bona fide dependents of sponsors assigned to a duty station outside the 50 United States or assigned to a duty station with an FPO or APO address as long as the sponsor appears on the DEERS data base. Before initiating nonemergency care, request collateral documentation showing relationship to sponsor when the relationship is or may be in doubt.

(G) *Survivors.* Dependents of deceased sponsors when the deceased sponsor failed to enroll in or have his or her dependents enrolled in DEERS. This situation will be evidenced when an eligibility check on the surviving widow or widower (or other dependent) finds that the sponsor does not appear (screen shows "Sponsor SSN Not Found") or the survivor's name appears as the sponsor but the survivor is not listed separately as a dependent. In any of these situations, if the survivor has a valid ID card, treat the individual on the first visit and refer him or her to the local personnel support detachment for correction of the DEERS data base. For second and subsequent visits prior to appearance on the DEERS data base, require survivors to present a DD 1172 issued per § 728.4(cc)(4)(viii)(A).

(H) *Patients Not Eligible for DEERS Enrollment.* (1) Secretarial designees are not eligible for enrollment in DEERS. Their eligibility determination is verified by the letter, on one of the service Secretaries' letterhead, of authorization issued.

(2) When it becomes necessary to make a determination of eligibility on other individuals not eligible for entry on the DEERS data base, patient administration department personnel will obtain a determination from the purported sponsoring agency, if appropriate. When necessary to treat or admit a person who cannot otherwise present proof of eligibility for care at the expense of the Government, do not deny care based only on the fact that the

individual is not on the DEERS data base. In such instances, follow the procedures in NAVMED P-5020 to minimize, to the fullest extent possible, the write-off of uncollectible accounts.

Subpart B—Members of the Uniformed Services on Active Duty

§ 728.11 Eligible beneficiaries.

(a) A member of a uniformed service, as defined in subpart A, who is on active duty is entitled to and will be provided medical and dental care and adjuncts thereto. For the purpose of this part, the following are also considered on active duty:

(1) Members of the National Guard in active Federal service pursuant to a "call" under 10 U.S.C. 3500 or 8500.

(2) Midshipmen of the United States Naval Academy.

(3) Cadets of the United States Military Academy.

(4) Cadets of the Air Force Academy.

(5) Cadets of the Coast Guard Academy.

(b) The following categories of personnel who are on active duty are entitled to and will be provided medical and dental care and adjuncts thereto to the same extent as is provided for active duty members of the Regular service (except reservists when on active duty for training as delineated in § 728.21).

(1) Members of the Reserve components.

(2) Members of the Fleet Reserve.

(3) Members of the Fleet Marine Corps Reserve.

(4) Members of the Reserve Officers' Training Corps.

(5) Members of all officer candidate programs.

(6) Retired members of the uniformed services.

§ 728.12 Extent of care.

Members who are away from their duty stations or are on duty where there is no MTF of their own service may receive care at the nearest available Federal MTF (including designated USTFs) with the capability to provide required care. Care will be provided without regard to whether the condition for which treatment is required was incurred or contracted in line of duty.

(a) *All uniformed services active duty members.*

(1) All eligible beneficiaries covered in this subpart are entitled to and will be rendered the following treatment and services upon application to a naval MTF whose mission includes the rendering of the care required. This entitlement provides that when required care and services are beyond the capabilities of the facility to which the member applies, the commanding officer of that facility will arrange for care from another USMTF, designated USTF, or other Federal source or will authorize and arrange for direct use of supplemental services and supplies from civilian non-Federal sources out of operation and maintenance funds.

(i) Necessary hospitalization and other medical care.

(ii) Occupational health services as defined in § 728.2(z).

(iii) Necessary prosthetic devices, prosthetic dental appliances, hearing aids, spectacles, orthopedic footwear, and other orthopedic appliances (see Subpart H). When these items need repair or replacement and the items were not damaged or lost through negligence, repair or replacement is authorized at Goverment expense.

(iv) Routine dental care.

(2) When a USMTF, with a mission of providing the care required, releases the medical management of an active duty member of the Navy, Marine Corps, Army, Air Force, or a commissioned corps member of USPHS or NOAA, the resulting civilian health care costs will be paid by the referring facility.

(3) The member's uniformed service will be billed for care provided by the civilian facility only when the referring MTF is not organized nor authorized to provide needed health care (see Part 732 of this chapter for naval members). Saturation of service or facilities does not fall within this exception. When a naval MTF retains medical management, the costs of supplemental care obtained from civilian sources is paid from funds available to operate the MTF which manages care of the patient. When it becomes necessary to refer a USPHS or NOAA commissioned corps member to a non-Federal source of care, place a call to the Department of Health and Human Services (DHHS), Chief, Patient Care Services on (301) 443-1943 or FTS 443-1943 if DHHS is to assume financial responsibility. Patient Care Services is the sole source for providing authorization for non-Federal care at DHHS expense.

(b) *Maternity episode for active duty female members.* A pregnant active duty member who lives outside the MHSS inpatient catchment area of all USMTFs is permitted to choose whether she wishes to deliver in a closer civilian hospital or travel to the USMTF for delivery. If such a member chooses to deliver in a naval MTF, makes application, and presents at that facility at the time for delivery, the provisions of § 728.12(a) apply with respect to the furnishing of needed care, including routine newborn care (i.e., nursery, newborn examination, PKU test, etc.); arrangements for care beyond the facility's capabilities; or the expenditure of funds for supplemental care or services. Pay expenses incurred for the infant in USMTFs or civilian facilities (once the mother has been admitted to the USMTF) from funds available for care of active duty members, *unless* the infant becomes a patient in his or her own right either through an extension of the birthing hospital stay because of complications, subsequent transfer to another facility, or subsequent admission. If the Government is to assume financial responsibility for:

(1) Care of pregnant members residing within the MHSS inpatient catchment area of a uniformed services hospital or in the inpatient catchment area of a designated USTF, such members are required to:

(i) Make application to that facility for care, or

(ii) Obtain authorization, per Part 732 of this chapter, for delivery in a civilian facility.

(2) Non-Federal care of pregnant members residing outside inpatient catchment areas of USMTFs and USTFs, the member must request and receive authorization per Part 732 of this chapter. Part 732 of this chapter also provides for cases of precipitious labor necessitating emergency care. OPNAVINST 6000.1, Management of Pregnant Servicewomen, contains medical-administrative guidelines on management prior to admission and after discharge from admission for delivery.

(c) *Reserve and National Guard personnel.* In addition to those services covered in § 728.12 (a) and (b), Reserve and National Guard personnel are authorized the following under conditions set forth. (See § 728.25 for additional benefits for National Guard personnel.)

(1) Personnel whose units have an active Army mission of manning missile sites are authorized spectacle inserts for protective field masks.

(2) Personnel assigned to units designated for control of civil disturbances are authorized spectacle inserts for protective field masks M17.

§ 728.13 Application for care.

Possession of an ID card (a green colored DD 2 (with letter suffix denoting branch of service), Armed Forces Identification Card; a green colored PHS 1866-1, Identification Card; or a red colored DD 2 Res (Reservists on active duty for training)) alone does not constitute sufficient proof of eligibility. Accordingly, make a DEERS check, per § 728.4(cc), before other than emergency

care is rendered to the extent that may be authorized.

§ 728.14 Pay patients.

Care is provided on a reimbursable basis to: Coast Guard active duty officers, enlisted personnel, and academy cadets; Public Health Service Commissioned Corps active duty officers; and Commissioned Corps active duty officers of the National Oceanic and Atmospheric Administration. Accordingly, patient administration personnel will initiate the collection action process in Subpart J in each instance of inpatient or outpatient care provided to these categories of patients.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Programs, and National Guard Personnel

§ 728.21 Navy and Marine Corps reservists.

(a) *Scope.* This § 728.21 applies to reservists, as those terms are defined in § 728.2, ordered to active duty for training or inactive duty training for 30 days or less. Reservists serving under orders specifying duty in excess of 30 days, such as Sea and Air Mariners (SAMS) while on initial active duty for training, will be provided care as members of the Regular service per subpart B.

(b) *Entitlement.* Per 10 U.S.C. 1074a(a), reservists who incur or aggravate an injury, illness, or disease in line of duty while on active duty for training or inactive duty training for a period of 30 days or less, including travel to and from that duty, are entitled to medical and dental care appropriate for the treatment of that injury, disease, or illness until the resulting disability cannot be materially improved by further hospitalization or treatment. Care is authorized for such an injury, illness, or disease beyond the period of training to the same extent as care is authorized for members of the Regular service (see subpart B) subject to the provisions of § 728.21(e).

(c) *Questionable circumstances.* If the circumstances are questionable, referral to the OMA or ODA is appropriate. If necessary, make referral to the Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental) on determinations of entitlements.

(d) *Line of duty.* For the purpose of providing treatment under laws entitling reservists to care, an injury, illness, or disease which is incurred, aggravated, or becomes manifest while a reservist is employed in the performance of active duty for training or inactive duty training (including authorized leave, liberty and travel to and from either duty) will be considered to have been incurred in line of duty (LOD) unless the condition was incurred as a result of the reservist's own misconduct or under other circumstances enumerated in JAG Manual, chapter VIII. While the LOD investigation is being conducted, such reservists remain entitled to care. If the investigation determines that the injury or illness was not incurred in line of duty, the civilian humanitarian nonindigent rate is applicable if further care is required in naval MTFs. (See DOD Military Pay and Allowances Entitlement Manual for allowable constructive travel times.)

(e) *Treatment and services authorized.* In addition to those services delineated above, the following may be rendered under circumstances outlined:

(1) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that are lost or have become damaged during training duty, not through negligence of the individual, may be repaired or replaced at Government expense.

(2) Reservists covered by this subpart may be provided the following only if approved by the appropriate OMA or ODA, or by the Commander, Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental) *prior* to initiation of services.

(i) Treatment for acute exacerbations of conditions that existed prior to a reservist's period of training duty. Limit care to that necessary for the prevention of pain or undue suffering until the patient can reasonably return to control of the member's private physician or dentist.

(A) Remediable physical defects and remediable treatment for other conditions.

(B) Elective surgery.

(ii) All dental care other than emergency treatment and that necessary to correct an injury incurred in the line of duty.

(f) *Authorization for care.* (1) Reservists covered by this subpart may be provided inpatient or outpatient care during a period of training duty without written authorization.

(2) Except in emergencies or when inpatient care initiated during a period of training duty extends beyond such period, reservists will be required to furnish written official authorization from their unit commanding officer, or higher authority, incident to receiving inpatient or outpatient care beyond the period of training duty. The letter of authorization will include name, grade or rate, social security number, and organization of the reservist; type of training duty being performed or that was being performed when the condition manifested; diagnosis (if known); and a statement that the condition was incurred in line of duty and that the reservist is entitled to care. If the reservist has been issued a notice of eligibility (NOE) (Subpart I), the NOE may then be accepted in lieu of the letter of authorization. When authorization has not been obtained beforehand, care may be provided on a civilian humanitarian basis (see Subpart G) pending final determination of eligibility.

§ 728.22 Members of other reserve components of the uniformed services.

(a) Members of reserve components of the Coast Guard may be provided care the same as Navy and Marine Corps reservists.

(b) Members of reserve components of the Army and Air Force may be provided care in naval MTFs to the same extent that they are eligible for such care in MTFs of their respective services. Consult current Army Regulation 40-3, Medical, Dental, and Veterinary Care, or Air Force Regulation 168-6, Persons Authorized Medical Care, as appropriate, for particular eligibility requirements or contact the nearest appropriate service facility.

(c) When the service directive requires written authorization, obtain such authorization from the reservist's unit commanding officer or other appropriate higher authority.

(d) Naval MTFs in the United States are authorized to conduct physical examinations of and administer immunizations to inactive reserve Public Health Service commissioned officers upon presentation of a written request from the Commissioned Personnel Operations Division, OPM/OAM, 5600 Fishers Lane, Rockville, MD 20852.

§ 728.23 Reserve Officers' Training Corps (ROTC).

(a) *Eligible beneficiaries.* (1) Members of the Senior Reserve Officers' Training Corps of the Armed Forces including students enrolled in the 4-year Senior ROTC Program or the 2-year Advanced Training Senior ROTC Program.

(2) Designated applicants for membership in the Navy, Army, and Air Force Senior ROTC Programs during their initial 6-weeks training period (practice cruises or field training).

(3) Medical, dental, pharmacy, veterinary or science allied to medicine students who are commissioned officers of a reserve component of an Armed Force who have been admitted to and

training in a unit of a Senior Reserve Officers' Training Corps.

(b) *Extent of care.* (1) While attending or en route to or from field training or practice cruises:

(i) Medical care for a condition incurred without reference to line of duty.

(ii) Routine dental care.

(iii) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that have become damaged or lost during training duty, not through negligence of the individual, may be repaired or replaced as necessary at government expense.

(iv) Care of remediable physical defects, elective surgery or other remediable treatment for conditions that existed prior to a period of training duty are not authorized without approval from the appropriate OMA or ODA, or from the Commander, Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental).

(v) Medical examinations and immunizations.

(vi) ROTC members are authorized continued medical care, including hospitalization, upon expiration of their field training or practice cruise period, the same as reservists in § 728.21(b) and § 728.22.

(2) While attending a civilian educational institution:

(i) Medical care in naval MTFs, including hospitalization, for a condition incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for purposes of making visits of observation, including participation in service-sponsored sports, recreational, and training activities.

(ii) Medical examinations, including hospitalization necessary for the proper conduct thereof.

(iii) Required immunizations, including hospitalization for severe reactions therefrom.

(c) *Authorization.* The individual's commanding officer will prepare a letter of authorization addressed to the commanding officer of the MTF concerned.

(d) *ROTC members as beneficiaries of the Office of Workers' Compensation Programs (OWCP).* Under circumstances described therein, render care as outlined in § 728.53 to members of the ROTC as beneficiaries of OWCP.

§ 728.24 Navy and Marine Corps Office Candidate Programs.

Members of the Reserve Officers Candidate Program and Platoon Leaders Class are entitled to the same medical and dental benefits as are provided members of the Navy and Marine Corps Reserve Components. Accordingly, the provisions of § 728.21 are applicable for such members. Additionally, candidates for, or persons enrolled in such programs are authorized access to naval MTFs for the purpose of conducting special physical examination procedures which have been requested by the Commander, Naval Medical Command to determine their physical fitness for appointment to, or continuation in such a program. Upon a request from the individual's commanding officer, the officer in charge of cognizant Navy and Marine Corps recruiting stations, or officer selection officer, naval MTFs are authorized to admit such persons when, in the opinion of the cognizant officer, hospitalization is necessary for the proper conduct of the special physical examinations. Hospitalization should be kept to a minimum and treatment other than for humanitarian reasons, except as provided in this part, is not authorized.

§ 728.25 Army and Air Force National Guard personnel.

(a) *Medical and dental care.* Upon presentation of a letter of authorization, render care as set forth in AR 40-3 (Medical, Dental, and Veterinary Care) and AFR 168-6 (Persons Authorized Medical Care) to members of the Army and Air Force National Guard who contract a disease or become ill in line of duty while on full-time National Guard duty, (including leave and liberty therefrom) or while traveling to or from that duty. The authorizing letter will include name, social security number, grade, and organization of the member; type and period of duty in which engaged (or in which engaged when the injury or illness occurred); diagnosis (if known); and will indicate that the injury suffered or disease contracted was in line of duty and that the individual is entitled to medical or dental care. Limit care to that appropriate for the injury, disease, or illness until the resulting disability cannot be materially improved by further hospitalization or treatment.

(b) *Physical examinations.* AR 40-3 and AFR 168-6 also authorize physical examinations for National Guard personnel. Accordingly, when requested by an Army or Air Force National Guard unit's commanding officer, naval MTFs may perform the requested physical examination per the appropriate service directive, subject to the availability of space, facilities, and the capabilities of the staff.

Subpart D—Retired Members and Dependents of the Uniformed Services

§ 728.31 Eligible beneficiaries and health benefits authorized.

(a) *Retired members of the uniformed services.* Retired members, as defined in § 728.2(aa), are authorized the same medical and dental benefits as active duty members subject to the availability of space and facilities, capabilities of the professional staff, and the priorities in § 728.3, except that:

(1) Periodic medical examinations for members on the Temporary Disability Retired List, including hospitalization in connection with the conduct thereof, will be furnished on the same priority basis as care to active duty members.

(2) When vision correction is required, one pair of standard issue spectacles, or one pair of nonstandard spectacles, are authorized when required to satisfy patient needs. Two pairs of spectacles may be furnished only when professionally determined to be essential by the examining officer. Military ophthalmic laboratories will not furnish occupational type spectacles, such as aviation, industrial safety, double segment, and mask insert, to retired military personnel (NAVMEDCOMINST 6810.1 refers).

(b) *Dependents of members of former members.* Include:

(1) The spouse.

(2) The unremarried widow.

(3) The unremarried widower.

(4) An unmarried legitimate child, including an adopted child or a stepchild, who either—

(i) Has not passed his or her 21st birthday;

(ii) Is incapable of self-support because of a mental or physical incapacity that existed before the 21st birthday and is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of his or her support; or

(iii) Has not passed the 23rd birthday, is enrolled in a full-time course of study in an institution of higher learning approved by the administering Secretary and is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of his or her support. (If such a child suffers a disabling illness or injury and is unable to return to school, the child remains eligible for benefits until 6 months after the disability is removed, or until the 23rd birthday is reached, whichever comes first.)

(5) An unmarried illegitimate child or illegitimate step-child who is, or was at the time of sponsor's death, dependent on the sponsor for more than one-half of

his or her support; residing with or in a home provided by the sponsor or the sponsor's spouse, as applicable, and is—

(i) Under 21 years of age; or

(ii) Twenty-one years of age or older but incapable of self-support because of a mental or physical incapacity that existed prior to the individual's 21st birthday; or

(iii) Twenty-one or 22 years of age and pursuing a full-time course of education that is approved per § 728.31(b)(4)(iii).

(6) A parent or parent-in-law, who is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of such parent's support and residing in the sponsor's household.

(7) An unremarried former spouse of a member or former member who does not have medical coverage under an employer-sponsored health plan, and who:

(i) On the date of the final decree of divorce, dissolution, or annulment, had been married to the member or former member at least 20 years during which period the member of former member performed at least 20 years of service creditable in determining that member's or former member's eligibility for retired or retainer pay, or equivalent pay.

(ii) Had been married to the member of former member at least 20 years, at least 15 of which were during the period the member of former member performed service creditable in determining the member's eligibility for retired or retainer pay, or equivalent pay. The former spouse's sponsor must have performed at least 20 years of service creditable in determining the sponsor's eligibility for retired or retainer pay, or equivalent pay.

(A) Eligibility for such former spouses continue until remarriage if the final decree of divorce, dissolution, or annulment occurred before 1 April 1985.

(B) Eligibility terminates the later of: Either 2 years from the date of the final decree of divorce, dissolution, or annulment; or 1 April 1988 for such former spouses whose final decree occured on or after 1 April 1985.

(iii) An unremarried former spouse of a deceased member of former member who meets the requirements of § 728.31(b)(7)(i) or (ii) may be provided medical and dental care as a dependent when the sponsor:

(A) Died before attaining age 60.

(B) At the time of death would have been eligible for retired pay under 10 U.S.C. 1331–1337 except that the sponsor was under 60 years of age; but the former spouse is not eligible for care until the date the sponsor would have attained age 60;

(C) Whether or not the sponsor elected participation in the Survivor Benefit Plan of 10 U.S.C. 1447–1455.

(c) *Eligibility factors.* Care that may be rendered to all dependents in this subpart D is subject to the availability of space and facilities, capabilities of the professional staff, and priorities in § 728.3. Additionally:

(1) Members of the uniformed services must be serving under orders specifying active duty for more than 30 days before their dependents are authorized benefits delineated in § 728.31(d).

(2) A dependent's eligibility begins on the date the member enters on active duty and ends as of midnight of the date the sponsor's period of active duty ends for any reason other than retirement or death. Dependents lose eligibility as of midnight of the date a member is officially place in a deserter status. Eligibility is restored on the date a deserter is returned to military control.

(3) A dependent (other than a former spouse) of a member or former member who died before attaining age 60 and at the time of death—

(i) Would have been eligible for retired pay under chapter 67 of title 10 U.S.C. but for the fact that the member of former member was under 60 years of age, and

(ii) Had elected to participate in the Survivor Benefit Plan, may not be rendered medical or dental care under the sponsor's entitlement until the date on which such member of former member would have attained age 60.

(4) A spouse, not qualifying as a former spouse, who is divorced from a member loses eligibility for benefits as of midnight of the date the divorce becomes final. This includes loss of maternity care benefits for wives who are pregnant at the time a divorce becomes final. A spouse does not lose eligibility through issuance of an interlocutory decree of divorce even when a property settlement has been approved which releases the member from responsibility for the spouse's support. A spouse's eligibility depends upon the relationship of the spouse to the member; so long as the relationship of husband and wife is not terminated by a final divorce or annulment decree, eligibility continues.

(5) Eligibility of children is not affected by the divorce of parents except that a stepchild relationship ceases upon divorce or annulment of natural parent and step-parent. A child's eligibility for health benefits is not affected by the remarriage of the divorced spouse maintaining custody unless the marriage is to an eligible service member.

(6) A stepchild relationship does not cease upon death of the member step-parent but does cease if the natural parent subsequently remarries.

(7) A child of an active duty or retired member, adopted after that member's death, retains eligibility for health benefits. However, the adoption of a child of a living member (other than by a person whose dependents are eligible for health benefits at USMTFs) terminates the child's eligibility.

(8) If a member's child is married before reaching age 21 to a person whose dependents are not eligible for health benefits in USMTFs, eligibility ceases as of midnight on the date of marriage. Should the marriage be terminated, the child again becomes eligible for benefits as a dependent child if otherwise eligible.

(d) *Health benefits authorized.* (1) Inpatient care including services and supplies normally furnished by the MTF.

(2) Outpatient care and services.

(3) Drugs (see chapter 21, MANMED).

(i) Prescriptions written by officers of the Medical and Dental Corps, civilian physicians and dentists employed by the Navy, designated officers of the Medical Service Corps and Nurse Corps, independent duty hospital corpsmen, and others designated to write prescriptions will be filled subject to the availability of pharmaceuticals, and consistent with control procedures and applicable laws.

(ii) Prescriptions written by civilian physicians and dentists (non-Navy employed) for eligible beneficiaries may be filled if:

(A) The commanding officer or CO's designee determines that pharmacy personnel and funds are available.

(B) The items requested are routinely stocked.

(C) The prescribed quantity is within limitations established by the command.

(D) The prescriber is in the local area (limits designated by the commanding officer).

(E) The provisions of chapter 21, MANMED are followed when such services include the dispensing of controlled substances.

(4) Treatment on an inpatient or outpatient basis of:

(i) Medical and surgical conditions.

(ii) Contagious diseases.

(iii) Nervous, mental, and chronic conditions.

(5) Physical examinations, including eye examinations and hearing evaluations, and all other tests and procedures necessary for a complete physical examination.

(6) Immunizations.

(7) Maternity (obstetrical) and infant care, routine care and examination of the newborn infant, and well-baby care for mothers and *infants* meeting the eligibility requirements of § 728.31(b). If a newborn infant of an unmarried dependent minor daughter becomes a patient in his or her own right after discharge of the mother, classify the infant as civilian humanitarian nonindigent inasmuch as § 728.31(b) does not define the infant as a dependent of the active duty or retired service member. Therefore, the minor daughter's sponsor (parent) should be counseled concerning the possibility of Secretarial designee status for the infant (see § 728.77).

(8) Diagnostic tests and services, including laboratory and x-ray examinations. Physical therapy, laboratory, x-ray, and other ambulatory diagnostic or therapeutic measures requeted by non-Navy employed physicians may be provided upon approval of the commanding officer or designated department heads. Rendering of such srvices is subordinate to and will not unduly interfere with providing inpatient and outpatient care to active duty personnel and others whose priority to receive care is equal to or greater than such dependents. Ensure that the release of any information to non-Navy employed physicians is in consonance with applicable provisions of SECNAVINST 5211.5C.

(9) Family planning services as delineated in SECNAVINST 6300.2A. Abortions, at the expense of the Government, may not be performed except where the life of the mother would be endangered if the fetus were carried to term.

(10) Dental care worldwide on a space available basis.

(11) Government ambulance services, surface or air, to transport dependents to, from, or between medical facilities when determined by the medical officer in charge to be medically necessary.

(12) Home calls when determined by the medical officer in charge to be medically necessary.

(13) Artificial limbs and artificial eyes, including initial issue, fitting, repair, replacement, and adjustment.

(14) Durable equipment such as wheelchairs, hospital beds, and resuscitators may be issued on a loan basis.

(15) Orthopedic aids, braces, crutches, elastic stockings, walking irons, and similar aids.

(16) Prosthetic devices (other than artificial limbs and eyes), hearing aids, orthopedic footwear, and spectacles or contact lenses for the correction of ordinary refractive error may not be provided dependents. These items, however, may be sold to dependents at cost to the Government at facilities outside the United States and at specific installations within the United States where adequate civilian facilities are unavailable.

(17) Special lenses (including intraocular lenses) or contact lenses for those eye conditions which require these items for complete medical or surgical management of the condition.

(18) One wig if the individual has alopecia resulting from treatment of a malignant disease: *Provided* the individual has not previously received a wig at the expense of the United States.

(e) *Dependents of reserves.* (1) A dependent, as defined in § 728.31(b), of a deceased member of the Naval Reserve, the Fleet Reserve, the Marine Corps Reserve, or the Fleet Marine Corps Reserve, who—

(i) Was ordered to active duty or to perform inactive-duty training for any period of time.

(ii) Was disabled in the line of duty from an injury while so employed, and

(iii) Dies from such a specific injury, illness, or disease is entitled to the same care as provided for dependents in § 728.31(c).

(2) The provisions of this subpart D are not intended to authorize medical and dental care precluded for dependents of members of Reserve components who receive involuntary orders to active duty under 10 U.S.C. 270b.

(f) *Unauthorized care.* In addition to the devices listed in § 728.31(d)(16) as unauthorized, dependents are not authorized care for elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.

§ 728.32 Application for care.

Possession of an ID card alone (DD 2 (Retired), PHS–1868–3 (Retired), or DD 1173 (Uniformed Services Identification and Privilege Card)) does not constitute sufficient proof of eligibility. Accordingly, a DEERS check will be instituted per § 728.4 (cc) before medical and dental care may be rendered except in emergencies. When required inpatient or outpatient care is beyond the capabilities of the naval MTF, the provisions of § 728.34 apply. When required inpatient care cannot be rendered and a decision is made to disengage a CHAMPUS-eligible beneficiary, the provisions of § 728.33 apply.

§ 728.33 Nonavailability statement (DD 1251).

(a) *General.* Per DODINST 6015.19 of 26 Nov. 1984, the following guidelines are effective as of 1 Jan. 1985. All previously issued Nonavailability Statement guidelines and reporting requirements are superseded.

(b) *Applicability.* The following provisions are applicable to nonemergency inpatient care only. A DD 1251 is not required:

(1) For emergency care (see § 728.33(d)(1)).

(2) When the beneficiary has other insurance (including Medicare) that provides primary coverage for a covered service.

(3) For medical services that CHAMPUS clearly does not cover.

(c) *Reasons for issuance.* DD 1251's may be issued for only the following reasons:

(1) Proper facilities are not available.

(2) Professional capability is not available.

(3) It would be medically inappropriate (as defined in § 728.2(u)) to require the beneficiary to use the USMTF and the attending physician has specific prior approval from the facility's commanding officer or higher authority to make such determination.

(i) Issuance for this reason should be restricted to those instances when denial of the DD 1251 could result in a significant risk to the health of any patient requiring any clinical specialty.

(ii) Issuing authorities have discretionary authority to evaluate each situation and issue a DD 1251 under the "medically inappropriate" reason if:

(A) In consideration of individual medical needs, personal constraints on an individual's ability to get to the USMTF results in an unreasonable limitation on that individual's ability to get required medical care, and

(B) The issuing authority determines that obtaining care from a civilian source selected by the individual would result in significantly less limitations on that individual's ability to get required medical care than would result if the individual was required to obtain care from a USMTF.

(C) A beneficiary is in a travel status. The commanding officer of the first facility contacted, in either the beneficiary's home catchment area or the catchment area where hospital care was obtained, has this discretionary authority. Travel in this instance means the beneficiary is temporarily on a trip away from his or her permanent residence. The reason the patient is traveling, the distance involved in the travel, and the time away from the permanent residence is not critical to the principle inherent in the policy. The issuing officer to whom the request for a Nonavailability Statement is made

should reasonably determine that the trip was not made, and the civilian care is not (was not) obtained, with the primary intent of avoiding use of a USMTF or USTF serving the beneficiary's home area.

(d) *Guidelines for issuing*—(1) *Emergency care.* Emergency care claims do not require an NAS; however, the nature of the service or care must be certified as an emergency by the attending physician, either on the claim form or in a separate signed and dated statement. Otherwise, a DD 1251 is required by CHAMPUS-eligible beneficiaries who are subject to the provisions of § 728.33.

(2) *Emergency maternity care.* Unless substantiated by medical documentation and review, a maternity admission would not be deemed as an emergency since the fact of the pregnancy would have been established well in advance of the admission. In such an instance, the beneficiary would have had sufficient opportunity to obtain a DD 1251 if required in her residence catchment area.

(3) *Newborn infant(s) remaining in hospital after discharge of mother.* A newborn infant remaining in the hospital continuously after discharge of the mother does not require a separate DD 1251 for the first 15 days after the mother is discharged. Claims for care beyond this 15-day limitation must be accompanied by a valid DD 1251 issued in the infant's name. This is due to the fact that the infant becomes a patient in his or her own right (the episode of care for the infant after discharge of the mother is not considered part of the initial reason for admission of the mother (delivery), and is therefore considered a separate admission under a different diagnosis).

(4) *Cooperative care program.* When a DD 2161, Referral for Civilian Medical Care, is issued for inpatient care in connection with the Cooperative Care Program (§ 728.4(z)(5)(iv)) for care under CHAMPUS, a DD 1251 must also be issued.

(5) *Beneficiary responsibilities.* Beneficiaries are responsible for determining whether an NAS is necessary in the area of their residence and for obtaining one, if required, by first seeking nonemergency inpatient care in the USMTF or USTF serving the catchment area. Beneficiaries cannot avoid this requirement by arranging to be away from their residence when nonemergency inpatient care is obtained, e.g., staying with a relative or traveling. Individuals requiring an NAS because they reside in the inpatient catchment area of a USMTF or USTF also require an NAS for nonemergency care received while away from their inpatient catchment area.

(e) *Issuing authority.* Under the direction of the Commander, Naval Medical Command, exercised through commanders of naval geographic medical commands, naval MTFs will issue Nonavailability Statements only when care required is not available from the naval MTF and the beneficiary's place of residence is within the catchment area (as defined in § 728.2(d)) of the issuing facility or as otherwise directed by the Secretary of Defense. When the facility's inpatient catchment area overlaps the inpatient catchment area of one or more other USMTFs or USTFs with inpatient capability and the residence of the beneficiary is within the same catchment area of one or more other USMTFs or USTFs with inpatient capability, the issuing authority will:

(1) Determine whether required care is available at any other USMTFs or USTFs whose inpatient catchment area overlaps the beneficiary's residence. If care is available, refer the beneficiary to that facility and do not issue a DD 1251.

(2) Implement measures ensuring that an audit trail related to each check and referral is maintained, including the check required before retroactive issuance of a DD 1251 as delineated in § 728.33(g). When other than written communication is made to ascertain capability, make a record in the log required in § 728.33(h) that "Telephonic (or other) determination was made on (date) that required care was not available at (name of other USMTF(s) or USTF(s) contacted)". The individual ascertaining this information will sign this notation.

(3) Once established that a DD 1251 is authorized and will be issued, the following will apply:

(i) Do not refer patients to a specific source of care.

(ii) Nonavailability Statements issued at commands outside the United States are not valid for care received in facilities located within the United States. Statements issued within the United States are not valid for care received outside the United States.

(iii) The issuing authority will:

(A) If capability permits, prepare a DD 1251 via the automated application of DEERS. Where this system is operational, it provides for transmitting quarterly reports to the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) by electronic means. System users should refer to their DEERS/NAS Users Manual for specific guidance on the use of the automated system. At activities where the DEER/NAS automated system is not operational, prepare each DD 1251 per instructions on the reverse of the form. After completion, if authorized by the facility CO, the issuing authority will sign the DD 1251. Give a copy to the patient for presentation to a participating civilian provider, or for submission with the claim of a nonparticipating provider. Retain a copy for the issuing activity's records. Retain the original for subsequent transmittal to the Naval Medical Data Services Center per § 728.33(j).

(B) Explain to the patient or other responsible family member the validity period of the DD 1251 (see § 728.33(f)).

(C) Ensure that beneficiaries are clearly advised of the cost-sharing provisions of CHAMPUS and of the fact that the issuance of a Nonavailability Statement does not imply that CHAMPUS will allow any and all costs incurred through the use of the DD 1251. The issuance of a DD 1251 indicates only that care requested is not available at a USMTF or USTF serving the beneficiary's residence inpatient catchment area.

(D) Review, with the patient or responsible family member, instructions 1 through 6 on the face of the DD 1251 and have the patient or responsible family member sign acknowledgement that such review has been made and is understood.

(E) Advise recipients that CHAMPUS fiscal intermediaries may deny claims of individuals who are not enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

(f) *Validity period.* DD 1251's issued for:

(1) Other than maternity care are valid for a hospital admission occurring within 30 days of issuance and remain valid from the date of admission until 15 days after discharge from the facility rendering inpatient care. This allows for any follow-on treatment related directly to the original admission.

(2) Maternity episodes are valid if outpatient of inpatient treatment related to the pregnancy is initiated within 30 days of its issuance. They remain valid for care of the mother through termination of the pregnancy and for 42 days thereafter to allow for postnatal care to be included in the maternity episode. (See § 728.33(d)(3) for the validity period of DD 1251's for infants remaining after discharge of the mother.)

(g) *Retroactive issuance.* Issue Nonavailability Statements retroactively only if required care could not have been rendered in a USMTF or USTF as specified in § 728.33(e) at the time services were rendered in the civilian sector. At the time a retroactive issuance is requested, the facility

receiving the request will determine whether capability existed at the USMTF or USTF serving the inpatient catchment area wherein the beneficiary resides (resided) or at any of the facilities in the overlapping area described in § 728.33(e). While the date of service will be recorded on the DD 1251, send the retained original to the Naval Medical Data Services Center along with others issued during the week of issuance (§ 728.33(j) refers).

(h) *Annotating DD 1251's.* Before issuance, annotate each DD 1251 per the instructions for completion on the reverse of the form. DD 1251's issued under the CO's discretionary authority for the "medically inappropriate reason (§ 728.33(c)(3)(ii)) will be annotated in the remarks section documenting the special circumstances necessitating issuance, the name and location of the source of care selected by the beneficiary, and approximate distance from the source selected to the nearest USMTF or USTF with capability (see instruction number 2 on the reverse of the DD 1251). Establish and maintain a consecutively numbered log to include for each individual to whom a DD 1251 is issued:

(1) Patient's name and identifying data.

(2) The facility unique NAS number (block number 1 on the DD 1251).

(i) *Appeal procedures.* Beneficiaries may appeal the denial of their request for a DD 1251. This procedure consists of four levels within Navy, any one of which may terminate action and order issuance of a Nonavailability Statement if deemed warranted:

(1) The first level is the chief of service, or director of clinical services if the chief of service is the cognizant authority denying the beneficiary's original request.

(2) The second level is the commanding officer of the naval MTF denying the issuance. Where the appeal is denied and denial is upheld at the commanding officer's level, inform beneficiaries that their appeal may be forwarded to the geographic commander having jurisdictional authority.

(3) The third level is the appropriate geographic commander, if the appeal is denied at this level, inform beneficiaries that their appeal may be forwarded to the Commander, Naval Medical Command, Washington, DC 20372–5120.

(4) The Commander, Naval Medical Command, the fourth level of appeal, will evaluate all documentation submitted and arrive at a decision. The beneficiary will be notified in writing of this decision and the reasons therefor.

(j) *Data collection and reporting.* Do not issue the original of each DD 1251 prepared at activities where the DEER/NAS automated system is not operational. Send the retained originals to the Commanding Officer, Naval Medical Data Services Center (Code–03), Bethesda, MD 20814–5066 for reporting under report control symbol DD-HA (Q) 1463(6320).

§ 728.34 Care beyond the capabilities of a naval MTF.

When either during initial evaluation or during the course of treatment of an individual authorized care in this subpart, a determination is made that required care or services are beyond the capability of the naval MTF, the provisions of § 728.4(z)(2) apply.

§ 728.35 Coordination of benefits—third party payers.

Title 10 U.S.C. 1095 directs the services to collect from third-party payers the reasonable costs of inpatient hospital care incurred by the United States on behalf of retirees and dependents. Naval hospital collection agents have been provided instructions relative to this issue and are responsible for initiating claims to third-party payers for the cost of such care. Admission office personnel must obtain insurance, medical service, or health plan (third-party payer) information from retirees and dependents upon admission and forward this information to the collection agent.

§ 728.36 Pay patients.

Care is provided on a reimbursable basis to retired Coast Guard officers and enlisted personnel, retired Public Health Service Commissioned Corps officers, retired Commissioned Corps officers of the National Oceanic and Atmospheric Administration, and to the dependents of such personnel. Accordingly, patient administration personnel will follow the provisions of subpart J to initiate the collection action process when inpatient or outpatient care is provided to these categories of beneficiaries.

Subpart E—Members of Foreign Military Services and Their Dependents

§ 728.41 General provisions.

(a) *Dependent.* As used in this subpart, the term "dependent" denotes a person who bears one of the following relationships to his or her sponsor:

(1) A wife.

(2) A husband if dependent on his sponsor for more than one-half of his support.

(3) An unmarried legitimate child, including an adopted or stepchild who is dependent on the sponsor for over one-half of his or her support and who either:

(i) Has not passed the 21st birthday; or

(ii) Is incapable of self-support due to a physical or mental incapacity that existed prior to reaching the age of 21; or

(iii) Has not passed the 23rd birthday and is enrolled in a full-time course of study in an accredited institution of higher learning.

(b) *Transfer to naval MTFs in the United States.* Do not transfer personnel covered in this subpart to the United States solely for the purpose of obtaining medical care at naval MTFs. Consideration may be given however, in special circumstances following laws of humanity or principles of international courtesy. Transfer to naval MTFs in the United States of such persons located outside the United States requires approval of the Secretary of the Navy. Naval commands, therefore, should not commit the Navy by a promise of treatment in the United States. Approval generally will not be granted for treatment of those who suffer from incurable afflictions, who require excessive nursing or custodial care, or those who have adequate facilities in their own country. When a request is received concerning transfer for treatment at a naval MTF in the United States, the following procedures apply:

(1) Forward the request to the Chief of Naval Operations (OP–61), with a copy to the Commander, Naval Medical Command, Washington, DC 20372–5120 for administrative processing. Include:

(i) Patient's full name and grade or rate (if dependent, the sponsor's name and grade or rate also).

(ii) Country of which a citizen.

(iii) Results of coordination with the chief of the diplomatic mission of the country involved.

(iv) Medical report giving the history, diagnosis, clinical findings, results of diagnostic tests and procedures, and all other pertinent medical information.

(v) Availability or lack thereof of professional skills and adequacy of facilities for treatment in the member's own country.

(vi) Who will assume financial responsibility for costs of hospitalization and travel.

(2) The Chief of Naval Operations (OP–61) will, if appropriate, obtain State Department clearance and guidance and advise the Secretary of the Navy accordingly. The Commander, Naval Medical Command will furnish the Chief of Naval Operations information and recommendations relative to the medical aspects and the name of the naval MTF with the capability to

provide required care. If approved, the Chief of Naval Operations will furnish, through the chain of command, the commanding officer of the designated naval MTF authorization for admission of the beneficiary for treatment.

§ 728.42 NATO.

(a) *NATO SOFA nations.* Belgium, Canada, Denmark, Federal Republic of Germany, France, Greece, Iceland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Turkey, the United Kingdom, and the United States.

(b) *Beneficiaries.* The following personnel are beneficiaries under the conditions set forth.

(1) *Members of NATO military services and their dependents.* Military personnel of NATO nations, who, in connection with their official duties, are stationed in or passing through the United States, and their dependents residing in the United States with the sponsor may be provided care in naval MTFs to the same extent and under the same conditions as comparable U.S. uniformed services personnel and their dependents. Accordingly, the provisions of § 728.12 are applicable to military personnel and § 728.31(d) through § 728.34 to accompanying dependents.

(2) *Military ships and aircraft personnel.* Crew and passengers of visiting military aircraft and crews of ships of NATO nations which land or come into port at NATO or U.S. military airfields or ports within NATO countries.

(3) *NATO liaison officers.* In overseas areas, liaison officers from NATO Army Forces or members of a liaison detachment from such a Force.

(c) *Application for care.* Military personnel of NATO nations stationed in the United States and their dependents will present valid Uniformed Services Identification and Privilege Cards (DD 1173) when applying for care. For other eligible persons passing through the United States on official business and those enumerated in § 728.42(b) (2) and (3), orders or other official identification may be accepted in lieu of the DD 1173.

(d) *Disposition.* When it becomes necessary to return individuals to their home country for medical reasons, make immediate notification to the NATO unit sponsoring the member or dependent's sponsor. Include all pertinent information regarding the physical and mental condition of the individual concerned. Following are details of agreements among the Armed Forces of NATO, CENTO, and SEATO Nations on procedures for disposition of allied country patients by DOD medical installations.

(1) *Transfer of patients.* (i) The patient's medical welfare must be the paramount consideration. When deciding upon transfer of a patient, give due consideration to any increased medical hazard which the transfer might involve.

(ii) Arrangements for disposition of patients should be capable of being implemented by existing organizations. Consequently, no new establishment should be required specially for dealing with the transferring of allied casualties.

(iii) Transfer patients to their own national organization at the earliest practicable opportunity consistent with the observance of principles established in § 728.42(d)(1) (i) and (ii) and under any of the following conditions:

(A) When a medical facility of their own nation is within reasonable proximity of the facility of the holding nation.

(B) When the patient is determined to require hospitalization in excess of 30 days.

(C) Where there is any question as to the ability of the patient to perform duty upon release from the MTF.

(iv) The decision as to whether a patient, other than one requiring transfer under § 728.42(d)(1)(iii), is fit for release from the MTF is the responsibility of the facility's commanding officer.

(v) All clinical documents, to include x-rays, relating to the patient will accompany such patients on transfer to their own national organization.

(vi) The decision of suitability for transfer and the arrangements for transfer will be the responsibility of the holding nation.

(vii) Final transfer channels should be arranged by local liaison before actual movement.

(viii) Patients not suitable for transfer to their own national organization must be dealt with for treatment and disposition purposes as patients of the holding nation until they are transferred, i.e., they will be dealth with in military hospitals, military medical installations, or in civilian hospitals that are part of the military medical evacuation system of the holding nation.

(2) *Classification of patients.* Different channels for disposition will be required for the following two types of patients:

(i) *Patients not requiring admission.* Patients not requiring admission to an MTF will be returned to their nearest national unit under arrangements to be made locally.

(ii) *Patients admitted to medical installations.* All such patients will be dealth with per § 728.42(d)(1).

(e) *Care authorized outside the 48 contiguous United States.* Major overseas commanders may authorize care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only, *Provided,* the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Administer dental treatment only as an adjunct to authorized inpatient care. Do not include dental prostheses or orthodontia.

§ 728.43 Members of other foreign military services and their dependents.

(a) *Foreign military service members.* For the purpose of § 728.43, members of foreign military services include only:

(1) Military personnel carried on the current Diplomatic List (Blue) or on the List of Employees of Diplomatic Missions (White) published by the Department of State.

(2) Military personnel assigned or attached to United States military units for duty; military personnel on foreign military supply missions accredited to and recognized by one of the military departments; and military personnel on duty in the United States at the invitation of the Secretary of Defense or one of the military departments. For the purpose of § 728.43, members of foreign Security Assistance Training Programs (SATP) and Foreign Military Sales (FMS) are not included (see § 728.44).

(3) Foreign military personnel accredited to joint United States defense boards or commissions when stationed in the United States.

(4) Foreign military personnel covered in agreements entered into by the Secretary of State, Secretary of Defense, or one of the military departments to include, but not limited to, United Nations forces personnel of foreign governments exclusive of NATO nations.

(b) *Care authorized in the United States.* Military personnel of foreign nations not covered in § 728.42 and their dependents residing in the United States with the sponsor may be routinely provided only outpatient medical care in naval MTFs on a reimbursable basis. *Provided,* the sponsor is in the United States in a status officially recognized by an agency of the Department of Defense. Dental care and hospitalization for such members and their dependents are limited to emergencies. All outpatient care and hospitalization in

emergencies are subject to reimbursement as outlined in § 728.46.

(c) *Application for care.* All personnel covered by § 728.43 will present orders or other official U.S. identification verifying their status when applying for care.

(d) *Disposition.* When it becomes necessary to return individuals covered by § 728.43 to their home country for medical reasons, make immediate notification to the sponsoring unit of the patient or patient's sponsor with a copy to the Chief of Naval Operations (OP-61). Include all pertinent information regarding the physical and mental condition of the individual concerned and full identification, diagnosis, prognosis, estimated period of hospitalization, and recommended disposition. Additionally, the provisions of § 728.42(d) (1) and (2) apply.

(e) *Care authorized outside the 48 contiguous United States.* Major overseas commanders may authorize care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only. *Provided,* the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Administer dental treatment only as an adjunct to authorized inpatient care. Do not include dental prostheses or orthodontia.

§ 728.44 Members of security assistance training programs, foreign military sales, and their ITO authorized dependents.

(a) *Policies.*—(1) *Invitational Travel Orders screening.* Prior to determining the levels of care authorized or the government or person responsible for payment for care rendered, carefully screen ITOs to detect variations applicable to certain foreign countries. For example, unless orders state differently, Kuwait has a civilian health plan to cover medical expenses of their trainees; trainees from the Federal Republic of Germany are personally responsible for reimbursing for inpatient care provided to their dependents; and all inpatient medical services for trainees from France and their dependents are to be borne by the individual trainee.

(2) *Elective and definitive surgery.* The overall policy with respect to elective and definitive surgery for Security Assistance Training Program (SATP), Foreign Military Sales (FMS) personnel and their dependents is that conservatism will at all times prevail, except bona fide emergency situations which might threaten the life or health of an individual. Generally, elective care is not authorized nor should be started. However, when a commanding officer of a naval MTF considers such care necessary to the early resumption and completion of training, submit the complete facts to the Chief of Naval Operations (OP-63) for approval. Include the patient's name (sponsor's also if patient is an ITO authorized dependent), grade or rate, country of origin, diagnosis, type of elective care being sought, and prognosis.

(3) *Prior to entering training.* Upon arrival of an SATP or FMS trainee in the United States or at an overseas training site, it is discovered that the trainee cannot qualify for training by reason of a physical or mental condition which will require a significant amount of treatment before entering or completing training, return such trainees to their home country immediately or as soon thereafter as travel permits.

(4) *After entering training.* When trainees require hospitalization or are disabled after entering a course of training, return them to their home country as soon as practicable when, in the opinion of the commanding officer of the medical facility, hospitalization or disability will prevent training for a period in excess of 30 days. Forward a copy of the patient's clinical records with the patient. When a trainee is accepted for treatment that is not expected to exceed 30 days, notify the commanding officer of the training acvitity. Further, when a trainee is scheduled for consecutive training sessions convening prior to the expected data of release from a naval MTF, make the next scheduled training activity an information addressee. Upon release from the MTF, direct such trainees to resume training.

(b) *Care authorized.* Generally, all SATP and FMS personnel and their ITO authorized dependents are entitled to care to the same extent. However, certain agreements require that they be charged differently and that certain exclusions apply.

(1) *NATO members and their ITO authorized dependents*—(i) *Foreign military sales (FMS).* Subject to reimbursement per § 728.46, FMS personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and their accompanying ITO authorized dependents will be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States military personnel and their dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International military education and training (IMET).* Subject to reimbursement for inpatient care at the appropriate IMET rate for members or at the full reimbursement rate for dependents, IMET personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and accompanying dependents will be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States military personnel and their dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(2) *Other foreign members and ITO authorized dependents*—(i) *Foreign military sales.* Subject to reimbursement by the trainee or the trainee's government for both inpatient and outpatient care at the full reimbursement rate, FMS personnel of non-NATO nations and ITO authorized accompanying dependents may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) Spectacles may be furnished when required to enable trainees to perform their assigned duties, *Provided* the required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for the military member and is not authorized for dependents.

(D) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International military education and training.* Subject to reimbursement for both inpatient and outpatient care at the appropriate rates for members and dependents, IMET personnel of non-NATO nations may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) spectacles may be furnished when required to enable trainees to perform their assigned duties, *Provided* the

required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for military members and is not authorized for dependents.

(D) Dependents are not authorized cooperative care under CHAMPUS.

(c) *Application for care.* Trainees and accompanying dependents will present official U.S. identification or orders verifying their status when applying for care. If any doubt exists as to the extent of care authorized, ITOs should be screened (see § 728.44(a)(1)).

(d) *Notification.* When trainees require hospitalization as a result of illness or injury prior to or after entering training, the training activity (the hospital if patient has been admitted) will make a message report through the normal chain of command to the Chief of Naval Operations (OP-63) with information copies to MAAG, COMNAV MEDCOM, Navy International Logistics Control Office (NAVIL CO), Unified Commander, the affected office, and the foreign naval attache concerned. Include details of the incident, estimated period of hospitalization, physical or mental condition of the patient, and diagnosis. For further amplification, see OPNAVINST 4950.1H and NAVCOMPTMAN 032103.

§ 728.45 Civilian components (employees of foreign military services) and their dependents.

(a) *Care authorized.* Beneficiaries covered in § 728.45 are only authorized care in naval MTFs in the United States and then only civilian humanitarian emergency care on a reimbursable basis (Subpart J) rendered at installations which have been designated as remote by the Secretary of the Navy. Make arrangements to transfer such beneficiaries to a civilian facility as soon as their condition permits.

(b) *Potential beneficiaries.*—(1) *NATO.* Civilian employee personnel (and their dependents residing with them) accompanying military personnel in § 728.42(b)(1), *Provided*, the beneficiaries are not stateless persons nor nationals of any state which is not a party to the North Atlantic Treaty, nor nationals of, nor ordinarily residents in the United States.

(2) *Others.* Civilian personnel not covered in § 728.45(b)(1) (and their dependents residing with them) accompanying personnel of foreign nations on duty in the United States at the invitation of the Department of Defense or one of the military departments.

(c) *Application for care.* Personnel covered by the provisions of § 728.45 will present orders or other official U.S. identification verifying their status when applying for care.

§ 728.46 Charges and collection.

(a) *Policy.* Pub. L. 99-591, section 9029, contains provisions prohibiting the expenditure of appropriated funds ". . . to provide medical care in the United States on an inpatient basis to foreign military and diplomatic personnel or their dependents unless the Department of Defense is reimbursed for the costs of providing such care: *Provided*, That reimbursements . . . shall be credited to the appropriations against which charges have been made for providing such care, except that inpatient medical care may be provided in the United States without cost to military personnel and their dependents from a foreign country if comparable care is made available to a comparable number of United States military personnel in that foreign country."

(b) *Canadian agreement.* On 3 November 1986, the Department of National Defence of Canada and DOD concluded a comparable care agreement that covers certain military personnel. The agreement stipulates that:

(1) DOD will, upon request, provide Canadian Forces members the same range of medical and dental services under the same conditions and to the same extent as such services are provided comparable United States military personnel. Inasmuch as the agreement covers only certain military personnel, the reimbursement provisions of Pub. L. 99-591 remain in effect for inpatient care provided to Canadian diplomatic personnel, Canadian dependents, and Canadian foreign military sales trainees who receive care in the United States. Further:

(2) Permanently stationed Canadian units with established strengths of more than 150 personnel are expected to have integral health care capability. Any health care services which members of such units receive from the host nation will be provided on a full reimbursement basis. Groups of larger than 150 personnel, which conduct collective training in the United States, are expected to deploy with an organic unit medical capability. Naval MTFs may be requested to provide services, beyond the capability of the organic unit, at full reimbursement rates.

(c) *Procedures.* (1) Until otherwise directed, naval MTFs in the 50 United States will collect the full reimbursement rate (FRR) for inpatient care provided to all foreign military personnel (except Canadians covered by the comparable care agreement in § 728.46(b), and military personnel connected with a Foreign Military Sales (FMS) case number), foreign diplomatic personnel, and to the dependents of both whether they are in the United States on official duty or for other reasons.

(2) Subpart J contains procedures for the initiation of collection action when inpatient care is rendered to beneficiaries from NATO nations and when either inpatient or outpatient care is rendered to all others enumerated in this part. Chapter II, part 4 of NAVMED P-5020 is applicable to the collection of and accounting for such charges.

Subpart F—Beneficiaries of Other Federal Agencies

§ 728.51 General provisions—the "Economy Act."

The Economy Act, 31 U.S.C. 1535, generally permits agency heads, or heads of major organizational units of agencies, to procure goods and services from other agencies or within their own agency so long as funds for procurement are available, the order is in the best interest of the Government, the source from which the goods or services are ordered can produce them or obtain them by contract, and the internal or inter-agency procurement is more convenient, or less expensive, than commercial procurement. Provisions of the Economy Act apply to requests from other Federal agencies for medical and dental care for beneficiaries for whom they are responsible. Consult specific provisions of the Act respecting financial and acounting limitations and requirements.

§ 728.52 Veterans Administration beneficiaries (VAB).

(a) *Eligible beneficiaries*—Those who have served in the Armed Forces, have been separated under conditions other than dishonorable, and have been determined by the Veterans Administration (VA) to be eligible for care at VA expense. Prior to 7 September 1980, veterans status could be obtained by virtue of 1 day's honorable service. The following restrictions do not apply to individuals who are discharged from active duty because of a disability or who were discharged for reasons of "early out" or hardship program under 10 U.S.C. 1171 and 1173.

(1) For individuals with an original enlistment in the military service after 7 September 1980, the law generally denies benefits, including medical care.

(2) For individuals entering service after 16 October 1981, the law generally denies medical benefits when such

individuals do not complete the shorter of:

(i) Twenty-four months of continuous active duty, or

(ii) The full period for which that person was called or ordered to active duty.

(b) *Inpatient control*—Each VAB admitted will be required to conform to regulations governing the internal administration of the naval facility. Restrictive or punitive measures, including disciplinary action or denial of privileges, will conform as nearly as possible to VA instructions.

(c) *Resolution of problems*—All problems pertaining to VABs, including admission, medical or other records, and all correspondence will be matters of resolution between the commanding officer of the naval facility and the VA office of jurisdiction authorizing admission. Questions of policy and administration which cannot be so resolved will be forwarded, through the normal chain of command, to the Administrator of Veterans Affairs via COMNAVMEDCOM for resolution.

(d) *Care in the United States*—(1) *Inpatient care.* An eligible VAB may be admitted to a naval MTF on presentation of a written authorization for admission signed by an official of the VA office of jurisdiction. Neurological and certain neuropsychiatric patients without obvious evidence of psychosis and not requiring restraints, and instances of suspected tuberculosis, may be admitted for diagnosis. When diagnosed, promptly report instances of psychosis, psychoneurosis, and tuberculosis of present clinical significance to the VA office of jurisdiction with a request for transfer to a VA facility.

(i) *Extent of care.* Provide eligible VABs medical and surgical care, including prostheses such as eyes and limbs and appliances such as hearing aids, spectacles, or orthopedic appliances when required for the proper treatment of the condition upon which eligibility is based.

(ii) *Disposition of emergency admission.* Notify the appropriate VA office of jurisdiction by message or other expeditious means within 72 hours after the date and hour of an emergency admission of a potential VAB. Include a request for an authorization for admission and emergency treatment. If VA denies VAB status to such a person admitted in an emergency, the provisions of § 728.81(a) are applicable. Once admitted in an emergency situation, discharage a VAB promptly upon termination of the emergency unless arrangements have been made with the VA office of jurisdiction:

(A) For transfer to a VA treatment facility if further treatment is required.

(B) To retain the patient as a VAB in the naval MTF.

(2) *Outpatient care.* Outpatient care, including post hospitalization outpatient care, may be provided upon authorization by the VA office of jurisdiction. When outpatient followup care is requested, commanding officers are responsible for determining whether capabilities and workload permit providing such care. In an emergency, provide necessary care.

(3) *Physical examinations.* Upon a determination by a naval MTF commanding officer that space, facilities, and capabilities exist, naval MTFs may provide physical examinations when requested by the VA for the purpose of adjudicating claims for VA physical disability compensation. If authorized by the VA, patients may be admitted when the examination requires more than 1 day.

(4) *Dental care.* Limit dental treatment to inpatients who require services adjunctive to medical or surgical conditions for which hospitalized.

(e) *Care outside the United States*—(1) *Eligible beneficiaries.* Beneficiaries described in § 728.52(a) who are citizens of the United States and residing or sojourning abroad may, within the capabilities of the facility as determined by the commanding officer, be provided inpatient and outpatient care upon presentation of an authorization from the appropriate VA office of jurisdiction listed in § 728.52(e)(3).

(2) *Emergency care.* Overseas naval MTFs furnishing emergency care to potential VABs will promptly notify the appropriate VA office of jurisdiction and request authorization for treatment and instructions for disposition of the patient.

(3) *Offices of jurisdiction.* The following activities are vested with responsibility for issuing authorizations for care and furnishing dispisition instructions for VABs in overseas naval MTFs:

(i) In the Trust Territory of the Pacific (Micronesia), VA Office, Honolulu, Hawaii.

(ii) In the Philippines, VA Regional Office, Manila, Philippines.

(iii) In Canada, Canadian Department of Veterans Affairs, Ottawa, Canada.

(iv) In all other foreign countries, consular offices of U.S. embassies.

(f) *Forms required.* (1) Complete a VA 10–10 (Application for Medical Benefits) when potential VABs are admitted for emergency care without prior authorization.

(2) Prepare a VA 10–10m (Medical Certificate and History) when care is rendered. All information required in the medical certificate thereon will be furnished whether the admission is subsequently approved or disapproved by the VA office of jurisdiction.

(3) Since the completion of VA 10–10m requires an examination of patients, admissions which are disapproved will be reported as medical examinations on DD 7A, Report of Treatment Furnished Pay Patients, Outpatient Treatment Furnished (Part B) (See Subpart J).

(4) Prepare and submit a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished (Part A)) on all VABs and potential VABs admitted (see Subpart J).

(5) Complete an SF 502 (Narrative Summary) or SF 539 (Abbreviated Clinical Record), as appropriate, when a VAB or potential VAB is discharged or otherwise released. When an interim report of hospitalization is requested by the VA office of jurisdiction, it may be prepared on an SF 502.

§ 728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) beneficiaries.

(a) *Potential beneficiaries.* The following may be beneficiaries of one of the programs sponsored by the Office of Workers' Compensation Programs (OWC) under the conditions set forth. They are not beneficiaries of OWCP until authorized as such by the appropriate district officer of OWCP. However, they may be carried as potential beneficiaries pending OWCP determination of eligibility. DOD civilian employees provided medical services under a Defense or service health program are not included under this authority (see subpart G).

(1) Members and applicants for membership in the Reserve Officers' Training Corps of the Navy, Army, and Air Force, provided the condition necessitating treatment was incurred in line of duty during an off-campus training regimen. Such care is authorized for injury (a disease or illness which is the proximate result of performance of training is considered an injury) incurred while engaged in:

(i) Training.

(ii) Flight instructions.

(iii) Travel to or from training or flight instructions.

(2) The following employees of the Government of the United States, regardless of nationality or place of work, are entitled to receive care as outlined in § 728.53(e) for work incurred traumatic injuries at the expense of OWCP. (In addition to injury by accident, a disease or illness which is the proximate result of performance of

employment duties is considered an injury.) This category includes but is not limited to:

(i) Civilian student employees in training at Navy and Marine Corps facilities.

(ii) Civilian seamen in the service of vessels operated by the Department of the Army (see § 728.53(a)(7) and § 728.80(c)(2) for civilian Military Sealift Command (MSC) personnel).

(iii) All civilian employees of the Government except nonappropriated-fund-activity employees. Nonappropriate fund employees may be covered under the Longshore and Harbor Workers' Compensation Act (contact cognizant district office of OWCP).

(3) Civilian members of the Civil Air Patrol (except Civil Air Patrol Cadets) for injury or disease which is the proximate result of active service or travel to and from such service, rendered in performance or support of operational missions of the Civil Air Patrol under the direction and written authority of the Air Force.

(4) Former Peace Corps enrollees for injury or disease which is the proximate result of their former employment with the Peace Corps or which was sustained or contracted while located with the Peace Corps outside the United States and its territories.

(5) Former Job Crops enrollees for injury or disease which is the proximate result of employment with the Job Corps.

(6) Former VISTA (Volunteers in Service to America) enrollees for injury or disease which is the proximate result of employment with VISTA.

(7) Military Sealift Command (MSC) civilian marine personnel (CIVMARPERS or CIVMARS) (including temporary employees, intermittent employees, and employees with less than 1 year's service) are entitled to occupationally related care at the expense of OWCP. CIVMARS are in a crew status only after reporting to their assigned ship. They are in a travel status from crewing point to ship and return. While in a travel status, they are entitled to the same health care benefits as other Federal civil service employees in a travel status (5 U.S.C. 8101). CIVMARS presenting for treatment with a properly completed CA-16, Request for Examination and/or Treatment, will:

(i) Enter the naval MTF's system through the occupational medicine service.

(ii) Be treated for any injury or disease proximately caused by their employment. Although the actual determination of whether an illness or injury is occupationally related is a function of OWCP, determinations are based on the required injury report along with the treatment record from the attending physician. Therefore, when doubt exists as to the relationship of the condition to the potential patient's employment, the physician should report an unbiased medical conclusion and the medical rationale therefor, indicating the conditions which are responsible for the claimant's disability. As a general rule, the following may be initially considered as occupationally related, however, it should be emphasized that OWCP is the final approval authority:

(A) Any injury or illness occurring as a direct result of employment. May occur on a ship, at a Government installation ashore, or in an aircraft while performing a requirement of employment.

(B) Any injury or illness which becomes manifest while away from work (on leave or liberty) while in a crew status or travel status as long as the condition may be directly related to job activities or to exposures incident to travel to ship assignment.

(C) Required immunizations.

(D) Required physical examinations.

(E) Periodic medical surveillance screening examinations for DOD occupational and industrial health programs, i.e., asbestos medical surveillance, hearing conservation, etc.

(iii) Be referred to a non-Federal source of care where back-to-work care may be provided at the CIVMAR's expense after, if necessary, the immediate emergency is alleviated when a reasonable determination can be made that the injury or illness is not occupationally related.

(A) Per 5 U.S.C. 7901(c)(3), the health service program for Federal civilian employees is limited to referral of employees, upon their request, to private sources of care.

(B) Long term extended care of chronic illnesses such as hypertension, diabetes, etc., is not authorized in naval MTFs at the expense of OWCP nor at the CIVMAR's personal expense.

(C) Patients who cannot be referred, because of medical reasons or because non-Federal sources are not available or available but inadequate, may be retained in naval MTFs at the expense of the CIVMAR or of his or her private insurance until transfer becomes possible. Although the means of access to the naval MTF may have been through the occupational medicine service, retention in the naval MTF is on a civilian humanitarian basis. This is also applicable when OWCP disallows a CIVMAR's claim (see § 728.53(c)).

(b) *Authorization required.* Personnel in § 728.53(a) (1) through (6) may be rendered inpatient and outpatient care as outlined in § 728.53(e), unless otherwise stipulated in § 728.53, upon presentation of a properly prepared and signed authorization from CA-16 (Request for Examination and/or Treatment). District offices of OWCP will honor these authorizations for 60 days unless written notice of termination of authorization is given earlier. Whereas the CA-16 is used primarily for traumatic injuries, it may also be used to authorize examination and treatment for disease or illness provided the affected agency has obtained prior permission from the cognizant district office of OWCP. If the condition for which treatment is requested appears related to employment, treatment of beneficiaries in § 728.53(a) (1) through (7) may be initiated without presentation of a CA-16. Patients provided treatment without a CA-16 may be carried as OWCP beneficiaries from the time of initial treatment, provided the appropriate district office of OWCP is notified and requested to submit a CA-16 within 48 hours giving authorization as of the date of actual treatment. OWCP will not be liable for payment of bills for unauthorized treatment. Post hospitalization care following authorized inpatient care does not require an additional authorization. First aid treatment rendered civilian employees does not require an authorization form

(c) *Disallowance by OWCP.* When OWCP determines that any claim should be disallowed, OWCP will advise the naval facility rendering care that no further treatment should be rendered at OWCP expense. The patient ceases to be an OWCP beneficiary as of the date of receipt of the notice of disallowance by the naval MTF and the patient will be so notified. Any treatment subsequent to the date of receipt of the notice of disallowance will be at the personal expense of the patient (see § 728.81(a)).

(d) *Authorization for transfer.* Prior approval of OWCP is required before a transfer can be effected, except in an emergency or when immediate treatment is deemed more appropriate in another Federal facility. When transfer is effected without approval, the transferring facility will immediately request such authorization from the appropriate district office of OWCP. When authorized by OWCP, evacuation to the United States can be effected per OPNAVINST 4630.25B. Medical records and a CA-16 will accompany such patients.

(e) *Care authorized*—(1) *Inpatient care.* Medical and surgical care necessary for the proper treatment of the condition upon which eligibility is based. Specific OWCP authorization is required before major surgical procedures can be performed unless the urgency of the situation is such that time does not permit obtaining said authorization. All necessary prostheses, hearing aids, spectacles, and orthopedic appliances will be furnished when required for proper treatment of the condition upon which eligibility is based. Upon specific authorization, damaged or destroyed medical braces, artificial limbs, and other orthopedic and prosthetic devices will be replaced or repaired, except that eyeglasses and hearing aids will not be replaced or repaired unless their damage or destruction is incidental to a personal injury requiring medical services.

(2) *Outpatient care.* Complete medical and surgical care not requiring hospitalization, and posthospitalization services following authorized inpatient care in a naval MTF for the proper treatment of the condition upon which eligibility is based.

(3) *Dental care.* Limit dental treatment to emergencies and that care necessary as an adjunct to inpatient hospital care authorized in advance. Such care will not include dental prostheses, unless specifically authorized, nor orthodontic treatment.

(f) *Reports and records.* (1) Copies of medical records will accompany OWCP patients being transferred from one medical treatment facility to another. Records accompanying OWCP patients to a debarkation hospital will be the same as for military personnel and will clearly identify the patient as an OWCP beneficiary.

(2) Forward a CA-20 (Attending Physician's Report) to the appropriate district office of OWCP on discharge of the patient unless hospitalization exceeds 1 month. In such instances, a report will be submitted every 30 days. When extensive hospitalization is required, use an SF 502 or a narrative format in lieu of CA-20. When submitted to OWCP, the physician's report will include:

(i) History.

(ii) Physical findings.

(iii) Laboratory findings.

(iv) Abstract of hospital records.

(v) Diagnosis for conditions due to injury and not due to injury.

(vi) Rationalized medical opinion for the physician's belief that the illness or disease treated was causally related to a specific condition or set of conditions to which the claimant was subjected.

(vii) Condition on discharge with opinion as to degree of impairment due to injury, if any.

(3) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to any OWCP beneficiary.

§ 728.54 U.S. Public Health Service (USPHS), other than members of the uniformed services.

(a) *Potential beneficiaries.* The following may be beneficiaries of the USPHS for care in naval MTFs upon submission of the necessary form from appropriate officials as outlined in § 728.54(b).

(1) *Within and Outside the United States.* Any individuals the USPHS may determine to be eligible for care on an interagency reimbursable basis.

(2) *Within the 48 Contiguous United States and the District of Columbia.* American Indians, Alaska Natives, Eskimos, and Aleuts.

(3) *In Alaska.* American Indians, Eskimos, and Aleuts.

(b) *Authorization required.*—(1) *Normal circumstances.* An American Indian or Alaska Native may be rendered inpatient care upon presentation of form HRSA 43 (Contract Health Service Purchase Order for Hospital Services Rendered) or HRSA form 64 (Purchase/Delivery Order for Contract Health Services Other Than Hospital Inpatient or Dental). Either form must be signed by an appropriate Indian Health Service or Alaska Native Health Service area/program official.

(2) *Emergencies.* In an emergency, care may be rendered upon written request of patient's commanding officer or superior officer, or the patient if neither of the above is available. When emergency care is rendered without prior authorization, the facility rendering care must notify the service unit director of the patient's home reservation within 72 hours from the time such care is rendered unless extenuating circumstances preclude prompt notification.

(c) *Care authorized.* Unless limited by the provisions stipulated in § 728.54(a) and subject to the provisions of § 728.3, the following care may be rendered, when requested, to all beneficiaries enumerated in § 728.54(a).

(1) *Inpatient care.* Necessary medical and surgical care.

(2) *Outpatient care.* Necessary medical and surgical care.

(3) *Dental care.* (i) Limit dental care in the United States, its territories, possessions, and the Commonwealth of Puerto Rico to emergencies for the relief of pain or acute conditions and that necessary as an adjunct to inpatient hospital care. Prosthetic dental appliances and permanent restorations are not authorized.

(ii) In overseas areas, dental care is authorized to the extent necessary pending the patient's return to the United States, its territories, possessions, or the Commonwealth of Puerto Rico.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or a DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.55 Department of Justice beneficiaries.

Upon presentation of a letter of authorization that includes disposition of SF 88 (Report of Medical Examination), SF 93 (Report of Medical History), and address for submission of claim, the following personnel may be furnished requested care as beneficiaries of the Department of Justice. See subpart J on completing and submitting forms for central collection of the cost of care provided.

(a) *Federal Bureau of Investigation.* Investigative employees of the Federal Bureau of Investigation (FBI) and applicants for employment as special agents with the FBI may be provided:

(1) Immunizations.

(2) Physical examinations and hospitalization when required to determine physical fitness. Use this period of hospitalization for diagnostic purposes only. Do not correct disqualifying defects.

(b) *U.S. Marshals.* U.S. Marshals may receive physical examinations and hospitalizations when required to determine physical fitness. Use this period of hospitalization for diagnostic purposes only. Do not correct disqualifying defects.

(c) *Claimants against the United States.* Claimants whose suits or claims against the United States are being defended by the Department of Justice may be furnished physical examinations to determine the extent and nature of the injuries or disabilities being claimed. Hospitalization is authorized for proper conduct of the examination. Upon completion, forward the report of the examination promptly to the U.S. Attorney involved.

§ 728.56 Treasury Department beneficiaries.

(a) *Potential beneficiaries.* The following may be beneficiaries of the Treasury Department and may be rendered care as set forth below.

(1) Secret Service Special Agents and support personnel.

(2) Secret Service Agents providing protection to certain individuals.

(3) Persons being provided protection by the Secret Service.

(4) Agents of the U.S. Customs Service.

(5) Prisoners (detainees) of the U.S. Customs Service.

(b) *Care authorized.* (1) Secret Service Special Agents may be provided routine annual physical examinations upon request and presentation of a letter of authorization. Conduct and record examinations in the same manner as routine examinations rendered naval officers except that they may be conducted only on an outpatient basis. If hospitalization is considered desirable in connection with an examination, patient administration department personnel will contact the United States Secret Service at (202) 535-5641 at the address in § 728.56(c). Enter a statement, attesting to the fact that hospitalization is desirable, in item 73 or 75 of the SF 88, as appropriate, before forwarding to the United States Secret Service as directed by the letter of authorization.

(2) Secret Service Agents providing protection to certain individuals and those persons being provided such protection may be rendered all required medical services including hospitalization subject to the provisions of § 728.3.

(3) Agents of the U.S. Customs Service and their prisoners (detainees) may be provided emergency medical treatment and evacuation services to the nearest medical facility (military or civilian) in those remote areas of the United States where no other such services are available. Limit evacuation to the continental United States and do not cross borders. The Navy's responsibility for medical care of such prisoners terminates once the medical emergency has been resolved. Guarding of prisoners, while they or their captors are receiving treatment at naval MTFs, remains the responsibility of the U.S. Customs Service or other appropriate Federal (nonmilitary) law enforcement agencies.

(c) *Reports and records.* (1) When examinations are rendered to Secret Service Special Agents and support personnel, forward one copy of the SF 88, one copy of the SF 93, and one copy of any forms provided with the letter of authorization to United States Secret Service, Administrative Operations Division, Safety and Health Branch, 1800 G Street, NW., Room 845, Washington, DC 20223 or as otherwise directed by the letter of authorization. Provide an information copy to the Deputy Comptroller of the Navy.

(2) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.57 Department of State and associated agencies.

Eligibility for care under the provisions of § 728.57 will be determined by the Department of State, Office of Medical Services.

(a) *Beneficiaries.* Officers and employees of the following agencies, their dependents, and applicants for appointment to such agencies are authorized inpatient and outpatient medical care as set forth below in addition to that care that may be authorized elsewhere within this part (i.e., §728.53, § 728.55, § 728.56, and § 728.58). Limit dental care to that delineated in § 728.57(b)(6).

(1) Department of State-U.S.Arms Control and Disarmament Agency and the Office of International Conferences.

(2) U.S. Agency for International Development.

(3) International Communications Agency.

(4) ACTION—Peace Corps Staff.

(5) Department of Agriculture—Foreign Agriculture Service.

(6) Department of Commerce—Bureau of Public Roads.

(7) Department of Interior—Bureau of Reclamation and the U.S. Geological Survey.

(8) Department of Transportation—Federal Aviation Administration and the Federal Highway Administration.

(9) Department of Justice—Drug Enforcement Agency.

(10) Department of Treasury—U.S. Customs, U.S. Secret Service, Office of International Affairs (OIA), U.S.—Saudi Arabian Joint Commission for Economic Cooperation (JECOR), and the Internal Revenue Service.

(11) National Aeronautics and Space Administration.

(12) Library of Congress.

(13) Beneficiaries of such other agencies as may be included in the Department of State Medical Program.

(b) *Care authorized*—(1) *General.* The Foreign Service Act of 1946, as amended, authorizes care delineated in § 728.57. Subject to the restrictions and priorities of § 728.3 and the restrictions of § 728.57, care may be rendered at the expense of the Department of State or one of the agencies listed in § 728.57(a). The law allows for payment when care is furnished for an illness or injury which results in hospitalization or equal treatment. Outpatient care is only authorized as an adjunct to hospitalization.

(2) *Overseas.* (i) When, in the opinion of the principal or administrative officer of an overseas post of the Department of State, an individual meets the conditions of eligibility, the post will furnish authorization to the naval MTF for care at the expense of the Department of State or one of the agencies listed in § 728.57(a).

(ii) Should the Department of State official determine that the illness or injury does not meet the conditions of eligibility for care at the expense of one of the agencies, all care provided will be at the expense of the patient or patient's sponsor and charged at the full reimbursement rate.

(3) *In the United States.* (i) Care is not authorized for an injury or illness incurred in the United States. Authorizations and other arrangements for care in the United States for individuals incurring injury or illness outside the United States will be provided by the Deputy Assistant Secretary for Medical Services, Department of State, using appropriate authorization form(s). When personnel are admitted in an emergency without prior authorization, the commanding officer of the admitting naval MTF will immediately request authorization from the Deputy Assistant Secretary for Medical Services.

(ii) The extent of care furnished in the United States, to individuals in § 728.57(a) who are evacuated to the United States for medical reasons, will be comparable in all respects to that which is authorized or prescribed for these individuals outside the United States. When determined appropriate by the Deputy Assistant Secretary for Medical Services, officers and employees and their accompanying dependents who have returned to the United States for nonmedical reasons may be furnished medical care at the expense of one of the above agencies for treatment of an illness or injury incurred while outside the United States.

(4) *Physical examinations.* The Secretary of State is authorized to provide for comprehensive physical examinations, including dental examinations and other specific testing, of applicants for employment and for officers and employees of the Foreign Service who are U.S. citizens and for

their dependents, including examinations necessary to establish disability or incapacity for retirement purposes. An authorization will be executed by an appropriate Department of State official and furnished in duplicate to the naval MTF, listing the type of examination required and stating that the individual is entitled to services at the expense of the Department of State. Furnish reports per the letter of authorization.

(5) *Immunizations.* Inoculations and vaccinations are authorized for officers, employees, and their dependents upon written authorization from an appropriate Department of State official. This authorization, in duplicate, will include the type of inoculation or vaccination required and will state that the individual is entitled to services at the expense of the Department of State. Furnish reports per the letter of authorization.

(6) *Dental care.* Limit dental care to emergencies for the relief of pain or acute conditions, or dental conditions as an adjunct to inpatient care. Do not provide prosthetic dental appliances.

(c) *Evacuation to the United States.* Should a beneficiary in an overseas naval MTF require prolonged hospitalization, the commanding officer of the overseas facility will report the requirement to the nearest Department of State principal or administrative officer and request authority to return the patient to the United States. Release dependents who decline evacuation to the custody of their sponsor. Aeromedical evacuation may be used per OPNAVINST 4630.25B. Travel of an attendant or attendants is authorized at Department of State expense when the patient is too ill or too young to travel unattended.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.58 Federal Aviation Agency (FAA) beneficiaries.

(a) *Beneficiaries.* Air Traffic Control Specialists (ATCS) of the FAA when appropriate authorization has been furnished by the FAA regional representative.

(b) *Authorization.* Written authorization from an FAA Regional Flight Surgeon is required and will include instructions for forwarding the results of services rendered.

(c) *Care authorized.* Subject to the provisions of § 728.3, authorized personnel may be rendered chest x-rays, electrocardiograms, basic blood chemistries, and audiograms, without interpretation in support of the medical surveillance program for ATCS personnel established by the FAA.

(d) *Report.* Complete and submit, per Subpart J, a DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) outpatient care is rendered.

§ 728.59 Peace Corps beneficiaries.

(a) *Potential beneficiaries.* (1) Applicants for the Peace Corps.

(2) Peace Corps Volunteers.

(3) Minor children of a Peace Corps volunteer living with the volunteer.

(b) *Care authorized in the United States.* Upon written request of a Peace Corps official, stating care to be provided and disposition of reports, the following may be provided subject to the provisions of § 728.3.

(1) *Physical examinations.* Physical examinations are authorized on an outpatient basis only. Except for interpretation of x-rays, make no assessment of the physical qualifications of examinees.

(i) Preselection physical examination may be provided applicants (volunteers) for the Peace Corps.

(ii) Separation or other special physical examinations may be provided volunteers and their dependents as listed in § 728.59(a)(3). Unless otherwise prescribed in written requests, report such examinations of Peace Corps volunteers on SF-88 and SF-93. Include:

(A) Medical history and systemic review.

(B) Chest x-ray with interpretation.

(C) Complete urinalysis, serology, and blood type.

(D) Pelvic examination and Pap smear for all female volunteers.

(E) Hematocrit or hemoglobin for all females and for all males over 40 years of age.

(F) Electrocardiogram for all volunteers over 40 years of age.

(2) *Immunizations.* Immunizations, as requested, may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical care.* Both inpatient and outpatient care may be provided volunteers for illnesses or injuries occurring during their period of service which includes all periods of training. Dependents of volunteers specified in § 728.59(a)(3) are authorized care to the same extent as their sponsor.

(4) *Dental care.* Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. All beneficiaries seeking dental care will be requested, whenever possible, to furnish advanced authorization.

(c) *Care authorized outside the United States*—(1) *Physical examinations.* Termination physical examinations may be provided volunteers and eligible dependents of volunteers. In most instances, Peace Corps staff physicians will provide these examinations; however, help may be required of naval MTFs for ancillary services.

(2) *Immunizations.* When requested, immunizations may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical care.* When requested in writing by a representative or physician of a Peace Corps foreign service post, volunteers, eligible dependents of volunteers, and trainees of the Peace Corps may be provided necessary medical care at Peace Corps expense. When emergency treatment is rendered without prior approval, forward a request to the Peace Corps foreign service post as soon as possible.

(4) *Dental care.* Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. All beneficiaries seeking dental care will be requested, whenever possible, to furnish advanced authorization.

(5) *Evacuation to the United States.* When a beneficiary in an overseas naval MTF requires prolonged hospitalization, the commanding officer of the overseas facility will report the requirement to the nearest Peace Corps foreign service post and request authorization to return the patient to the United States. Releases custody of dependents to their sponsor when evacuation is declined. Aeromedical evacuation may be used per OPNAVINST 4630.25B. Travel of attendant(s) is authorized when the patient is too ill or too young to travel unattended.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment Part B) when outpatient or inpatient care is rendered.

§ 728.60 Job Corps and Volunteers in Service to America (VISTA) beneficiaries.

(a) *Beneficiaries.* Job Corps and VISTA enrollees and Job Corps applicants may be provided services as set forth. For former members, see § 728.53.

(b) *Authorization required.* (1) *Job Corps enrollees.* Presentation of a Job Corps Identification Card after appointment has been made by the corpsmember's Job Corps center.

(2) *Job Corps applicants.* Presentation of a letter from a screening agency (e.g.,

State Employment Service) after an appointment has been made by that agency.

(3) *VISTA Volunteers and VISTA Trainees.* A "Blue-Cross and Blue Shield Identification Card" is issued to such personnel as identification. Each card has a VISTA identification number which will be used on all records and correspondence.

(c) *Care authorized.* Normally, medical services are provided only when civilian of VA facilities are not available. or if available, are incapable of providing needed services. However, upon presentation of an appropriate authorization, the following services may be rendered subject to the provisions of § 728.3.

(1) Job Corps enrollees are authorized emergency medical care upon presentation of their Job Corps Identification Card; however, the corpsmember's Job Corps center should be notified immediately.

(2) Job Corps applicants may be provided preenrollment physical examinations and immunizations on an outpatient basis only.

(3) Job Corps enrollees, VISTA trainees, and VISTA volunteers are authorized:

(i) Outpatient medical examinations, outpatient treatment, and immunizations.

(ii) Inpatient care for medical and surgical conditions which, in the opinion of the attending physician, will benefit from definitive care within a reasonable period of time. When found probable that a patient will require hospitalization in excess of 45 days, notify the Commander, Naval Medical Command (MEDCOM-33) by the most expeditious means.

(iii) Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. Beneficiaries seeking dental care will be requested to furnish, whenever possible, advanced authorization.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.61 Medicare beneficiaries.

(a) *Care authorized.* Emergency hospitalization and other emergency services are authorized for beneficiaries of the Social Security Health Insurance Program for the Aged and Disabled (Medicare) who reside in the 50 United States and the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, and the Northern Mariana Islands. Such care in naval MTFs may be rendered when emergency services, as defined in § 728.61(b), are necessary.

(b) *Emergency services.* Services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(1) Placing the patient's health in serious jeopardy.

(2) Serious impairment to bodily functions of serious dysfunction of any bodily organ or part.

(c) *General provisions*—(1) *Limitations.* Benefit payments for emergency services under Medicare can be made for only that period of time during which the emergency exists. Therefore, when the emergency is terminated and it is permissible from a medical standpoint, discharge or transfer the patient to a facility that participates in Medicare.

(2) *Notification.* Notify the nearest office of the Social Security Administration as soon as possible when a Medicare beneficiary is rendered treatment.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

Subpart G—Other Persons

§ 728.71 Ex-service maternity care.

(a) *Eligible beneficiaries.* After separation from the service under honorable conditions because of pregnancy, or separated from the service under honorable conditions and found to have been pregnant at the time of separation, the following former members and their newborn infant(s) may be provided care as set forth below. The rendering of this care is subject to the provisions of § 728.3. When certified by medical authorities that the pregnancy existed prior to entry into service (EPTE), maternity benefits are not authorized.

(1) Former women members of the Army, Air Force, Navy, and Marine Corps.

(2) On or after 12 August 1985, former women members of the Commissioned Corps of the United States Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA).

(b) *Care authorized.* (1) Former women members may be rendered medical and surgical care in naval MTFs incident to that pregnancy, prenatal care, hospitalization, postnatal care, and, when requirements of SECNAVINST 6300.2A are met, abortions. Limit postnatal care to 6 weeks following delivery. Do not promise civilian sources under any circumstances for either the mother or the infant as such care is not authorized.

(2) Treatment of the newborn infant in USMTFs includes care, both inpatient and outpatient, only during the first 6 weeks (42 days) following delivery. If the newborn infant requires care beyond the 6-weeks postnatal period, the mother or other responsible family member must make arrangements for disposition to private, State, welfare, or another Federal facility.

(c) *Application for care.* In making application for care authorized by § 728.71, former women members should apply either in person or in writing to the Armed Forces inpatient MTF nearest their home and present either their DD 214 (Armed Forces of the United States Report of Transfer or Discharge) or DD 256A (Honorable Discharge Certificate) as proof of eligibility for requested care. In areas with more than one Armed Forces MTF available and capable of providing required care, application should be made to the MTF of the service from which separated, as applicable. Disengagement in such areas to MTFs of other services may be made only when space is not available or capability does not exist in the MTF of the services from which the individual was separated.

(d) *Charges and collection.* Charges and reimbursement procedures for care rendered to beneficiaries in § 728.71(a)(2) are the same as prescribed by current regulations for active Coast Guard, USPHS, and NOAA members.

§ 728.72 Applicants for enrollment in the Senior Reserve Officers' Training Program.

When properly authorized, designated applicants (including applicants for enrollment in the 2-year program and Military Science II enrollees applying for Military Science III) may be furnished medical examinations at naval MTFs including hospitalization necessary for the proper conduct thereof. Medical care, including hospitalization, is authorized for diseases contracted or injuries incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for visits of observation.

§ 728.73 Applicants for enlistment or reenlistment in the Armed Forces, and applicants for enlistment in the reserve components.

(a) Upon referral by a commander of a Military Enlistment Processing Station (MEPS), applicants will be furnished necessary medical examinations, including hospitalization when qualifications for service cannot otherwise be determined. Use the hospitalization period only for diagnostic purposes. Do not correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.74 Applicants for appointment in the regular Navy or Marine Corps and reserve components, including members of the reserve components who apply for active duty.

(a) Necessary medical examinations may be furnished, including hospitalization when qualifications for service cannot otherwise be determined. Use such a period of hospitalization only for diagnostic purposes. Do not correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.75 Applicants for cadetship at service academies and applicants for the Uniformed Services University of Health Sciences (USUHS).

(a) Upon presentation of a letter of authorization from the Department of Defense Medical Examination Review Board (DODMERB), applicants for cadetship at Service Academies (Navy, Army, Air Force, Coast Guard, and Merchant Marine) and applicants for the Uniformed Services University of Health Sciences (USUHS) will be furnished medical examinations at facilities designated by the DODMERB. Hospitalization is authorized when qualifications for service cannot otherwise be determined. Use the hospitalization period for diagnostic purposes only, and not to correct disqualifying or other defects. Perform examinations and make disposition of completed forms per BUMEDINST 6120.3M.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or at MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.76 Naval Home residents.

Provide necessary medical and dental care, both inpatient and outpatient, to residents of the Naval Home when requested by the Governor of the Home. In an emergency, care may be rendered without prior approval of the Governor; however, the Governor of the Home should be contacted immediately and requested to furnish authorization.

§ 728.77 Secretarial designees.

Subject to the capabilities of the professional staff and the availability of space and facilities, naval MTFs and DTFs will provide treatment to individuals that have been granted Secretarial designee status by any of the three service Secretaries (Navy, Army, or Air Force), the Secretary of Commerce for NOAA personnel, the Secretary of Health and Human Services for USPHS personnel, or the Secretary of Transportation for Coast Guard personnel.

(a) *Potential designees.* Upon a showing of sufficient cause, the Secretary of the Navy may authorize individuals, not otherwise authorized by law, to receive such care as is available in naval MTFs in the United States. Designation may be extended on a worldwide basis for preadoptive children and wards of active duty members, and for abused dependents delineated in §728.77(a)(6). Temporary in loco parents or foster parent status of the member with regard to a minor is insufficient for approval. Also, civilian health care under the CHAMPUS program cannot be authorized for other than abused dependents. The Secretary's discretionary authority is exercised most conservatively, however, favorable action is usually taken on requests involving the following situations:

(1) Preadoption proceedings wherein an active duty member or a retired member has taken affirmative legal action to adopt a child.

(2) Custodianships and guardianships authorized by a court order wherein the member is designated by the court as the custodian or guardian and the child is fully dependent upon the active duty or retired member sponsor.

(3) Evaluation and selection of nonbeneficiaries who are donor candidates for an organ or tissue transplant procedure in behalf of a military service beneficiary.

(4) Nonbeneficiary participants in officially approved clinical research studies.

(5) Unremarried former spouses who: Require care for a condition incurred during or caused/aggravated by conditions associated with the member's or former member's creditable service; do not qualify under the former spouses act; and do not have medical coverage under an employer-sponsored health plan which will provide for the care required.

(6) Abused dependents of discharged or dismissed former uniformed services members in need of medical or dental care resulting from knowledge of the abuse or for an injury or illness resulting from abuse by the former member. Eligibility will terminate the earliest of 1 year after the date on which the member is discharged or dismissed from a uniformed service, or when care is no longer needed.

(7) In other instances wherein the circumstances clearly merit the providing of treatment in naval MTFs, and in which the best interest of the patient, the Navy, *and* the Government will be served, favorable Secretarial action may result. The mere need of medical care by a former beneficiary or other person, alone, will not support approval of such a request.

(b) *Requests for consideration.* Requests for consideration will be submitted to the Commander, Naval Medical Command (MEDCOM-33) by applicants via their command, when applicable, or by the Medical Department command concerned. Requests should include any pertinent information which will support resolution and a return address. Requests involving:

(1) Preadoption must include a legible reproducible copy of an interim court order or adoption agency placement agreement which names the sponsor and identifies the other participating parties. A petition for a court order is insufficient to support a recommendation for approval.

(2) Custodianships and guardianships must include a legible reproducible copy of the court order, identification of the parties, and also identify any amounts of income to which the ward is entitled.

(3) Participants in clinical research studies must include:

(i) Sufficient clinical information concerning the nature of the study.

(ii) Benefits which may accrue to the individual.

(iii) The extent, if any, to which access by other authorized beneficiaries will be impaired.

(iv) Benefits which will accrue to the command, e.g., enhancement of training, maximum use of specialized facilities, etc.

(v) Recommended duration of designation.

(vi) Whether the consenting individual has been informed concerning the nature of the study, its personal implications, and freely consents.

(4) Unremarried former spouses must include:

(i) A notarized copy of the marriage license.

(ii) A statement attesting to the fact that the sponsoring former spouse achieved 20 or more years of creditable military service.

(iii) Copy of divorce decree with official date.

(5) Abused depdendents must include:

(i) Full name, social security number, grade or rate, branch or service, and date and type of discharge or dismissal of the former member. Such a member must have received a dishonorable or bad-conduct discharge or dismissal from a uniformed service as a result of court-martial conviction for an offense involving abuse of a dependent of the member.

(ii) Full names, social security numbers (if assigned), and relationship to the former member of any dependent in need of medical or dental care to treat adverse health conditions resulting from such dependent's knowledge of the abuse or any injury or illness suffered by the abused person as a result of such abuse.

(c) *Blanket designation.* (1) The Secretary of Defense has granted Secretarial designee status to full-time Schedule "A" faculty members of the Uniformed Services University of Health Sciences (USUHS). They have been provided documentation substantiating their eligibility and, where necessary, an eligibility termination date. These personnel are authorized routine care at the Naval Hospital, Bethesda, MD. At other naval MTFs, only emergency treatment is authorized while they are traveling on official university business. The letter of authorization excludes routine dental care, prosthetic appliances, and spectacles.

(2) The following officials within the Government, the Department of Defense, and military departments have been granted blanket Secretarial designation for medical and emergency dental care in naval MTFs in the United States:

(i) The President.

(ii) The Vice President.

(iii) Members of the Cabinet.

(iv) Article III Federal Judges.

(v) U.S. Court of Military Appeals Judges.

(vi) Members of Congress.

(vii) The Secretary, Deputy Secretary, and the Assistant Secretaries of Defense.

(viii) The Under Secretary of Defense for Policy.

(ix) The Under Secretary of Defense for Research and Engineering.

(x) The Secretaries, Under Secretaries, and the Assistant Secretaries of the Military Departments.

(d) *Authorization.* Designees will present a signed letter bearing the letterhead of the designating service. Secretarial designees are not included in the DEERS data base and may not possess Government identification cards. Therefore, the only proof of their eligibility for treatment may be the letter of authorization. When a Secretarial designee presents for treatment:

(1) Ask for identification of the individual presenting the letter of authorization to assure that the person seeking care is the individual to whom the letter was issued.

(2) Check the expiration date on the letter of authorization. Many authorizations are issued for only a specified period of time, e.g., abused dependents—no longer than 1 year.

(3) Check to assure that the individual is applying for care authorized by the letter of authorization. Designation is often granted for a specific diagnosis or specific mode of treatment.

(4) Check to assure that the individual has not been designated for care only as specific facility. Many authorizations are granted for conditions or for care that can be rendered only by a specified physician or under a specific program.

(5) Place a copy of the letter of authorization in the individual's Health Record or outpatient treatment record on the left side at the first visit or admission.

(e) *Charges and collection.* (1) Interagency rates are applicable for inpatient and outpatient care provided outside the National Capital Region to all individuals listed in § 728.77(c)(2) with the exception of Members of Congress. Charges are at full reimbursement rates for Members of Congress provided inpatient or outpatient care outside the National Capital Region.

(2) In the National Capital Region:

(i) Charges are waived for outpatient care provided to all categories listed in § 728.77(c)(2).

(ii) Charge interagency rates for inpatient care of all individual in § 728.77(c)(2) except Members of Congress. Charge Members of Congress at full reimbursement rates.

(3) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to Secretarial designees whose charges for care have not been waived.

§ 728.78 American Red Cross representatives and their dependents.

(a) *Potential beneficiaries.*

(1) Volunteer workers.

(2) Full-time, paid employees.

(3) Dependents of personnel enumerated in § 728.78(a) (1) and (2) when accompanying their sponsor outside the continental United States, including Alaska, Hawaii, and Puerto Rico.

(b) *Care authorized.* (1) When services of the American Red Cross (ARC) have been accepted in behalf of the Federal Government under applicable DOD regulations, beneficiaries in § 728.78(a)(1) are considered "employees" of the Government for the purpose of this part and are authorized health care in USMTFs, both in and outside the United States for work-related conditions. See § 728.53(a)(2) regarding the specific application of this authorization.

(2) Beneficiaries enumerated in § 728.78(a) (1) and (2) are authorized health care in USMTFs located outside the United States for both work and nonwork-related conditions. See § 728.53(a)(2) for treatment of work-related conditions of those in § 728.78(a)(1).

(3) Beneficiaries identified in § 728.78(a) (1), (2), and (3) are authorized emergency care in USMTFs outside the continental United States, including Alaska, Hawaii, and Puerto Rico where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible non-Federal facilities.

(c) *Records disposal.* Upon completion of treatment of accredited representatives of the American Red Cross or their dependents, forward medical records, including all clinical records and x-ray films, to the Medical Director, National Headquarters, American Red Cross, 20th and D Street NW., Washington, DC 20006.

(d) *Charges and collection.* Charge beneficiaries in § 728.78(a) (1) and (2)

the rate applicable to officer personnel and dependents in § 728.78(a)(3) the dependent rate. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to ARC personnel or to their dependents.

§ 728.79 Employees of Federal contractors and subcontractors.

(a) *Beneficiaries.* (1) U.S. citizen contractor, engineering, and technical service personnel designated as U.S. Navy Technicians.

(2) Civilian employees of contractors and subcontractors operating under U.S. Government contracts.

(3) Dependents of personnel enumerated in § 728.79(a) (1) and (2) when accompanying their sponsor outside the continental United States or in Alaska.

(b) *Care authorized.* (1) Beneficiaries identified in § 728.79(a) (1) and (2) may be provided emergency care in naval MTFs for illnesses and injuries occurring at work in or outside the United States.

(2) While serving outside the continental United States or in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities, beneficiaries identified in § 728.79(a) (1), (2), and (3) may receive hospitalization and necessary outpatient services in naval MTFs on a reimbursable basis. Except for beneficiaries in § 728.79(a)(1) who are serving aboard naval vessels, all others enumerated may only be hospitalized for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(c) *Charges and collection.* Care is authorized on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.80 U.S. Government employees.

(a) Civil service employees of all Federal agencies, including teachers employed by Department of Defense Dependent's Schools (DODDS) and their dependents, may be provided hospitalization and necessary outpatient services, (other than occupational health services), on a reimbursable basis, outside the continental limits of the United States and in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Except for employees who are serving aboard naval vessels, hospitalization may be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(b) Such civilian employees and their dependents may be provided medical, surgical, dental treatment, hospitalization, and optometric care at installations in the United States which have been designated remote by the Secretary of the Navy for the purpose of providing medical care.

(c) The major objective of the following programs for civil service employees, regardless of location, is emergency treatment for relief of minor ailments or injuries to keep the employee on the job:

(1) The Department of Labor, Office of Workers' Compensation Programs (OWCP), governs the overall medical care program for employees of the Government who sustain injuries while in the performance of duty, including diseases proximately caused by conditions of employment (see § 728.53).

(2) Federal civil service employees and applicants for such employment are authorized services as outlined in chapter 22, section XIII, of the Manual of the Medical Department (MANMED). When appropriated fund and nonappropriated fund employees, including unpaid volunteer employees, require emergency and nonemergency occupational health services due to an illness or an injury on the job, provide this limited care through your occupational health service, emergency room, or evening primary care clinic, as appropriate. This care is rendered free of charge to the employee, the employee's command, or insurance carrier. Included with this group are Military Sealift Command (MSC) civilian marine personnel (authorized additional care and services as outlined in BUMINST 6320.52 and care under § 728.53(a)(7)) and members of the National Oceanic and Atmospheric Administration (NOAA) serving with the Navy.

(3) Under the technical control of the Surgeon General of the Army, the DOD Civilian Employees' Health Service is responsible for administering the health program for all Federal civil service employees in the District of Columbia area.

(d) Care, other than occupational health services, is provided on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.81 Other civilians.

(a) *General.* In an emergency, any person may be rendered care in naval MTFs to prevent undue suffering or loss of life or limb. Limit care to that necessary only during the period of the emergency, and if further treatment is indicated, initiate action to transfer the patient to a private physician or civilian facility as soon as possible. Further, subject to the provisions of § 728.3, the following personnel are authorized care as set forth.

(b) *Beneficiaries and extent of care.*

(1) Provide all occupational health services to civilian employees paid from nonappropriated funds, including Navy exchange employees and service club employees, free of charge (see § 728.80(c)(2)). Provide treatment of occupational illnesses and injuries other than in emergencies per rules and regulations of the Office of Workers' Compensation Programs (see § 728.53).

(2) Civilians attending the Federal Bureau of Investigation (FBI) Academy, Marine Corps Development and Education Command, Quantico, VA, may be rendered care at the Naval Medical Clinic, Quantico, VA, for emergencies. Such persons who are in need of hospitalization for injuries or disease may be hospitalized and classed as civilian humanitarian nonindigents with the approval of the cognizant hospital's commanding officer. EXCEPTION: Certain individuals, such as employees of the Federal Bureau of Investigation who are injured in the line of duty, may be entitled to care at the expense of the Office of Workers' Compensation Programs (OWCP) (see § 728.53).

(3) The following civilians who are injured or become ill while participating in Navy or Marine Corps sponsored sports, recreational or training activities may be rendered care on a temporary (emergency) basis until such time as

disposition can be effected to another source of care.

(i) Members of the Naval Sea Cadet Corps.

(ii) Junior ROTC/NDCC (National Defense Cadet Corps) cadets.

(iii) Civilian athletes training or competing as part of the U.S. Olympic effort.

(iv) Civilians competing in Navy or Marine Corps sponsored competitive meets.

(v) Members of Little League teams and Youth Conservation groups.

(vi) Boy Scouts and Girl Scouts of America.

(4) Other civilian personnel included below are not normally eligible for care in naval MTFs; however, under the conditions set forth, care may be rendered.

(i) *Potential beneficiaries.*

(A) Civilian representatives of religious groups.

(B) Educational institutions representatives.

(C) Athletic clinic instructors.

(D) USO representatives.

(E) Celebrities and entertainers.

(F) Social agencies representatives.

(G) Others in a similar status to those in § 728.81(b)(4)(i) (A) through (F).

(H) News correspondents.

(I) Commercial airline pilots and employees.

(i) Volunteer workers. This category includes officially recognized welfare workers, other than Red Cross.

(ii) *Care authorized.*

(A) Persons enumerated in § 728.81(b)(4)(i) (A) through (G), who are contracted to provide direct services to the Armed Forces and who are acting under orders issued by the Department of Defense or one of the military departments to visit military commands overseas, and their accompanying dependents, may be provided medical care in naval MTFs outside the 48 contiguous United States and the District of Columbia provided local civilian facilities are not reasonably available or are inadequate. Limit inpatient care to acute medical and surgical conditions exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Routine dental care, other than dental prostheses and orthodontia, is authorized on a space available basis outside the United States, provided such care is not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(B) Persons enumerated in § 728.81(b)(4)(i) (H) and (I) are authorized emergency medical and dental care in naval MTFs outside the 48 contiguous United States and the District of Columbia provided local civilian facilities are not reasonably available or are inadequate.

(C) Persons enumerated in § 728.81(b)(4)(i)(J), both within and outside the 48 contiguous United States and the District of Columbia, may receive care in naval MTFs for injuries or diseases incurred in the performance of duty as beneficiaries of OWCP (see § 728.53). Additionally, if such volunteers are sponsored by an international organization (e.g., the United Nations) or by a voluntary nonprofit-relief agency registered with and approved by the Advisory Committee on Voluntary Aid (e.g., CARE), they may receive other necessary nonemergency medical care and occupational health services while serving outside the 48 contiguous United States and the District of Columbia.

(c) *Charges and collection.* Care is provided on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.82 Individuals whose military records are being considered for correction.

Individuals who require medical evaluation in connection with consideration of their individual circumstances by the Navy, Army, and Air Force Board for Correction of Military Records are authorized evaluation, including hospitalization when necessary for the proper conduct thereof.

§ 728.83 Persons in military custody and nonmilitary Federal prisoners.

(a) *Potential beneficiaries.*

(1) Military prisoners.

(2) Nonmilitary Federal prisoners.

(3) Enemy prisoners of war and other detained personnel.

(b) *Care authorized*—(1) *Military prisoners.*

(i) Whose punitive discharges have been executed but whose sentences have not expired are authorized all necessary medical and dental care.

(ii) Whose punitive discharges have been executed and who require hospitalization beyond expiration of sentences are not eligible for care but may be hospitalized as civilian humanitarian nonindigents until final disposition can be made to some other appropriate facility.

(iii) On parole pending completion of appellate review or whose parole changes to an excess leave status following completion of sentence to confinement while on parole are members of the military service and as such are authorized care as outlined in subpart B.

(iv) On parole whose punitive discharge has been executed are not members of the military service and are therefore not entitled to care at Government expense. If the circumstances are exceptional, individuals herein who are not authorized care may request Secretarial designee status under the provisions of § 728.77.

(2) *Nonmilitary Federal prisoners.* Under the provisions of § 728.83, nonmilitary Federal prisoners are authorized only emergency medical care. When such care is being rendered, the institution to which prisoners are sentenced must furnish necessary guards to effectively maintain custody of prisoners and assure the safety of other patients, staff members, and residents of the local area. Under no circumstances will military personnel be voluntarily used to guard or control such prisoners. Upon completion of emergency care, make arrangements for immediate transfer of the prisoners to a nonmilitary MTF or for return to the facility to which sentenced.

(3) *Enemy prisoners of war and other detained personnel.* Subject to the provisions of § 728.3, enemy prisoners of war and other detained personnel are entitled to and may be rendered all necessary medical and dental care.

(c) *Charges and collection.* Care provided individuals enumerated in § 728.83(b)(1) (ii), (iv), and § 728.83(b)(2) is on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

Subpart H—Adjuncts to Medical Care

§ 728.91 General 28.

Adjuncts to medical care include but are not limited to prosthetic devices such as artificial limbs, artificial eyes, hearing aids, orthopedic footwear, spectacles, wheel chairs, hospital beds, and similar medical support items or aids which are required for the proper care and management of the condition being treated. Generally, expenses incurred for procurement of such items, either from civilian sources as supplemental care or from stocks maintained by the facility, are payable from operation and maintenance funds

available for support of naval MTFs. However, certain adjuncts may be cost-shared under CHAMPUS for CHAMPUS-eligible individuals under circumstances enumerated in the cooperative care or services criteria of § 728.4(z).

§ 728.92 Policy.

(a) Provide adjuncts to medical care to eligible beneficiaries receiving inpatient or outpatient care when, in the opinion of the attending physician, such adjuncts will offer substantial assistance in overcoming the handicap or condition and thereby contribute to the well-being of the beneficiary.

(b) Unless necessary for humanitarian reasons, do not furnish orthopedic and prosthetic appliances on an elective basis to members of the naval service with short periods of service remaining when the defect requiring the appliance existed prior to entry into service and when such members will be separated from the service because of these defects.

(c) For active duty members, make the initial allowance of orthopedic footwear and orthopedic alterations to standard footwear the same quantity as provided in the initial clothing allowance.

(d) Base the number of orthopedic and prosthetic appliances issued or replaced for other authorized recipients upon the individual's requirements as determined by the attending physician to be consistent with the highest standards of modern medicine.

(e) Former members of the uniformed service should be advised that they may obtain durable medical equipment, medical care, and adjuncts from Veterans Administration facilities.

(f) Dependents are authorized certain adjuncts per §§ 728.31 (c) and (d) and in instances where items are not normally authorized at the expense of the Government, they may be provided at cost to the United States if available from Government stocks under the following conditions:

(1) Outside the United States.

(2) At specific stations within the United States which have been authorized by the Secretary of the Navy to sell these items.

§ 728.93 Chart of adjuncts.

The following chart and footnotes provide information relative to adjuncts which may be furnished the several categories of beneficiaries eligible for medical care at naval MTFs.

Adjuncts	Active duty and retired members	Others authorized the same benefits as active duty or retired members(8)	Dependents authorized the same benefits	Other beneficiaries(8)
Ambulance service	Yes	Yes	Yes(1)	No
Artificial eyes	Yes	Yes	Yes	Maybe(3)
Artificial limbs	Yes	Yes	Yes	Maybe(3)
Contact or special lenses(11)	Yes(4)	Yes(4)	Maybe(2) (4) (6)	No
Crutches(7)	Yes	Yes	Yes	Yes
Dental prostheses	Yes	Yes	Maybe(9)	Maybe(9)
Elastic stockings	Yes	Yes	Yes	Yes
Hearing aids(10)	Yes(5)	Yes(5)	Maybe(2)	Maybe(3)
Hearing aid parts and batteries	Yes(10)	Yes(10)	Maybe(2) (10)	No
Hospital beds (7)	Yes	Yes	Yes	Yes
Joint braces	Yes	Yes	Yes	Yes
Orthopedic footware	Yes	Yes	Maybe(2)	Maybe(3)
Prosthetic devices, other(7)	Yes	Yes	Maybe(2)	No
Respirators and inhalators(7)	Yes	Yes	Yes	Yes(1)
Resuscitators (7)	Yes	Yes	Yes	Yes(1)
Spectacles	Yes	Yes	Maybe(2) (6)	No
Walking irons(7)	Yes	Yes	Yes	Yes
Wheel chairs(7)	Yes	Yes	Yes	Yes

(1) When considered medically appropriate by the attending physician.

2 See § 728.92(f).

3 Outside the United States and at designated remote stations when considered medically appropriate by the attending physician.

4 Contact or special lenses are not to be issued solely for cosmetic reasons. Further guidelines are contained in NAVMEDCOMINST 6810.1.

5 In addition to the hearing aid, include in initial issue one spare receiver cord, approximately 1 month's supply of batteries, and a statement indicating make, model, type of receiver, serial number, code, part numbers, "B" battery voltage, and type of "A" and "B" batteries, as appropriate. Provide replacement of hearing aids upon the same basis as initial issue and, except in unusual circumstances, will not be replaced within 2 years of the initial furnishing or the last replacement of the appliance.

6 Spectacles, contact lenses, or intraocular lenses may be provided dependents with eye conditions which require these items for complete medical or surgical management of a condition other than ordinary refractive error. For further information, consult NAVMEDCOMINST 6810.1.

7 May be loaned on a custody basis at the discretion of the attending physician.

8 See subpart of this part relating to specific beneficiary.

9 When considered by the attending physician and dentist to be an adjunct to a medical or surgical condition other than dental and when in consonance with existing legislation and directives.

10 For further guidelines, consult BUMEDINST 6320.41B.

11 Includes intraocular lenses required for implantation upon removal of cataracts:

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

§ 728.101 General.

(a) *Notice of eligibility (NOE).* While the NOE is basically a document that substantiates entitlement to a disability benefit equal to pay and allowances, it may be accepted when required to substantiate eligibility for benefits other than pay and allowances, i.e., treatment in USMTFs under the provisions of title 10, United States Code.

(b) *Physical disability benefits.* The following, excerpted and paraphrased from SECNAVINST 1770.3, paragraph 10, is applicable when a reservist may be entitled to physical disability benefits.

(1) When a notice of eligibility (NOE) has been issued to a member hospitalized in a naval MTF and the attending physician is of the opinion that recovery is not anticipated or that the reservist is not expected to be fit for return to full duty within a reasonable period, a medical board will be convened and the case managed the same as that of a Regular member. Assure that a copy of the NOE accompanies the medical board report forwarded to the Central Physical Evaluation Board. Disability benefits, equal to pay and allowances, will continue in such instances until final disposition.

(2) There is no limited duty status, per se, for inactive reservists. However, if the attending physician determines that a reservist is temporarily unfit for full duty, but will be fit for full duty following a period of convalescence or following duty with physical limitations, not to exceed 6 months, the physician may return the reservist to duty with a summary of the hospitalization or treatment. The summary will set forth the limitations posed by the member's disability and the period of such limitations. Followup hospitalization, treatment, and evaluation for the same condition may be provided at USMTFs during the period of restricted duty, if required. If, during the period of the restricted duty, it appears that the reservist will be *permanently* unfit for full duty, promptly authorize the reservist to report for evaluation, treatment if required, and appearance before a medical board at the nearest naval MTF capable of accomplishing same. Admission to the sicklist is authorized, when required. Should the medical board recommend appearance before a physical evaluation board, disability benefits equal to pay and allowances should continue until final disposition is effected.

§ 728.102 Care from other than Federal sources.

The provisions of this subpart do not authorize care for reservists at other than Federal facilities nor out of funds available for operation of USMTFs (supplemental care) after a period of active duty or a period of training duty ends, including travel to and from such training. Such care may be rendered under the provisions of Part 732 of this chapter.

Subpart J—Initiating Collection Action on Pay Patients

§ 728.111 General.

The Comptroller of the Navy has approved a system of transactions that generates reports to COMNAV MEDCOM on unfunded reimbursable transactions. The purpose of the final report is to provide data on services furnished by naval health care facilities for which central collection from other Government agencies and private parties is required.

§ 728.112 Responsibilities.

(a) *Patient administration departments.* The initiation of the collection process begins with patient administration departments. Collection action cannot be accomplished unless patient administration departments take the initial step to complete:

(1) *DD 7, Report of Treatment Furnished Pay Patients, Hospitalization Furnished (Part A).* Prepare a separate substantiating DD 7, in triplicate, for each category of pay patient receiving inpatient care. At the end of each day that any pay patient is admitted, submit DD 7's to the collection agent.

(2) *DD 7A, Report of Treatment Furnished Pay Patients, Outpatient Treatment Furnished (Part B).* Prepare a separate substantiating DD 7A, in triplicate, for each category of pay patient receiving outpatient care. At the end of each day that any pay patient is treated on an outpatient basis, submit DD 7A's to the collection agent.

(b) *Collection agents.* Upon receipt of a completed DD 7 or DD 7A, collection agents will take the action indicated in paragraph 24304 of the Resource Management Handbook, NAVMED P-5020, to effect central collection action.

§ 728.113 Categories of pay patients.

The categories of patients for whom collection action must be initiated are:

(a) *Coast Guard.* (1) Active Officers. (2) Retired Officers. (3) Active Enlisted. (4) Retired Enlisted. (5) Dependents. (6) Cadets.

(b) *Public Health Service.* (1) Active Officers. (2) Retired Officers. (3) Dependents of Officers.

(c) *National Oceanic and Atmospheric Administration (NOAA).* (1) Active Officers. (2) Retired Officers. (3) Dependents of Officers.

(d) *Foreign.* (1) NATO Officers (Except Canadians provided care under the comparable care agreement.). (2) NATO Enlisted (Except Canadians provided care under the comparable care agreement.). (3) NATO Dependents. (4) Civilians Accompanying NATO Members. (5) Foreign Military Sales (FMS) Officers. (6) FMS Enlisted. (7) FMS Dependents. (8) FMS Civilians. (9) Military Grant Aid Officers. (10) Military Grant Aid Enlisted. (11) Military Grant Aid Dependents. (12) Military Grant Aid Civilians. (13) Military Officers From Other Than NATO Nations. (14) Military Enlisted From Other Than NATO Nations. (15) Dependents of Officers and Enlisted From Other Than NATO Nations. (16) Civilians Accompanying Military Members of Other Than NATO Nations. (17) Nationals and Their Dependents.

(e) *Secretarial Designees Not Exempted From Paying.*

(f) *Others.* (1) Merchant Marines. (2) Military Sealift Command (MSC) Personnel. (3) Public Health Service Beneficiaries (Other than Commissioned Corps). (4) Veterans Administration Beneficiaries. (5) Peace Corps Beneficiaries. (6) Job Corps Beneficiaries. (7) Volunteers In Service to America (VISTA) Beneficiaries. (8) Office of Workers Compensation Program (OWCP) Beneficiaries. (9) Bureau of Employees Compensation (BEC) Beneficiaries. (10) Department of State and Other Federal Agencies Beneficiaries (prepare a separate form for each Federal agency). (11) Civilian Humanitarian Nonindigents (CHNI). (12) Trust Territory Beneficiaries. (13) Others Not Specified Above Who Are Not Entitled to Health Benefits at the Expense of the Government.

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Part V

Department of Energy

Federal Energy Regulatory Commission

18 CFR Parts 2 and 284

Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol; Data Request

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2 and 284

[Docket No. RM87-34-000]

Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol

Issued: August 28, 1987.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of data request.

SUMMARY: The Federal Energy Regulatory Commission has sent to forty-five interstate natural gas pipelines the attached data request concerning the nature and extent of their take-or-pay problems. While only pipelines are required to respond to this data request, the Commission also invites any producers desiring to do so to file responses to the request.

DATE: All responses must be filed within thirty days of the effective date of Order No. 500.[1]

ADDRESS: The cover letter, paper copy, and magnetic tape, if any, must be submitted to: Office of the Secretary, Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426.

Hand delivery may be made to: Office of the Secretary, Federal Energy Regulatory Commission, Room 3110, 825 N. Capitol Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Marilyn L. Rand, (202) 357-8674
John E. Moriarty, (202) 357-8824
Office of Pipeline and Producer Regulation, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426.

SUPPLEMENTARY INFORMATION:

Take notice that on August 26, 1987, the Federal Energy Regulatory Commission sent to forty-five interstate natural gas pipelines a data request concerning the nature and extent of their take-or-pay problems. In Order No. 500,[1A] the Commission stated that it would issue this data request in order to obtain information necessary to respond to the decision of the United States Court of Appeals for the District of Columbia in *Associated Gas Distributors* v. *FERC*.[2] In particular, the information sought in this data request is necessary to enable the Commission to respond to the Court's direction that the Commission reassess its decision in Order No. 436 not to invoke its power under NGA section 5 to modify or set aside jurisdictional contracts with troublesome take-or-pay provisions.

While only pipelines are required to respond to this take-or-pay data request, the Commission also invites any producers desiring to do so to file responses to the attached data request. Those producers filing responses need not submit responses to all questions in all schedules. However producers should file their responses, to the maximum extent possible, in the format described in the instructions to the data request. At a minimum, producers must identify the schedule and the particular questions within each schedule, to which responses are made. Producers are also encouraged, to the maximum extent possible, to submit their responses on magnetic computer tape as prescribed in the instructions to the data request. Producers filing responses must comply with all other instructions set forth on pages 1 and 2 of the data request under "General Information for Take-or-Pay Data Request." The Commission strongly encourages those producers filing responses to conform their responses to the procedures and format required for pipelines so that the Commission can process all responses promptly. Producer responses, like pipeline responses, must be filed within thirty days of the effective data of Order No. 500.

Kenneth F. Plumb.
Secretary.

TAKE-OR-PAY DATA REQUEST

[FERC-593; OMB No. 19020149; Expires 11/7/87]

August 26, 1987.

General Information for Take-or-Pay Data Request

A. How To Submit

All data is to be submitted on 9-track magnetic computer tape(s) conforming in all respects to the requirements of the Federal Information Processing Standard Publication, FIPS Pub. 79, "Magnetic Tape Tables and File Structure for Information Interchange." Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, Virginia 22161. Level three labeling standards described in the federal standard should be utilized for file formats, tape labels and record formats. All tapes will be returned to the respondent within 30 days of their receipt at the Commission. The respondent should include file names, file attributes and recording density in a cover letter accompanying each tape.

Each tape must be accompanied by one paper copy tape listing of the data submitted on magnetic tape. The specifications for the magnetic tape layout are included in Exhibit A. The specifications for the paper copy are included in Exhibit B.

B. Where to Submit

(1) Submit the tape, the cover letter, and the paper copy to: Office of the Secretary, Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426.

(2) Hand delivery can be made to: Office of the Secretary, Federal Energy Regulatory Commission, Room 3110, 825 N. Capitol Street, NE., Washington, DC 20426.

Retain a copy of the tape for your files.

C. Attestation

All filings with the Commission require the subscription and attestation prescribed in § 385.2005 of the Commission's regulations. Accordingly, the cover letter, mentioned above, should also attest that the information on the paper copy tape listing is the same as the information on the magnetic tape and that the contents of the paper copy and magnetic tape are true to the best knowledge and belief of the signer.

D. Records Retention To Support Tape

The respondent is required to maintain records which support the tape for a period of at least one (1) year.

E. Waivers

Waivers from the magnetic tape provision and other requirements, including the time by which the data must be filed, may be granted on a case-by-case basis for good cause shown.

F. Requests For Confidential Treatment

Respondents may request confidential treatment of their responses. *See*, 18 CFR 388.110 (1987).

G. Whom To Contact

For general questions contact: Marilyn L. Rand, (202) 357-8674.

For technical reporting questions contact: John E. Moriarty, (202) 357-8824.

General Instructions for Take-or-Pay Data Request

A. Introduction

This data request consists of six contract-summary schedules. Three of these same schedules (i.e., Schedules

[1] The Federal Energy Regulatory Commission will publish a notice of the effective date of Order No. 500. See 52 FR 30334, August 14, 1987.

[1A] 52 FR 30334 (Aug. 14, 1987).

[2] No. 85-1811, et. al.

No. 4, 5, and 6, see below) are to be used to report on an aggregated basis data for company-totals only. A narrative-text schedule may also be provided at the option of the respondent to *supplement* (not substitute for) data reported on Schedules 1 through 6.

1. The contract-summary schedules are:

Schedule 1. Contract Summary Information
Schedule 2. Contract Take-or-Pay Provisions (As of July 1, 1987)
Schedule 3. Contract Pricing Provisions (As of July 1, 1987)
Schedule 4. Take-or-Pay History (One for each calendar year 1983–1986 and for the first six months of 1987)
Schedule 5. Take-or-Pay Obligations, Prepayments, and Settlements (One for each calendar year 1983–1986 and for the first six months of 1987)
Schedule 6. Contract Reformations and Terminations (One for each calendar year 1983–1986 and for the first six months of 1987)

2. The summary schedules are:

Schedule 4. A summary of Schedule 4 for all contracts (One for each calendar year 1983–1986 and for the first six months of 1987)
Schedule 5. A summary of Schedule 5 for all contracts (One for each calendar year 1983–1986 and for the first six months of 1987)
Schedule 6. A summary of Schedule 6 for all contracts (One for each calendar year 1983–1986 and for the first six months of 1987)

3. The narrative-text schedule is:

Schedule 7. Narrative Text Schedule (This schedule provides the respondent the opportunity to clarify the data reported on Schedules 1 through 6. Note, however, that Schedule 7 cannot be used as a substitute for Schedules 1 through 6.)

B. Reports for Individual Contracts

1. Which Contracts to Report Individually

A contract should be reported individually if:

(a) It is an active contract (i.e., not an expired or terminated contract), and had an annual deliverability of more than one billion cubic feet between January 1, 1983 and June 30, 1987.

(b) It is an expired or terminated contract and had a deliverability of more than one billion cubic feet between January 1, 1983 and June 30, 1987, and is associated with any of the following five conditions:

(i) A remaining unresolved take-or-pay exposure;

(ii) An outstanding prepayment for gas not taken;

(iii) A settlement payment to extinguish or mitigate take-or-pay exposure;

(iv) A payment to terminate or reform the contract in consideration of take-or-pay related to this or any other contract; or

(v) Non-cash consideration to terminate or reform the contract in consideration of take-or-pay related to this or any other contract.

(c) It does not meet the criteria identified in (a) or (b) but would be necessary to be added to those contracts reported under (a) and (b) so that the sum effect of contracts reported on an individual basis would account for 90 percent of the "Pipeline Estimate of Cumulative Take-or-Pay Obligation at End of Year," as would be reported at Schedule 5 column (1), for the period ending December 31, 1986.

2. Schedules to Report for Individual Contracts

Schedules for individual contracts should be reported as follows:

(a) Schedule 1 should be reported for all contracts which are subject to individual reporting. (See item B.1. above.) Note, however, that if a contract does not now nor did at any time since 1982 include a take-or-pay provision, only Items 1 through 6 and 11(e) should be reported on Schedule 1 for that contract.

(b) Schedules 2 and 3 should be reported only for those contracts which now, or did since 1982, include a take-or-pay provision. That is, if the answer to Question 6 on Schedule 1 is "Yes," then Schedules 2 and 3 should be reported.

(c) Schedules 4 and 5 should be reported only for those contracts for which:

(i) There is or has been a past or present take-or-pay exposure, a gas prepayment, or take-or-pay settlement associated with the contract, or

(ii) Gas covered by the contract was temporarily or permanently released with take-or-pay credit, or

(iii) The contract was reformed or terminated as either partial or complete consideration for take-or-pay related to this or any other contract, or

(iv) The contract does now or did since 1982 include a take-or-pay clause. That is, if the answer to either Question 6, or to any portion of Question 11 (a) through (d) is "Yes," then Schedules 4 and 5 should be reported.

(d) Schedule 6 should be reported only if there has been a contract reformation or termination for the purpose of resolving take-or-pay related to this contract or any other contract since 1982. That is, if the answer to Question 11(e) on Schedule 1 is "Yes," then Schedule 6 should be reported.

C. Company-Summary Schedules

The company summary schedules are company total data. The company-summary schedules should be submitted for each year 1983 through 1986 and for the first six months of 1987. Only the "Totals" line need be completed in reporting company-total data. That is, the company-total data does not have to be reported by "NGPA Section" category. Moreover, only the following columns need be completed in reporting company-total data:

Schedule 4: Column (g)
Schedule 5: Columns (a) through (n)
Schedule 6: Column (i)

D. Miscellaneous Instructions

1. All data on Schedule No. 1 should be reported on a contract-summary basis (i.e., not segregated by NGPA category or subcategory). All data on Schedule Nos. 2 through 6 should be reported separately for each NGPA category or subcategory of gas covered by the contract. However, in regard to Schedule Nos. 2 and 3, the data should be reported on the "Whole Contract" line, if all of the provisions and terms of the contract apply consistently and equally to all gas covered by the contract, regardless of the NGPA category or subcategory of gas.

2. Report all gas volumes in MMMBtu's (i.e., Billion Btu's).

3. Report all dollars in thousands of dollars.

4. Report all percentages to the nearest whole percentage (e.g., 75).

5. The various terms used here are intended to have the same meanings as in the documents recently issued by the Commission. See, for example:

"Statement of Policy;" Take-or-Pay Provisions in Gas Purchase Contracts; Docket No. PL81-1-000 (Issued December 16, 1982).

"Statement of Policy and Interpretive Rule;" Regulatory Treatment of Payments Made in Lieu of Take-or Pay Obligations; Docket No. PL85-1-000 (Issued April 10, 1985).

"Proposed Statement of Commission Policy;" Recovery of Take-or-Pay Buy-Out and Buy-Down Costs by Interstate Natural Gas Pipelines; Docket No. PL87-3-000 (Issued March 5, 1987).

6. Where an answer is requested on a yes or no basis, enter a "Y" for yes or "N" for no.

7. Schedule-specific instructions are given to clarify data items and to make reference to source publications. Unless otherwise instructed, all items are self-explanatory.

8. Note: Previous experience has shown that respondents occasionally report dollars and volumes in the wrong units (e.g., MMBtu or dollars). This can lead to very serious problems in processing and analyzing data. Respondents are therefore requested to be particularly careful in reporting the correct units.

9. Use the following codes for the NGPA categories in the computer tape submission:

Code = 1 Whole Contract
Code = 2 102(d)
Code = 3 Other 102
Code = 4 103 (Price Controlled)
Code = 5 Other 103
Code = 6 104 Pre 1973
Code = 7 104 1973–74 Biennium
Code = 8 104 Post 1974
Code = 9 104 Other
Code = 10 106(a)
Code = 11 107(c)(5)
Code = 12 Other 107
Code = 13 108 Jurisdictional
Code = 14 108 Non-jurisdictional
Code = 15 105/106(b)
Code = 16 109
Code = 17 Totals

10. "Casinghead gas," as used here, is gas which is produced concurrently with the production of crude oil.

Specific Instruction for Take-or-Pay Data Request

Schedule No. 1—Contract Summary Information

Schedule reference	Instructions
1(a), 1(b), 3(a), 3(b)	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176.
2	Enter the respondent's own designation for the contract or agreement as it would appear in the purchaser's Form No. 542-PGA filings.
3	Complete items 3(a) through 3(d) and 3(f) for each seller who is a signatory to the contract being reported and has a working interest of at least 10 percent. These items must be reported for the operator, even if it has no working interest in the leases covered by the contract.
3(e)	Enter the FERC Gas Rate Schedule Number assigned to the contract. If not applicable, enter "NA" (Not Applicable).
4(a) through 4(h)	Enter as defined in "Instructions For Filing FERC Form No. 542-PGA Purchased Gas Adjustment (PGA) Filing." Note: If the contract covers gas produced in more than one field, area, or state, the largest or principal location data (field, area, etc.) should be entered. The respondent may provide supplemental data or notations on Schedule 7.
6	Enter "Y" or "N" as to whether the contract does now or did at any time since 1982, include a take-or-pay provision.
Complete 7 through 11(d) *only* if the answer in 6 is "Y." Complete 11 (e) regardless of answer to 6.	
8	Enter the date of the most recent rollover or significant renegotiation of this contract. "Significant" means a permanent change of 10 percent or more in the price and/or take-or-pay quantity provisions of this contract.
9(a)	Enter month, day, and year, if the contract contains a fixed expiration data; otherwise enter "NA" in each data field (i.e., enter "NA" for "mm," "dd," and "yy."
10	A "market-out clause" means a clause giving the purchaser the right to terminate the contract at the purchaser's discretion.

Schedule No. 2—Contract Take-Or-Pay Provisions

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (Same as Schedule 1, Item 2).
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter "Y" if take-or-pay is based on reserves; if not, enter "N."
(b)	Enter "Y" if take-or-pay is based on deliverability; if not, enter "N."
(c)	Enter "Y" if take-or-pay is based on a method other than reserves or deliverability; if not, enter "N."
(d)	If take-or-pay is based on deliverability, enter the annual percentage which applies to casinghead gas (gas which is produced concurrently with the production of crude oil).
(e)	If take-or-pay is based on deliverability, enter the annual percentage which applies to all gas other than casinghead gas.
(f)	If take-or-pay for casinghead gas is based on reserves, enter the number which completes the ratio 1:_____. For example, if the reserve ratio is 1:7300, enter 7300.
(g)	If take-or-pay for all gas other than casinghead gas is based on reserves, enter the number which completes the ratio 1:_____. For example, if the reserve ratio is 1:7300, enter 7300.
(h)	Enter the number of years during which the contract permits the purchaser to make up any gas. If no make-up right exists, enter "0" (Zero).
(i)	Enter "Y" if there are make-up rights after the contract expires or is terminated; if not, enter "N."
(j)	Enter "Y" if the contract provides that the seller will refund payment upon expiration or termination of the contract for gas paid for but not taken; if not, enter "N."

Schedule No. 3—Contract Pricing Provisions

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (Same as Schedule 1, Item 2).
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter "Y" if the contract contains a price provision which allows the contract price to escalate to the NGPA Maximum Lawful Price; otherwise, enter "N."
(b)	Enter "Y" if the contract price is referenced to NGPA prices; otherwise, enter "N."
(c)	Enter "Y" if the contract states a fixed price or states a fixed rate of price escalation; otherwise, enter "N."
(d) through (h)	If the contract does not contain a price redetermination clause, enter "N" in columns (d) through (h). If the contract does contain a redetermination clause, columns (d) through (h) should be completed as follows:
(d)	Enter the code indicating the frequency with which the contract allows the price to be redetermined: A—1 year or less B—Greater than 1, up to 3 years C—Greater than 3 years D—Upon request E—Not specified F—Other G—Required by contract deregulation
(e)	Enter "Y" if the contract contains a market sensitive pricing clause which allows the price to adjust to reflect current market conditions. This includes provisions with language such as the price will be based on the "fair market value" or the price will reflect an "economic analysis of all factors affecting value."
(f)	If the contract has a redetermination clause which ties the price to an alternate fuel price or index, enter one of the following codes: A—Price tied to No. 2 fuel oil with an adjustment for transportation and distribution charges. B—Price tied to No. 2 fuel oil with no adjustment for transportation and distribution charges. C—Price tied to No. 6 fuel oil with an adjustment for transportation and distribution charges. D—Price tied to No. 6 fuel oil with no adjustment for transportation and distribution charges. E—Price tied to other fuel prices such as crude oil or an average of prices for more than one type of fuel oil; e.g., a mix of No. 2 and No. 6 fuel oil.

SCHEDULE NO. 3—CONTRACT PRICING PROVISIONS—Continued

Schedule reference	Instructions
(g)	Enter "Y" if the redetermination clause has a most-favored-nation provision, i.e., the contract calls for the redetermination to be based on any of the clauses detailed below. This may mean it is either the single determination factor or it shall be considered along with other factors in the negotiation. Most-favored-nation clauses require the contract prices to be tied to the: —Highest contract price paid by buyer for same area —Highest contract price from same area paid by any purchaser —Average of several of the highest contract prices from the same area
(h)	Enter "Y" if the contract redetermination process includes any other factors not included in columns (e) through (g).
(i)	Enter "Y" if the contract has a "buyer protection" clause currently operable under which the price of gas can be adjusted below the price called for under redetermination or other price adjustment terms. Enter "N" if the contract does not have such a clause, or if the contract has a "buyer protection" clause which becomes effective only when a given category of gas is deregulated, and that gas is still price controlled.
(j)	Enter "Y" if the contract does not allow the price to fall below a specified level; otherwise, enter "N."
(k)	Enter "Y" if the actual price paid is based on a unilateral action by the purchaser; otherwise, enter "N."
(l)	Enter "Y" if the actual price paid is set under a market-out clause; otherwise, enter "N."
(m)	Enter "Y" if the actual price paid is a renegotiated price; otherwise, enter "N."
(n)	Enter "Y" if the actual price paid is equal to the NGPA Maximum Lawful Price; otherwise, enter "N."
(o)	Enter "Y" if the actual price paid is determined under some mechanism other than those in (k) through (n); otherwise, enter "N."

SCHEDULE NO. 4—TAKE-OR-PAY HISTORY

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter the physical annual deliverability of the gas covered by the contract.
(b)	Enter the annual take-or-pay quantity obligation. For example, if take-or-pay were 90%, the quantity in column (b) would equal 90% times column (a).
(c)	Enter the quantity actually taken under the contract during the year.
(d)	Enter the take-or-pay quantity not taken but released, and for which a take-or-pay credit was received.
(e)	Enter the take-or-pay quantity obligation which was not taken nor released. This quantity should equal columns (b), less (c), less (d). This quantity should also equal the quantity reported at Schedule 5, column (c).
(f)	Enter the portion of (e) which the purchaser expects to ultimately recover or recoup.
(g)	Enter the portion of (e) which the purchaser does not expect to ultimately recover or recoup; because, for example, there are no make-up rights in the contract, the contract has expired, the make-up period specified in the contract has expired, the reserves are not sufficient to permit recovery of the prepayments, prepayments have been made or requested to be made repeatedly on the same gas reserves, etc. This quantity should equal columns (e), less (f).

SCHEDULE NO. 5—TAKE-OR-PAY OBLIGATIONS, PRE-PAYMENTS, AND SETTLEMENTS

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No..	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter the cumulative quantity for which the purchaser has an outstanding take-or-pay obligation. Column (a) for 1983 should be the cumulative quantity on January 1, 1983. For all years after 1983, the amount in column (a) will be the amount from column (k) of the preceding year.
(b)	Enter the cumulative dollar amount associated with the quantity in (a).
(c)	Enter the quantity of additional take-or-pay obligation during the year. This quantity should equal the quantity reported at Schedule 4, column (e).
(d)	Enter the dollar amount associated with the quantity in (c).
(e)	Enter the quantity of conventional, recoupable gas prepayments.
(f)	Enter the dollar amount associated with the quantity in (e).
(g)	Enter the quantity resolved by a settlement payment or non-cash consideration in lieu of a conventional prepayment.
(h)	Enter the dollar amount associated with the quantity in (g).
(i)	Enter the dollar amount or value paid to settle the quantity and dollar amount in (g) and (h).
(j)	When the schedule reports on an individual-contract basis, enter "Y" if the settlement included a non-cost consideration; if not, enter "N." When the schedule reports on an aggregated contract basis, enter "A."
(k)	Enter the cumulative quantity of gas for which the purchaser has an outstanding take-or-pay obligation on December 31. This amount is equal to the sum of (a) plus (c) less the sum of (e) and (g).
(l)	Enter the dollar amount associated with the quantity (k). This amount is equal to the sum of (b) plus (d) less the sum of (f) and (h).
(m)	Enter the cumulative quantity of gas for which a take-or-pay claim has actually been billed by the producer.
(n)	Enter the dollar amount associated with the quantity in (m).

SCHEDULE NO. 6—CONTRACT REFORMATIONS AND TERMINATIONS

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No..	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
When reporting contracts on an individual basis, the following instructions apply:	
(a), (b)	Enter "Y" or "N."
(c) through (f)	Enter the take-or-pay obligation that existed before and after the contract reformation/termination. If the take-or-pay obligation is based on deliverability enter the obligation as a percent. If the take-or-pay obligation is based on reserves enter the number which completes the ratio 1:_____. For example, if the reserve ratio is 1:7300, enter 7300. Where termination applies, enter "T" in (e) and (f).
(g), (h)	Enter "Y" or "N" if there was a market out clause in the contract either before or after reformation/termination. A "market out clause" means a clause giving the purchaser the right to determine the contract at the purchaser's discretion. Where termination applies, enter "T" in (h).
(i)	Enter the amount of any cash paid by the purchaser to reform or terminate this contract in consideration of take-or-pay related to this or any other contract.
(j)	Enter "Y" or "N" as to whether any non-cash consideration was given by the purchaser to reform or terminate this contract in consideration of take-or-pay related to this or any other contract.
When reporting contracts on an aggregate basis, the following instructions apply:	
(a) through (h), (j)	Enter "A."
(i)	Enter the amount of any cash paid by the purchaser to reform or terminate contracts in consideration of take-or-pay.

SCHEDULE NO. 7—NARRATIVE-TEXT SCHEDULE

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
All	This Schedule provides the respondent the opportunity to clarify the data reported on Schedules 1 through 6. Note, however, that Schedule 7 cannot be used as a substitute for Schedules 1 through 6. Schedule 7 may be used by the respondent to, for example, clarify the data reported at Schedule 4, column (g), "Quantity Not Recoupable." The instructions for this item specify that any unrecoverable or unrecoupable take-or-pay quantity (MMMBtu's) should be reported on an aggregate basis. The respondent is encouraged to segregate and quantify the reason(s) why the gas is not recoverable or recoupable. The respondent is also encouraged to assign dollar values to any segregated quantities. Schedule 7 may also be used to clarify and quantify the respondent's future take-or-pay obligations, costs, etc: These and other types of clarification and quantification may be very useful in evaluating possible future actions by the Commission.

Schedule 1—Contract Summary Information (as of July 1, 1987, Except as Otherwise Specified)

1. Purchaser:
   (a) Name _____
   (b) Pipeline Code Number _____
2. PGA Identification: Contract Number ____
3. Seller(s) with gross working interest of at least 10 percent.
   (a) Name _____
   (b) Seller Code Number _____
   (c) Gross Working Interest Percent _____
   (d) Operator, yes/no _____
   (e) Rate Schedule Number _____
   (f) Seller and Purchaser Affiliated? yes/no _____
4. Production Area
   (a) Field Name _____
   (b) Field Code _____
   (c) Area Name _____
   (d) Area Code _____
   (e) State Name _____
   (f) State Code _____
5. Is any of the gas covered by this contract now or has it ever been since 1982:
   (a) Purchaser-owned production? yes/no ____
   (b) Affiliated company production? yes/no ____
6. Does this contract now or did it at any time since 1982 include a take-or-pay provision? yes/no ____
7. What is the date of the initial contract? mm____ dd____ yy____
8. What is the date of the most recent renegotiation or rollover of this contract? mm____ dd____ yy____
9. What determines the expiration of this contract? (complete all that apply)
   (a) Fixed expiration date? mm____ dd____ yy____
   (b) Life of lease/life of reserves covered by this contract? yes/no ____
   (c) Short-term agreement? (such as purchases on a year-to-year or more frequent basis; currently in force until one party gives notice; spot purchase contract; etc.) yes/no ____
   (d) Other? yes/no ____
10. Does this contract now or did it at any time since 1982 include a market-out clause? yes/no ____
11. In regard to this contract, is there now or has there been at any time since 1982: yes/no ____
   (a) Take-or pay exposure? yes/no ____
   (b) Prepayment for gas? yes/no ____
   (c) Settlement of take-or-pay? yes/no ____
      (i) Partial? yes/no ____
      (ii) Complete? yes/no ____
   (d) Release, with take-or-pay credit, of any of the gas covered by this contract? yes/no ____
   (e) Reformation or termination of contract as consideration for settlement of take-or-pay related to this contract or any other contract? yes/no ____

Contract No. _____
Purchaser Name _____
Pipeline Code No. _____

SCHEDULE 2.—CONTRACT TAKE-OR-PAY PROVISIONS

[As of July 1, 1987]

NGPA section	Based on			If deliverability basis, percent of del. required		If reserve basis, take/res. ratio		Make up rights		Refund provision Y/N
	Res. Y/N	Del. Y/N	Other Y/N	Csgnhd.	Other	Csgnhd.	Other	Yrs.	After cont. term. Y/N	
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
"Whole Contract"										
102(d)										
Other 102										
103 (Price Controlled)										
Other 103										
104 Pre 1973										
104 1973–74 Biennium										
104 Post 1974										
104 Other										
106(a)										
107(c)(5)										
Other 107										
108 Jurisdictional										
108 Non-jurisdictional										
105/106(b)										
109										

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE 3.—CONTRACT PRICING PROVISIONS

[As of July 1, 1987]

NGPA SECTION	Pricing provisions										Current price basis				
	NGPA ceiling price	Referenced to NGPA price	Fixed rate or fixed esc	Price redetermination clause					Buyer protection clause	Is there a price floor	Unilateral action	Market out	Renegotiation	NGPA ceiling price	Other
				Frequency of redetermination	Market sensitive	Fuel parity	Most favored nation	Other							
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)
"Whole Contract"															
102(d)															
Other 102															
103 (Price Controlled)															
Other 103															
104 Pre 1973															
104 1973-74 Biennium															
104 Post 1974															
104 Other															
106(a)															
107(c)(5)															
Other 107															
108 Jurisdictional															
108 Non-jurisdictional															
105/106(b)															
109															

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE 4.—TAKE-OR-PAY HISTORY (MMMBTU)

[Year] ____]

NGPA Section	Deliverability contracted to buyer	Take-or-pay quantity obligation	Quantity actually taken	Quantity released w/ T-O-P credit	Quantity not taken nor released [(b)-(c)-(d)]	Quantity recoupable	Quantity not recoupable [(e)-(f)]
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
102(d)							
Other 102							
103 (Price Controlled)							
Other 103							
104 Pre 1973							
104 1973-74 Biennium							
104 Post 1974							
104 Other							
106(a)							
107(c)(5)							
Other 107							
108 Jurisdictional							
108 Non-jurisdictional							
105/106(b)							
109							
Totals							

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE 5.—TAKE-OR-PAY OBLIGATIONS, PRE-PAYMENTS, AND SETTLEMENTS

[Year____]

NGPA Section	Pipeline estimate of cumulative take-or-pay obligation at beginning of year		Take-or-pay obligation incurred during year		Take-or-pay obligation resolved during year						Pipeline estimate of cumulative take-or-pay obligation at end of year		Cumulative unresolved take-or-pay actually billed to pipeline at end of year	
					By pre-payment		By settlement							
									Basis of settlement					
	MMMbtu	$ (1,000s)	MMMbtu	$ (1,000s)	MMMbtu	$ (1,000s)	MMMbtu	$ (1,000s)	$ (1,000s)	Non-cost Y/N	MMMbtu	$ (1,000s)	MMMbtu	$ (1,000s)
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)
102(d)														
Other 102														
103 (Price Controlled)														
Other 103														
104 Pre 1973														
104 1973-74 Biennium														
104 Post 1974														
104 Other														
106(a)														
107(c)(5)														
Other 107														
108 Jurisdictional														
108 Non-jurisdictional														
105/106(b)														
109														
Totals														

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE 6.—CONTRACT REFORMATIONS AND TERMINATIONS

[Year ____]

NGPA section	Contract status at end of year		Contract changes in effect at end of year						Considerations given by pipeline	
			Take-or-pay obligation				Market out provision			
			Before		After		Before	After		
	Reformed Y/N	Terminated Y/N	Percent	T/R	Percent	T/R	Y/N	Y/N	Cash ($1,000s)	Non-cash Y/N
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
102(d)										
Other 102										
103 (Price Controlled)										
Other 103										
104 Pre 1973										
104 1973-74 Biennium										
104 Post 1974										
104 Other										
106(a)										
107(c)(5)										
Other 107										
108 Jurisdictional										
108 Non-jurisdictional										
105/106(b)										
109										
Totals										

Schedule 7

Schedule 7 is not printed in the **Federal Register.** It consists of the heading "NARRATIVE TEXT" with blank space provided below it for the text.

Exhibit A—Tape Layout for Take-or-Pay Data Request

The specific instructions provide the necessary directions for filling out the various schedules. The tape layout merely provides a means for submitting that data on computer tape.

SCHEDULE 1

Item	Character position	Data type	Comments
Schedule No	1-2	Numeric	Sch=1
Purchaser Name	3-23	Character	
Purchaser Code	24-29	Character	
Contract No	30-35	Character	
Seller Name	36-56	Character	See Note 1 Below
Code Number	57-62	Character	
Gross Working Interest	63-64	Numeric	
Operator	65	Character	
Rate Schedule No	66-71	Character	
Affiliated	72	Character	
Field Name	73-93	Character	
Field Code	94-99	Character	
Area Name	100-120	Character	
Area Code	121-126	Character	
State Name	127-147	Character	
State Code	148-149	Numeric	
Purchaser Owned Coverage	150	Character	
Affiliated Coverage	152	Character	
Take-or-Pay Provision	153	Character	
Date of Initial Contract	154-159	Numeric	
Renegotiation/Rollover	160-165	Numeric	
Fixed Expiration Date	166-171	Numeric	
Life of Lease/Life	172	Character	
Short-term Agreement	173	Character	
Other	174	Character	
Market-Out	175	Character	
Take-or-Pay Expense	176	Character	
Prepayment	177	Character	
Partial Settlement	178	Character	
Complete Settlement	179	Character	
Release	180	Character	

SCHEDULE 1—Continued

Item	Character position	Data type	Comments
Reformation/Termination	181	Character	

Note 1: Since there can be up to 10 sellers reported per contract, repeat positions 1-72 for each seller.

SCHEDULE 2

Item	Character position	Data type	Comments
Schedule No.	1-2	Numeric	Sch=2
Purchaser Name	3-23	Character	
Purchaser Code	24-29	Character	
Contract No	30-35	Character	
NGPA Code	36-37	Numeric	See General Instructions. See also Note 2 below
Reserve	38	Character	
Delivery	39	Character	
Other	40	Character	
Casinghead Delivery	41-42	Numeric	
Other Delivery	43-44	Numeric	
Casinghead Reserve	45-49	Numeric	
Other Reserve	50-54	Numeric	
Rights Years	55-56	Numeric	
Terminations	57	Character	
Refund	58	Character	

Note 2: Repeat entire Schedule, positions 1-58, for each NGPA code used.

SCHEDULE 3

Item	Character position	Data type	Comments
Schedule No.	1-2	Numeric	Sch=3.
Purchaser Name	3-23	Character	
Purchaser Code	24-29	Character	
Contract No.	30-35	Character	
NGPA Code	36-37	Character	See General Instructions.
Ceiling Price	38	Character	
NGPA Price	39	Character	
Fixed	40	Character	
Frequency	41	Character	
Market Sensitive	42	Character	
Fuel Parity	43	Character	
Most Favored Nation	44	Character	
Other	45	Character	
Buyer Protection	46	Character	
Price Floor	47	Character	
Unilateral Action	48	Character	
Market Out	49	Character	
Renegotiation	50	Character	
NGPA Ceiling Price	51	Character	
Other	52	Character	

Note 3: Repeat entire Schedule, positions 1-52, for each NGPA code used.

SCHEDULE 4

Item	Character position	Data type	Comments
Schedule No.	1-2	Numeric	Sch=4.
Purchaser Name	3-23	Character	
Purchaser Code	24-29	Character	

SCHEDULE 4—Continued

Item	Character position	Data type	Comments
Contract No.	30–35	Character	See Note 3 below.
NGPA Code	36–37	Numeric	See General Instructions.
Deliverability	38–46	Numeric	
Take-or-Pay	47–55	Numeric	
Quantity Taken	56–64	Numeric	
Quantity Released	65–73	Numeric	
Quantity Not Taken	74–82	Numeric	
Quantity Recoupable	83–91	Numeric	
Quantity Not Recoupable	91–100	Numeric	

Note 4: If Schedule 4 is being used to report a Take-or-Pay history for an individual contract, use the contract number in positions 30–35. If Schedule 4 is being used to report total company data use the code "AGR" in positions 30–35 and report data in only positions 91–100.

Note 5: Repeat entire Schedule, positions 1–100, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 5

Item	Character position	Data type	Comments
Schedule No.	1–2	Numeric	Sch=5.
Purchaser Name	3–23	Character	
Purchaser Code	24–29	Character	
Contract No	30–35	Character	See Note 4 below.
NGPA Code	36–37	Numeric	See General Instructions.
Cumulative Volume	38–46	Numeric	
Beginning Obligations	47–55	Numeric	
Volume During Year	56–64	Numeric	
Obligation	65–73	Numeric	
Pre-Pay Volume	74–82	Numeric	
Pre-Pay Dollars	83–91	Numeric	
Settlement Volume	92–100	Numeric	
Settlement Dollars	101–109	Numeric	
Basis Dollars	110–118	Numeric	
Non-Cost	119	Character	
Ending Volume	120–128	Numeric	
Ending Dollars	129–137	Numeric	
Ending Billed Volume	138–146	Numeric	
Ending Billed Dollars	147–155	Numeric	

Note 6: If Schedule 5 is being used to report for an individual contract, use the contract number in positions 30–35. If Schedule 5 is being used to report total company data use the code "AGR" in positions 30–35 and report only total data in positions 38–155.

Note 7: Repeat entire Schedule, positions 1–155, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 6

Item	Character position	Data type	Comments
Schedule No.	1–2	Numeric	Sch=6.
Purchaser Name	3–23	Character	
Purchaser Code	24–29	Character	
Contract No	30–35	Character	See Note 5 below.
NGPA Code	36–37	Numeric	See General Instructions.
Reformed	38	Character	
Terminated	39	Character	
TOP Before Percent	40–41	Numeric	
TOP Before T/R	42–47	Numeric	
TOP After Percent	48–49	Character	Numeric for %.
TOP After T/R	50–55	Character	Numeric for T/R.
Market Before	56	Character	
Market After	57	Character	
Cash	58–66	Numeric	
Non-Cash	67	Character	

Note 8: If Schedule 6 is being used to report for an individual contract, use the contract number in positions 30-35. If Schedule 6 is being used to report total company data use the code "AGR" in positions 30-35, and report data in only positions 58-66.

Note 9: Repeat entire Schedule, positions 1-67, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 7

Item	Character position	Data type	Comments
Schedule No.	1-2	Numeric	Sch=7.
Schedule Reference	3-4	Numeric	Schedule to which text applies.
Line Counter	5-6	Numeric	Enter consecutively as additional lines of text are added.
Text	7-78	Character	

Exhibit B—Paper Copy Specifications

The Commission requires all respondents to submit a paper copy that is attested to as valid. This paper copy also reflects the data submitted on tape and is considered a paper copy duplicate of the electronically stored data. This section specifies the rules for creating paper copies.

The following conventions will apply to paper copies from a mainframe:

1. A CHARACTER item for the print image is defined as not more than 120 alphanumeric characters and punctuation.

2. A TEXT item for the print image may exceed 120 alphanumeric characters including punctuation.

3. A line of printout will be 132 or fewer columns.

4. Each NUMERIC item in a record, except the last item, will be printed with a trailing comma. (ASCII-44 decimal)

5. Each CHARACTER item in a record, except the last item, will be printed with a trailing bar. (ASCII-124 decimal)

6. If the sum of the lengths of the items to be printed that are not text, and including commas and bars, exceed 132 columns, then the record continuation can be printed on a second and subsequent lines but do not split a field when continuing. The second and any subsequent lines must be indented 6 spaces from the left hand margin (except for TEXT items as described below). The last whole item on a given line, other than the last item of the record, must be printed with the appropriate trailing comma or bar. The end of the record should be marked by the end of a line in the printout.

7 If the last item available for the line is TEXT, then alternately print the non-TEXT items on the first line, the line of TEXT on the second line without indenting, the non-TEXT items on the third line and the line of TEXT on the fourth and so on until the entire record is printed.

8. Use commas to denote blank fields.

9. Between the last record of one record type and the first record of another type, there should be three blank lines.

10. The first record of each schedule should be printed on a new page.

11. The data collection layout, definitions, instructions and footnotes define the terms and printing order.

[FR Doc. 87-20313 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

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18 CFR Parts 2 and 284

[Docket No. RM87-34-000; Order No. 500]

Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol; Information Collection Requirements Approved by OMB

August 20, 1987.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of data request; OMB Control Number.

SUMMARY: On August 7, 1987, the Federal Energy Regulatory Commission issued an interim rule (Order No. 500) in Docket No. RM87-34-000, 52 FR 30334 (August 14, 1987), readopting the open access transportation regulations, originally promulgated in Order No. 436, with modifications intended to respond to the concerns of the United States Court of Appeals for the District of Columbia Circuit in *Associated Gas Distributors v. FERC* (No. 85-1811, *et al.*). As a result of the interim rule the Commission is sending interstate natural gas pipeline companies a data request (FERC-593) (published elsewhere in this issue of the **Federal Register**) to determine the extent and nature of pipelines' take-or-pay obligations with respect to various NGPA pricing categories for natural gas. This data request was submitted to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act. OMB has provided an OMB control number.

EFFECTIVE DATE: The OMB approval of the information requirements is effective from August 20, 1987 until November 7, 1987.

FOR FURTHER INFORMATION CONTACT: Richard O. Howe, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington, DC 20426, Phone: (202) 357-8308.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act, 44 U.S.C. 3501-3520 (1982), and the Office of Management and Budget's (OMB) regulations, 5 CFR Part 1320 (1987) require that OMB approve information collection requirements imposed by agency rule. OMB has temporarily approved the information collection requirements of the Commission's data request contained in FERC-593 for 90 days and issued Control Number 1902-0149. The information requirements are discussed in the preamble to the interim rule but are not codified in the regulatory text. The information collected will be used in preparation of a final rule. This OMB Control Number is effective until November 7, 1987.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-19634 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

federal register

Friday
September 4, 1987

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 58

Good Laboratory Practice Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 58

[Docket No. 83N-0142]

Good Laboratory Practice Regulations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the regulations that specify good laboratory practice (GLP) for nonclinical laboratory studies. The amendments clarify, delete, or amend several provisions of the GLP regulations to reduce the regulatory burden on testing facilities. The changes will also achieve a substantial reduction in the paperwork burden imposed upon the regulated industries by the current regulations. Significant changes are made in the provisions respecting quality assurance, protocol preparation, test and control article characterization, and retention of specimens and samples based on FDA's experience in implementing the regulations. The agency has determined that the changes will not compromise the objective of the GLP regulations, which is to assure the quality and integrity of the safety data submitted in support of the approval of regulated products.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Paul D. Lepore, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2390.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of October 29, 1984 (49 FR 43530), FDA published a proposal to amend the agency's regulations in 21 CFR Part 58, which prescribe good laboratory practice for conducting nonclinical laboratory studies (the GLP regulations). The proposal was the result of an evaluation of the GLP regulations and of the data obtained by the agency's inspection program to assess laboratory compliance with the regulations. The evaluation led the agency to conclude that some of the provisions of the regulations could be revised to permit nonclinical testing laboratories greater flexibility in conducting nonclinical laboratory studies without compromising public protection. FDA invited comments on all aspects of the proposal and provided 60 days for interested persons to submit comments, views, data, and information on the need to revise any other provisions of Part 58.

Comments

FDA received 33 comments: 19 from manufacturers of articles regulated by FDA, 4 from associations, 8 from foreign or domestic testing or consulting laboratories, and 2 from individuals within FDA. The majority of these comments endorsed the proposed changes. Many of the comments suggested additional revisions to the GLP regulations or modifications to the proposed changes. A summary of the comments received by FDA during the comment period and the agency's response to them follows.

General

1. One comment urged FDA to initiate training procedures for its field personnel so that the regulated community would obtain maximum benefit from the revisions to the GLP regulations.

FDA agrees that agency field personnel who conduct inspections of nonclinical testing laboratories need to understand the specific requirements of the GLP regulations to follow appropriate inspectional practices and procedures. FDA has, to date, conducted 17 training courses at its National Center for Toxicological Research in Jefferson, AR, to provide training in good laboratory practice and the associated laboratory inspection techniques. FDA intends to continue to provide such training for its personnel.

2. Eight comments urged FDA to encourage the Environmental Protection Agency (EPA) to adopt similar revisions to its good laboratory practice standards. The comments noted that unless EPA amends its good laboratory practice standards to conform them to FDA's GLP regulations, nonclinical laboratories will still be required to comply with EPA's more stringent requirements. Therefore, regardless of any changes that FDA makes in its regulations, laboratories will not benefit from the revisions unless the EPA regulations are similarly revised.

FDA recognizes that certain nonclinical laboratories that are subject to FDA's regulations are also subject to the good laboratory practice standards established by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2600 et seq.). When this final rule becomes effective, some of the provisions of the GLP regulations will differ from the good laboratory practice standards established by EPA. FDA has consulted with EPA officials respecting the changes to FDA's regulations effected by this final rule and will cooperate fully with EPA when that agency propose to revise its regulations.

Scope

3. Except for editorial changes to § 58.1, FDA did not propose to change the scope of Part 58. One comment, however, urged the agency to revise § 58.1 further to make clear that batch release safety tests performed on specific batches of biological products intended for use in clinical trials after tests to establish the basic safety profile have been conducted are subject to the GLP regulations.

FDA declines to change final § 58.1 on the ground that the studies described by the comment are within the current scope of Part 58. The animal tests performed with an investigational biological product prior to licensing, including the batch release safety tests, are intended to establish the safety of the product. Accordingly, any such test would constitute a nonclinical laboratory study as defined in § 58.3(d). Because such test would also be intended to support a marketing application for a product regulated by FDA, it would be subject to the GLP regulations.

Definitions

4. Four comments endorsed FDA's proposal to change the definition of "control article" in § 58.3(c) to exclude from the definition feed and water administered to control groups of a test system. One comment, however, expressed concern that, by relaxing essential standards, the proposed change would compromise the quality of the animal test.

FDA does not agree that excluding feed and water from the definition of "control article" will compromise test quality. The regulations will continue to contain provisions adequate to control the use of feed and water in a nonclinical laboratory study. For example, § 58.31(e) requires management to assure that materials are available as scheduled, § 58.45 provides for proper feed storage, § 58.81(b)(2) requires the preparation of standard operating procedures for animal care (e.g., nutrition), § 58.90(g) requires periodic analysis of feed and water for interfering contaminants, and final § 58.120(a)(7) (formerly § 58.120(a)(9)) requires the protocol to contain a description or an identification of the diet, including specifications for acceptable levels of contaminants Other sections of the regulations also

apply to feed or water that is used as a carrier for the test or control article. For example, § 58.31(d) requires management to assure that test and control article mixtures have been appropriately tested, § 58.47 requires that a testing facility include storage areas that are adequate to preserve the identity, strength, purity, and stability of such mixtures, and § 58.113 requires the laboratory to conduct appropriate analyses for uniformity of the mixture, as well as concentration and stability of the test article in the mixture. As discussed at length in the preamble to the proposal (49 FR 43531), the amendment to § 58.3(c) will mean that the feed and water provided to the control groups of a test system will not be subject to certain provisions of the regulations, e.g., those requiring control articles to be characterized and tested for stability (§ 58.105), retained as reserve samples (§ 58.195), or accountable with respect to use (§ 58.107). As discussed above, however, the regulations will continue to require the provision of adequate supplies of feed and water, a description of the feed, proper storage, and use accountability procedures as directed by the protocol, and standard operating procedures. Further, only feed and water shown to be free from unacceptable contamination may be used in a study.

For the reasons above, FDA concludes that the change to § 58.3(c) will not compromise the quality of the animal test and that the term "control article" should be reserved for the discrete substances/articles and vehicles other than feed and water administered to groups of the test system to provide a basis of comparison with the test article.

5. Four comments on proposed § 58.3(d) endorsed FDA's proposal to allow laboratories to conduct several experiments using the same test article under a single, comprehensive protocol. One comment, however, expressed concern that by amending the definition of "nonclinical laboratory study," FDA may inadvertently encourage laboratories to establish protocols that (1) are too brief to assure the quality and integrity of safety data developed through a study conducted under the protocol, or (2) do not describe study procedures in sufficient detail for such assurance, because lengthy "umbrella protocols" may be difficult to administer and track during the amendment process.

Under the revised definition in § 58.3(d), a single "umbrella" protocol may be used for concurrent testing of more than one test article using a single common procedure, e.g., mutagenicity testing, or for a battery of studies of one test article conducted in several test systems. Section 58.120 requires that each study have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study, and § 58.33 requires the study director to assure that the protocol is approved and followed.

FDA notes that the changed definition of "nonclinical laboratory study" does not require any laboratory to establish "umbrella" protocols—it only allows it as an option. The agency recognizes that a longer, more complex protocol might be more difficult to manage than a simpler one; however, using an "umbrella" protocol should be more efficient than using several closely related protocols. The quality or accuracy of test data and procedures should not be compromised, while the paperwork burden should be reduced. In any event, the laboratory remains responsible for assuring that the validity of any study that it conducts is not adversely affected due to an inadequate protocol.

6. One comment urged FDA to revise further the definition of nonclinical laboratory study to define the terms "study initiation" and "study termination."

FDA recognizes that differing words and phrases are used within the GLP regulations to denote dates respecting significant events that occur during a laboratory study. For this reason, the agency agrees that it may be useful to add to the regulations definitions of the terms "study initiation" and "study completion."

FDA advises that the study initiation date represents the date on which the study director has completed plans in preparation for the technical conduct of a study (see § 58.33) and on which, under § 58.31(e), management is required to make certain that personnel, resources, facilities, equipment, materials, and methodologies for the study are available as scheduled. On the study initiation date, the study is entered on the master schedule sheet (see § 58.35(b)(1)). After this date, any protocol changes are to be made only in accordance with the procedure described in § 58.120(b). Accordingly, FDA is adding new § 58.3(o) to define "study initiation" to mean the date the protocol is signed by the study director.

The study completion date is the date on which the study director signs the final report (see final § 58.185(b)). On the study completion date, the study director is required to make certain that raw data, documentation, protocols, specimens, and final reports are transferred to the archives (see § 58.33(f)), and under § 58.35, the quality assurance unit may retire the study from the master schedule sheet. This date also specifies the beginning of the record retention period under § 58.195(b). After the study completion date, final reports may be amended only in accordance with the procedure described in § 58.185(c). Accordingly, FDA is adding new § 58.3(p) to define "study completion" to mean the date the final report is signed by the study director. As a necessary conforming amendment, FDA is also amending § 58.185(b) to provide that the final report shall contain the dated signature of the study director.

FDA advises that the phrase "close of the study" as used in § 58.33(f) refers to the study completion date. Also, the terms "terminate" and "discontinue" as used in § 58.195(b)(3) are used in their ordinary senses to mean stop, cease, break off, or give up, denoting that a study has been ended before the planned study completion date. For these reasons, FDA believes that these terms do not need any further definition to make clear their meanings.

7a. Three comments urged FDA to expand the definition of "raw data" under § 58.3(k) to provide that the computer record of "hand-recorded data entered into the computer verbatim and verified" could be substituted for the original source as raw data.

FDA does not agree that the computer record of hand-recorded data may be considered as raw data. Individuals who enter data from a laboratory study into the computer commonly do not have any knowledge of the conditions under which the data were collected and may not understand the data originator's notations that regularly are included on the hand-recorded data sheets. The probability of error in data entry is greatly increased under these circumstances.

7b. One comment urged the agency to revise § 58.3(k) to make clear that the term "raw data" as it pertains to the findings of the histopathological examinations refers only to the signed and dated final report of the pathologist.

FDA does not agree that it needs to amend the definition of raw data relative to the findings of histopathological examinations. In pertinent part, § 58.3(k) defines raw data as laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities and are necessary for the reconstruction and evaluation of the final report. Although the notes taken by a pathologist during

histopathological examination of slides are indeed the result of original observations, these notes are not necessary for the reconstruction and evaluation of the final report. The final report is evaluated by an analysis of the pathology syndrome as described in the pathologist's report, which is required under § 58.185(a)(12). Further, because § 58.190(a) requires histopathological blocks, tissues, and slides to be retained as specimens, the final report can be reconstructed by verification of the pathology findings by, e.g., a second pathologist or by a team of pathologists.

The pathologist's interim notes, therefore, which are subject to frequent changes as the pathologist refines the diagnosis, are not raw data because they do not contribute to study reconstruction. Accordingly, only the signed and dated final report of the pathologist comprises raw data respecting the histopathological evaluation of tissue specimens.

Testing Facility Management

8. One comment objected to FDA's proposal to delete the provision in § 58.31(b) that requires testing facility management to document as "raw data" the replacement of a study director. The comment argued that it could be difficult to retrieve such documentation if data were transferred to another location after completion of a study.

FDA proposed to delete the requirement in § 58.31(b) to document study director replacement as "raw data" in the agency's belief that other provisions of the GLP regulations adequately require documentation of this event. The agency continues to believe that the requirement in § 58.31(b) is redundant to such other provisions and is not necessary to assure the quality and integrity of the safety data developed through a study conducted by a laboratory. For example, § 58.35(b)(1) provides that the master schedule sheet shall contain the name of the study director. Thus, replacement of the study director would necessitate an updating of the master schedule sheet. The master schedule sheet itself is "raw data" because it is a record that is the result of laboratory activities and is necessary for the reconstruction of the study. Also, § 58.120(b) requires that any change in an approved protocol and the reason or reasons for the change are to be documented. Because § 58.120(a)(11) of the final rule (previously § 58.120(a)(15)) requires that the protocol contain the dated signature of the study director, replacement of the study director would constitute such a change. Other provisions of the regulations require the quality assurance unit to retain the master schedule sheet and copies of protocols as an easily accessible system of records for a specified period after completion of the study (§ 58.195(d)). Therefore, it should not be difficult to identify the term of each study director even if records are transferred elsewhere after study completion.

Study Director

9. Several comments objected to § 58.33 in its entirety on the grounds that (1) the regulation does not clearly define the responsibility of the study director and (2) the wording of the regulation implies that the study director must be technically competent in all areas of a study. One comment argued that the study director should be responsible only for "coordinating" the technical conduct, interpretation, analysis, documentation, and reporting of results.

FDA discussed at length in the preamble to the GLP final rule the intent of § 58.33 and the requirements applicable to the individual who is designated the study director for any study (43 FR 59986, 59995; December 22, 1978). As discussed in that preamble, the study director represents the single, fixed point of responsibility for overall conduct of each study. Although "coordination" of the pieces of a study logically is part of the study director's responsibilities, to limit his or her responsibilities to mere "coordination" would compromise public protection if another person were not such designated fixed point and would add an unnecessary burden if FDA were to require a laboratory to employ an additional person to provide such a point. The study director is charged with the technical conduct of a study, including interpretation, analysis, documentation, and reporting of results. FDA does not intend, however, that the individual is to be technically competent in all areas of a study. FDA's inspectional experiences have demonstrated that if responsibility for proper study conduct is not assigned to one person, a potential exists for the issuance of conflicting instructions and improper protocol implementation.

FDA concludes that the comments did not provide any new data or information to negate the agency's original determinations and that it should retain § 58.33 as it was established in the December 22, 1978, final rule.

10. One comment objected to FDA's proposal to delete the phrase "and verified" from § 58.33(b), which currently requires that the study director assure that all experimental data are "verified" as well as accurately recorded. The comment argued that removing the study director's obligation to assure that the data have been verified would dilute the responsibility of the study director for proper conduct of the study.

FDA has carefully reevaluated its proposal to remove the phrase "and verified" from § 58.33(b). FDA proposed to delete the phrase from the regulation in response to arguments from management of testing facilities that they misinterpreted the provision, apparently believing that it required the study director personally to witness each data observation. FDA did not intend the provision to so require. Rather, the agency regards the study director as responsible for assuring that all experimental data are verified.

Ordinarily the verification required by § 58.33(b) is obtained by the individual collecting the data, using data verification procedures described in the protocol or in the specific standard operating procedure, and by the individual's supervisor as part of the supervisory quality control procedures. "Verified" is used to describe the study director's responsibility to assure the accurate recording of data. Verification in this sense does not require the study director to observe every data collection event but does require the study director to make certain that the study conduct procedures designated in the protocol for a study and the standard operating procedures established for a study are followed. For all these reasons, FDA has decided to retain the phrase "and verified" to confirm the need for data verification in nonclinical laboratory studies.

11. Two comments urged that the study director's responsibility for assuring placement in the archives of the study records specified under § 58.33(f) be transferred to testing facility management under § 58.31. The comments argued that raw data and documentation are under the immediate control of facility management rather than the study director.

The change suggested by the comments would conflict with the study director's responsibility identified in § 58.33 of representing the single point of study control (see paragraph 9 of this preamble). The archived materials of each study, including raw data and documentation, constitute lasting proof of study validity. The transfer of such materials to the archives is a critical step in study control that assures that the archived materials are complete and adequate for study reconstruction. Indeed, these revised regulations further emphasize the study director's control function by defining the study

completion date as the date the final report is signed and dated by the study director; after this date, the study director assures that all required materials are transferred to the archives. Consequently, FDA declines to accept the change proposed by the comments.

Quality Assurance Unit

12. FDA received eight comments regarding § 58.35(a), which sets forth the composition and function of the Quality Assurance Unit (QAU). One comment endorsed FDA's proposal to substitute "which" for the current phrase, "composed of one or more individuals who," to make clear the personnel who can perform quality assurance duties. The comment suggested, however, that the agency use the term "function" or "activity" in § 58.35(a) in place of the current term "unit" to make it clear that quality assurance monitoring need not be performed by individuals of a permanently staffed unit. Four comments disagreed strongly with the proposed change to § 58.35(a), arguing that the change inappropriately implies that assurance of a well-conducted study does not require special training or experience. The comments also asserted that verifiable data are produced as a result of the current requirement for an independent, fixed and permanently staffed quality assurance unit. Other comments argued that individuals should not monitor studies similar to their own work. Some comments requested further clarification of the required composition of the QAU.

FDA does not believe that identification of the quality assurance unit as a "function" or "activity" would serve to clarify the composition or function of the QAU. FDA never has intended that the QAU necessarily has to be a separate entity or a permanently staffed "unit" (see 43 FR 59996). "Quality assurance unit" has become an accepted term to describe those individuals responsible for quality assurance as described in § 58.35. FDA also does not agree that the proposed revision to § 58.35(a) implies that assurance of a well-conducted study does not require special training or experience on the part of individuals monitoring the conduct and reporting of a nonclinical laboratory study. FDA continues to believe that well-qualified and trained personnel are essential to quality assurance under the GLP regulations and that one of management's most important responsibilities in maintaining effective quality assurance is to provide an adequate number of such personnel (§ 58.31 (c) and (e)).

FDA concludes from the comments that the requirements set forth in § 58.35(a) have been misinterpreted in some instances to mean that the regulations require that the QAU be composed of individuals whose sole duties are in quality assurance. In fact, the agency intends only that quality assurance activities be separated from study direction and conduct activities; that is, a trained and qualified person who works on one study can perform quality assurance duties on any study in which he or she is not involved. FDA's reason for requiring separation of quality assurance functions from study conduct functions is fundamental—to assure that quality assurance personnel can act candidly, without bias or a real or perceived conflict of interest. In effecting the separation required by the GLP regulations, FDA was aware that many small laboratories could not afford the operation of a permanently staffed QAU. For this reason, the agency concluded that the separation of functions on a study-by-study basis as permitted in the existing and revised regulations would provide effective quality assurance. The agency's intent in defining the composition and function of the QAU was discussed at length in the preamble to the current GLP regulations (see 43 FR 59996). FDA believes that the change now being made more clearly reflects the agency's original intent.

13. One comment recommended that FDA delete the word "sheet" from the term "master schedule sheet" in § 58.35(b)(1) on the ground that there are methods for maintaining a master schedule other than use of an actual "sheet."

FDA acknowledges that current technology allows for various methods for maintaining a master schedule, ranging from sophisticated computerized procedures to procedures whereby such information is contained in written records. Regardless of the method utilized, however, the master schedule information is "raw data" within the meaning of the GLP regulations and copies of the master schedule are required to be retained in the study archives in accordance with § 58.195(b). The agency is, therefore, retaining the term "master schedule sheet" to emphasize that the master schedule constitutes raw data subject to agency inspection and that the records must be retained.

14. One comment suggested that FDA delete the current provision in § 58.35(b)(1), which requires a laboratory to include the name of the sponsor of each study on the master schedule sheet for all studies conducted at the facility. The comment urged the agency to allow sponsor identification by code.

FDA agrees that including the sponsors' name on the master schedule sheet is not essential either for the conduct of management's functions listed in § 58.31 or for the conduct of proper quality assurance under § 58.35. Sponsor identification by code is an adequate procedure, provided that the name of any sponsor is made available to FDA upon request. Accordingly, FDA is amending § 58.35(b)(1) to read "* * * identity of the sponsor * * *."

15. One comment suggested that FDA further revise § 58.35(b)(1) to allow the master schedule sheet to be indexed by study number rather than test article on the ground that multiple studies may be performed on each test article.

FDA recognizes that a nonclinical laboratory may have in progress several studies on each test article that is listed on the master schedule sheet. The agency concludes, however, that indexing by study number alone and not by test article would be inappropriate. The master schedule sheet is the mechanism through which the QAU can assure management that the facilities are adequate and that there are sufficient numbers of qualified personnel available to accomplish the scheduled work (see 43 FR 59997). In addition, § 58.31(e) requires management to assure that study materials (e.g., test articles) are available as scheduled. The use of study numbers rather than test articles as index terms would, therefore, frustrate a major purpose of the master schedule sheet and impede the conduct of an important management function.

16. Three comments endorsed FDA's proposal to delete the current requirement under § 58.35(b)(1) that the status of the final report be a distinct entry on the master schedule sheet. One comment, however, objected to the proposal on the basis that frequently there are delays in completing the final report, and the study status often is different from the expected date of completion of the report.

FDA believes that the comment that objected to the proposal misconstrued the purpose of revising § 58.35(b)(1). Section 58.35(b)(1) currently requires that the master schedule sheet contain separate headings for the "current status" of the study and for the "status of the final report" of the study. FDA considers the preparation of the final report to be a study event, current status of which should be reflected on the master schedule sheet. Preparation of the final report is similar to other study

events (e.g., test article-mixture preparation, test system dosing, in life observations) that are listed under "current status." Under this revision to § 58.35(b)(1), the master schedule sheet would contain the same information respecting the final report as is required under the current GLP regulations, but the information would be included only under the "current status" heading. The agency advises that "expected date of completion of a final report" is not a "status" entry. Such information has not been required in the past nor is this information being required now.

17. FDA proposed to revise § 58.35(b)(3) to provide specifically that the QAU need only inspect "each nonclinical laboratory study" on a schedule adequate to assure the integrity of the study. Four comments recommended that the agency further revise the regulation to substitute the word "studies" for the phrase "each nonclinical laboratory study" alleging that inspection of multiple short duration studies can result in expenditure of significant time and effort with little derived benefit. Two comments argued that inspection of short duration studies conducted repeatedly at the same facility by the same personnel is not necessary and suggested that, in lieu of requiring inspection of each study, standard operating procedures be developed to determine the inspection frequency of various types of studies. These comments also recommended that such inspections be used to demonstrate compliance of other similar studies conducted in the same time frame.

FDA does not agree with the comments. The quality of each nonclinical laboratory study submitted to the agency in support of an application for a research or marketing permit for a product regulated by FDA is critical to a determination of the safety of the product. The principle of quality assurance advanced in the GLP regulations is to inspect studies to identify and correct problems in a timely fashion. FDA is convinced that such problems can be detected only through a program of vigorous inspection of each study. This does not mean, however, that every phase of every study needs to be inspected by the QAU (see paragraph 18 of this preamble).

18. Two comments disagreed with FDA's proposal to modify the current requirement in § 58.35(b)(3) that the QAU inspect each phase of a study at specified intervals. The comments argued that elimination of specified quality assurance inspection intervals may result in decreased compliance by cost-cutting laboratories. Another comment urged FDA to identify the critical phases of a nonclinical laboratory study to be inspected by the QAU.

Section 58.35(b)(3) currently provides that the QAU is to inspect at periodic intervals each phase of a nonclinical laboratory study. For studies lasting more than 6 months, the inspections are to be conducted every 3 months. For studies lasting less than 6 months, the inspections are to be conducted at intervals adequate to assure the integrity of the study (including each phase at least once). The term "each phase" was intended to emphasize the need for repeated surveillance so that the QAU observes at least once during the course of the study each critical operation. The term "periodic" was included in the regulation to indicate the need for more than one inspection of certain repetitive, continuing operations. In light of current information, however, FDA does not believe that such a rigid schedule is essential to assure study quality. The agency has learned through its inspection program that the quality of toxicology testing is much higher than that envisioned in 1976 when FDA proposed to establish the GLP regulations (see 41 FR 51206, 51207–51208; November 19, 1976).

Contemporary concepts of quality assurance emphasize the effectiveness of thorough, in-depth inspections of study processes (i.e., all operations required to accomplish a study phase) in place of quick, spot checks of individual operations with a study. Thorough examination of personnel, facilities, equipment, standard operating procedures, data collection procedures, raw data books, and other features associated with a study phase can achieve more effective quality assurance than does a more superficial observation of the conduct of the same study phase in a series of studies.

The agency has concluded that the QAU's inspection schedule should take into account the need for inspection of each study on a schedule adequate to assure the integrity of the study being monitored. The change in § 58.35(b)(3) permits the QAU to exercise reasonable flexibility and judgment so that inspections can be scheduled to best achieve the goal of assuring that studies are properly conducted. The agency advises, however, that each study, no matter how short, needs to be inspected in-process at least once. Further, across a series of studies all phases should be inspected in order to assure the integrity of the studies. For these reasons, FDA does not believe that the regulation as revised will result in decreased compliance with the GLP regulations or that the term "critical phase" needs to be defined.

19. Eight comments addressed FDA's proposal to delete § 58.35(b)(4), which currently requires the QAU to submit periodic written status reports to management and to the study director. One of the comments supported the proposal on the basis that the provisions of § 58.35(b)(3), which require reports to management on problems likely to affect study integrity, are adequate to assure study quality. Several comments questioned whether deleting § 58.35(b)(4) would provide any practical benefit to testing facilities, noting that management is likely to continue to expect periodic reports. One comment noted that elimination of the requirement for status reports could allow management to disregard quality assurance problems if management is only marginally supportive of good laboratory practice and quality assurance. Three comments argued that, by deleting the provision, FDA would inappropriately place on the QAU rather than on the study director the obligation of determining what constitutes a problem likely to affect the integrity of a study. One comment argued that, because management is required to be involved in corrective actions under the provisions of §§ 58.31(g) and 58.35(b)(3), management must be kept informed respecting the status and the progress of any study inspected by the QAU. Another comment suggested that FDA delete the requirement that status reports be provided to the study director but retain the requirement that management receive such reports.

After careful consideration of these comments, FDA has concluded that § 58.35(b)(4) should be retained in its current form. The agency proposed to delete the paragraph based on its tentative conclusion that routine reports of unremarkable findings by the QAU are not essential to study quality. The comments, however, are persuasive in that such reports are necessary to demonstrate to management that the QAU is functioning properly. It is also necessary that the study director continue to receive such reports because that individual is responsible for all aspects of any study being conducted by a facility, including GLP compliance.

20. One comment suggested that, in lieu of deleting the entire paragraph, § 58.35(b)(4) be modified by removing the requirement for status reports on each study, thereby reducing paperwork.

In accord with the conclusions stated in paragraph 19 of this preamble, FDA

believes that it is inappropriate to eliminate the requirement for status reports for each study. Without status reports on each study, there would not be adequate assurances concerning the quality of the ongoing studies.

21. One comment urged FDA to revise current § 58.35(b)(5) to hold the QAU responsible only to (1) determine that known deviations from approved protocols or standard operating procedures were not made without proper documentation, and (2) require authorization for anticipated deviations. The comment argued that the current wording of the regulation implies that the QAU shall have prior knowledge of any deviations and shall approve such deviations, which is not the case in most instances.

FDA would not consider a laboratory to have violated § 58.35(b)(5) if a deviation was not authorized in advance because it was unanticipated. For example, as recognized in the preamble to the final rule (43 FR 59998), a fire in the facility would necessitate immediate action. Also, as discussed at length at 43 FR 59998, FDA does not intend that the QAU is responsible for authorizing any deviations from the protocol or standard operating procedures, rather it is responsible for detecting any such deviations by its inspection and audit procedures. The revision suggested by the comment would remove the accountability of the QAU for detecting deviations and would undermine the requirements for quality assurance.

22. FDA proposed to revise current § 58.35(b)(7) to provide that the statement which the QAU prepares to accompany the final report would be required to identify the phases of the study inspected and the number of inspections conducted. Eleven comments objected to the proposed change to the regulation, which currently requires only that the statement by the QAU specify the dates that inspections of the study were made and the dates that findings were reported to management and to the study director. Most of the comments were concerned with the additional reporting burden imposed by the proposed revision. Some of the comments argued that the information sought by FDA through the proposed revision in § 58.35(b)(7) is currently required under the provisions of § 58.35 (b)(3) and (c). These comments pointed out that requiring additional documentation would be duplicative and contrary to the stated purposes of the proposed revisions to the GLP regulations.

FDA has carefully reevaluated its proposal to require that the QAU statement identify the phases of a study inspected and the number of inspections conducted. The agency is persuaded that the proposal would have provided information redundant to that which is available under other provisions of the GLP regulations. Accordingly, FDA has decided not to change § 58.35(b)(7) and is retaining this provision in its current form. Proposed § 58.35(b)(6) (as § 58.35(b)(7) would have been renumbered) is not being adopted.

Animal Care Facilities

23. One comment objected to the proposed modification to § 58.43(c), which would delete the current requirement that all laboratory facilities include separate areas for the diagnosis, treatment, and control of laboratory animal diseases. The comment noted that animal health is a major problem in toxicology testing. For this reason, the comment argued that any relaxation of the current requirements in the GLP regulations for animal care is ill-advised and contradictory to FDA's responsibility for the welfare of animals.

As discussed in the preamble to the proposed amendments to the GLP regulations (49 FR 43532), a laboratory may elect to dispose of diseased animals, thereby obviating the need for dedicated areas for such animals. FDA believes that it is not cost-effective to require separate areas in every case and has concluded that the decision concerning appropriate separation of animals should be made by the study director in consultation with other scientific personnel. The agency does not believe that providing for dedicated laboratory areas as appropriate compromises FDA's continuing commitment to animal welfare, which is specifically dealt with in § 58.90. Indeed, FDA believes that the GLP regulations foster quality animal testing under defined conditions so that fewer animals are required to establish product safety.

Animal Supply Facilities

24. FDA proposed to revise § 58.45 to permit laboratories to store perishable supplies or feed by methods most appropriate to the characteristics of the materials. One comment urged FDA to amend § 58.45 further to permit storage of animal feed in rooms housing small animals or small groups of animals that are isolated from other studies.

FDA declines to amend § 58.45 as recommended by the comment. In developing the current GLP regulations, the agency carefully considered whether animal feed or bedding might be stored within any test areas. FDA concluded at that time that storage areas needed for feed and bedding should be separate from the areas housing the test system to preclude mixups and contamination of test article-carrier mixtures and inadvertent exposure of the test system to potentially interfering contaminants. FDA continues to believe that separate storage areas for feed and animal bedding should be required and the comment did not provide any data to counter this belief. FDA advises, however, that § 58.45 does not preclude holding of limited quantities of test or control article-feed mixtures for short periods of time in properly constructed and labeled containers in the animal rooms.

25. One comment objected to the proposed changes to § 58.47, arguing that it believed the current requirements respecting facilities for handling test and control articles have resulted in fewer mixups.

Based on the comment, FDA has reconsidered the proposed revision of § 58.47. The agency agrees with the comment, in principle. Indeed, the agency intended the revision to be only editorial to simplify and to make clear that laboratories shall provide separate areas for receipt, mixing, and storage of test and control articles and their mixtures as necessary to prevent contamination or mixups. Inadvertently, however, the proposed revision would have deleted an essential requirement of good laboratory practice, i.e., the need to provide storage areas for test and control article mixtures adequate to preserve the identity, strength, purity, and stability of the mixtures. For this reason, the agency has concluded that the regulation is appropriate as currently stated and existing § 58.47 is retained.

Maintenance and Calibration of Equipment

26. FDA proposed to revise § 58.63(b) to provide that written standard operating procedures respecting maintenance and calibration of equipment would allow laboratories to discard faulty equipment as an alternative to the current provisions of § 58.63(b), which provide only for the repair of equipment that fails or malfunctions. Under FDA's proposal, a testing facility would need to specify remedial action in the event of equipment failure or malfunction only when remedial action is "appropriate" to the particular piece of equipment. Three comments recommended that FDA amend § 58.63(a) to require testing, calibration, and/or standardization of equipment in accord with written standard operating procedures. The comments argued that by changing

current § 58.63(a) in this fashion, FDA might delete § 58.63(b) in its entirety without substantively affecting the requirements of the GLP regulations applicable to laboratory equipment.

FDA advises that § 58.63(b) concerns not only setting forth in standard operating procedures the details of routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, but it also concerns describing remedial actions to be taken when appropriate if the equipment fails or malfunctions. In promulgating existing § 58.63(b), FDA concluded that the specific features set forth in the regulations need to be included in equipment standard operating procedures because of the crucial role that properly used equipment plays in study conduct; a role which pervades every phase of a study and is vital to study quality and final report integrity. The comments did not provide any data that negate FDA's original determination. The agency continues to believe that specification of these features provides useful guidance to persons subject to the GLP regulations and concludes, therefore, that it would be inappropriate to delete § 58.63(b) from the regulations.

27. Section 58.63(b) requires in part that written standard operating procedures designate the person responsible for certain operations respecting equipment, i.e., routine inspection, cleaning, maintenance, testing, calibration, and/or standardization. Although FDA did not propose to revise these requirements of § 58.63(b), three comments stated that by requiring that standard operating procedures designate an individual responsible for performing each operation, FDA obligates testing facilities to change their standard operating procedures frequently. The comments further argued that the requirement to make a copy of the standard operating procedures available to laboratory personnel is redundant to the requirements set forth in § 58.81(c) and should be deleted.

The comments misconstrue the meaning of the word "person" as it is used in § 58.63(b). The second sentence of § 58.63(b) requires, in pertinent part, that "the written standard operating procedures shall designate the person responsible for the performance of each operation * * *." As explained in paragraph 120 of the preamble to the final rule (43 FR 60001), FDA adopted the term "person" as defined in § 58.3(h) rather than the originally proposed term "individual" to allow the standard operating procedures to designate an organizational unit.

The agency agrees with the comment that § 58.63(b) is redundant to § 58.81(c) insofar as it provides for standard operating procedure availability. Accordingly, FDA is removing the phrase "and copies of the standard operating procedures shall be made available to laboratory personnel" from § 58.63(b).

28. Section 58.63(c) requires that a testing facility maintain written records of all equipment inspection, maintenance, testing, calibration, and/or standardizing operations. Two comments recommended that FDA delete § 58.63(c) in its entirety, arguing that if management is satisfied that the standard operating procedures are adequate, further requirements are unnecessary.

FDA does not agree with the comments. FDA carefully considered the necessity for maintaining the records specified in § 58.63(b) when the agency developed the current GLP regulations. FDA concluded that such records are necessary to reconstruct a study and to ensure the validity and integrity of the data that are obtained from a study (see paragraph 26 of this preamble and 43 FR 60001). The purpose of the record retention requirement is to provide documentation throughout the study of equipment function in accord with design specifications for the equipment, and equipment use in accord with standard operating procedures for maintenance and calibration of the equipment. FDA'S experience in administering the GLP regulations has shown the benefit of maintaining such records. For example, through FDA's laboratory inspection program, the agency has been able to identify the precise period of time of equipment malfunction by an examination of the equipment records. Thus, § 58.63(c) has made it possible to disregard the data collected by a single defective piece of equipment without having to disregard all the data obtained from a specific study.

Standard Operating Procedures

29. Two comments on the requirements for standard operating procedures suggested that § 58.81(a) be amended to permit appropriate supervisory personnel to authorize deviations from the written standard operating procedures, arguing that the study director may not have the technical expertise to evaluate such deviations. One of the comments further argued for the change on the ground that the principles of good laboratory practice established by the Organization for Economic Cooperation and Development of the World Health Organization do not require study director approval of all standard operating procedure deviations.

FDA does not accept the suggestion. As discussed in paragraph 9 of this preamble, it is not necessary for the study director to be technically competent in all aspects of a study to assure that appropriate action is taken in response to any circumstances that may affect the quality and integrity of a study. The study director, however, has to be aware of and authorize any deviations that could have an impact on the study. FDA does not agree that the responsibility of the study director, as set forth in § 58.81(a), is inconsistent with the Organization for Economic Cooperation and Development principles of GLP. Chapter 2, section 2.3 (Ref. 1, p. 27) of the Organization for Economic Cooperation and Development document defines the responsibilities of the study director, in part, as "ensur[ing] that the procedures specified in the study plan are followed, and that authorization for any modification is obtained and documented together with the reasons for them * * *." Accordingly, both the GLP regulations and the Organization for Economic Cooperation and Development principles of GLP require that the study director make certain that specified procedures are followed and that all modifications to the procedures in the approved study plan (i.e., standard operating procedures) are documented and approved.

30. One comment recommended that FDA amend § 58.81(b) to delete all examples of standard operating procedures that FDA requires a testing facility to establish on the ground that the list is not all-inclusive and may lead to misinterpretation.

FDA disagrees with the recommendation. The examples listed in § 58.81(b) are those minimal laboratory procedures which the agency believes are essential to assuring the quality and integrity of the data generated in the course of any study (see 41 FR 51213). FDA recognizes that circumstances may necessitate establishment of additional standard operating procedures. The list is not intended to be all-inclusive and should not be interpreted as such.

31. Three comments objected to the proposed deletion of examples of laboratory manuals and standard operating procedures required to be in the laboratory under § 58.81(c). The comments argued that the listing of examples serves to spell out the agency's intent, helps laboratories

decide which areas to cover, and that without such guidance a potential exists for misinterpretation of FDA's intent.

FDA does not agree. Section 58.81(c) requires that each laboratory area have immediately available standard operating procedures relative to the laboratory procedures being performed. Unlike the list in § 58.81(b), which represents specific minimal requirements, the examples listed in § 58.81(c) encompass very broad areas. Each of the areas presented would require the preparation of a group of standard operating procedures to cover adequately the operations within that area. Consequently, the agency concludes that the list in § 58.81(c) is too broad to serve as useful guidance.

Reagents and Solutions

32. FDA received five comments that recommended that the agency amend § 58.83. Four comments stated that only those reagents and solutions used in the conduct of nonclinical laboratory studies need to be labeled in accord with the requirements of § 58.83, i.e., "to indicate identity, titer or concentration, storage requirements, and expiration date" of the material. These comments argued that such a modification would allow the laboratory flexibility in designing the most suitable system to assure that deteriorated or outdated reagents and solutions are not used. The fifth comment recommended that FDA insert into the first sentence of § 58.83 the phrase "as appropriate" to make the provision read "all reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and, as appropriate, expiration date." This comment argued that it was not necessary to have expiration dates on certain stable reagents and solutions such as water and saline.

FDA declines to amend § 58.83. The agency continues to believe, as discussed in paragraph 148 of the preamble to the final rule (43 FR 60003), that all reagents and solutions maintained in the laboratory area for use in the conduct of nonclinical laboratory studies should be labeled as required by § 58.83. Accordingly, the label should include the identity, titer or concentration, storage requirements, and expiration date. This label information is the minimum information necessary to make clear to the laboratory personnel that the reagents and solutions are suitable for use in the procedures specified in the protocol and to protect against inadvertent mixups of reagents and solutions that are used in nonclinical laboratory studies with those that are not intended for such use. Further, FDA disagrees with the comment that suggested that expiration dating is not necessary for some reagents and solutions. FDA believes that expiration dates should be required on all reagents and solutions, without regard to their stability so that there is no doubt about the suitability of the materials for use in nonclinical laboratory studies.

Animal Care

33. One comment recommended that FDA delete § 58.90(a) on the basis that requiring standard operating procedures for housing, feeding, handling, and care of animals is redundant to other provisions of the GLP regulations.

FDA recognizes that § 58.81(b)(2) requires testing facilities to establish standard operating procedures for animal care. Section 58.90(a), however, expressly specifies that standard operating procedures shall also cover animal housing, feeding, and handling. The agency believes that these items are essential features for providing adequate humane treatment of animals and, therefore, is retaining § 58.90(a).

34. Two comments objected to the proposed amendment of the requirements under §§ 58.90 (b) and (c) to provide that animals may be isolated rather than quarantined. The comments argued that allowing laboratories to develop isolation and health status evaluation procedures in lieu of quarantine may not provide adequate assurance of test animal health because such evaluations are done only on a small randomly selected number of animals and are not as reliable as an adequate quarantine period. One comment suggested that the term "segregated" or the term "separated" may more accurately reflect FDA's intent in amending §§ 58.90 (b) and (c) than does the term "isolated."

As discussed in the preamble to the proposed amendments (49 FR 43533), substitution of a requirement for isolation and health status evaluations in lieu of quarantine of newly received animals will permit laboratories to develop specific isolation and health status evaluation procedures in concert with the age, species, and class of animals, and with the type of study to be done. As used in current § 58.90(b), the term "quarantine" connotes a rigid set of prestudy procedures which a facility is obligated to follow, including a mandatory holding period, specified diagnostic procedures, and the use of specialized facilities and animal care practices. The agency has concluded that isolation and health status evaluations should provide adequate precautions against entry of unhealthy animals into a study. Health status evaluations may be performed during the prestudy acclimation period. Under § 58.90(b), the health status of each animal is to be evaluated soon after receipt. Section 58.90(c) prohibits the entry of any diseased animal into the study.

The agency has also concluded that a devoted area equipped to provide isolation of diseased animals is not necessary in all cases. As discussed in the preamble to the proposal (49 FR 43533), FDA believes that it should allow certain options for handling diseased animals, thereby permitting increased flexibility in laboratory operation. FDA agrees that the term "segregate" or the term "separate" rather than the term "isolate" could be used in as much as each term connotes "to set apart." Because "isolate" is a term commonly used and understood in contemporary veterinary medical practice, however, FDA will continue to use that term in these regulations.

35. One comment recommended that FDA amend § 58.90(d) to permit procedural means to provide "appropriate identification" of individual animals in a study.

FDA does not accept the recommendation. The agency notes that proper animal identification throughout a study is essential to study integrity. When animals are housed individually in cages, procedural means can be used to identify each individual animal, i.e., a cage card may be used if it provides all the information necessary to identify the animal specifically, and the animal handling standard operating procedures specify detailed procedures for preventing animal mixups. The agency is not aware, however, of any procedural means that could be used to identify adequately individual animals that are housed within a group in a cage. FDA advises that § 58.90(d) does not preclude identification by means other than the examples enumerated in that section provided that individual identification can be maintained and documented throughout a study.

Test and Control Article Characterization

36. One comment urged the agency to delete the requirement in § 58.105(b) for stability determination of test and control articles before initiation of the study. The comment argued that changing § 58.105(b) as recommended would make it consistent with FDA's proposed changes to § 58.105(a), which would allow test and control article characterization after completion of the study.

FDA disagrees with the recommendation. As discussed in the preamble to the proposal (49 FR 43533), FDA has concluded that characterization of test and control articles need not be performed until initial toxicology studies with the test article show reasonable promise of the article's reaching the marketplace. In arriving at this conclusion, the agency considered that prior knowledge of the precise molecular structure of a test article is not vital to the conduct of a valid toxicology test. It is important, however, to know the strength, purity, and stability of a test or control article that is used in a nonclinical laboratory study.

A stability determination of a test or control article conducted after completion of the nonclinical laboratory test with the article does not provide any information about the continued strength of either the test or control article previously given to the test system. Determining that the test and control articles are stable for the duration of the study is fundamental to interpreting the results of the study. For this reason, it would be inappropriate to allow for stability determinations only after-the-fact.

The agency does believe, however, that the continued strength of the test or control article may adequately be determined either by stability testing before initiation of the study or through appropriate periodic analysis of each batch. Section 58.105(b) currently allows stability testing of the test and control articles through periodic analysis only if it is not possible to determine their stability before study initiation. Because experience has shown that it is adequate either to determine stability of the test and control articles before initiation of a study or by periodic analysis of the articles while the study is in progress, the agency on its own initiative is revising § 58.105(b) to provide facilities and sponsors the flexibility to use either approach. Therefore, § 58.105(b) has been revised to provide for determination of the stability of the test or control article either before study initiation or through periodic analysis of each batch according to established standard operating procedures.

37. One comment observed that § 58.105(a) provides that testing facilities may rely on the labeling of marketed products for purposes of characterizing such products used as control articles in a study. The comment recommended that the agency also revise § 58.105(b) to allow product labeling to serve as documentation of stability for marketed products used as control articles.

FDA declines to adopt this recommendation. The only stability information typically included on the labeling of marketed products is the expiration date. The manufacturer's expiration dating on a marketed product is not adequately precise to provide data on the strength of the control article used throughout a nonclinical laboratory study. Lacking precise stability information respecting the control article could raise doubts concerning whether the test and control articles are comparable. Furthermore, mixing the marketed product with a carrier or use of the product in a manner not in accord with its labeling could alter the stability characteristics of the product. For these reasons, FDA concludes that determination of the stability in accordance with the procedures in § 58.105(b) still is appropriate for any products used as control articles.

38. Several comments recommended that FDA revise § 58.105(c) to remove the current requirement that storage containers be assigned to a test article for the duration of a nonclinical laboratory study. The comments argued that the requirement is unnecessary and is inconsistent with the Organization for Economic Cooperation and Development principles of GLP. One comment alleged that the statement is vague and questioned whether the provision would permit a storage container that a laboratory emptied during the conduct of, but before completion of, a study to be destroyed or reused. The same comment also questioned whether, as the test article is depleted during the conduct of a study, the provision would permit a laboratory to transfer the test article into a container smaller than that originally assigned to the article.

FDA does not believe that it would be appropriate to eliminate the storage container provision in § 58.105(c). FDA advises that the provision simply requires that each test article storage container be assigned to a test article at the beginning of a study and remain so assigned until the study is completed, terminated, or discontinued. The test article may not be transferred to different sized storage containers as a study progresses, nor may assigned storage containers be destroyed while a study is in progress.

The agency recognizes that it may be inconvenient for laboratories, especially small laboratories, to devote space to a test article container which is emptied before a study is completely terminated, or discontinued, or which might be replaced by progressively smaller containers while a study is in progress. Destroying or reusing or otherwise substituting for originally assigned, identified test article storage containers, however, could adversely affect the integrity of the study. FDA established the current provision because the agency observed a lack of accountability for test materials, ostensibly due to the very acts proscribed by the regulation, i.e., transfer of test articles to different sized containers and destruction of empty containers during the progress of nonclinical laboratory studies.

FDA continues to believe that the requirement concerning assignment of storage containers is necessary to ensure the integrity of a study. For example, the mere act of transferring a test article from one storage container to another introduces the opportunity for contamination of the test article by other laboratory materials or for mix-ups with other laboratory materials. In addition, during a transfer the test article would be exposed to air-borne contaminants as well as to moisture, either of which may compromise the integrity of the test article.

FDA also believes that requiring that containers be assigned to a test article for the duration of a study is fully consistent with the Organization for Economic Cooperation and Development principles of GLP. Chapter 2, section 2.3 (Ref. 1, p. 31) of the Organization for Economic Cooperation and Development document states that "storage container(s) should carry identification information, earliest expiration date, and specific storage instructions." Although the Organization for Economic Cooperation and Development document does not further characterize storage instructions that the Organization for Economic Cooperation and Development would recommend be included on containers, FDA concludes that its regulation identifies a "specific" storage instruction that is necessary to assure the integrity of the test article.

Mixtures of Articles with Carriers

39. Two comments argued that the requirements in § 58.113(a) to determine the uniformity, concentration, and stability of test and control articles in mixtures is unnecessarily burdensome for short-term studies. One comment stated that such tests are not necessary for test articles that are prepared and dispensed on the same day as used in single-dose acute toxicity tests. The comments suggested that the agency

revise § 58.113(a) to require that tests of mixtures of test and control articles need be conducted only "for studies other than short-term."

Section 58.113(a) requires, for all test or control articles mixed with a carrier, a determination of the uniformity of the mixture and a periodic analysis of the concentration of the test or control article in the mixture. In addition, § 58.113(a)(2), as amended, requires a determination of the stability of the test or control article in the mixture adequate to support time of use. Each of these analyses is necessary to assure that the test system is exposed to the test or to the control article in the amounts specifically designated in the protocol for a study. Determination of the uniformity of a mixture assures that each member of the test system receives the intended dose of test or control article. Periodic analysis of the concentration of the test or control article serves as a spot check to assure that the test or control article mixture has been prepared properly and in accord with the protocol and with applicable standard operating procedures. Determining the stability of the test or control article in the mixture helps to determine the period of time during which the test or control article mixture may be suitable for administration to the test system. FDA believes that knowledge of the dose of test or control article used in any test is essential for the proper evaluation of the results of that test. For these reasons, FDA has concluded that the requirements of § 58.113(a) should continue to apply to short-term tests as well as to studies other than short term.

As discussed in paragraph 36 of this preamble, however, FDA has decided to allow facilities and sponsors the flexibility to determine the stability of test and control articles either before study initiation or through periodic analysis of each batch according to established standard operating procedures. The agency believes that it is appropriate to allow similar flexibility with respect to determining the stability of mixtures of articles with carriers. For this reason, on its own initiative, FDA has revised § 58.113(a)(2) to allow determination of the stability of test and control articles in the mixture either before study initiation or through periodic analysis of the mixture according to established standard operating procedures.

40. One comment recommended that FDA delete § 58.113(a)(1), alleging that periodic determinations of the test or control article in mixtures is routine and provisions respecting such determination would more appropriately be included in § 58.35(b)(3).

The comment miscontrues the function of the QAU (see especially paragraphs 12 and 18 of this preamble). Current § 58.35(b)(3), as well as § 58.35(b)(3) as revised by this final rule assigns responsibility for periodic inspection of laboratory operations to the QAU. The QAU does not, indeed, under § 58.35(a), the QAU may not conduct any portion of a study. Rather, it is responsible for assuring that a study is conducted according to the protocol, the standard operating procedures, and the GLP regulations.

Protocol

41. A comment urged the agency to delete the provision in current § 58.120(a)(14) (final § 58.120(a)(10)) that requires that the protocol for each study identify the records for the study to be maintained. The comment argued that the requirement in renumbered § 58.120(a)(10) is redundant to the same requirements in §§ 58.33(f), 58.190(a), and 58.195(b).

FDA recognizes that §§ 58.33(f), 58.190(a), and 58.195(b) address records that the GLP regulations require a testing facility to retain in all events. As the authorized master plan for a study, however, the protocol should identify all records of the study to be maintained by the testing facility to inform all study participants fully of recordkeeping obligations. The agency believes that inclusion of this information in the protocol is essential to ensure adequate documentation of the conduct of the study.

For these reasons, FDA declines to remove § 58.120(a)(10) from the GLP regulations.

42. One comment recommended that FDA delete the provision in current § 58.120(a)(16) (final § 58.120(a)(12)) that requires that the protocol for each study include a statement of the proposed statistical methods to be used in the study. The comment argued that a determination of the statistical methods used to evaluate data can, in many cases, be made only after data have been reviewed.

FDA recognizes that circumstances occasionally require a testing facility to modify the proposed statistical methods for analysis of the data in a given study. Good scientific practice, however, requires consideration of the statistical analysis of a study as part of the design of the study to assess whether the objectives of the study can be met. FDA concludes that the requirement is appropriate.

Conduct of a Nonclinical Laboratory Study

43. Section 58.130(c) provides that materials derived from a test system for examination or analysis (specimens) are to be identified by test system, study, nature, and the date of collection, and requires that such identification is to be located on the specimen container or is to accompany the specimen in a manner that precludes error in the recording and storage of data. Five comments argued that the requirements under § 58.130(c) for specimen identification are overly restrictive and suggested that management should be responsible for determining methods for identifying specimens.

The identification requirements specified in § 58.130(c) are designed to preclude error during the conduct of a nonclinical laboratory study. FDA has reviewed the requirements and has concluded that the identifying information specified in the regulation is the minimum information needed to distinguish each specimen from all others that have been collected in the facility thereby protecting against mixups and permitting orderly storage of specimens. Such information also shows whether the data collected on each specimen are assigned to the correct component of the test system.

FDA has always provided flexibility in the methods to be used for identifying the specimens in that the identifying information can be encoded through, for example, the use of accession numbers affixed to the specimen with the numbers decoded in accompanying information (see, e.g., paragraph 205 of the preamble to the final rule (43 FR 60008)). The agency believes that the requirements with respect to specimen identification are the minimum requirements necessary to prevent mixup of specimens or lost specimen identity.

44. Two comments disagreed with FDA's proposal to revise § 58.130(d), which currently requires that records of gross findings for a specimen from postmortem (necropsy) observations shall, in all cases, be provided to a pathologist during study of the specimen. The proposed revision provides only that such records "should" be made available to the pathologist. Four comments supported the proposed change on the ground that the resulting flexibility allows "blinding" of the pathologist. One comment suggested that § 58.130(d) be deleted in its entirety or, alternatively, modified by specifying that the records

are to be provided to the pathologist "if required by the protocol."

FDA established § 58.130(d) in the belief that the provision would increase the pathologist's ability to describe correctly microscopic findings and to relate such findings properly with the gross postmortem observations (41 FR 51214). FDA continues to believe that for most studies it is important for the pathologist to have available the records of gross findings when examining a specimen histopathologically. The agency recognizes, however, that for certain nonclinical laboratory studies it may be appropriate for pathologists to evaluate the histopathological specimens without being informed of the necropsy findings. The change made in the regulation will permit the study director, in concert with management, to determine the need for "blinding" in relation to the specific objectives of the study.

FDA advises that it continues to believe that for most studies it is a preferred practice not to use "blinding" in histopathological evaluation. For this reason, the agency is not deleting § 58.130(d) as suggested by one comment. The alternative phrase "if required by the protocol" suggested by the comment would serve the same purpose as the modification proposed by the agency. Therefore, the agency is adopting § 58.130(d) as proposed.

45. One comment on § 58.130(e) requested that FDA clarify the meaning of the term "automated data collection systems," stating that it is unclear whether § 58.130(e) applies to tabulation of source data from "hard" copy by automated systems.

As discussed in paragraph 7a. of this preamble, hand-recorded data collected during a study are "raw data." The subsequent entry of these hand-recorded data into a computer system, for example, by data processing clerks or through the use of optical readers, does not alter the status of the hand-recorded data as "raw data." The processing of these data by the computer, e.g., tabulation, is not "direct data input" and is, therefore, not encompassed by the requirements of § 58.130(e).

Reporting of Nonclinical Laboratory Study Results

46. Section 58.185(a) requires that a final report be prepared for each nonclinical laboratory study conducted and specifies the minimum information that shall be included in a final report. One comment urged that § 58.185(a) should be modified to require final reports to include the specified information only "where appropriate" to make the requirements respecting final reports consistent with FDA's proposal to change § 58.120(a) respecting protocols. Alternatively, the comment urged that, at the least, § 58.185(a)(8), which requires that any final report shall include a description of the dosage, dosage regimen, route of administration, and duration, should be so modified. The comment argued that some of the information required under this paragraph is not applicable to certain studies involving medical devices.

FDA proposed to change § 58.120(a) in recognition of the fact that certain of the enumerated items are not necessary for the protocols for all studies. FDA has carefully reviewed each of the items listed in § 58.185(a) and has concluded that the information required by this section to be included in a final report for a nonclinical laboratory study is necessary to evaluate any such study. FDA notes that § 58.185 currently allows certain appropriate flexibilities where specified information is determined by the laboratory not to be relevant to a study. For example, § 58.185(a)(4) provides that test and control articles may be identified by "other appropriate characteristics" and § 58.185(a)(7) includes the term "where applicable." The agency believes that the information required by § 58.185(a)(8) is applicable to studies involving medical devices. For example, "dosage" and "dosage regimen" for devices may be expressed in units used per animal at a designated frequency of use. "Route of administration" may describe the means by which the device is used in relation to the animal. "Duration" would pertain to the period of time the device was tested in the animal. These clarifications should permit nonclinical laboratory studies on medical devices to be reported properly.

47. Section 58.185(a)(10) requires that each final report of a nonclinical laboratory study include the name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study. One comment recommended that FDA revise § 58.185(a)(10) to require identification only of the study director and of the principal scientists involved in the study.

FDA disagrees with this suggestion. Supervisors play an important role in the data collection process. They supervise those who perform the procedures, may recommend or actually provide training, and assure that data collection is carried out in accordance with the protocol, the standard operating procedures, and the GLP regulations. The names of all scientists, professionals, and supervisors are needed to assure the accountability of all of those individuals responsible for the integrity of the study. The comment did not provide any data or information to support its recommendation to revise § 58.185(a)(10) and the agency concludes that it should retain the current requirement.

48a. Section 58.185(a)(12) requires that the final report of a nonclinical laboratory study include the signed and dated reports of each of the individual scientists or other professionals who were involved in the study. Two comments recommended that FDA revise § 58.185(a)(12) to allow for combined reports signed by the principal scientists. According to the comments, allowing for such combined reports would be consistent with the Organization for Economic Cooperation and Development principles of GLP.

The agency does not believe that a combined report from scientists of different disciplines would be appropriate. Each individual scientist involved in a study has to be accountable for reporting data, information, and views within his or her designated area of responsibility. Reports which combine the data, information, and views of more than one such person would obscure the individual's accountability for accurate reporting. Furthermore, FDA believes that the comment has misinterpreted the standard that the Organization for Economic Cooperation and Development established respecting reports of persons involved in a nonclinical laboratory study. Chapter 2, section 2.3 (Ref. 1, p. 36) of the Organization for Economic Cooperation and Development document provides that "if reports of principal scientists from co-operating disciplines are included in the final report, they should sign and date them." It provides further that the final report should contain the "names of other principal personnel having contributed reports to the final report." These provisions do not imply that combined reports would be appropriate. Rather, they support the need for individual accountability. The Organization for Economic Cooperation and Development provisions are entirely consistent with the provisions of § 58.185(a)(12).

48b. On its own initiative, FDA is amending § 58.185(b) to provide that the final report shall contain the dated signature of the study director to conform the provision to the definition of "study completion date" being added by this final rule (see paragraph 6 of this preamble).

Storage and Retrieval of Records and Data

49. FDA proposed to revise § 58.190(a) to allow wet specimens and specimens from mutagenicity tests to be discarded after evaluation and recording. The agency's proposal was supported by several comments. One comment, however, requested that the agency clarify the meaning of "mutagenicity tests" as the term is used in § 58.190(a). The comment asked whether, for example, in vitro cell transformation is interpreted to be a mutagenicity test under this provision.

FDA advises that, for the purpose of § 58.190(a), the agency considers mutagenicity tests to be those tests designed to assess the capacity of a test or control article to induce heritable changes in a test system. Accordingly, FDA considers in vitro cell transformation to be a mutagenicity test as the term is used in the GLP regulations.

50. One comment recommended that FDA further revise § 58.190(a) to assure that the regulation makes clear that final reports must be retained.

As discussed at length in the preamble to the proposal (49 FR 43534), FDA intended to exclude from the retention requirements of the GLP regulations specimens that are relatively fragile or contribute only in a minor way to safety evaluation. FDA did not intend to change the current requirement that final reports of any nonclinical laboratory study are to be retained in accordance with § 58.195. To preclude any possible confusion regarding the requirement that final reports must be retained, FDA is rewording § 58.190(a) to read "all raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained."

Retention of Records

51. FDA proposed to delete from current § 58.195(c) the listed examples of materials that the agency believes need to be retained only so long as the quality of the preparation affords evaluation. One comment noted that § 58.195(c) should be further revised to delete wet specimens to be consistent with the proposed revisions in § 58.190(a) (see paragraph 50 of this preamble).

FDA agrees with the comment and in this final rule is conforming § 58.195(c) to revised § 58.190(a). In pertinent part, § 58.195(c) now reads "Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material * * *."

52. Two comments suggested that FDA should specifically provide in new § 58.195(g) that records to be retained under the GLP regulations may be retained as magnetic media.

Section 58.195(g), which is being added to Part 58 by this final rule, provides that records respecting a nonclinical laboratory study may be retained as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Magnetic media could qualify as either "original records" or "accurate reproductions of the original records." This conclusion is consistent with § 58.3(k), which includes "magnetic media" within the meaning of "raw data." Consequently, the agency does not believe that it is necessary to change new § 58.195(g) in order to achieve the result desired by the comments.

Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. "Good Laboratory Practice in the Testing of Chemicals," Organization for Economic Cooperation and Development Publications, Paris, France, 1982.

Economic Assessment

As announced in the proposal, FDA has examined the economic consequences of this final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). At that time, the agency concluded that the changes would not constitute a major rule as defined in the Order and that no regulatory flexibility analysis would be required. The agency also certified that the revisions would not have a significant impact on a substantial number of small entities. The agency has not received any new information or comments that would alter its previous determination.

Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) 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.

Paperwork Reduction Act of 1980

Sections 58.35(b) (1), (3), and (6), 58.63(b), 58.90(c), 58.105(a), 58.120(a), 58.130(e), and 58.190 (a) and (e) of this final rule contain collection of information requirements. FDA submitted a copy of the proposed rule containing the same requirements to the Office of Management and Budget (OMB). These collection of information requirements were approved under OMB Control No. 0910-0203.

List of Subjects in 21 CFR Part 58

Laboratories.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under 21 CFR 5.11, Part 58 is amended as follows:

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

1. The authority citation for 21 CFR Part 58 is revised to read as follows:

Authority: Secs. 306, 402(a), 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 701(a), 706, 801, Pub. L. 717, 52 Stat. 1045-1046 as amended, 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 336, 342(a), 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360f, 360h-360j, 371(a), 376, 381); secs. 215, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n); 21 CFR 5.11.

2. In § 58.1 by designating the existing text as paragraph (a) and adding new paragraph (b), to read as follows:

§ 58.1 Scope.

* * * * *

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

3. In § 58.3 by removing the phrase "of this chapter" wherever it appears; by revising paragraphs (c), (d), and (e)(8); by removing and reserving paragraph (e)(12); by replacing "in section 513 of the act" with "in Part 860" in paragraph (e)(17); by replacing "section 514 of the act" with "in Part 861" in paragraph (e)(18); and by adding new paragraphs (o) and (p), to read as follows:

§ 58.3 Definitions.

* * * * *

(c) "Control article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory

study for the purpose of establishing a basis for comparison with the test article.

(d) "Nonclinical laboratory study" means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

(e) * * *

(8) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in Parts 109 and 509.

* * * * *

(12) [Reserved]

* * * * *

(o) "Study initiation date" means the date the protocol is signed by the study director.

(p) "Study completion date" means the date the final report is signed by the study director.

4. In § 58.31 by revising paragraph (b), to read as follows:

§ 58.31 Testing facility management.

* * * * *

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

* * * * *

5. In § 58.35 by removing paragraph (e), by revising paragraphs (a) and (b) introductory text, (1) and (3), and by adding an OMB number at the end of the section to read as follows:

§ 58.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall: (1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

* * * * *

(3) Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910–0203.)

6. By revising § 58.41, to read as follows:

§ 58.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

7. In § 58.43 by removing paragraph (e) and by revising the first sentence of paragraph (c) to read as follows:

§ 58.43 Animal care facilities.

* * * * *

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. * * *

* * * * *

8. In § 58.45 by revising the last sentence, to read as follows:

§ 58.45 Animal supply facilities.

* * * Perishable supplies shall be preserved by appropriate means.

9. By revising § 58.49, to read as follows:

§ 58.49 Laboratory operation areas.

Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by nonclinical laboratory studies.

§ 58.53 [Removed]

10. By removing § 58.53 *Administrative and personnel facilities.*

11. By revising § 58.61, to read as follows:

§ 58.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

12. In § 58.63 by revising paragraph (b) and by adding an OMB numbert at the end of the section, to read as follows:

§ 58.63 Maintenance and calibration of equipment.

* * * * *

(b) The written standard operating procedures required under § 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910–0203.)

13. In § 58.81 by revising the first sentence of paragraph (c), to read as follows:

§ 58.81 Standard operating procedures.

* * * * *

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. * * *

* * * * *

14. In § 58.90 by revising paragraphs (b) and (c) and by adding an OMB number at the end of the section, to read as follows:

§ 58.90 Animal care.

* * * * *

(b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.

(c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that

such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

15. In § 58.105 by revising the first sentence of paragraph (a), by revising paragraph (b), and by adding an OMB number at the end of the section, to read as follows:

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. * * *

(b) The stability of each test or control article shall be determined by the testing facility or by the sponsor either: (1) Before study initiation, or (2) concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

16. In § 58.113 by revising paragraph (a)(2), to read as follows:

§ 58.113 Mixtures of articles with carriers.

(a) * * *

(2) To determine the stability of the test and control articles in the mixture as required by the conditions of the study either (i) before study initiation, or (ii) concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.

* * * * *

17. In § 58.120 by revising paragraph (a) and by adding an OMB number at the end of the section, to read as follows:

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, as applicable, the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control articles by name, chemical abstract number, or code number.

(3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(5) The procedure for identification of the test system.

(6) A description of the experimental design, including the methods for the control of bias.

(7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.

(9) The type and frequency of tests, analyses, and measurements to be made.

(10) The records to be maintained.

(11) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(12) A statement of the proposed statistical methods to be used.

* * * * *

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

18. In § 58.130 by revising paragraphs (d) and (e) and by adding an OMB number at the end of the section, to read as follows:

§ 58.130 Conduct of a nonclinical laboratory study.

* * * * *

(d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

19. In § 58.185 by revising paragraph (b), to read as follows:

§ 58.185 Reporting of nonclinical laboratory study results.

* * * * *

(b) The final report shall be signed and dated by the study director.

20. In § 58.190 by revising paragraphs (a) and (e) and by adding an OMB number at the end of the section, to read as follows:

§ 58.190 Storage and retrieval of records and data.

(a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained.

* * * * *

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

21. In § 58.195 by revising paragraph (c), redesignating paragraph (g) as paragraph (h), and adding new paragraph (g), to read as follows:

§ 58.195 Retention of records.

* * * * *

(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

* * * * *

(g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

* * * * *

§ 58.204 [Amended]

22. In § 58.204 *Notice of and opportunity for hearing on proposed disqualification* in paragraph (b) by removing "of this chapter."

§ 58.213 [Amended]

23. In § 58.213 *Public disclosure of information regarding disqualification* in paragraph (b) by removing "of this chapter."

§ 58.219 [Amended]

24. In § 58.219 *Reinstatement of a disqualified testing facility* by removing "of this chapter."

Frank E. Young,
Commissioner of Food and Drugs.
Otis R. Bowen,
Secretary of Health and Human Services.

Dated: August 10, 1987.

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Friday
September 4, 1987

Part VII

Department of Labor

Employment and Training Administration

Invitation to Comment on Design Issues for Release of Quality Control Data for Unemployment Insurance Program; Notice

DEPARTMENT OF LABOR

Employment and Training Administration

Invitation to Comment on Design Issues for Release of Quality Control Data for Unemployment Insurance Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice and opportunity to comment on issues relating to release of Quality Control data for the Unemployment Insurance program.

SUMMARY: The final regulation to establish a permanent Quality Control program for the Federal-State Unemployment Insurance system has been issued. Consistent with this regulation, the results of the Quality Control program will be released each year using a standardized format prescribed by the Department. States will have the opportunity to release this information before any release by the Department.

This notice sets forth design issues and requests public comment on issues relating to the format, method, and timing of the release.

DATE: Written comments must be received by the close of business on October 5, 1987.

ADDRESS: Submit comments to Carolyn M. Golding, Director, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, Room S-4231, Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Golding, Director, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, Room S-4231, Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 535-0600 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

Introduction

The final Unemployment Insurance (UI) Quality Control (QC) regulation will be published in the **Federal Register** on September 3, 1987 (52 FR).
QC is a requirement for all States. It is being implemented incrementally and initially covers intrastate benefit payments under the three largest permanently authorized programs (Regular UI, including Combined Wage Claims; and the Federally-funded programs providing Unemployment Compensation for Ex-servicemembers and Federal Employees). The Department of Labor (Department) intends to expand QC to encompass other major aspects of the UI program such as benefit denials, tax collection operations, interstate benefit payments, and extended benefit programs.

The QC methodology has a unique ability to assess the accuracy of UI operations. It is thus an essential tool for State managers to improve their UI programs, and from the standpoint of their use, QC's main orientation is toward program improvement.

The benefit payment portion of UI QC was launched voluntarily in April 1986, after an intensive public policy review which established or confirmed several fundamental QC design principles. One is that the decision to make a program improvement is up to the State; States will not be forced or given incentives to achieve a certain error rate. Another is that QC findings will be released publicly, to enable persons and organizations with an interest in the UI programs to assess how well each State program is operating and to communicate to UI management their desires for changes to aspects of the program they judge should be improved. Consequently, § 602.21(g) of the QC regulation provides that each State shall:

> Release the results of the QC program at the same time each year, providing calendar year results using a standardized format to present the data as prescribed by the Department; States will have the opportunity to release this information prior to any release by the Department.

Each week, the QC program systematically selects a sample of cases. For each such case, which "stands for" thousands of noninvestigated cases, an extensive amount of data is carefully verified through field investigation. QC assembles data identifying the claimant, the nature of his or her prior job and job sought, the type of contacts made by the UI agency, and information pertaining to all stages of the claim process and its validity, such as earnings in the base period, reason for separation, and availability for work. On the basis of this information and the investigation developing it, the QC staff conclude whether or not a payment was proper. If improper, they assess the dollar value of the error, why it occurred, and who (claimant, employer, agency) was responsible. Using the results of QC investigations over a period of time, the Unemployment Insurance Service (UIS) and each State can determine the proportion of both cases and dollars paid properly, underpaid and overpaid. This can be done for all cases, or a selected subgroup, e.g., those paid in a single local office or region, or for a given claim type. The extensive information available on each case enables a State's payment activities to be analyzed from a variety of viewpoints.

The public release of QC data is intended to afford all interested parties—including claimants and their advocates, employers, and the general public—a balanced and objective summary of what QC shows about UI operations. Only in this way can it respond to the public's right to know how well a tax-supported, public program is operating. Such users thus should also be the final judge of the form, content, and frequency of such reports. The Department is placing this notice in the **Federal Register** to give all such potential users an opportunity to participate in the development of the public release.

This notice poses general questions, the responses to which will help guide the initial development of proposed procedures governing the public release of QC data on benefit payments. A subsequent **Federal Register** notice will offer these procedures for review and comment. Based on comments received on the proposal, a final procedure will be developed and issued to the States and published as a notice in the **Federal Register**. Persons interested in more indepth QC information are encouraged to work directly with the individual State Employment Security Agencies (SESAs). They maintain an extensive QC data base that is not practical to release more broadly.

Settled Aspects of the Release and Release Process

The QC regulations together with the realities of the QC investigative procedure establish some broad outlines for the QC data release format and procedures:

1. States must release results at the same time each year using a standardized format. They have the option of releasing results before that time if they wish.

2. The release will reflect calendar year results. Because case investigations can take up to 90 days to complete, all results of a year's last case reviews are not available until the end of the following March. At least 2 additional months is needed to prepare and clear report language. Thus, this implies a release date in May of the following year, at the earliest.

3. Since the QC regulations require each State to "classify benefit case findings resulting from QC investigations as proper payments,

underpayments, or overpayments . . ." the annual report must contain at least this level of detail on QC results.

Issues on Which Comment is Being Sought

Within these broad limits, many options exist for shaping the final report format and procedures. The Department is seeking public comment on the principles that should be applied in making these decisions. Public comment is sought particularly on the following aspects of the report which are intended to be as mutually exclusive as possible: (1) Objectives and focus of the release; (2) the level of detail in the report; (3) qualifications of reported error rates; (4) who should release the data; (5) the vehicle for the release; and (6) the timing and scope of data in the initial release. The public is also requested to identify and comment on other issues.

1. *What Should be the Objectives and Focus of the QC Data Release?* One primary objective is to enable persons and organizations interested in the UI system to make informed judgments about the accuracy of a State's UI operations. This information should also enable them to work constructively to improve UI program operations if they want to do so. At the same time, the potential audience for the report extends beyond UI beneficiaries and taxpayers to all educational, governmental and public interest organizations as well. The QC's system's potential for developing information of interest to various parties is substantial. Various interested parties may have objectives they want to fulfill through this report. Among the objectives are:

A report oriented toward inducing program improvement. Such a report would focus on improper payment amounts and rates, where they occur within a State's operation, their major causes, and who is responsible. This information would permit interested parties to become aware of UI issues, discuss them more fully with proper officials, and induce those officials to take action.

A comprehensive report that provides other information on the UI system and the claimant population in addition to factual QC data. The QC system has the clear potential for doing this. The release could serve other purposes in addition to providing information conducive to program improvement.

2. *What level of detail should the Report include?* Closely related to the issue of objectives and focus of the report is the extent or level of detail displayed. The QC data record contains over 100 data elements on each case investigated (see Appendix), all of which could be displayed in some way in the report. On the other hand, the items specified in the regulations (i.e., proper payments, underpayments and overpayments) are few in number. The objectives of the report, and the need to meet essential information needs while avoiding overwhelming and confusing detail, should determine the actual content of the report. Respondents are urged to consider their objectives for the report and suggest the classifications and extent of QC data needed to satisfy those objectives. The effect of greater detail on the size and usability of, and time required to prepare, the release must be considered in this context.

A minimal report, which implies a single objective and focus, would probably be limited to data on rates of proper payments, overpayments and underpayments, where in the process errors are occurring (e.g. unreported or errors in reporting earnings in the Benefit Year; errors related to continuing eligibility issues) and who (agency, claimant, employer) is responsible. Because such a report would be oriented toward providing a basis to support program improvements, it might also emphasize data on any correlations between errors identified and particular aspects of the program's operations.

The release could be more extensive and provide additional information on locations, types and causes of errors (e.g., error rates by local office or sub-State region; fraud vs. nonfraud errors; error due to lack of sufficient worksearch or misreported wages).

3. *How much explanatory information should accompany the data?* An important consideration in shaping the release is its balance between numerical data obtained from the QC data base and qualifying or explanatory narrative, especially about a State's error rates. Because each State's UI program is in many respects unique, comparing error rates and other aspects of accuracy requires an awareness of the major differences in law, policy, structure, and economic conditions that can affect error rates from State to State or from year to year in addition to other variables.

The report could contain data with a minimum of text. The advantage of this approach is that it would keep the report short. Its disadvantage is that major differences in law, policy, economic conditions, etc., known to influence error rates would not be provided to permit the users to evaluate the statistical data in light of these other variables. Lack of qualifying information may lead readers to erroneously or naively compare error rates between States.

The release could include explanatory factors known to have a marked effect on error rates, such as particular requirements of State law and policies affecting major aspects of the program, e.g., requirements for claimants to search for work. While this would enable users to better compare QC error rates across States, it would also lengthen the report. Such explanations could also reduce the impact of publishing only observed error rates and thus undermine the report's use as a force for change.

The release could identify rates of error officially acted upon as well as total error rates. State laws and policies differ considerably with respect to what *officially* constitutes an overpayment or underpayment that can be collected when a payment is determined after the fact to have been made incorrectly. In some States, if a QC investigation is completed after a "finality" date, or its law required a warning which was not given, the State may not act to correct an error identified by QC. Should the QC report contain the error rates *identified by QC,* or should it present only the State's "official error rate", or both?

The release could explain program improvement actions planned or underway. Some States may have already taken or initiated program improvements to correct problems identified through QC. Is a narrative explanation of such actions a desirable feature of such a report? What is its potential effect on the length and complexity of the report?

Other Combinations. The release could be some combination whereby a basic report would show "hard numbers" which may satisfy many readers and appropriate appendices may be attached to explain law differences and other factors causing State differences and an explanation of corrective actions planned or underway.

4. *Who Should Release the Data?* The regulation cited earlier specifies that calendar year QC data must be released by each State at the same time each year, using a common format. It does not indicate whether the responsibility for releasing the report should rest with the Federal Government, the various States or both.

Each State could release its own data. Each State could be required to release its QC data on a given date using a common format. This approach would tend to minimize State-to-State comparisons which are difficult to make and focus most attention on this issue at the State level. Individual State reports would be shorter; and, because each

State is responsible for its own performance and for taking corrective action, most interest groups would focus only on their own State's program.

The Department could issue a single comprehensive report, having obtained the necessary data from each State. This report would present all States' QC findings using a common format thus highlighting inter-State differences. This report could be long and cumbersome, if it also contained extensive narrative. Because there are no nationwide accuracy standards, the only way to assess one State's performance against another would be comparing it with others, and attempt to make necessary adjustments for relevant factors affecting accuracy.

There could be a combined Federal-State release; the Department could obtain individual State reports and release them en masse at the same time or after each State releases the same information within its State.

5. *What type of publication should be used to disseminate data?* The answer to this issue could be determined by the decision on Issue 4.

If each State is to release its own report, the publication could be an *official State report,* suitably publicized and made available from a State office source and/or sent to a published list of known interested parties.

If the report is a Federal report, it could be issued as a Department of Labor report, announced nationwide through a **Federal Register** or similar notice or published in full in the **Federal Register**. This latter approach would make the report immediately accessible to all who get, or who can copy, the **Federal Register**. With both this and the previous option, the Department would send copies of the report to known interested parties.

In the case of individual State reports, or a combined Federal-State release, State publicity could be supplemented by a **Federal Register** notice informing interested parties how to obtain each State's report or all States' reports.

6. *Timing and Scope of Data in the First Report.* Deciding when the first release should occur involves a tradeoff. If the first release is to conform to all subsequent releases, it must contain a full calendar year's data under the permanent program—meaning it could not be available before June 1, 1989. Earlier release dates mean the data may not be of the same quality, or will not be consistent in other respects with data in subsequent releases.

The first Release could be June 1, 1988 and contain data for calendar year 1987. This release would combine findings under both the voluntary and mandatory phases of QC. Three quarters of the data would have been gathered under the voluntary program, during which some States ran only partial programs or deviated from standard QC methodology.

Release Date June 1, 1988; Data for Balance of Calendar Year 1987 Under Mandatory Program. This would involve about one fourth of a year's worth of data. Although the data quality would be high, the precision would be low because of the small number of cases, and comparisons with subsequent reports' data would be of questionable value.

Release Date 150 Days After Completion of First Full Year Under Mandatory Program. One quarter of the data in this release would be from calendar 1987 and three quarters from calendar 1988. The second release, containing all calendar year 1988 data, would occur about June 1, 1989. Both the precision and data quality of this first release would be good. However, there would be a considerable overlap between Releases 1 and 2, making it difficult to judge progress in making program improvements between these two periods or between them and subsequent years.

First Release June 1, 1989; Data for Calendar Year 1988. Data quality and precision for this release are good and are consistent with subsequent releases. However, the cost is a nearly 2-year wait.

7. *Are there any other issues and recommendations which should be considered during design of procedures for release of benefit payment QC data?* In preparing this notice, the Department has attempted to identify for comment all dimensions of the release and its procedures for which public comment is warranted. Comment is also sought on any other report design issues the Department should consider.

Signed at Washington, DC, this 29th day of August 1987.

Roger D. Semerad,

Assistant Secretary of Labor.

Appendix

The Appendix is provided to assist the reader to respond to questions in the Notice. The identification and description of the data elements collected by the QC system is preceded by definitions of some terms which are used.

Definition of Terms

SESA—(State Employment Security Agency) The agency of a State government which administers the unemployment insurance program.

Key Week—A specific week of unemployment, for which a claimant has received compensation, that is investigated to verify that all information pertaining to eligibility and payments is treated in conformity with State written law and policy.

Before Investigation—Information as found in the SESA records before the QC investigation.

After Investigation—Information as verified through the QC investigation which is correct and should have been used for the claim.

New Claim—A claim for benefits which establishes a new benefit year.

Additional Claim—A claim filed at the beginning of new unemployment within a benefit year when a break of one week or more has occurred in the claim series with intervening employment.

Non-Separation Issue—An issue that could affect eligibility for benefits that does not concern the claimant's separation from employment, e.g., availability for work, failure to look for work, refusal of job referral, etc.

Base Period—The period of time prior to a claim in which a claimant must have had a specified minimum amount of insured work in order to qualify for benefits.

Benefit Year—The one year period beginning with the first day of the first week in which an individual first files a claim for benefits and during which payment of benefits may be made.

Weekly Benefit Amount (WBA)—The maximum amount of benefits (before adding dependents allowance) that a claimant can receive weekly, based upon wages earned during the base period.

Maximum Benefit Amount (MBA)—The total amount of benefits payable in a benefit year.

Remaining Balance (RB)—The amount of benefits left to be claimed during the benefit year at a given point in the benefit year.

Dependents Allowance—Additional allowance provided in some States because of dependent family members of claimant.

Finality—Provisions of law prohibiting modifications of decisions after a specified period of time.

Description of Information Collected Under the Quality Control Program

Part A—Control Information

(1) Social Security Number.

(2) State I.D. Code—Federal Information Processing Standard (FIPS) code.

(3) Batch Number—identifies week from which case sampled.
(4) Compensable Week Ending Date of Key Week.
(5) Local Office Number—the SESA local office or itinerant point number through which the Key Week claim was filed.
(6) Investigator Identification Code—the identification code of investigator to whom the case was assigned.

Part B—Claimant Information

(1) Primary Method by which Claimant QC Information Obtained—identifies the method by which the information contained on the claimant questionnaire was obtained, e.g., in-person interview, telephone interview, mail.
(2) U.S. Citizen—citizenship or alien status.
(3) Education—highest level of academic education completed.
(4) Vocational or Technical School Training—whether or not attended.
(5) Currently in Training.
(6) Occupation Code (Last job prior to most recent Initial/Additional Claim)—the major occupational group code for claimant's last job as classified in the *Dictionary of Occupational Titles*, US DOL/ETA 4th Edition 1977.
(7) Occupation Code for Usual Job—the major occupational group code for claimant's primary occupation.
(8) Normal Hourly Wage, Usual Job.
(9) Occupation Code (Seeking Work)—the major occupational group code for type of work that claimant is seeking.
(10) Lowest Acceptable Hourly Wage—the lowest hourly wage that the claimant was willing to accept during the Key Week.
(11) Date of Birth.
(12) Sex.
(13) Ethnic Classification.

Part C—Benefit Year Information

(1) Program Code—the code that identifies the program that the benefits were paid under, e.g., Unemployment Insurance (UI), Unemployment Compensation for Ex-Servicemembers (UCX), Unemployment Compensation for Federal Employees (UCFE).
(2) Combined Wage Claim—indicates whether or not the wages from two or more States were combined to determine eligibility for benefits.
(3) Benefit Year Beginning—the effective date of most recent new claim.
(4) New/Additional Claim Filing Method—e.g., Mail Claim, In Person Claim, Employer Filed Claim.
(5) Benefit Rights Given—the method(s) by which claimant was given Benefits Rights Interview.
(6) Number of Eligibility Review Program Interviews (ERPs) Held, Current Benefit Year.
(7) Last ERP Date.
(8) Number of Prior Nonseparation Issues Disposed of.
(9) Number of Prior Nonseparation Issues Resulting in Disqualification.

Part D—Separation Information.

(1) Reason for Separation before Investigation—from the last job prior to the Key Week.
(2) Date of Separation before Investigation—the date of separation from last employer.
(3) Recall Status Before Investigation—categorization of likelihood of claimant returning to work with previous employer.
(4) Tax Rate for Last Employer—the last employer's UI tax rate at the time of filing for the most recent new or additional claim.
(5) Industry Code (Last Employer)—the four digit standard industry code (SIC) for the claimant's last employer, prior to most recent new or additional claim as of the Key Week.
(6) Reason for Separation After Investigation.
(7) Recall Status After Investigation.

Part E—Monetary Eligibility

(1) Number of Base Period Employers Before Investigation—the number of subject base period employers that was used in calculating entitlement for the monetary determination in effect as of the Key Week.
(2) Base Period Wages Before Investigation—the total amount of all wages used to compute entitlement.
(3) Industry Code (Primary Base Period Employer)—the four digit industry code for claimant's primary base period employer from whom the *most* wages were earned.
(4) High Quarter Wages Before Investigation—the total amount of claimant's high quarter base period wages used in the monetary determination from which the original Key Week payment was made.
(5) Number of Weeks Worked in Base Period Before Investigation.
(6) Weekly Benefit Amount (WBA) Before Investigation—the claimant's maximum WBA for the Key Week, based on the monetary determination from which the original Key Week payment was made.
(7) Maximum Benefit Amount (MBA) Before Investigation—the maximum benefit amount, based on the monetary determination from which the original Key Week payment was made.
(8) Monetary Redetermination Before Investigation—indicates whether the SESA redetermined claimant's monetary eligibility prior to Key Week payment date.
(9) Remaining Balance as of Key Week Ending Date—the remaining balance of claimant's benefits at the time the Key Week was claimed.
(10) Number of Base Period Employers After Investigation.
(11) Base Period Wages After Investigation.
(12) High Quarter Wages After Investigation.
(13) Number of Weeks Worked in Base Period After Investigation.
(14) Weekly Benefit Amount (WBA) After Investigation.
(15) Maximum Benefit Amount (MBA) After Investigation.
(16) Number of Dependents Claimed Before Investigation.
(17) Dependents' Allowance Before Investigation.
(18) Number of Dependents claimed After Investigation.
(19) Dependents' Allowance After Investigation.

Part F—Benefit Payment History Information

(1) First Compensated Week Ending Date—the week ending date of first week compensated in the benefit year.
(2) Date of First Payment.
(3) Key Week Filing Method—e.g. in person claim, mail claim, employer filed.
(4) Key Week Certification Procedure—the cycle under which the Key Week was certified, e.g., weekly, bi-weekly.
(5) Original Amount Paid and/or Offset for Key Week—original whole dollar amount paid and/or offset for the Key Week.
(6) Total Earnings for Key Week Before Investigation—the whole dollar amount of earnings during Key Week.
(7) Earnings Deduction for Key Week Before Investigation—amount of claimant's earnings deducted from WBA.
(8) Total Other Deductible Income for Key Week Before Investigation—amount of claimant's other income (e.g., pension, separation pay, etc.) deducted from WBA.
(9) Other Income Deductions for Key Week Before Investigation—the actual amount deducted from WBA.
(10) Total Earnings for Key Week After Investigation.
(11) Earnings Deduction for Key Week After Investigation.
(12) Total Other Deductible Income for Key Week After Investigation.
(13) Other Income Deduction for Key Week After Investigation.

Part G—Registration/Work Search Efforts

(1) Work Search Requirements—the Work Search policy that applies to the Key Week according to State UI law and policy.

(2) Job Service Registration Required for the Key Week—indicates whether the claimant was required to register with Job Service during the Key Week.

(3) Actively/Currently Registered with Job Service as of Key Week.

(4) Reason Job Service Registration Deferred—e.g., union member, job attached, approved training.

(5) Number of Job Service Referrals—the number of times Job Service referred claimant for employment during current benefit year.

(6) Registered with Private Employment Agency.

(7) Number of Private Employment Agency Referrals.

(8) Union Referral Status—indicates whether claimants, who are union members, were eligible to be referred to job openings.

(9) Number of Union Referrals for the Key Week.

(10) Number of Job Contacts Listed for the Key Week.

(11) Number of Job Contacts Made Prior to Key Week but Used to Satisfy Work Search Requirements for Key Week.

(12) Number of Work Search Contacts Investigated for Key Week Eligibility.

(13) Number of Acceptable Work Search Contacts—indicates whether contacts made by claimant were considered acceptable according to SESA written law/policy.

(14) Number of Unacceptable Work Search Contacts.

(15) Number of Work Search Contacts for Key Week that Could not be Verified as Either Acceptable or Unacceptable.

Part H—Error Classification/Completion Information

(1) Dollar Amount of Key Week Error.

(2) Key Week Action.

(a) Proper Payments.

(b) Improper Payments.

Overpayments

—Fraud overpayment.

—Nonfraud recoverable overpayment.

—Nonfraud nonrecoverable overpayment or official action taken to adjust future benefits by decreasing entitlement.

—QC determines payment was too large, although payment "technically" proper due to finality rules.

—QC determines payment would have been too large except for formal warning rule that prohibits official action. Payment "technically" proper due to law/rules requiring formal warnings for unacceptable worksearch efforts.

—QC determines payment was too large, although payment "technically" proper due to rules other than finality or formal warning rule.

Underpayments

—Supplemental check issued/offset applied or increase in entitlement.

—QC determines payment was too small, although payment "technically" proper due to finality rules.

—QC determines payment was too small, although payment "technically" proper due to rules other than finality.

(3) Error Responsibility—party responsible, e.g., claimant, employer, agency.

(4) Error Cause

(a) In the Benefit Year, unreported or errors in reporting/recording earnings or days/hours of work affecting the Key Week due to:

—Unreported (concealed) earnings or days/hours of work.

—Earnings or days/hours of work incorrectly estimated/reported/recorded or deducted.

—Errors in reporting or unreported severance pay.

—Errors in reporting or unreported vacation pay.

—Errors in reporting or unreported Social Security or pension benefits.

—Other causes related to reporting or recording of earnings or days/hours of work for Key Week.

(b) In the Base Period, errors in reporting/recording earnings or weeks, days, or hours of work affecting the Key Week due to:

—Earnings or weeks/days/hours of work incorrectly estimated/reported/recorded.

—One or more base period employers not reported by claimant.

—Other causes related to errors in reporting or recording earnings or weeks/days/hours of work for base period.

(c) Separation Issues Due to:

—Voluntary quits.

—Discharges.

—Other causes related to separation issues.

(d) Eligibility Issues Due to:

—Ability to work.

—Availability for work.

—Active work search.

—Refusal of suitable work.

—Self-employment.

—Illegal alien status.

—Other causes related to eligibility issues.

(e) Dependents' Allowances Incorrect Due to:

—Dependents' information incorrectly reported/recorded or allowance incorrectly calculated.

—Other causes related to dependents' allowances.

(f) Other Causes Due to:

—Benefits paid during a period of disqualification, even though a stop-pay order was in effect.

—Redetermination (at deputy level) or reversal (appeal or higher authority).

—Back pay award.

—All other causes.

(5) QC Detection Point

—Verification of work search contact.

—Verification of wages and/or separation.

—Claimant interview.

—Verification of eligibility with third parties.

—UI records.

—Job Service/Employment Service records.

—Verification with union.

(6) Prior Agency Action—indicates any action(s) taken by the SESA on the Key Week issue as of the date sample selected.

(7) Prior Employer Action—indicates action(s) taken by the employer affecting the Key Week issue as of the date sample was selected.

(8) QC Action Regarding Key Week Appealed—identifies party appealing QC action, e.g., claimant, employer, SESA.

(9) Total Whole $ Amount of Overpayments (include Key Week)—officially established as a result of QC investigation.

(10) Total Whole $ Amount of Underpayments (include Key Week)—officially established as a result of QC investigation.

(11) Investigation Completed—date.

(12) Supervisory Approval Completed—date.

(13) Federal Monitor Case Review Completed—date.

[FR Doc. 87-20462 Filed 9-3-87; 8:45 am]

BILLING CODE 4510-30-M

federal register

Friday
September 4, 1987

Part VIII

Department of Housing and Urban Development

Emergency Shelter Grants Program; Notices

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-87-1724; FR-2388]

Emergency Shelter Grants Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The Emergency Shelter Grants program authorizes HUD to make grants to States, units of general local government, and private nonprofit organizations for the rehabilitation or conversion of buildings for use as emergency shelters for the homeless, for the payment of certain operating expenses, and for essential social service expenses in connection with emergency shelters for the homeless. This Notice informs the public of the requirements that will govern the allocation and use of amounts appropriated for the program by the Supplemental Appropriations Act, 1987 (Pub. L. 100-71, approved July 11, 1987).

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: James R. Broughman, Director, Entitlement Cities Division, Room 7282, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755-5977. For matters relating to Emergency Shelter Grants to States, James N. Forsberg, Director, State and Small Cities Division, Room 7184, telephone (202) 755-6322. [These are not toll-free telephone numbers].

SUPPLEMENTARY INFORMATION:

Background

The Emergency Shelter Grants ("ESG") program was first enacted as Part C of Title V of HUD's appropriation for fiscal year 1987.[1] HUD published a proposed rule and program requirements to implement the program on December 17, 1986 (51 FR 45278). In accordance with section 525(a) of Title V, the proposed rule served two purposes. First, it sought public comment to assist the Department in developing a final rule for the program. Second, it established the requirements necessary to carry out the program until the final rule is made effective. The proposed rule and requirements have governed, and continue to govern, the allocation and use of funds appropriated for the 1986 ESG program. The Department is currently developing the final rule for the 1986 program and intends to make it effective before the October 18, 1987 statutory deadline. The program will then be administered under that final rule.

On July 22, 1987, the President approved the Stewart B. McKinney Homeless Assistance Act ("the Act") (Pub L. 100-77). Title IV of the Act contains a number of housing assistance provisions to be administered by HUD. The Department has implemented the Comprehensive Homeless Assistance Plan ("Plan") requirements contained in Subtitle A (*see* 52 FR 30628, dated August 14, 1987), and the allocation provisions contained in Subtitle B (as described in this Notice).

Subtitle A of Title IV establishes requirements for the Plan. It prohibits assistance under the other provisions of Title IV (including the ESG program) from being made available to, or within the jurisdiction of, States and ESG formula cities and counties, unless the jurisdiction has a HUD-approved Plan. Any State or ESG formula city or county applying for assistance under Title IV must certify that its proposed activities are consistent with its Plan. Any other applicant for ESG reallocated funds must provide a certification from the State or ESG formula city or county in which the activities will be carried out (as appropriate) that the applicant's proposed activities are consistent with the Plan.

Subtitle B of Title IV [2] reauthorizes the ESG program with numerous substantive changes. As discussed later in this notice, several of these changes will be implemented immediately, while others will not take effect until notice and comment rulemaking is completed. These changes include:

The minimum formula grant for metropolitan cities and urban counties is changed from a flat $30,000 to .05 percent of the amounts appropriated for the program for any fiscal year.

—If an ESG formula city or county fails to obtain approval of its Plan under Subtitle A within a specified period, HUD must reallocate the amounts to the State in which the city or county is located, provided the State has an approved Plan.

—HUD must reallocate the following amounts to other States, cities, and counties that demonstrate extraordinary need or large numbers of homeless individuals (as determined by HUD):

1. Any city or county formula amounts that cannot be reallocated to the State; and

2. Any State formula amount, if the State fails to secure HUD approval of its Plan on or before November 27, 1987.

—HUD must establish a separate allocation formula for assistance to the Virgin Islands, Guam, America Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands (Palau).

—HUD may waive the 15 percent limitation on the use of assistance for "essential services," if the local government receiving the assistance demonstrates that the other eligible activities under the program are already being carried out in the locality with other resources.

—The requirement that program grantees submit a Homeless Assistance Plan as part of their application is replaced by the certification (described above) that the proposed activities are consistent with the Comprehensive Homeless Assistance Plan.

Requirements for the Allocation and Use of Funds Appropriated by the Supplemental Appropriations Act

1. General

The Supplemental Appropriations Act (Pub. L. 100-71, approved July 11, 1987), states that its appropriation for the ESG program is "subject to the requirements" of the 1987 ESG program. Section 416(a) of the Act requires HUD to go through notice and comment rulemaking to implement the program, with a proposed rule to be published by September 21, 1987, and a final rule to be published by July 22, 1988. Until a final rule can be made effective, section 416(a) provides that HUD's requirements for the 1986 ESG program will govern.

Consistent with these directives, funds authorized under the 1987 program and appropriated under the Supplemental Appropriations Act will be governed by the proposed rule and program requirements for the 1986 ESG program (51 FR 45278, December 17, 1986, adding a new 24 CFR Part 575) and by the modifications discussed in this Notice (below). When a final rule for the 1986 ESG program becomes effective, that rule and the modifications contained in this Notice will govern the 1987 program.

The Department will implement by notice and comment rulemaking the

[1] Section 101(g), Pub. L. 99-500 (approved October 18, 1986) and Pub. L. 99-591 (approved October 30, 1986), making appropriations as provided for in H.R. 5313, 99th Cong., 2d Sess. (1986) (as passed by the House of Representatives and by the Senate), to the extent and in the manner provided for in H. Rep. No. 977, 99th Cong., 2d Sess. (1986). For ease of reference, this Notice refers to this program as the "1986 ESG program."

[2] For ease of reference, the Notice refers to the program as the "1987 ESG program."

remainder of the 1987 ESG legislation, including the 15 percent waiver provision in section 414(b) and certain reallocation provisions in section 413(d). Consequently, these provisions will not take effect until the final rule is promulgated sometime in 1988.

2. Comprehensive Homeless Assistance Plan

Section 416(a) of the Act calls for HUD's requirements under the 1986 ESG program to govern until a final rule for the 1987 program takes effect. These regulatory requirements include the submission and approval of a Homeless Assistance Plan as a condition to the receipt of ESG assistance. However, the Homeless Assistance Plan overlaps the Comprehensive Plan/certification approach which the new Act requires to be implemented immediately, and, accordingly, the filing of a Homeless Assistance Plan will not be required under the 1987 program.

The Department has reviewed the statutory text and legislative history of Subtitle A and section 416(a) of the Act, and has determined that the provisions establishing the Comprehensive Homeless Assistance Plan (and not the Homeless Assistance Plan) apply to the allocation and use of funds appropriated for the program by the Supplemental Appropriations Act, 1987. The language of Subtitle A establishes the Plan as an independent, specific condition to the receipt of funding under each of the other Subtitles of Title IV. The Department believes that this clear funding condition takes precedence over section 416(a), which makes the 1987 ESG program subject to the 1986 program requirements by means of a general incorporation by reference, without any attention to specific features of the programs, including how the Homeless Assistance Plan and the Comprehensive Homeless Assistance Plan fit together.

In addition, to hold the Comprehensive Homeless Assistance Plan inapplicable to the 1987 ESG program's appropriation would frustrate the Act's purpose of according States and localities the responsibility for coordinating all of Title IV's assistance in a comprehensive manner. As the Conference Report accompanying the Act states:

> The conference report improves upon current law (1) by providing a streamlined requirement for one comprehensive plan covering all facets of assistance to the homeless under this Act, and (2) by placing at the relevant State or local level clear responsibility for coordinating assistance under various sections of this Act with other forms of assistance. (H. Rep. No. 174, 100th Cong., 1st Sess. 73 (1987).)

Thus, for purposes of the 1987 ESG program, HUD has determined that applicants will be subject to the Comprehensive Homeless Assistance Plan/certification requirements of Subtitle A of Title IV of the Act, and will not have to submit Homeless Assistance Plans, as provided in §§ 575.33(b)(2) (formula allocation) and 575.41(c)(3)(ii) (reallocation) of the original program.

Subtitle A of Title IV of the Act prohibits ESG assistance from being made available to, or within the jurisdiction of, a State or ESG formula city or county that does not have a HUD-approved Comprehensive Homeless Assistance Plan. The Department published a Notice in the **Federal Register** on August 14, 1987 (52 FR 30628) establishing requirements for the Plan. Among other things, the Notice specifies the jurisdictions that are subject to the Plan's funding prohibition, and describes Subtitle A's effect on the applicants and recipients under each of the programs of Title IV of the Act, including the ESG program. The Notice also specifies the required Plan's content, timing and procedures for the submission of proposed Plans to HUD, HUD's review and approval of Plans, and State or local reviews and reports on progress in carrying out the Plans. All potential grantees and recipients of ESG assistance—both those that may receive amounts directly by formula or reallocation and those that may receive amounts through other grantees or recipients—are encouraged to familiarize themselves with the requirements contained in the August 14, 1987 Notice.

3. Application Requirements

The Department is currently notifying States and formula ESG cities and counties of their grants allocations under the Emergency Shelter Grants program. These letters of notification will trigger the 45-day (in the case of formula cities and counties) and 75-day (in the case of States) deadlines for filing an ESG application that are specified in § 575.33(a) of the proposed rule. All applications to HUD for ESG assistance must include the following:

A. *Comprehensive homeless assistance plan certification:* Any State or ESG formula city or county that applies to HUD for ESG assistance must include a certification, by the public official responsible for submitting the Plan for the jurisdiction to be served by the proposed activities, that the activities are consistent with the Plan. In addition, any other applicant for ESG reallocated funds must provide a certification from the State or ESG formula city or county in which the activities will be carried out (as appropriate) that the applicant's proposed activities are consistent with the Plan. This certification will take the place of the Homeless Assistance Plan contained in the 1986 ESG program. In Appendix B of its Notice published in the **Federal Register** on August 14, 1987 (52 FR 30628, 30634), the Department listed the States, territories, and ESG formula cities and counties that are subject to Plan requirements.

B. *Other certifications and assurances:* The ESG application must contain the certifications and assurances listed under § 575.33 (b)(3), (b)4) and (b)(5) of the December 17, 1986 proposed rule and program requirements, and Standard Form 424 (§ 575.33(b)(1)).

C. *Budget data and verification of program consistency:* In the case of a metropolitan city or urban county, item (7) of Standard Form 424 must contain budgetary information identifying the applicant's proposed use of grants amounts for each of the three categories of eligible activities under §§ 575.21 (a)(1), (a)(2), and (a)(3). States must provide a statement, at item (7), (1) of how they intend to implement the requirements in § 575.23(a) that the entire formula allocation will be made available to units of general local government in the State, or (2) identifying the specific units of local government that will receive these amounts.

4. Funding Allocation Provisions

The 1987 ESG program contains a number of modifications to the fund allocation system used in the 1986 program. The Department has determined that the allocation of amounts appropriated by the Supplemental Appropriations Act, 1987, will be subject to these changes. Section 416(b) of the Act contains special provisions dealing with the initial allocation of assistance under the 1987 ESG program. These provisions are distinct from the guidance provided by section 416(a) concerning what regulations govern the program, and make clear that each State and ESG formula grantee is to have its allocation determined under the 1987 Act.

In making allocations, the Department will follow these procedures:

a. *Funding threshold.* The funding threshold for formula cities and counties will be $25,000 (.05 percent of the $50 million appropriation), rather than the $30,000 threshold contained in

§ 575.31(c) of the 1986 ESG program. As under the 1986 program, allocations below the threshold amount will be added to the allocation for the State in which the city or county is located.

b. *Territories.* HUD has set aside grants amounts for allocation to the Virgin Islands, Guam, American Samoa, Northern Mariana Islands, and the Trust Territory of the Pacific (Palau). Under section 416(b) of the McKinney Act, the Secretary of HUD is required to allocate ESG funds to each "State, metropolitan city and urban county" within 60 days of the date of enactment of the Supplemental Appropriations Act (approved July 11, 1987). The Act further provides that "[S]uch assistance shall be allocated and may be used"; notwithstanding the failure of the Department to issue final requirements implementing the 1987 ESG program. The Department interprets this provision as also requiring the allocation of grant funds to be the individual territories, and will allocate the amount set aside for the territories based upon each territory's proportionate share of the total population of the territories. Nevertheless, since the choice of this particular allocation method involves an exercise of discretion by HUD, the Department intends to solicit public comment on this formula in its forthcoming proposed rule. Any revisions made to this allocation formula would then be incorporated into the final rule for the 1987 ESG program and would govern future funding of the territories under the program.

It also requires noting that, while the Act includes territories in its definition of "States", the unique governmental structure of these entities requires that for purposes of program administration they be treated as metropolitan cities. Consequently, the 1986 ESG program requirements in Part 575 applicable to metropolitan cities and urban counties will also govern the territories.

c. *Reallocations for failure to have an approved Plan.* If an ESG formula city or county fails to obtain approval of its Plan on or before November 27, 1987,[3] will reallocate the amounts to the State in which the city or county is located—provided the State has an approved Plan. If a State cannot secure approval of its Plan on or before November 27, 1987,[3] HUD will take back the amounts, but will not reallocate them until a final rule for the 1987 program takes effect. This is because reallocation of these amounts is to be made to "States, cities, and counties that demonstrate extraordinary need or large numbers of homeless individuals", as determined by HUD. The Department believes that establishing procedures for reallocation of these amounts involves an exercise of HUD discretion that must first be subjected to notice and comment rulemaking. The reallocation to States, cities, and counties under this provision of the 1987 program was not contained in the 1986 program and, thus, is not coverted by 24 CFR Part 575. Consequently, HUD will retain amounts to be reallocated under this provision until the 1987 program's final rule is made effective.

Amounts reallocated because of failure of cities and counties to obtain approval of their Plans will (assuming an approved State Plan) be added to the State formula allocation, and will be subject to the same requirements that govern the use of State formula amounts.

5. Timing Considerations

The applicability of the Comprehensive Homeless Assistance Plan requirements to the 1987 ESG program may cause some timing questions. For example, section 416(b) requires HUD to allocate, and permits grantees to use at a reasonable time thereafter, formula amounts at the end of the 60-day period after funds are appropriated for the program, *i.e.*, September 9, 1987. In addition, reallocations of formula amounts are triggered where grantees do not obtain Comprehensive Plan approval within 90 days of the date that funds become available for allocation.

The Department believes that Congress intended the Comprehensive Plan to be an integral and essential part of the Act's homeless assistance strategy. As such, it has interpreted section 416(b)'s 60-day trigger to apply only to HUD's obligation to *allocate* grant funds by September 9, 1987. The ability of grantees to actually *use* ESG funds is dependent upon the Department's receiving a satisfactory Plan and supporting application documents. To construe section 416(b) otherwise would permit the use of ESG amounts before Plan approval, thereby vitiating the Plan's role in the initial ESG allocation. Thus, the Department will not permit use of ESG funds until the relevant Comprehensive Homeless Assistance Plan has been approved and the grant application (including the certification of consistency with the Plan) has been reviewed and approved.

With respect to the reallocation provisions triggered by failure to have an approved Plan (section 413(d)(3) of the Act), the Department considers that these provisions are intended to give States and formula cities and counties a reasonable period within which to obtain Plan approval. Consequently, HUD interprets the 90-day statutory deadline to begin running 15 days after the Department published its Notice on the Comprehensive Homeless Assistance Plan, *i.e.*, 15 days after August 14, 1987, or August 29, 1987. If a State fails to meet the 90-day deadline, the amounts involved are to be reallocated for use by or in a jurisdiction that has an approved Plan. The Department believes that the policy behind the Comprehensive Plan and the reallocation provisions can be best effectuated by providing a reasonable period, keyed to the August 14, 1987 publication date of the Comprehensive Homeless Assistance Plan Notice, within which Plans must be approved to avoid reallocation of the amounts involved.

Other Matters

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket clerk, at the above address.

The information collection requirements contained in this Notice have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act. The OMB control number, when it is assigned, will be announced by separate notice in the **Federal Register**.

Authority: Sections 401 and 416 of the Stewart B. McKinney Homeless Assistance Act, Pub. L. 100-77, approved July 22, 1987; section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: August 28, 1987.

Jack R. Stokvis,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 87-20472 Filed 9-3-87; 8:45 am]

BILLING CODE 4210-29-M

[3] November 27, 1987 is 105 days after the August 14, 1987 **Federal Register** publication of the Notice establishing requirements for the Comprehensive Homeless Assistance Plan. Selection of this date is discussed in paragraph 5, *Timing Considerations*, below.

Office of the Secretary

[Docket No. D-87-859; FR-2388]

Emergency Shelter Grants Program; Delegation of Authority

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of concurrent delegation of authority.

SUMMARY: The Emergency Shelter Grants program was reauthorized by Subtitle B of the Stewart B. McKinney Homeless Assistance Act, Pub. L. 100-77, approved July 22, 1987. This Notice delegates to the Assistant Secretary and the General Deputy Assistant Secretary for Community Planning and Development the Secretary's power and authority with respect to this program, subject to specified exceptions.

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Don I. Patch, Director, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755-6587. [This is not a toll-free number].

SUPPLEMENTARY INFORMATION: This Notice states the scope of authority given to the Assistant Secretary and General Deputy Assistant Secretary for Community Planning and Development for the Emergency Shelter Grants Program. All of the Secretary's authority with respect to this program is delegated except the power to sue and be sued. The authority delegated includes the authority to redelegate to employees of the Department, except for the authority to issue rules and regulations.

The Emergency Shelter Grants Program has been reauthorized by Title IV, Subtitle B of the Stewart B. McKinney Homeless Assistance Act. A Notice describing the program requirements for the 1988 fiscal year is published elsewhere in today's issue of the **Federal Register**. Accordingly, the Secretary delegates as follows:

Section A. Authority Delegated

The Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development are authorized individually to exercise the power and authority of the Secretary of Housing and Urban Development with respect to the Emergency Shelter Grants Program as authorized by Subtitle B of the Stewart B. McKinney Homeless Assistance Act, Pub. L. 100-77, approved July 22, 1987, except as indicated in section B below. This includes the authority to issue or waive rules and regulations.

Section B. Authority Excepted

There is excepted from the authority delegate under Section A the power to sue or be sued.

Section C. Authority to Redelegate

The Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development are authorized, individually, to redelegate to employees of the Department any of the power and authority delegated under section A that is not excepted under section B of this delegation. In addition, the Assistant Secretary and the General Deputy Assistant Secretary are not authorized to redelegate the authority to issue or waive rules and regulations, except with respect to the extension of grantee submission and obligation of grant amount deadlines.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: August 28, 1987.

Carl D. Covitz,

Under Secretary.

[FR Doc. 87-20473 Filed 9-3-87; 8:45 am]

BILLING CODE 4210-32-M

Office of the Assistant Secretary for Community Planning and Development

[Docket No. 87-860; FR-2388]

Emergency Shelter Grants Program; Redelegation of Authority

AGENCY: Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority.

SUMMARY: The Assistant Secretary for Community Planning and Development is redelegating his power and authority with respect to the Emergency Shelter Grants Program to Regional Administrators and Category A Field Office Managers, subject to certain specified exceptions.

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Don I. Patch, Director, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington DC 20410, telephone (202) 755-6587. [This is not a toll-free number].

SUPPLEMENTARY INFORMATION: The Secretary of Housing and Urban Development has delegated his power and authority with respect to the Emergency Shelter Grants Program to the Assistant Secretary and to the Deputy Assistant Secretary for Community Planning and Development, subject to certain exceptions. These exceptions include the authority to sue or be sued and the authority to redelegate responsibility and authority for the issuance or waiver of rules and regulations. Notice of the Secretary's delegation is published elsewhere in today's issue. In this redelegation, the Assistant Secretary for Community Planning and Development is redelegating his authority with respect to the Emergency Shelter Grants Program to specified officials of HUD Field Offices, subject to additional exceptions. This redelegation is intended to maximize the authority of HUD Field Offices to administer the Emergency Shelter Grants Program within departmental regulations, subject to the specific exception set out in section B of this Notice.

Accordingly, the Assistant Secretary for Community Planning and Development redelegates as follows:

Section A. Authority Redelegated

Each Regional Administrator and Category A Office Manager, and the Deputy of each such official, is authorized by the Assistant Secretary for Community Planning and Development to exercise the power and authority of Assistant Secretary with respect to the Emergency Shelter Grants Program authorized by Subtitle B of the Stewart B. McKinney Homeless Assistance Act, Pub. L. 100-77 (approved July 22, 1987), except as indicated in section B below.

Section B. Authority Excepted

There is excepted from the authority delegated under Section A: the authority

to issue or waive rules and regulations (except with respect to the extension of up to 30 days of grantee submission and obligation of grant amount deadlines); the authority to impose sanctions under 24 CFR 575–63 (other than to issue a warning letter); the authority to reallocate grant amounts that are returned to HUD by a metropolitan city or urban county for use outside the respective jurisdiction; and the authority to reallocate any grant amounts outside the State to which they were allocated.

Authority: Sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: August 28, 1987.

Jack R. Stokvis,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 87–20474 Filed 9–3–87; 8:45 am]

BILLING CODE 4210-29-M

federal register

Friday
September 4, 1987

Part IX

Securities and Exchange Commission

17 CFR Part 202

Temporary Lockbox Rule; Extension of Temporary Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 202

[Release Nos. 33-6733; 34-24866; 35-24452; 39-2112; IC-15953; IA-1080]

Temporary Lockbox Rule

AGENCY: Securities and Exchange Commission.

ACTION: Extension of temporary rule.

SUMMARY: The Commission is extending for one year the effectiveness of a temporary rule, adopted in June, 1984, which permits filing and other fees to be remitted to a U.S. Treasury designated lockbox depository located in Pittsburgh, Pennsylvania. This action will permit registrants to continue to use the procedures specified by the temporary rule pending the Commission's consideration of whether to adopt amendments to the rule.

EFFECTIVE DATES: September 1, 1987–September 1, 1988.

FOR FURTHER INFORMATION CONTACT: Jeanne G. Hartford, Special Counsel, (202-272-2700), Office of the Executive Director, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: In Securities Act Release No. 6540, dated June 27, 1984 (49 FR 27306), the Commission adopted a temporary amendment to rule 202.3a, to permit filing and other fees to be remitted to a lockbox depository. Under this amendment, filers may continue to submit fees to the Commission with filings or may transmit required fees to a lockbox depository in Pittsburgh, Pennsylvania by mail, wire transfer, or hand delivery. When the temporary amendments were adopted, the Commission stated that in approximately twelve months it would consider whether to eliminate payment of fees directly to the Commission and instead mandate payment of fees to a lockbox. The effectiveness of the temporary rule has been extended on two previous occasions, November 10, 1986 (51 FR 40791) and February 3, 1986 (51 FR 4160). In addition, amendments to rule 202.3a, which would change its provisions from permissive to mandatory, were proposed in January, 1986 (51 FR 6267, February 21, 1986). Subsequent issues have been raised as a result of Commission concerns and comments received from the public. In addition, the staff has recommended redesign of the Commission's existing fee collection system. Pending its decision concerning whether to adopt the proposed changes, the Commission has determined that the effectiveness of temporary rule 202.3a should be extended for a period of one year (until September 1, 1988) to permit the continuation of existing procedures.

Administrative Procedure Act

The Commission finds, in accordance with the Administrative Procedure Act, 5 U.S.C. 553(b)(A), that temporary rule 202.3a relates solely to agency organization, procedure or practice and, therefore, advance notice and opportunity for comment is unnecessary in connection with this action.

By the Commission.

Jonathan G. Katz,

Secretary.

August 31, 1987.

[FR Doc. 87-20412 Filed 9-3-87; 9:44 am]

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