AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

11-23-83
Vol. 48 No. 227
Pages 52867-53078

federal register

Wednesday
November 23, 1983

Selected Subjects

Animal Diseases
Animal and Plant Health Inspection Service

Animal Feeds
Environmental Protection Agency

Arms and Munitions
Alcohol, Tobacco and Firearms Bureau

Authority Delegations (Government Agencies)
Architectural and Transportation Barriers Compliance Board
Civil Aeronautics Board

Claims
Civil Aeronautics Board

Customs Duties and Inspection
Customs Service

Exports
International Trade Administration

Fisheries
National Oceanic and Atmospheric Administration

Food Additives
Food and Drug Administration

Government Contracts
Architectural and Transportation Barriers Compliance Board

Government Employees
Personnel Management Office

CONTINUED INSIDE

Selected Subjects

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by Act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The **Federal Register** will be furnished by mail to subscribers for $300.00 per year, or $150.00 for six months, payable in advance. The charge for individual copies is $1.50 for each issue, or $1.50 for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

There are no restrictions on the republication of material appearing in the **Federal Register**.

Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

Handicapped
Defense Department
Housing and Urban Development Department

Hazardous Waste
Environmental Protection Agency

Imports
Agriculture Department

Income Taxes
Internal Revenue Service

Loan Programs—Housing and Community Development
Housing and Urban Development Department

Marketing Agreements
Agricultural Marketing Service

Medical Devices
Food and Drug Administration

Milk Marketing Orders
Agricultural Marketing Service

Mortgage Insurance
Federal Housing Commissioner—Office of Assistant Secretary for Housing

Pesticides and Pests
Environmental Protection Agency

Railroads
Interstate Commerce Commission

Securities
Securities and Exchange Commission

Waste Treatment and Disposal
Environmental Protection Agency

Contents

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

Agency for International Development
NOTICES
Meetings:
52987 Research Advisory Committee

Agricultural Marketing Service
RULES
52969 Lemons grown in Ariz. and Calif.
Milk marketing orders:
52969 Puget Sound, Wash.

Agriculture Department
See also Agricultural Marketing Service; Animal and Plant Health Inspection Service; Farmers Home Administration; Foreign Agricultural Service; Forest Service.
PROPOSED RULES
Import quotas and fees:
52926 Licenses for importation or transfer of sugar to be reexported; sugar containing products
NOTICES
52954 Agency information collection activities under OMB review
Meetings:
52954 Agribusiness Promotion Council

Air Force Department
NOTICES
Meetings:
52956 Scientific Advisory Board

Alcohol, Drug Abuse, and Mental Health Administration
NOTICES
Meetings, advisory committees:
52979 December

Alcohol, Tobacco and Firearms Bureau
RULES
Firearms and ammunition, commerce in:
52908 State laws and published ordinances; incorporation by reference

Animal and Plant Health Inspection Service
RULES
Livestock and poultry quarantine:
52885 Highly pathogenic avian influenza; interim

Architectural and Transportation Barriers Compliance Board
RULES
53074 Authorities and Delegations
52911 Federal contracting policies; policy statement
52910 Litigation as amicus curiae

Arts and Humanities, National Foundation
NOTICES
Grants; availability, etc.:
52990 Museum services general operating support program
52990 Museum assessment program

Civil Aeronautics Board
RULES
Delegations and review of action under delegation, etc.:
52889 Claims agent; collection of debts owed to United States
Procedural regulations:
52887 Collection of claims owed the United States
NOTICES
Hearings, etc.:
52954 Executive Express, Ltd.

Commerce Department
See International Trade Administration; National Oceanic and Atmospheric Administration.

Commodity Futures Trading Commission
NOTICES
53008, 53009 Meetings; Sunshine Act (11 documents)

Conservation and Renewable Energy Office
NOTICES
Consumer products; petitions for waiver of test procedures:
52971 Coleman Co., Inc.

Consumer Product Safety Commission
RULES
Coal and wood burning appliances:
52889 Performance and technical data; correction

Customs Service
RULES
52897 Vessels; search and boarding

Defense Department
See also Air Force Department; Engineers Corps.
RULES
Civilian health and medical program of uniformed services (CHAMPUS):
52910 Hearing impairments; determination criteria

Drug Enforcement Administration
NOTICES
Registration applications, etc.; controlled substances:
52988 Western Fher Laboratories, Inc.
52988 Wyeth Laboratories, Inc.

Economic Regulatory Administration
NOTICES
Remedial orders:
52959 Fedco Oil Co.
52959 Mar-Low Corp. et al.

Education Department
NOTICES
Meetings:
52958 Women's Educational Programs National Advisory Council

Energy Department
See Conservation and Renewable Energy Office; Economic Regulatory Administration; Federal Energy Regulatory Commission; Hearings and Appeals Office, Energy Department; Western Area Power Administration.

Engineers Corps
NOTICES
Environmental statements; availability, etc.:
52957 Limestone Creek, Fayetteville, N.Y.
52957 Oil Shale Facility, Montgomery County, Ky.

Environmental Protection Agency
RULES
Hazardous waste programs; interim authorizations:
52915 State programs; Maryland
Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc.:
52914 Chlorpyrifos
52913 Flucythrinate
52912 Primary n-alkylamines
52914 Sulfuric acid
Pesticides; tolerances in animal feeds:
52917 Flucythrinate
Pesticides; tolerances in food and animal feeds:
52902 Propetamphos
PROPOSED RULES
Hazardous waste programs; interim authorizations; State programs:
52952 Florida
Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc:
52951 Dimethoate
52950 Sodium dihydrogen phosphate
Toxic substances:
52953 Polychlorinated biphenyls; exemptions from processing and distribution in commerce prohibitions; correction
Water pollution; effluent guidelines for point source categories:
52953 Inorganic chemical manufacturing; hearing
NOTICES
Meetings:
52975 State FIFRA Issues Research and Evaluation Group
Pesticide, food, and feed additive petitions:
52974 Rhome-Poulenc Inc. et al.
52976 Pesticides; receipts of State registration

Farmers Home Administration
PROPOSED RULES
Loan and grant programs:
52931 Coordinated financial statements; correction

Federal Emergency Management Agency
PROPOSED RULES
Flood elevation determinations:
52953 Connecticut et al.; correction
52953 Wisconsin; correction

Federal Energy Regulatory Commission
NOTICES
Hearings, etc.:
52962 Canal Electric Co.
52962, 52963 Central Maine Power Co. (2 documents)
52963 Central Vermont Public Service Corp
52963 Cranberry Pipeline Corp. et al.
52964 El Paso Natural Gas Co.
52964 Great Lakes Gas Transmission Co.
52965 Gulf States Utilities Co.
52965 JM Resources
52965 National Fuel Gas Supply Corp.
52966 Southern California Edison Co.
52967 Southwestern Power Administration
52967 Tenneco Oil Co. et al.
52969 Transcontinental Gas Pipe Line Corp.
52969 TXP Operating Co. et al.
52970 United Gas Pipe Line Co. (2 documents)
53009 Meetings; Sunshine Act
Natural gas companies:
52967 Certificates of public convenience and necessity; applications, abandonment of service and petitions to amend (Zenith Exploration Co. et al.)
Natural Gas Policy Act:
52966 Jurisdictional agency determinations; well category withdrawals, etc. (Nortex Gas & Oil Co.)
Small power production and cogeneration facilities; qualifying status; certification applications, etc.:
52969 Abbott Energy, Inc.

Federal Highway Administration
NOTICES
Environmental statements; availability, etc.:
53003 Carteret County, N.C.; intent to prepare

Federal Housing Commissioner—Office of Assistant Secretary for Housing
PROPOSED RULES
Mortgage and loan insurance programs:
52931 Property improvement and mobile loans; approval of lending institutions

Federal Reserve System
NOTICES
Applications, etc.:
52977 BankAmerica Corp.
52978 Farmers Bancshares, Inc., et al.
Bank holding companies; proposed de novo nonbank activities:
52978 Norwest Corp. et al.
53009 Meetings; Sunshine Act

Fish and Wildlife Service
NOTICES
52984 Endangered and threatened species permit applications

Food and Drug Administration
RULES
Food additives:
52899 Aspartame
Medical devices:
53012 Gastroenterology-Urology devices; classification
53032 Physical medicine devices; classification

Foreign Agricultural Service
PROPOSED RULES
52926 Licenses for importation or transfer of sugar to be reexported in sugar containing products. (Editorial Note: For a document on this subject, see entry under Agriculture Department.)

Foreign Assets Control Office
NOTICES
Cuban assets control:
53006 Nickel-bearing materials for importation from U.S.S.R.; detention

Forest Service
NOTICES
Meetings:
52954 Modoc National Forest Grazing Advisory Board

Health and Human Services Department
See Alcohol, Drug Abuse, and Mental Health Administration; Food and Drug Administration; National Institutes of Health; Public Health Service.

Hearings and Appeals Office, Energy Department
NOTICES
Applications for exception:
52960, 52961 Cases filed (2 documents)
52960 Decisions and orders
Remedial orders:
52959 Objections filed

Housing and Urban Development Department
See also Federal Housing Commissioner—Office of Assistant Secretary for Housing.
PROPOSED RULES
Low income housing:
52934 Comprehensive improvement assistance program; "non-routine maintenance" definition replacing "major repairs"
52941 Elderly or handicapped housing; payment and performance bond requirement
52936 Housing assistance payments program (Section 8); construction and substantial rehabilitation; contract rent adjustment
NOTICES
52983 Agency information collection activities under OMB review
Authority delegations:
52983 Pittsburgh Regional Office, Region III; order of succession

Interior Department
See also Fish and Wildlife Service; Land Management Bureau.
NOTICES
Meetings:
52984 Indian Reservation Economies Presidential Commission

Internal Revenue Service
RULES
Income taxes:
52903 Credit for employment of targeted group new employees
PROPOSED RULES
Income taxes:
52943 Credit for employment of certain new employees

International Development Cooperation Agency
See Agency for International Development.

International Trade Administration
RULES
Export licensing:
53064 China; export control policy
NOTICE
Meetings:
52955 President's Export Council (2 documents)

International Trade Commission
NOTICES
53009 Meetings; Sunshine Act

Interstate Commerce Commission
RULES
Practice and procedure:
52920 Railroad lines, bankrupt; forced sale procedures
Railroad car service orders; various companies:
52918 Chicago, Rock Island & Pacific Railroad Co.; track use by various railroads
NOTICES
Railroad operation, acquisition, construction, etc.:
52988 Seaboard System Railroad, Inc.
52988 Seaboard System Railroad, Inc., et al.
Railroad services abandonment:
52987 St. Louis Southwestern Railway Co.

Justice Department
See Drug Enforcement Administration.

Land Management Bureau
NOTICES
Alaska native claims selection; applications, etc.:
52984, 52985 Cook Inlet Region, Inc. (3 documents)
Management framework plans, review and supplement, etc.:
52986 California
52986 New Mexico
Meetings:
52987 Albuquerque District Advisory Council
52987 Casper District Advisory Council
Sale of public lands:
52986 Wyoming (2 documents)

Management and Budget Office
NOTICES
53060 Budget rescissions and deferrals

National Aeronautics and Space Administration
NOTICES
Environmental statements; availability, etc.:
52989 Space Shuttle program launch, Kennedy Space Center, Fla.

National Institutes of Health
NOTICES
Recombinant DNA molecules research:
53056 Actions under guidelines

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
52922 Western Pacific spiny lobster

National Science Foundation
NOTICES
52991 Agency information collection activities under OMB review

Nuclear Regulatory Commission
PROPOSED RULES
52931 Regulatory agenda; quarterly report
NOTICES
Applications, etc.:
52992, 52993 Cleveland Electric Illuminating Co. et al. (2 documents)
52995 General Public Utilities Nuclear Corp.
52996 George Washington University Medical Center
52998 Kansas Gas & Electric Co. et al.
52998 Power Authority of State of New York
52992 Export and import license applications for nuclear facilities or materials (Westinghouse Electric Corp. et al.)
Meetings:
52999 Reactor Safeguards Advisory Committee
53000 Three Mile Island Unit 2 Decontamination Advisory Panel

Personnel Management Office
RULES
Career and career-conditional employment, etc.:
52867 Noncompetitive appointment of former overseas employees
NOTICES
Senior Executive Service:
53000 Performance Review Board; membership

Public Health Service
NOTICES
Meetings:
52979 Vital and Health Statistics National Commission (2 documents)
52980 Privacy Act; systems of records

Securities and Exchange Commission
RULES
Securities:
52889 Delayed or continuous offering and sale (shelf registration rule)
NOTICES
Hearings, etc.:
53000 Eastern Edison Co. et al.
Self-regulatory organizations; proposed rule changes:
53001 Municipal Securities Rulemaking Board

Synthetic Fuels Corporation
NOTICES
53009 Meetings; Sunshine Act

Textile Agreements Implementation Committee
NOTICES
Cotton, wool, and man-made textiles:
52955 Hungary
52956 Poland

Transportation Department
See also Federal Highway Administration.
NOTICES
53001 Agency information collection activities under OMB review

Treasury Department
See also Alcohol, Tobacco and Firearms Bureau; Customs Service; Foreign Assets Control Office; Internal Revenue Service.
NOTICES
53005 Agency information collection activities under OMB review (2 documents)
Boycotts, international:
53003 Guidelines; question and answers; Tax Reform Act provisions; inquiry
Meetings:
53006 Worldwide Unitary Taxation Working Group

Western Area Power Administration
NOTICES
Environmental statements; availability, etc.:
52972 Fort Peck-Havre transmission line project, Mont.

Separate Parts in This Issue

Part II
53012 Department of Health and Human Services, Food and Drug Administration

Part III
53032 Department of Health and Human Services, Food and Drug Administration

Part IV
53056 Department of Health and Human Services, National Institutes of Health

Part V
53060 Office of Management and Budget

Part VI
53064 Department of Commerce, International Trade Administration

Part VII
53074 Architectural and Transportation Barriers Compliance Board

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

5 CFR
301 52867
315 52867
316 52867

7 CFR
910 52869
1125 52869
1133 52869

Proposed Rules:
6 52926
1910 52931
1924 52931
1930 52931
1941 52931
1945 52931

9 CFR
81 52885

10 CFR

Proposed Rules:
Ch. I 52931

14 CFR
316 52887
385 52889

15 CFR
368 53064
370 53064
371 53064
372 53064
373 53064
374 53064
375 53064
376 53064
379 53064
385 53064
386 53064
399 53064

16 CFR
1406 52889

17 CFR
230 52889

19 CFR
162 52897

21 CFR
172 52899
193 52902
561 (2 documents) 52902, 52917
876 53012
890 53032

24 CFR

Proposed Rules:
202 52931
868 52934
880 52936
881 52936
883 52936
884 52936
885 52941
886 52936
888 52936
899 52936

26 CFR
1 52903
5 52903

Proposed Rules:
1 52943
5 52943

27 CFR
178 52908

32 CFR
199 52910

36 CFR
1151 (2 documents) 52910, 52911
1153 53074

40 CFR
180 (4 documents) 52912–52914
271 52915

Proposed Rules:
180 (2 documents) 52950, 52951
271 52952
415 52053
761 52953

44 CFR

Proposed Rules:
67 (2 documents) 52953

49 CFR
1033 52918
1180 52920

50 CFR
681 52922

Rules and Regulations

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

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 month.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 301, 315 and 316

Noncompetitive Appointment of Certain Former Overseas Employees

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management is issuing final regulations to implement Executive Order 12362. This Executive order permits U.S. Government dependents who work in Federal activities overseas to earn eligibility for direct civil service appointment when they return to the United States. The regulations define the eligibility criteria applicants must meet for appointment under this order and specify the procedures Federal agencies must follow in appointing these individuals.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: Ed McHugh, 202-632-6817.

SUPPLEMENTARY INFORMATION: Interim regulations, which enabled Federal agencies to appoint eligibles under E.O. 12362, were published in the **Federal Register** on July 2, 1982 (47 FR 28905).

The interim regulations, which were in effect pending the issuance of final regulations, also provided for a comment period. Over 100 written and oral comments were received during the comment period from Federal departments and agencies, military commands, unions, professional organizations, Federal civilian employees, military personnel and their family members.

The majority of comments dealt with the eligibility criteria which former overseas employees must meet in order to qualify civil service appointments when they return, to the United States. Many of the comments questioned the requirement in the interim regulations that eligibles must be current family members of U.S. civilian or military personnel (called sponsors) at the time they exercise eligibility for employment in the United States, as well as having been in this status while serving overseas. Several of the comments indicated that this requirement poses a particular hardship for family members who earn civil service employment eligibility overseas, but whose sponsors retire from the military or die on active duty before the family member can exercise eligibility for Stateside employment. Under the revised criteria specified in the final regulations, eligibles are no longer required to be family members of U.S. civilian or military personnel at the time they apply for employment in the United States. Once family members earn eligibility overseas, they may exercise it in the United States regardless of the status of, or their relationship with, their sponsor.

Several comments requested redefinition of the requirement that eligibles must physically reside with the sponsor during their employment in the overseas area. This definition was identified as posing potential hardships for overseas family members whose sponsors are temporarily deployed away from their normal overseas station on ships or to other posts to meet diplomatic or military commitments. The final regulations redefine this to require that eligibles reside in the general overseas area while their sponsor is officially assigned overseas and during the period of their employment, without the requirement that they physically reside with their sponsor at all times.

Several comments requested additions to the list of types of overseas employment which will enable a family member to meet the eligibility criteria for Stateside civil service appointment under E.O. 12362. The definition of creditable overseas employment for this purpose in the final regulations was expanded to include nonpermanent employment as a local national employee paid from appropriated funds, nonpermanent employment with the Central Intelligence Agency, Defense Intelligence Agency, and National Security Agency, and nonpermanent employment under the Berlin Tariff Agreement—which is the employment system used for all U.S. family members working at military activities in Berlin. A consolidated definition of creditable overseas service was also included in the final regulations.

A request to include contract work and employment in nonappropriated fund (NAF) instrumentalities under the definition of creditable overseas Federal employment could not be adopted because this type of work is not included in the statutory definition of Federal civilian employment [5 U.S.C. 2105(c)], which governs eligibility for this program.

Several agencies also asked that the definition of a civilian employee sponsor, i.e. an individual whose family members may qualify under the terms of the Executive order, be expanded to include sponsors who work in nonappropriated fund positions. This proposal could not be accepted for the reason indicated above.

The final regulations in Part 301 establish a general merit principle which Federal agencies must follow in filling overseas positions, and require that overseas agencies begin using a performance appraisal system by January 1, 1984, to determine that eligibles have received a fully successful or better (or equivalent) performance rating for their overseas service. These two provisions of Executive Order 12362 had been suspended pending the issuance of final regulations.

The final regulations also make technical revisions in sections defining the period within which family members must earn eligibility overseas and be appointed under E.O. 12362 upon return to the United States.

A request to waive time-in-grade restrictions which govern the pay grade at which overseas employees can be appointed upon return to the United States was not adopted because it would provide a special advantage to former overseas employees not available to career civil service employees.

One agency suggested that individuals who are not U.S. citizens, but who owe permanent allegiance to the United States, be made eligible for appointment under the Order since such individuals are eligible for career appointments in the competitive civil service under 5 CFR 338.101. This suggestion was adopted.

A request to extend eligibility for Stateside appointment beyond the two years provided in the interim regulations was rejected because the Executive order specifically indicates that eligibles must be appointed within two years of their return to the United States.

E. O. 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects Federal employees.

List of Subjects in 5 CFR Parts 301, 315 and 316

Government employees.

Office of Personnel Management.

Donald J. Devine,

Director.

Accordingly, OPM is amending Parts 301, 315 and 316 of Title 5, Code of Federal Regulations, as follows:

PART 301—OVERSEAS EMPLOYMENT

1. Subpart C is added to Part 301 to read as follows:

Subpart C—Overseas Employees Eligible for Noncompetitive Appointment Upon Return to the United States

Sec.

301.201 Eligibility under the authority of Executive Order 12362.
301.202 Overseas appointing procedures.
301.203 Performance appraisal.

Authority: E.O. 12362, 47 FR 21231 3 CFR, 1982 Comp., p. 182.

§ 301.201 Eligibility under the authority of Executive Order 12362.

Employees who serve under overseas local hire appointments as defined in § 315.608(b) of this chapter and meet the eligibility criteria of § 315.608(a) of this chapter are eligible for noncompetitive career-conditional, term, or temporary limited appointment when they return to the United States.

§ 301.202 Overseas appointing procedures.

Overseas agencies are required to insure that selection of employees for local hire appointments in the overseas area is made on the basis of the ability, knowledge, and skills of eligible candidates, in accordance with applicable law and regulation.

§ 301.203 Performance appraisal.

As soon as practicable, but beginning not later than January 1, 1984, overseas agencies are required to evaluate the performance of employees who serve under overseas local hire appointments as defined in § 315.608(b) of this chapter and who are eligible to meet the criteria established in § 315.608(a), of this chapter in accordance with the agency's performance appraisal plan established under Chapter 43 of title 5, U.S. Code, unless the agency is exempt from the provisions of that chapter.

PART 315—CAREER AND CAREER-CONDITIONAL EMPLOYMENT

2. In Subpart F, § 315.608 is revised to read as follows:

§ 315.608 Noncompetitive appointment of certain former overseas employees.

(a) Under the authority of Executive Order 12362, an agency in the executive branch may appoint noncompetitively to a competitive service position within the United States an individual who is a citizen of or owes permanent allegiance to the United States and who:

(1) Accumulated 24 months of creditable overseas service in an appropriated fund position(s) under a local hire appointment(s) within any ten-year period beginning after January 1, 1980;

(2) Received a fully successful or better (or equivalent) performance rating for the period of creditable overseas service (this requirement applies to service accrued after January 1, 1984).

(3) Was a family member of a civilian employee or of a member of a uniformed service (the civilian or uniformed sponsor) who was officially assigned to the overseas area and was in this status during the 24-month period of creditable overseas service;

(4) Accompanied the civilian or uniformed sponsor on official assignment in the overseas area during the period of creditable overseas service;

(5) Is appointed within two years after returning to the United States from the overseas tour of duty during which he or she acquired eligibility by meeting the requirements of paragraphs (a) (1) through (4) of this section.

(b) *Definitions.* In this subpart:

"Accompanied the civilian or uniformed sponsor on official assignment in the overseas area" means family members residing in the overseas area while their sponsor is officially assigned to an overseas post of duty. This definition does not require the family member to physically reside with the sponsor at all times or to have travelled with the sponsor to or from the overseas area.

"Creditable overseas service" means the period of employment when the employee was serving under a local hire appointment(s) with a fully successful or better performance rating and residing in the overseas area as a family member accompanying a civilian employee or member of a uniformed service on official assignment.

"Family member" means a spouse or unmarried child (under 23 years of age) of a member of a uniformed service or Federal civilian employee officially assigned to the overseas area.

"Federal civilian employee" means an employee of the executive, judicial, and legislative branches of the Government of the United States who is officially assigned to the overseas area and serves in an appropriated fund position.

"Local hire appointments" are appointments made from applicants residing in the overseas area which are not actually or potentially permanent. For purposes of this subpart only, this definition includes nonpermanent employment as a local national employee paid from appropriated funds, or under 50 U.S.C. 403j., Public Law 86-36, or the Berlin Tariff Agreement; overseas limited appointments under 5 CFR 301.201, nonpermanent excepted appointments under Schedule A 213.3106(b)(6) or Schedule A 213.3106(d)(1); an "American family member" or "Part-time intermittent temporary" appointment in U.S. diplomatic establishments; or any other nonpermanent overseas appointment in the competitive or excepted service so designated by the Office of Personnel Management in the Federal Personnel Manual.

"Member of a uniformed service" means personnel of the Armed Forces (including the Coast Guard), the commissioned corps of the Public Health Service, and the commissioned corps of the National Oceanic and Atmospheric Administration officially assigned to the overseas area.

"Overseas area" means duty locations outside the 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

"Sponsor" means a member of a uniformed service or civilian employee on official assignment to the overseas area who is the spouse or parent of the family member.

"United States" means the 50 States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(c) *Conditions.* Any law, Executive order or regulation that disqualifies an

applicant for appointment also disqualifies an applicant for appointment under this section.

(d) *Tenure of appointment.* A person appointed under this section becomes a career-conditional employee.

(e) *Acquisition of competitive status.* A person appointed under this section acquires competitive status automatically upon completion of probation.

PART 316—TEMPORARY AND TERM EMPLOYMENT

3. In Subpart C, § 316.302(c)(3) is revised to read as follows:

§ 316.302 Selection of term employees.

* * * * *

(c) * * *

(3) A person eligible for career or career-conditional appointment under §§ 315.601, 315.605, 315.606, or 315.608 of this chapter;

* * * * *

4. In Subpart D, § 316.402(b)(2) is revised to read as follows:

§ 316.402 Authorities for temporary appointments.

* * * * *

(b) * * *

(2) A person eligible for career or career-conditional appointment under §§ 315.601, 315.605, 315.606, 315.607 or 315.608 of this chapter;

* * * * *

(E.O. 12362, 47 FR 21231)

[FR Doc. 83-31429 Filed 11-22-83; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 437, Amdt. 1]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Amendment to final rule.

SUMMARY: This action increases the quantity of California-Arizona lemons that may be shipped to the fresh market during the period November 13–19, 1983. Such action is needed to provide for orderly marketing of fresh lemons for the period due to the marketing situation confronting the lemon industry.

DATES: Effective for the period November 13–19, 1983.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This final rule 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 of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the Act.

This action is consistent with the marketing policy currently in effect. The committee met by telephone on November 16, 1983, to consider the current and prospective conditions of supply and demand and recommended an increase in the quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is improved.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this amendment is based and the effective date necessary to effectuate the declared policy of the Act. Interested persons were given an opportunity to present information and views on the amendment during the telephone meeting, and it relieves restrictions on the handling of lemons. 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.

PART 910—[AMENDED]

1. Section 910.737 Lemon Regulation 437 (48 FR 51634) is revised to read as follows:

§ 910.737 Lemon Regulation 437.

The quantity of lemons grown in California and Arizona which may be handled during the period November 13, 1983, through November 19, 1983, is established at 260,000 cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: November 18, 1983.

Charles R. Brader,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 83-31504 Filed 11-22-83; 8:45 am]

BILLING CODE 3410-02-M

---

7 CFR Parts 1125 and 1133

[Docket Nos. AO–226–A29 and AO–275–A32]

Milk in the Puget Sound-Inland and Certain Other Marketing Areas Order Amending and Merging Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action merges the Puget Sound and Inland Empire Federal milk orders, based on industry proposals considered at a public hearing held in September 1981. In addition to the presently regulated marketing areas of the separate orders, the combined "Puget Sound-Inland" marketing area includes eight additional unregulated north central Washington counties and the remaining portions of two other Washington counties. The provisions of the merged order are patterned largely after those of the Puget Sound order, except, that the merged order does not contain a Class I base plan. The merged order reflects current marketing conditions in that the two separately regulated areas have become, in effect, one common market.

EFFECTIVE DATE: January 1, 1984.

FOR FURTHER INFORMATION CONTACT: Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250, (202) 475–4128.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of Sections 556 and 557 of Title 5 of the United State Code and, therefore, is excluded from the requirements of Executive Order 12291.

Prior documents in this proceeding:

Notice of Hearing: Issued June 11, 1981; published June 16, 1981 (46 FR 31424).

Notice of Postponement of Hearing: Issued June 30, 1981; published July 6, 1981 (46 FR 34805).

Notice of Rescheduling of Hearing: Issued July 23, 1981; published July 28, 1981 (46 FR 38524).

Notice of Proposed Suspension: Issued November 6, 1981; published November 12, 1981 (46 FR 55707).

Suspension Order: Issued December 7, 1981; published December 10, 1981 (46 FR 60412).

Recommended Decision: Issued April 28, 1983; published May 4, 1983 (48 FR 10058).

Extension of Time: Issued June 2, 1983; published June 8, 1983 (48 FR 26460).

Final Decision: Issued October 19, 1983; published October 25, 1983 (48 FR 49255).

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the orders were first issued. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) *Findings.* A public hearing was held upon certain proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the Puget Sound, Washington, and Inland Empire marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure (7 CFR Part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The Puget Sound-Inland order, which amends and merges the Puget Sound, Washington, and Inland Empire orders, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the Puget Sound-Inland marketing area, and the minimum prices specified in the Puget Sound-Inland order are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest;

(3) The Puget Sound-Inland order regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held;

(4) All milk and milk products handled by handlers, as defined in the Puget Sound-Inland order are in the current of interstate commerce or directly burden, obstruct, or affect intrastate commerce in milk or its products; and

(5) It is hereby found that the necessary expense of the market administrator for maintenance and functioning of such agency will require the payment of each handler, as his pro rata share of such expense, 4 cents per hundredweight or such lesser amount as the Secretary may prescribe, with respect to milk specified in § 1125.85 of the Puget Sound-Inland order.

(b) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in Sec. 8c (9) of the Act) of more than 50 percent of the milk, which is marketed in the Puget Sound-Inland marketing area, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of the Puget Sound-Inland order, which amends and merges the aforesaid orders, is the only practical means pursuant to the declared policy of the Act of advancing the interest of producers as defined in the Puget Sound-Inland order; and

(3) The issuance of the Puget Sound-Inland order is approved or favored by at least two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the Puget Sound-Inland marketing area.

List of Subjects in 7 CFR Parts 1125 and 1133

Milk marketing orders, Milk, Dairy products.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof the orders regulating the handling of milk in the Puget Sound, Washington, and Inland Empire marketing areas (Parts 1125 and 1133, respectively) shall be amended and merged into one order. Part 1133 is superseded thereby, and such vacated Part designation shall be reserved for future assignment. The handling of milk in the merged marketing area to be designated as the "Puget Sound-Inland Marketing Area" (Part 1125), shall be in conformity to and in compliance with the terms and conditions of the following attached order.

For the reasons set forth in the preamble, Chapter X of Title 7 of the Code of Federal Regulations is amended as follows:

PART 1133—[RESERVED]

1. Part 1133 is removed and reserved.

2. Part 1125 is revised to read as follows:

PART 1125—MILK IN THE PUGET SOUND-INLAND MARKETING AREA

Subpart—Order Regulating Handling

General Provisions

Sec.
1125.1 General Provisions.

Definitions

1125.2 Puget Sound-Inland marketing area.
1125.3 Route disposition.
1125.4 Plant.
1125.5 Distributing plant.
1125.6 Supply plant.
1125.7 Pool plant.
1125.8 Nonpool plant.
1125.9 Handler.
1125.10 Producer-handler.
1125.11 [Reserved].
1125.12 Producer.
1125.13 Producer milk.
1125.14 Other than milk.
1125.15 Fluid milk product.
1125.16 Fluid cream product.
1125.17 Filled milk.
1125.18 Cooperative association.
1125.19 Product prices.

Handler Reports

1125.30 Reports of receipts and utilization.
1125.31 Payroll reports.
1125.32 Other reports.

Classification of Milk

1125.40 Classes of utilization
1125.41 Shrinkage.
1125.42 Classification of transfers and diversions.
1125.43 General classification rules.
1125.44 Classification of producer milk.
1125.45 Market administrator's reports and announcements concerning classification.

Class Prices

1125.50 Class prices.
1125.51 Basic formula price.
1125.51a Basic Class II formula price.
1125.52 Plant location adjustments for handlers.
1125.53 Announcement of class prices.
1125.54 Equivalent price.

Uniform Price

1125.60 Handler's value of milk for computing uniform price.
1125.61 Computation of uniform price.
1125.62 Announcement of uniform price and butterfat differential.

Payments for Milk

1125.70 Producer-settlement fund.
1125.71 Payments to the producer-settlement fund.
1125.72 Payments from the producer-settlement fund.
1125.73 Payments to producers and to cooperative associations.
1125.74 Butterfat differential.

Sec.
1125.75 Plant location adjustments for producers and on nonpool milk.
1125.76 Payments by a handler operating a partially regulated distributing plant.
1125.77 Adjustment of accounts.

Administrative Assessment and Marketing Service Deduction

1125.85 Assessment for order administration.
1125.86 Deduction for marketing services.

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

Subpart—Order Regulating Handling

General Provisions

§ 1125.1 General provisions.

The terms, definitions, and provisions in Part 1000 of this chapter are hereby incorporated by reference and made a part of this order.

Definitions

§ 1125.2 Puget Sound-Inland marketing area.

"Puget Sound-Inland marketing area" (hereinafter called the "marketing area") means all territory geographically within the places listed below, including all territory wholly or partly therein occupied by government (Municipal, State or Federal) reservations, facilities, installations, or institutions:

Idaho Counties

Benewah, Bonner, Boundary, Kootenai, Latah, Shoshone.

Washington Counties

Adams, Chelan, Douglas, Ferry, Grant, Grays Harbor, Island, King, Kittitas, Lewis (except the town of Vader), Lincoln, Okanogan, that portion of Pacific county north of township 11N (except Long Island and North Beach Peninsula), Pend Orielle, Pierce (except Fox, McNeil, and Anderson Islands and the peninsulas adjacent to Kitsap County), San Juan, Skagit, Snohomish, Spokane, Stevens, Thurston, Whatcom, and Whitman.

§ 1125.3 Route disposition.

"Route disposition" means any delivery of a fluid milk product classified as Class I milk from a plant to a retail or wholesale outlet (including any delivery through a distribution point as provided by this section, by a vendor, from a plant store or through a vending machine). The term "route disposition" does not include:

(a) *A delivery to a plant.* However, packaged fluid milk products that are transferred to a pool distributing plant from another pool distributing plant, and classified as Class I under § 1125.42(a), shall be considered route disposition from the transferor-plant for the sole purpose of qualifying it as a pool distributing plant under § 1125.7(a), and the transferor-plant shall be assigned in-area dispositions but not in excess of the in-area dispositions of the transferee plant;

(b) A delivery in bulk to a commercial food processing establishment pursuant to § 1125.40(b)(3); or

(c) A delivery to a military or other ocean transport vessel leaving the marketing area, of fluid milk products which originated at a plant located outside the marketing area and were not received or processed at any pool plant.

§ 1125.4 Plant.

"Plant" means the building, facilities and equipment, whether owned or operated by one or more persons, constituting a single operating unit or establishment, which is maintained and operated primarily for the receiving, handling and/or processing of milk or milk products (including filled milk). Separate facilities used only as a distribution point for storing packaged fluid milk products in transit for route disposition or separate facilities used only as a reload point for transferring bulk milk from one tank truck to another shall not be a "plant" under this definition.

§ 1125.5 Distributing plant.

"Distributing plant" means a plant in which a fluid milk product approved by a duly constituted regulatory agency for fluid consumption, or filled milk, is processed or packaged and that has route disposition in the marketing area during the month.

§ 1125.6 Supply plant.

"Supply plant" means a plant from which a fluid milk product approved by a duly constituted regulatory agency for fluid consumption, or filled milk, is transferred during the month to a pool distributing plant.

§ 1125.7 Pool plant.

Except as provided in paragraph (c) of this section, "pool plant" means:

(a) A distributing plant from which there is route disposition (except filled milk) in the marketing area during the month equal to not less than 10 percent of receipts of Grade A milk at such plant (exclusive of transfers of packaged fluid milk products from plants qualifying as pool plants pursuant to this paragraph) or diverted therefrom pursuant to § 1125.13.

(b) A supply plant from which there is transferred to a pool distributing plant fluid milk products that represent not less than the following percentages of the total quantity of Grade A milk that is physically received at such plant directly from dairy farmers, or a cooperative association pursuant to § 1125.9(c) or diverted therefrom as producer milk pursuant to § 1125.13:

Months and Applicable Percentage

January, February, or September–40
March through August–30
October through December–50

Any such plant that has transferred the applicable percentage of its receipts during the entire September through February period shall be a pool plant for the months of March through August immediately following. Any plant which otherwise meets the requirement of this paragraph may withdraw from pool supply plant status in the March through August period if the operator of the plant files with the market administrator prior to the first day of such month a written request for such withdrawal. The plant may regain pool status during such period only by meeting the applicable qualifying percentage.

(c) The term "pool plant" shall not apply to the following plants:

(1) A producer-handler plant;

(2) A plant qualified pursuant to paragraph (a) of this section which also meets the pooling requirements of another Federal order and from which, the Secretary determines, there is a greater quantity of route disposition during the month in such other Federal order marketing area than in this marketing area, except that if such plant was subject to all the provisions of this part in the immediately preceding month it shall continue to be subject to all the provisions of this part until the fourth consecutive month in which a greater proportion of its route disposition is made in such other marketing area unless, notwithstanding the provisions of this paragraph, it is regulated under such other order;

(3) A plant qualified pursuant to paragraph (a) of this section which also meets the pooling requirements of another Federal order on the basis of route disposition in such other marketing area and from which, the Secretary determines, there is a greater quantity of route disposition in this marketing area than in such other marketing area but which plant maintains pooling status for the month under such other Federal order;

(4) A plant qualified pursuant to paragraph (b) of this section which also meets the pool plant requirements of another Federal order and from which greater shipments are made during the month to plants regulated under such order than are made to plants regulated under this order;

(5) A distributing plant from which total route disposition (except filled milk) in the marketing area during the month averages 300 pounds or less per day; or

(6) That portion of a plant that is physically separated from the Grade A portion of such plant, is operated separately, and is not approved by any regulatory agency for the receiving, processing, or packaging of any fluid milk products for Grade A disposition.

§ 1125.8 Nonpool plant.

"Nonpool plant" means any plant other than a pool plant. The following categories of nonpool plants are further defined as follows:

(a) "Other order plant" means a plant that is fully subject to the pricing and pooling provisions of another order issued pursuant to the Act.

(b) "Producer-handler plant" means a plant operated by a producer-handler as defined in any order (including this part) issued pursuant to the Act.

(c) "Partially regulated distributing plant" means a nonpool plant that is neither an other order plant nor a producer-handler plant, from which during the month an average of more than 300 pounds daily of fluid milk products is disposed of as route disposition in the marketing area.

(d) "Unregulated supply plant" means a nonpool plant that is neither an other order plant nor a producer-handler plant, from which fluid milk products are moved to a pool plant during the month.

(e) "Exempt distributing plant" means a plant, other than a pool supply plant or a regulated plant under another Federal order that meets all the requirements for status as a pool distributing plant except that its route disposition (exclusive of filled milk) in the marketing area in the month does not exceed an average of 300 pounds daily. For purposes of this paragraph, route disposition shall not include receipts from a transferor-plant pursuant to the proviso of § 1125.3(a).

§ 1125.9 Handler.

"Handler" means:

(a) The operator of one or more pool plants;

(b) Any cooperative association with respect to producer milk which it caused to be diverted for the account of such cooperative association from a pool plant to a nonpool plant, or pursuant to § 1125.40(b)(3);

(c) Any cooperative association with respect to milk that it receives for its account from the farm of a producer for delivery to a pool plant of another handler in a tank truck owned and operated by, or under the control of, such cooperative association, unless both the cooperative association and the operator of the pool plant notify the market administrator prior to the time that such milk is delivered to the pool plant that the plant operator will be the handler for such milk and will purchase such milk on the basis of weights determined from its measurement at the farm and butterfat tests determined from farm bulk tank samples. Milk for which the cooperative association is the handler pursuant to this paragraph shall be deemed to have been received by the cooperative association at the location of the pool plant to which such milk is delivered;

(d) The operator of a partially regulated distributing plant;

(e) A producer-handler;

(f) The operator of an other order plant from which route disposition is made in the marketing area during the month;

(g) The operator of an unregulated supply plant; and

(h) The operator of an exempt distributing plant.

§ 1125.10 Producer-handler.

"Producer-handler" means a person who is engaged in the production of milk and also operates a plant from which during the month an average of more than 300 pounds daily of fluid milk products, except filled milk, is disposed of as route disposition within the marketing area and who has been so designated by the market administrator upon his determination that all of the requirements of this section have been met, and that none of the conditions therein for cancellation of such designation exists. All designations shall remain in effect until canceled pursuant to paragraph (c) of this section. Any state institution shall be a producer-handler exempt from the provisions of this section and §§ 1125.30 and 1125.32 with respect to milk of its own production and receipts from pool plants processed or received for consumption in State institutions and with respect to movements of milk to or from a pool plant.

(a) *Requirements for designation.* (1) The producer-handler has and exercises (in his capacity as a handler) complete and exclusive control over the operation and management of a plant at which he handles and processes milk received from his milk production resources and facilities (designated as such pursuant to paragraph (b)(1) of this section), the operation and management of which are under the complete and exclusive control of the producer-handler (in his capacity as a dairy farmer).

(2) The producer-handler neither receives at his designated milk production resources and facilities nor receives, handles, processes or distributes at or through any of his milk handling, processing or distributing resources and facilities (designated as such pursuant to paragraph (b)(2) of this section) milk products for reconstitution into fluid milk products, or fluid milk products derived from any source other than: (i) His designated milk production resources and facilities, (ii) pool plants within the limitation specified in paragraph (c)(2) of this section, or (iii) nonfat milk solids which are used to fortify fluid milk products.

(3) The producer-handler is neither directly nor indirectly associated with the business or management of, nor has a financial interest in, another handler's operation; nor is any other handler so associated with the producer-handler's operation.

(4) Designation of any person as a producer-handler following a cancellation of his prior designation shall be preceded by performance in accordance with paragraphs (a) (1), (2), and (3) of this section for a period of 1 month.

(b) *Resources and facilities.* Designation of a person as a producer-handler shall include the determination and designation of the milk production, handling, processing and distributing resources and facilities, all of which shall be deemed to constitute an integrated operation, as follows:

(1) As milk production resources and facilities: All resources and facilities (milking herd(s), buildings housing such herd(s), and the land on which such buildings are located) used for the production of milk:

(i) Which are directly, indirectly or partially owned, operated or controlled by the producer-handle;

(ii) In which the producer-handler in any way has an interest including any contractual arrangement; and

(iii) Which are directly, indirectly or partially owned, operated or controlled by any partner or stockholder of the producer-handler. However, for purposes of this paragraph any such milk production resources and facilities which the producer-handler proves to the satisfaction of the market administrator do not constitute an actual or potential source of milk supply for the producer-handler's operation as such shall not be considered a part of his milk production resources and facilities; and

(2) As milk handling, processing and distribution resources and facilities: All resources and facilities (including store

outlets) used for handling, processing and distributing any fluid milk product:

(i) Which are directly, indirectly or partially owned, operated or controlled by the producer-handler; or

(ii) In which the producer-handler in any way has an interest, including any contractual arrangement, or with respect to which the producer-handler directly or indirectly exercises any degree of management or control.

(c) *Cancellation.* The designation as a producer-handler shall be canceled under any of the conditions set forth in paragraphs (c) (1) and (2) of this section or upon determination by the market administrator that any of the requirements of paragraphs (a) (1), (2), and (3) of this section are not continuing to be met, such cancellation to be effective on the first day of the month following the month in which the requirements were not met, or the conditions for cancellation occurred.

(1) Milk from the designated milk production resources and facilities of the producer-handler is delivered in the name of another person as producer milk to another handler.

(2) The producer-handler handles fluid milk products derived from sources other than the designated milk production facilities and resources, with the exception of purchases from pool plants in the form of fluid milk products which do not exceed in the aggregaete a daily average during the month of 100 pounds.

(d) *Public Announcement.* The market administrator shall publicly announce the name, plant location and farm location(s) of persons designated as producer-handlers, of those whose designations have been canceled and the effective dates of producer-handler status or loss of producer-handler status for each. Such announcements shall be controlling with respect to the accounting at plants of other handlers for fluid milk products received from any producer-handler.

(e) *Burden of establishing and maintaining producer-handler status.* The burden rests upon the handler who is designated as a producer-handler to establish through records required pursuant to § 1000.5 of this chapter that the requirements set forth in paragraph (a) of this section have been and are continuing to be met, and that the conditions set forth in paragraph (c) of this section for cancellation of designation do not exist.

§ 1125.11 [Reserved]

§ 1125.12 Producer.

(a) Except as provided in paragraph (b) of this section, "producer" means any person who produces milk approved by a duly constituted regulatory agency for disposition as Grade A milk and whose milk is:

(1) Received at a pool plant directly from such person;

(2) Received by a handler described in § 1125.9(c); or

(3) Diverted from a pool plant in accordance with § 1125.13.

(b) "Producer" shall not include:

(1) A producer-handler as defined in any order (including this part) issued pursuant to the Act;

(2) Any person with respect to milk produced by him that is diverted to a pool plant from an other order plant if the other order designates such person as a producer under that order and such milk is allocated to Class II or Class III utilization pursuant to § 1125.44(a)(9)(iii) and the corresponding step of § 1125.44(b);

(3) Any person with respect to milk produced by him that is reported as diverted to an other order plant if any portion of such person's milk so moved is assigned to Class I under the provisions of such order;

(4) Any person who during the month has disposed of as route disposition or to consumers at the farm an average of more than 110 pounds daily of fluid milk or fluid cream products; or

(5) Any person (known as a dairy farmer for other markets) whose milk was received at a nonpool plant or a commercial food processing establishment during the month as other than producer milk under this or any other Federal milk order.

§ 1125.13 Producer milk.

"Producer milk" or "milk received from producers" means skim milk and butterfat in milk produced by producers which is received for the account of a handler as follows:

(a) With respect to receipts at a pool plant, producer milk shall include:

(1) Milk received at such plant directly from producers;

(2) Milk diverted from such pool plant to a nonpool plant or pursuant to § 1125.40(b)(3) for the account of the operator of the pool plant, subject to the conditions set forth in paragraph (c) of this section; and

(3) Milk received at such pool plant from a cooperative association in its capacity as a handler pursuant to § 1125.9(c) for all purposes other than those specified in paragraph (b)(2)(i) of this section;

(b) With respect to milk for which a cooperative association is a handler in a capacity other than as the operator of a pool plant, producer milk shall include:

(1) Milk diverted from a pool plant to a nonpool plant or pursuant to § 1125.40(b)(3) for the account of the cooperative association, subject to the conditions set forth in paragraph (c) of this section; and

(2) Milk for which the cooperative association is a handler pursuant to § 1125.9(c) to the following extent:

(i) For purposes of reporting pursuant to §§ 1125.30(c) and 1125.31(a) and making payments to producers pursuant to § 1125.73(a); and

(ii) For all purposes, with respect to any such milk which is not delivered to the pool plant of another handler;

(c) With respect to diversions to nonpool plants or pursuant to § 1125.40(b)(3):

(1) Milk of any producer may be diverted by a cooperative association or its agent for its account pursuant to § 1125.9(b) from pool distributing plants to nonpool plants or pursuant to § 1125.40(b)(3). The total quantity of milk diverted may not exceed 80 percent during the months of September through April of the producer milk which the association or its agent causes to be delivered to pool distributing plants, or diverted therefrom. No percentage limit shall apply during the months of May through August;

(2) Milk of any producer may be diverted by a cooperative association or its agent for its account pursuant to § 1125.9(b) from pool supply plants to nonpool plants or pursuant to § 1125.40(b)(3). The total quantity of milk so diverted may not exceed 50 percent of the producer milk which the association or its agent causes to be delivered to all such pool supply plants or diverted therefrom during the month;

(3) A handler, other than a cooperative association, operating a pool distributing plant may divert therefrom for his account to nonpool plants or pursuant to § 1125.40(b)(3). The total quantity of milk diverted may not exceed 80 percent during the months of September through April of the milk received at or diverted from such handler's pool distributing plant from any producer other than a member of a cooperative association which markets milk under paragraph (c)(1) or (c)(2) of this section and for which the operator of such plant is the handler during the month. No percentage limit shall apply during the months of May through August;

(4) A handler, other than a cooperative association, operating a pool supply plant may divert therefrom for his account to nonpool plants or pursuant to § 1125.40(b)(3). The total quantity of milk so diverted may not

exceed 50 percent of the total milk received at or diverted from such pool plant during the month from any producer other than a member of a cooperative association which markets milk under paragraph (c)(1) or (c)(2) of this section and for which the operator of such plant is the handler during the month;

(5) Milk diverted in excess of the limits specified shall not be considered producer milk, and the diverting handler shall specify the producers whose milk is ineligible as producer milk. If a handler fails to designate such producers, producer milk status shall be forfeited with respect to all milk diverted by the handler during the month;

(6) Two or more cooperative associations may have their allowable diversions computed on the basis of their combined deliveries of producer milk which the associations cause to be delivered to pool plants or diverted from pool plants during the month if each association has filed a request in writing with the market administrator on or before the first day of the month the agreement is to be effective. This request shall specify the basis for assigning overdiverted milk to the producer deliveries of each cooperative according to a method approved by the market administrator;

(7) For purposes of location adjustments pursuant to §§ 1125.52 and 1125.75, milk diverted to a nonpool plant or pursuant to § 1125.40(b)(3) shall be priced at the location of the plant or commercial food processing establishment to which diverted; and

(d) In the case of any bulk tank load of milk originating at farms and subsequently divided among plants, the proportion of the load received at each plant shall be prorated among the individual producers involved on the basis of their respective percentage of the total load.

§ 1125.14 Other source milk.

"Other source milk" means all skim milk and butterfat contained in or represented by:

(a) Receipts of fluid milk products and bulk products specified in § 1125.40(b)(1) from any source other than producers, handlers described in § 1125.9(c), or pool plants;

(b) Receipts in packaged form from other plants of products specified in § 1125.40(b)(1);

(c) Products (other than fluid milk products, products specified in § 1125.40(b)(1), and products produced at the plant during the same month) from any source which are reprocessed, converted into, or combined with another product in the plant during the month; and

(d) Receipts of any milk product (other than a fluid milk product or a product specified in § 1125.40(b)(1)) for which the handler fails to establish a disposition.

§ 1125.15 Fluid milk product.

(a) Except as provided in paragraph (b) of this section, "fluid milk product" means any of the following products in fluid or frozen form: milk, skim milk, lowfat milk, milk drinks, buttermilk, mixtures of cream and milk or skim milk containing less than 18 percent butterfat (including those which are sterilized or aseptically packaged), filled milk, and milkshake and ice milk mixes containing less than 20 percent total solids, including any such products that are flavored, cultured, modified with added nonfat milk solids, concentrated (if in a consumer-type package), or reconstituted.

(b) The term "fluid milk product" shall not include:

(1) Evaporated or condensed milk (plain or sweetened), evaporated or condensed skim milk (plain or sweetened), formulas especially prepared for infant feeding or dietary use and milk or milk products (including filled milk) that are sterilized and packaged in hermetically sealed glass or all-metal containers, any product that contains by weight less than 6.5 percent nonfat milk solids, and whey; and

(2) The quantity of skim milk in any modified product specified in paragraph (a) of this section that is in excess of the quantity of skim milk in an equal volume of an unmodified product of the same nature and butterfat content.

§ 1125.16 Fluid cream product.

"Fluid cream product" means cream (other than plastic cream or frozen cream), sour cream, or a mixture (including a cultured mixture) of cream and milk or skin milk containing 18 percent or more butterfat, with or without the addition of other ingredients.

§ 1125.17 Filled milk.

"Filled milk" means any conbination of nonmilk fat (or oil) with skim milk (whether fresh, cultured, reconstituted or modified by the addition of nonfat milk solids), with or without milkfat, so that the product (including stabilizers, emulsifiers, or flavoring) resembles milk or any other fluid milk product; and contains less than 6 percent nonmilk fat (or oil).

§ 1125.18 Cooperative association.

"Cooperative association" means any cooperative marketing association of producers, which the Secretary determines, after application by the cooperative association:

(a) To be qualified under the provisions of the Act of Congress of February 18, 1922, known as the "Capper-Volstead Act";

(b) To have full authority in the sale of milk of its members and to be engaged in making collective sales of or marketing milk for its members; and

(c) To have its entire activities under the control of its members.

§ 1125.19 Product prices.

The following product prices shall be used in calculating the basic Class II formula price pursuant to § 1125.51a:

(a) *Butter price.* "Butter price" means the simple average, for the first 15 days of the month, of the daily prices per pound of Grade A (92-score) butter. The prices used shall be those of the Chicago Mercantile Exchange as reported and published weekly by the Dairy Division, Agricultural Marketing Service. The average shall be computed by the Director of the Dairy Division, using the price reported each week as the daily price for that day and for each following work-day until the next price is reported. A work-day is each Monday through Friday, except national holidays. For any week that the Exchange does not meet to establish a price, the price for the following week shall be the last price that was established.

(b) *Cheddar cheese price.* "Cheddar cheese price" means the simple average, for the first 15 days of the month, of the daily prices per pound of cheddar cheese in 40-pound blocks. The prices used shall be those of the National Cheese Exchange (Green Bay, WI), as reported and published weekly by the Dairy Division, Agricultural Marketing Service. The average shall be computed by the Director of the Dairy Division, using the price reported each week as the daily price for that day and for each following work-day until the next price is reported. A work-day is each Monday through Friday, except national holidays. For any week that the Exchange does not meet to establish a price, the price for the following week shall be the last price that was established.

(c) *Nonfat dry milk price.* "Nonfat dry milk price" means the simple average, for the first 15 days of the month, of the daily prices per pound of nonfat dry milk, which average shall be computed

by the Director of the Dairy Division as follows:

(1) The prices used shall be the prices (using the midpoint of any price range as one price) of high heat, low heat and Grade A nonfat dry milk, respectively, for the Central States production area, as reported and published weekly by the Dairy Division, Agricultural Marketing Service.

(2) For each week, determine the simple average of the prices reported for the three types of nonfat dry milk. Such average shall be the daily price for the day that such prices are reported and for each preceding work-day until the day such prices were previously reported. A work-day is each Monday through Friday except national holidays.

(3) Add the prices determined in paragraph (c)(2) of this section for the first 15 days of the month and divide by the number of days for which there is a daily price.

(d) *Edible whey price.* "Edible whey price" means the simple average, for the first 15 days of the month, of the daily prices per pound of edible whey powder (nonhygroscopic). The prices used shall be the prices (using the midpoint of any price range as one price) of edible whey powder for the Central States production area, as reported and published weekly by the Dairy Division, Agricultural Marketing Service. The average shall be computed by the Director of the Dairy Division, using the price reported each week as the daily price for that day and for each preceding work-day until the day such price was previously reported. A work-day is each Monday through Friday, except national holidays.

Handler Reports

§ 1125.30 Reports of receipts and utilization.

On or before the 9th day of each month each handler shall report to the market administrator, in the detail and on forms prescribed by the market administrator, the following information for the preceding month:

(a) Each handler operating a pool plant(s) shall report separately for each pool plant:

(1) The quantities of skim milk and butterfat contained in:

(i) Milk received directly from producers, showing separately any milk of own-farm production;

(ii) Milk received from a cooperative association pursuant to § 1125.9(c);

(iii) Fluid milk products and bulk fluid cream products received from other pool plants showing filled milk separately;

(iv) Other source milk showing filled milk separately; and

(v) Inventories at the beginning and end of the month of fluid milk products and products specified in § 1125.40(b)(1).

(2) The utilization of all skim milk and butterfat required to be reported, including separate statements of quantities in route disposition inside and outside the marketing area.

(b) Each producer-handler shall report:

(1) The quantities of skim milk and butterfat contained in:

(i) Milk of own-farm production;

(ii) Receipts of fluid milk products and fluid cream products from pool plants, showing separately receipts in packaged form and in bulk; and

(iii) Other source milk, showing separately any receipts from another dairy farmer.

(2) As specified in paragraph (a)(2) of this section.

(c) Each cooperative association shall report with respect to milk for which it is the handler pursuant to either § 1125.9 (b) or (c):

(1) The quantities of skim milk and butterfat received from producers;

(2) The utilization of skim milk and butterfat for which it is the handler pursuant to § 1125.9(b); and

(3) The quantities of skim milk and butterfat delivered to each pool plant pursuant to § 125.9(c).

(d) Each handler who operates a partially regulated distributing plant shall report as specified in paragraphs (a) (1) and (2) of this section except that receipts from dairy farmers in Grade A milk shall be reported in lieu of those in producer milk. Such report shall include separate statements, respectively, showing the respective amounts of skim milk and butterfat disposed of as route disposition in the marketing area as Class I milk and the quantity of reconstituted skim milk in fluid milk products disposed of as route disposition in the marketing area.

(e) Each handler who operates an other order plant with route disposition of fluid milk products in the marketing area shall report the quantities of skim milk and butterfat in such disposition.

§ 1125.31 Payroll reports.

On or before the 22nd day of each month handlers shall report to the market administrator as follows:

(a) Each handler with respect to each of his pool plants and each cooperative association which is a handler pursuant to § 1125.9 (b) or (c) shall submit his producer payroll for deliveries (other than his own-farm production) in the preceding month which shall show:

(1) The total pounds of milk received from each producer, the pounds of butterfat contained in such milk, and the number of days on which milk was delivered by such producer in such month;

(2) The amount of payment to each producer and cooperative association; and

(3) The nature and amount of any deductions or charges involved in such payments.

(b) Each handler operating a partially regulated distributing plant who wishes computations pursuant to § 1125.76(a) to be considered in the computation of his obligation pursuant to § 1125.76 shall submit his payroll for deliveries of Grade A milk by dairy farmers which shall show:

(1) The total pounds of milk and the butterfat content thereof received from each dairy farmer;

(2) The amount of payment to each dairy farmer (or to a cooperative association on behalf of such dairy farmer); and

(3) The nature and amount of any deductions or charges involved in such payments.

§ 1125.32 Other reports.

At such time and in such manner as the market administrator may prescribe, each handler shall report to the market administrator such information in addition to that required under §§ 1125.30 and 1125.31 as may be requested by the market administrator with respect to milk and milk products (including filled milk) handled by him.

Classification of Milk

§ 1125.40 Classes of utilization.

Except as provided in § 1125.42 all skim milk and butterfat required to be reported by a handler pursuant to § 1125.30 shall be classified as follows:

(a) *Class I milk.* Class I milk shall be all skim milk and butterfat:

(1) Disposed of in the form of a fluid milk product, except as otherwise provided in paragraphs (b) and (c) of this section;

(2) In packaged inventory of fluid milk products at the end of the month; and

(3) Not specifically accounted for as Class II or Class III milk.

(b) *Class II milk.* Class II milk shall be all skim milk and butterfat:

(1) Disposed of in the form of a fluid cream product, eggnog, yogurt, and any product containing 6 percent or more non-milk fat (or oil) that resembles a fluid cream product, eggnog, or yogurt, except as otherwise provided in paragraph (c) of this section;

(2) In packaged inventory at the end of the month of the products specified in paragraph (b)(1) of this section;

(3) In all bulk fluid milk products and bulk fluid cream products disposed of to any commercial food processing establishment, or in producer milk diverted to a commercial food processing establishment in Pacific County, Washington, subject to the conditions of § 1125.42(e), at which food products (other than milk products and filled milk) are processed and from which there is no disposition of fluid milk products or fluid cream products other than those received in consumer-type packages; and

(4) Used to produce:

(i) Cottage cheese, lowfat cottage cheese, and dry curd cottage cheese;

(ii) Milkshake and ice milk mixes (or bases) containing 20 percent or more total solids, frozen desserts, and frozen dessert mixes;

(iii) Any concentrated milk product in bulk fluid form other than that specified in paragraph (c)(1)(iv) of this section;

(iv) Plastic cream, frozen cream and anhydrous milkfat;

(v) Custards, puddings, and pancake mixes;

(vi) Formulas especially prepared for infant feeding or dietary use that are packaged in hermetically sealed glass or all-metal containers; and

(vii) Any milk or milk product sterilized and packaged in hermetically sealed metal or glass containers.

(c) *Class III milk.* Class III milk shall be all skim milk and butterfat:

(1) Used to produce:

(i) Cheese (other than cottage cheese, lowfat cottage cheese, and dry curd cottage cheese);

(ii) Butter;

(iii) Any milk product in dry form;

(iv) Any concentrated milk product in bulk fluid form that is used to produce a Class III product;

(v) Evaporated or condensed milk (plain or sweetened) in a consumer-type package and evaporated or condensed skim milk (plain or sweetened) in a consumer-type package; and

(vi) Any product not otherwise specified in this section;

(2) In inventory at the end of the month of fluid milk products in bulk form and products specified in paragraph (b)(1) of this section in bulk form;

(3) In fluid milk products and products specified in paragraph (b)(1) of this section that are disposed of by a handler for animal feed;

(4) In fluid milk products and products specified in paragraph (b)(1) of this section that are dumped by a handler if the market administrator is notified of such dumping in advance and is given the opportunity to verify such disposition;

(5) In skim milk in any modified fluid milk product that is in excess of the quantity of skim milk in such product that was included within the fluid milk product definition pursuant to § 1125.15; and

(6) In shrinkage assigned pursuant to § 1125.41(a) to the receipts specified in § 1125.41(a)(2) and in shrinkage specified in § 1125.41 (b) and (c).

§ 1125.41 Shrinkage.

For purposes of classifying all skim milk and butterfat to be reported by a handler pursuant to § 1125.30, the market administrator shall determine the following:

(a) The pro rata assignment of shrinkage of skim milk and butterfat, respectively, at each pool plant to the respective quantities of skim milk and butterfat:

(1) In the receipts specified in paragraphs (b) (1) through (6) of this section on which shrinkage is allowed pursuant to such paragraph; and

(2) In other source milk not specified in paragraphs (b) (1) through (6) of this section which was received in the form of a bulk fluid milk product or a bulk fluid cream product;

(b) The shrinkage of skim milk and butterfat, respectively, assigned pursuant to paragraph (a) of this section to the receipts specified in paragraph (a)(1) of this section that is not in excess of:

(1) Two percent of the skim milk and butterfat, respectively, in producer milk (excluding milk diverted by the plant operator to a nonpool plant or to a commercial food processing establishment pursuant to § 1125.40(b)(3) and milk received from a handler described in § 1125.9(c));

(2) Plus 1.5 percent of the skim milk and butterfat, respectively, in milk received from a handler described in § 1125.9(c), except that if the operator of the plant to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm and butterfat tests determined from farm bulk tank samples, the applicable percentage under this paragraph shall be 2 percent;

(3) Plus 0.5 percent of the skim milk and butterfat, respectively, in producer milk diverted from such plant by the plant operator to a nonpool plant or to a commercial food processing establishment pursuant to § 1125.40(b)(3), except that if the operator of the plant or establishment to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm and butterfat tests determined from farm bulk tank samples, the applicable percentage under this paragraph shall be zero;

(4) Plus 1.5 percent of the skim milk and butterfat, respectively, in bulk fluid milk products received by transfer from other pool plants;

(5) Plus 1.5 percent of the skim milk and butterfat, respectively, in bulk fluid milk products received by transfer from other order plants, excluding the quantity for which Class II or Class III classification is requested by the operator of both plants;

(6) Plus 1.5 percent of the skim milk and butterfat, respectively, in bulk fluid milk products received from unregulated supply plants, excluding the quantity for which Class II or Class III classification is requested by the handler; and

(7) Less 1.5 percent of the skim milk and butterfat, respectively, in bulk fluid milk products transferred to other plants that is not in excess of the respective amounts of skim milk and butterfat to which percentages are applied in paragraphs (b) (1), (2), (4), (5), and (6) of this section; and

(c) The quantity of skim milk and butterfat, respectively, in shrinkage of milk from producers for which a cooperative association is the handler pursuant to § 1125.9 (b) or (c) but not in excess of 0.5 percent of the skim milk and butterfat, respectively, in such milk. If the operator of a plant or a commercial food processing establishment pursuant to § 1125.40(b)(3) to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm and butterfat tests determined from farm bulk tank samples, the applicable percentage under this paragraph for the cooperative association shall be zero.

§ 1125.42 Classification of transfers and diversions.

(a) *Transfers to pool plants.* Skim milk or butterfat transferred in the form of a fluid milk product or a bulk fluid cream product from a pool plant to another pool plant shall be classified as Class I milk unless the operators of both plants request the same classification in another class. In either case, the classification of such transfers shall be subject to the following conditions:

(1) The skim milk or butterfat classified in each class shall be limited to the amount of skim milk and butterfat, respectively, remaining in such class at the transferee-plant after the computation pursuant to § 1125.44(a)(13) and the corresponding step of § 1125.44(b);

(2) If the transferor-plant received during the month other source milk to be

allocated pursuant to § 1125.44(a)(8) or the corresponding step of § 1125.44(b), the skim milk or butterfat so transferred shall be classified so as to allocate the least possible Class I utilization to such other source milk; and

(3) If the transferor-handler received during the month other source milk to be allocated pursuant to § 1125.44(a) (12) or (13) or the corresponding steps of § 1125.44(b), the skim milk or butterfat so transferred up to the total of the skim milk and butterfat, respectively, in such receipts of other source milk, shall not be classified as Class I milk to a greater extent than would be the case if the other source milk had been received at the transferee-plant.

(b) *Transfers and diversions to other order plants.* Skim milk or butterfat transferred or diverted in the form of a fluid milk product or a bulk fluid cream product from a pool plant to an other order plant shall be classified in the following manner. Such classification shall apply only to the skim milk or butterfat that is in excess of any receipts at the pool plant from the other order plant of skim milk and butterfat, respectively, in fluid milk products and bulk fluid cream products, respectively, that are in the same category as described in paragraph (b) (1), (2), or (3) of this section:

(1) If transferred as packaged fluid milk products, classification shall be in the classes to which allocated as a fluid milk product under the other order;

(2) If transferred in bulk form, classification shall be in the classes to which allocated under the other order (including allocation under the conditions set forth in paragraph (b)(3) of this section);

(3) If the operators of both plants so request in their reports of receipts and utilization filed with their respective market administrators, transfers or diversions in bulk form shall be classified as Class II or Class III milk to the extent of such utilization available for such classification pursuant to the allocation provisions of the other order;

(4) If information concerning the classes to which such transfers or diversions were allocated under the other order is not available to the market administrator for the purpose of establishing classification under this paragraph, classification shall be as Class I, subject to adjustments when such information is available;

(5) For purposes of this pargraph, if the other order provides for a different number of classes of utilization than is provided for under this part, skim milk or butterfat allocated to a class consisting primarily of fluid milk products shall be classified as Class I milk, and skim milk or butterfat allocated to the other classes shall be classified as Class III milk; and

(6) If the form in which any fluid milk product that is transferred to an other order plant is not defined as a fluid milk product under such other order, classification under this paragraph shall be in accordance with the provisions of § 1125.40.

(c) *Transfers and diversions to producer-handlers.* Skim milk or butterfat transferred or diverted in the following forms from a pool plant to a producer-handler under this or any other Federal order shall be classified:

(1) As class I milk if transferred or diverted in the form of a fluid milk product; and

(2) In accordance with the utilization assigned to it by the market administrator, if transferred in the form of a bulk fluid cream product. For this purpose, the transferee's utilization of skim milk and butterfat in each class, in series beginning with Class III, shall be assigned to the extent possible to his receipts of skim milk and butterfat, respectively, in bulk fluid cream products, pro rata to each source.

(d) *Transfers and diversions to other nonpool plants.* Skim milk or butterfat transferred or diverted in the following forms from a pool plant to a nonpool plant that is not an other order plant or a producer-handler plant shall be classified:

(1) As Class I milk, if transferred in the form of a packaged fluid milk product; and

(2) As Class I milk, if transferred or diverted in the form of a bulk fluid milk product or a bulk fluid cream product, unless the following conditions apply:

(i) If the conditions described in paragraphs (d)(2)(i) (*a*) and (*b*) of this section are met, transfers or diversions in bulk form shall be classified on the basis of the assignment of the nonpool plant's utilization to its receipts as set forth in paragraphs (d)(2) (ii) through (viii) of this section:

(*a*) The transferor-handler or divertor-handler claims such classification in his report of receipts and utilization filed pursuant to § 1125.30 for the month within which such transaction occurred; and

(*b*) The nonpool plant operator maintains books and records showing the utilization of all skim milk and butterfat received at such plant which are made available for verification purposes if requested by the market administrator;

(ii) Route disposition in the marketing area of each Federal milk order from the nonpool plant and transfers of packaged fluid milk products from such nonpool plant to plants fully regulated thereunder shall be assigned to the extent possible in the following sequence:

(*a*) Pro rata to receipts of packaged fluid milk products at such nonpool plant from pool plants;

(*b*) Pro rata to any remaining unassigned receipts of packaged fluid milk products at such nonpool plant from other order plants;

(*c*) Pro rata to receipts of bulk fluid milk products at such nonpool plant from pool plants; and

(*d*) Pro rata to any remaining unassigned receipts of bulk fluid milk products at such nonpool plant from other order plants;

(iii) Any remaining Class I disposition of packaged fluid milk products from the nonpool plant shall be assigned to the extent possible pro rata to any remaining unassigned receipts of packaged fluid milk products at such nonpool plant from pool plants and other order plants;

(iv) Transfers of bulk fluid milk products from the nonpool plant to a plant fully regulated under any Federal milk order, to the extent that such transfers to the regulated plant exceed receipts of fluid milk products from such plant and are allocated to Class I at the transferee-plant, shall be assigned to the extent possible in the following sequence:

(*a*) Pro rata to receipts of fluid milk products at such nonpool plant pool plants; and

(*b*) Pro rata to any remaining unassigned receipts of fluid milk products at such nonpool plant from other order plants;

(v) Any remaining unassigned Class I disposition from the nonpool plant shall be assigned to the extent possible in the following sequence:

(*a*) To such nonpool plant's receipts from dairy farmers who the market administrator determines constitute regular sources of Grade A milk for such nonpool plant; and

(*b*) To such nonpool plant's receipts of Grade A milk from plants not fully regulated under any Federal milk order which the market administrator determines constitute regular sources of Grade A milk for such nonpool plant;

(vi) Any remaining unassigned receipts of bulk fluid milk products at the nonpool plant from pool plants and other order plants shall be assigned pro rata among such plants, to the extent possible first to any remaining Class I utilization, then to Class III utilization, and then to Class II utilization at such nonpool plant;

(vii) Receipts of bulk fluid cream products at the nonpool plant from pool plants and other order plants shall be assigned, pro rata among such plants, to the extent possible first to any remaining Class III utilization, then to any remaining Class II utilization, and then to Class I utilization at such nonpool plant; and

(viii) In determining the nonpool plant's utilization for purposes of this subparagraph, any fluid milk products and bulk fluid cream products transferred from such nonpool plant to a plant not fully regulated under any Federal milk order shall be classified on the basis of the second plant's utilization using the same assignment priorities at the second plant that are set forth in this subparagraph.

(e) *Transfers and diversions to a commercial food processing establishment.* Skim milk and butterfat transferred or diverted to a commercial food processing establishment shall be classified:

(1) Subject to the provisions of § 1125.13(c) and, except as provided in paragraph (e)(2) of this section, as Class II milk if diverted pursuant to § 1125.40(b)(3); or

(2) Transfers or diversions shall be classified as Class I milk unless the market administrator is permitted to audit the records of the commercial food processing establishment for the purpose of verification.

§ 1125.43 General classification rules.

In determining the classification of producer milk pursuant to § 1125.44 , the following rules shall apply:

(a) Each month the market administrator shall correct for mathematical and other obvious errors all reports filed pursuant to § 1125.30 and shall compute separately for each pool plant and for each cooperative association with respect to milk for which it is the handler pursuant to § 1125.9 (b) or (c) the pounds of skim milk and butterfat, respectively, in each class in accordance with §§ 1125.40, 1125.41, and 1125.42;

(b) If any of the water contained in the milk from which a product is made is removed before the product is utilized or disposed of by a handler, the pounds of skim milk in such product that are to be considered under this part as used or disposed of by the handler shall be an amount equivalent to the nonfat milk solids contained in such product plus all of the water originally associated with such solids;

(c) The classification of producer milk for which a cooperative association is the handler pursuant to § 1125.9 (b) or (c) shall be determined separately from the operations of any pool plant operated by such cooperative association; and

(d) For classification purposes, pursuant to §§ 1125.40 through 1125.45, butterfat in skim milk, either disposed of to others or used in the manufacture of milk products shall be accounted for at a butterfat content of 0.060 percent unless the handler has adequate records of the actual butterfat content of such skim milk.

§ 1125.44 Classification of producer milk.

For each month the market administrator shall determine the classification of producer milk of each handler described in § 1125.9(a) for each of his pool plants separately and of each handler described in § 1125.9 (b) and (c) by allocating the handler's receipts of skim milk and butterfat to his utilization as follows:

(a) Skim milk shall be allocated in the following manner:

(1) Subtract from the total pounds of skim milk in Class III the pounds of skim milk in shrinkage specified in § 1125.41(b);

(2) Subtract from the total pounds of skim milk in Class I the pounds of skim milk in receipts of packaged fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk disposed of to such plant by handlers fully regulated under any federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

(3) Subtract from the pounds of skim milk remaining in each class the pounds of skim milk in fluid milk products received in packaged form from another order plant, except that to be subtracted pursuant to paragraph (a)(8)(vi) of this section, as follows:

(i) From Class III milk, the lesser of the pounds remaining or 2 percent of such receipts; and

(ii) From Class I milk, the remainder of such receipts;

(4) Subtract from the remaining pounds of skim milk in Class I the pounds of skim milk in packaged fluid milk products in inventory at the beginning of the month. This paragraph shall apply only if the pool plant was subject to the provisions of this paragraph or comparable provisions of another Federal milk order in the immediately preceding month;

(5) Subtract from the pounds of skim milk in Class II the pounds of skim milk in products specified in § 1125.40(b)(1) that were received in packaged form from other plants, but not in excess of the pounds of skim milk remaining in Class II;

(6) Subtract from the remaining pounds of skim milk in Class II the pounds of skim milk in products specified in § 1125.40(b)(1) that were in inventory at the beginning of the month in packaged from, but not in excess of the pounds of skim milk remaining in Class II. This paragraph shall apply only if the pool plant was subject to the provisions of this paragraph or comparable provisions of another Federal milk order in the immediately preceding month;

(7) Subtract from the remaining pounds of skim milk in Class II the pounds of skim milk in other source milk (except that received in the form of a fluid milk product or a fluid cream product) that is used to produce, or added to any product specified in § 1125.40(b) but not in excess of the pounds of skim milk remaining in Class II;

(8) Subtract in the order specified below from the pounds of skim milk remaining in each class, in series beginning with Class III, the pounds of skim milk in each of the following:

(i) Other source milk (except that received in the form of a fluid milk product) and, if paragraph (a)(6) of this section applies, packaged inventory at the beginning of the month of products specified in § 1125.40(b)(1) that was not subtracted pursuant to paragraphs (a)(5), (6), and (7) of this section;

(ii) Receipts of fluid milk products (except filled milk) for which Grade A certification is not established;

(iii) Receipts of fluid milk products from unidentified sources;

(iv) Receipts of fluid milk products from a producer-handler as defined under this or any other Federal milk order and from an exempt distributing plant;

(v) Receipts of reconstituted skim milk in filled milk from an unregulated supply plant that were not subtracted pursuant to paragraph (a)(2) of this section;

(vi) Receipts of reconstituted skim milk in filled milk from an other order plant that is regulated under any Federal milk order providing for individual-handler pooling, to the extent that reconstituted skim milk is allocated to Class I at the transferor-plant; and

(vii) Receipts of fluid milk products from a person described in § 1125.12(b)(5);

(9) Subtract in the order specified below from the pounds of skim milk remaining in Class II and Class III, in sequence beginning with Class III:

(i) The pounds of skim milk in receipts of fluid milk products from an unregulated supply plant that were not subtracted pursuant to paragraphs (a)(2)

and (8)(v) of this section for which the handller requests a classification other than Class I, but not in excess of pounds of skim milk remaining in Class II and Class III combined;

(ii) The pounds of skim milk in receipts of fluid milk products from an unregulated supply plant that were not subtracted pursuant to paragraphs (a)(2), (8)(v), and (9)(i) of this section which are in excess of the pounds of skim milk determined pursuant to paragraphs (a)(9)(ii) (*a*) through (*c*) of this section. Should the pounds of skim milk to be subtracted from Class II and Class III combined exceed the pounds of skim milk remaining in such classes, the pounds of skim milk in Class II and Class III combined shall be increased (increasing as necessary Class III and then Class II to the extent of available utilization in such classes at the nearest other pool plant of the handler, and then at each successively more distant pool plant of the handler) by an amount equal to such excess quantity to be subtracted and the pounds of skim milk in Class I shall be decreased by a like amount. In such case, the pounds of skim milk remaining in each class at this allocation step at the handler's other pool plants shall be adjusted in the reverse direction by a like amount:

(*a*) Multiply by 1.25 the sum of the pounds of skim milk remaining in Class I at this allocation step at all pool plants of the handler (excluding any duplication of Class I utilization resulting from reported Class I transfers between pool plants of the handler);

(*b*) Subtract from the above result the sum of the pounds of skim milk in receipts at all pool plants of the handler of producer milk, fluid milk products from pool plants of other handlers, and bulk fluid milk products from other order plants that were not subtracted pursuant to paragraph (a)(8)(vi) of this section; and

(*c*) Multiply any plus quantity resulting above by the percentages that the receipts of skim milk in fluid milk products from unregulated supply plants that remain at this pool plant is of all such receipts remaining at this allocation step at all pool plants of the handler; and

(iii) The pounds of skim milk in receipts of bulk fluid milk products from an other order plant that are in excess of bulk fluid milk products transferred or diverted to such plant and that were not subtracted pursuant to paragraph (a)(8)(vi) of this section, if Class II or Class III classification is requested by the operator of the other order plant and the handler but not in excess of the pounds of skim milk remaining in Class II and Class III combined;

(10) Subtract from the pounds of skim milk remaining in each class, in series, beginning with Class III, the pounds of skim milk in fluid milk products and products specified in § 1125.40(b)(1) in inventory at the beginning of the month that were not subtracted pursuant to paragraphs (a) (4), (6), and (8)(i) of this section;

(11) Add to the remaining pounds of skim milk in Class III the pounds of skim milk subtracted pursuant to paragraph (a)(1) of this section;

(12) Subject to the provisions of paragraphs (a)(12) (i) and (ii) of this section, subtract from the pounds of skim milk remaining in each class at the plant, pro rata to the total pounds of skim milk remaining in Class I and in Class II and Class III combined at this allocation step at all pool plants of the handler (excluding any duplication of utilization in each class resulting from transfers between pool plants of the handler), with the quantity prorated, to class II and Class III combined being subtracted first from Class III and then from Class II, the pounds of skim milk in receipts of fluid milk products from an unregulated supply plant that were not subtracted pursuant to paragraphs (a)(2), (8)(v), (9) (i) and (ii) of this section and that were not offset by transfers or diversions of fluid milk products to the same unregulated supply plant from which fluid milk products to be allocated at this step were received:

(i) Should the pounds of skim milk to be subtracted from Class II and Class III combined pursuant to this paragraph exceed the pounds of skim milk remaining in such classes, the pounds of skim milk in Class II and Class III combined shall be increased (increasing as necessary Class III and then Class II to the extent of available utilization in such classes at the nearest other pool plant of the handler, and then at each successively more distant pool plant of the handler) by an amount equal to such excess quantity to be subtracted, and the pounds of skim milk in Class I shall be decreased by a like amount. In such case, the pounds of skim milk remaining in each class at this allocation step at the handler's other pool plants shall be adjusted in the reverse direction by a like amount; and

(ii) Should the pounds of skim milk to be subtracted from Class I pursuant to this paragraph exceed the pounds of skim milk remaining in such class, the pounds of skim milk in Class I shall be increased by an amount equal to such excess quantity to be subtracted, and the pounds of skim milk in Class II and Class III combined shall be decreased by a like amount (decreasing as necessary Class III and then Class II). In such case, the pounds of skim milk remaining in each class at this allocation step at the handler's other pool plants shall be adjusted in reverse the direction by a like amount, beginning with the nearest plant at which Class I utilization is available;

(13) Subtract in the manner specified below from the pounds of skim milk remaining in each class the pounds of skim milk in receipts of bulk fluid milk products from an other order plant that are in excess of bulk fluid milk products transferred or diverted to such plant and that were not subtracted pursuant to paragraphs (a)(8)(vi) and (9)(iii) of this section:

(i) Subject to the provisions of paragraphs (a)(13) (ii), (iii), and (iv) of this section, such subtraction shall be pro rata to the pounds of skim milk in Class I and in Class II and Class III combined, with the quantity prorated to Class II and Class III combined being subtracted first from Class III and then from Class II, with respect to whichever of the following quantities represents the lower proportion of Class I milk:

(*a*) The estimated utilization of skim milk of all handlers in each class as announced for the month pursuant to § 1125.45(a); or

(*b*) The total pounds of skim milk remaining in each class at this allocation step at all pool plants of the handler (excluding any duplication of utilization in each class resulting from transfers between pool plants of the handler);

(ii) Should the proration pursuant to paragraph (a)(13)(i) of this section result in the total pounds of skim milk at all pool plants of the handler that are to be subtracted at this allocation step from Class II and Class III combined exceeding the pounds of skim milk remaining in Class II and Class III at all such plants, the pounds of such excess shall be subtracted from the pounds of skim milk remaining in Class I after such proration at the pool plants at which such other source milk was received;

(iii) Except as provided in paragraph (a)(13)(ii) of this section, should the computations pursuant to paragraph (a)(13) (i) or (ii) of this section result in a quantity of skim milk to be subtracted from Class II and Class III combined that exceed the pounds of skim milk remaining in such classes, the pounds of skim milk in class II and Class III combined shall be increased (increasing as necessary Class III and then Class II to the extent of available utilization in such classes at the nearest other pool plant of the handler, and then at each successively more distant pool plant of the handler) by an amount equal to such

excess quantity to be subtracted, and the pounds of skim milk in Class I shall be decreased by a like amount. In such case, the pounds of skim milk remaining in each class at this allocation step at the handler's other pool plant(s) shall be adjusted in the reverse direction by a like amount; and

(iv) Except as provided in paragraph (a)(13) (ii) of this section, should the computations pursuant to paragraph (a)(13) (i) or (ii) of this section result in a quantity of skim milk to be subtracted from Class I that exceeds the pounds of skim milk remaining in such class, the pounds of skim milk in Class I shall be increased by an amount equal to such excess quantity to be subtracted, and the pounds of skim milk in Class II and Class III combined shall be decreased by a like amount (decreasing as necessary Class III and then Class II). In such case, the pounds of skim milk remaining in each class at this allocation step at the handler's other pool plants shall be adjusted in the reverse direction by a like amount beginning with the nearest plant at which Class I utilization is available;

(14) Subtract from the pounds of skim milk remaining in each class the pounds of skim milk in receipts of fluid milk products and bulk fluid cream products from another pool plant according to the classification of such products pursuant to § 1125.42(a); and

(15) If the total pounds of skim milk remaining in all classes exceed the pounds of skim in producer milk, subtract such excess from the pounds of skim milk remaining in each class in series beginning with Class III. Any amount so subtracted shall be known as "overage";

(b) Butterfat shall be allocated in accordance with the procedure outlined for skim milk in paragraph (a) of this section; and

(c) The quantity of producer milk in each class shall be the combined pounds of skim milk and butterfat remaining in each class after the computations pursuant to paragraph (a)(15) of this section and the corresponding step of paragraph (b) of this section.

§ 1125.45 Market administrator's reports and announcements concerning classification.

The market administrator shall make the following reports and announcements concerning classification:

(a) Whenever required for the purpose of allocating receipts from other order plants pursuant to § 1125.44(a)(13) and the corresponding step of § 1125.44(b), estimate and publicly announce the utilization (to the nearest whole percentage) in each class during the month of skim milk and butterfat, respectively, in producer milk of all handlers. Such estimate shall be based upon the most current available data and shall be final for such purpose.

(b) Report to the market administrator of the other order, as soon as possible after the report of receipts and utilization for the month is received from a handler who has received fluid milk products or bulk fluid cream products from an other order plant, the class to which such receipts are allocated pursuant to § 1125.44 on the basis of such report, and thereafter, any change in such allocation required to correct errors disclosed in the verification of such report.

(c) Furnish to each handler operating a pool plant who has shipped fluid milk products or bulk fluid cream products to an other order plant the class to which such shipments were allocated by the market administrator of the other order on the basis of the report by the receiving handler, and, as necessary, any changes in such allocation arising from the verification of such report.

(d) On or before the 14th day after the end of each month, report to each cooperative association which so requests the amount and class utilization of producer milk delivered by members of such cooperative association to each handler receiving such milk. For the purpose of this report the milk so received shall be prorated to each class in accordance with the total utilization of producer milk by such handler.

Class Prices

§ 1125.50 Class prices.

Subject to the provisions of § 1125.52, the class prices for the month, per hundredweight of milk, shall be as follows:

(a) *Class I price.* The Class I price shall be the basic formula price for the second preceding month plus $1.85.

(b) *Class II price.* A tentative Class II price shall be computed by the Director of the Dairy Division and transmitted to the market administrator on or before the 15th day of the preceding month. The tentative Class II price shall be the basic Class II formula price for the month plus the amount that the value computed pursuant to paragraph (b)(1) of this section exceeds the value computed pursuant to paragraph (b)(2) of this section, except that in no event shall the final Class II price be less than the Class III price. If the Class III price for the month is computed pursuant to paragraphs (c) (1) through (3) of this section, the final Class II price shall be reduced by the amount that the Class III price is less than the basic formula price to the extent such reduction does not cause the Class II price to be less than the Class III price.

(1) Determine for the most recent 12-month period the simple average (rounded to the nearest cent) of the basic formula prices computed pursuant to § 1125.51 and add 25 cents; and

(2) Determine for the same 12-month period as specified in paragraph (b)(1) of this section the simple average (rounded to the nearest cent) of the basic Class II formula prices computed pursuant to § 1125.51a.

(c) *Class III price.* The Class III price shall be the basic formula price for the month but not to exceed the price computed as follows:

(1) Multiply the Chicago butter price pursuant to § 1125.51 by 4.2;

(2) Multiply by 8.2 the weighted average of carlot prices per pound for nonfat dry milk solids, spray process, for human consumption, f.o.b. manufacturing plants in the Chicago area, as published for the period from the 26th day of the immediately preceding month through the 25th day of the current month by the Department; and

(3) From the sum of the results arrived at under paragraphs (c) (1) and (2) of this section subtract 48 cents, and round to the nearest cent.

§ 1125.51 Basic formula price.

The "basic formula price" shall be the average price per hundredweight for manufacturing grade milk, f.o.b. plants in Minnesota and Wisconsin, as reported by the Department for the month, adjusted to 3.5 percent butterfat basis and rounded to the nearest cent. For such adjustment, the butterfat differential (rounded to the nearest one-tenth cent) per one-tenth percent butterfat shall be 0.12 times the simple average of the wholesale selling prices (using the midpoint of any price range as one price) of Grade A (92-score) bulk butter per pound at Chicago, as reported by the Department for the month.

§ 1125.51a Basic Class II formula price.

The "basic Class II formula price" for the month shall be the basic formula price determined pursuant to § 1125.51 for the second preceding month plus or minus the amount computed pursuant to paragraphs (a) through (d) of this section:

(a) The gross values per hundredweight of milk used to manufacture cheddar cheese and butter-nonfat dry milk shall be computed, using price data determined pursuant to

§ 1125.19 and yield factors in effect under the Dairy Price Support Program authorized by the Agricultural Act of 1949, as amended, for the first 15 days of the preceding month and, separately, for the first 15 days of the second preceding month as follow:

(1) The gross value of milk used to manufacture cheddar cheese shall be the sum of the following computations:

(i) Multiply the cheddar cheese price by the yield factor used under the Price Support Program for cheddar cheese;

(ii) Multiply the butter price by the yield factor used under the Price Support Program for determining the butterfat component of the whey value in the cheese price computation; and

(iii) Subtract from the edible whey price the processing cost used under the Price Support Program for edible whey and multiply any positive difference by the yield factor used under the Price Support Program for edible whey.

(2) The gross value of milk used to manufacture butter-nonfat dry milk shall be the sum of the following computations:

(i) Multiply the butter price by the yield factor used under the Price Support Program for butter; and

(ii) Multiply the nonfat dry milk price by the yield factor used under the Price Support Program for nonfat dry milk.

(b) Determine the amounts by which the gross value per hundredweight of milk used to manufacture cheddar cheese and the gross value per hundredweight of milk used to manufacture butter-nonfat dry milk for the first 15 days of the preceding month exceed or are less than the respective gross values for the first 15 days of the second preceding month.

(c) Compute weighting factors to be applied to the changes in gross values determined pursuant to paragraph (b) of this section by determining the relative proportion that the data included in each of the following subparagraphs is of the total of the data represented in paragraphs (c) (1) and (2) of this section:

(1) Combine the total American cheese production for the States of Minnesota and Wisconsin, as reported by the Statistical Reporting Service of the Department for the most recent preceding period, and divide by the yield factor used under the Price Support Program for cheddar cheese to determine the quantity of milk used in the production of American cheddar cheese; and

(2) Combine the total nonfat dry milk production for the States of Minnesota and Wisconsin, as reported by the Statistical Reporting Service of the Department for the most recent preceding period, and divide by the yield factor used under the Price Support Program for nonfat dry milk to determine the quantity of milk used in the production of butter-nonfat dry milk.

(d) Compute a weighted average of the changes in gross values per hundredweight of milk determined pursuant to paragraph (b) of this section in accordance with the relative proportions of milk determined pursuant to paragraph (c) of this section.

§ 1125.52 Plant location adjustments for handlers.

(a) The following zones are defined for the purpose of determining location adjustments:

(1) Zone 1 shall include the Washington counties of King, Kitsap, Pierce, and Snohomish;

(2) Zone 2 shall include:

(i) The Idaho counties of Benewah, Bonner, Boundary, Kootenai, Latah, and Shoshone;

(ii) The Oregon counties of Benton, Clackamas, Columbia, Hood River, Linn, Marion, Multnomah, Polk, Wasco, Washington, and Yamhill; and

(iii) The Washington counties of Clark, Cowlitz, Ferry, Lincoln, Pend Orielle, Skamania, Spokane, Stevens, Wahkiakum, and Whitman;

(3) Zone 3 shall include the Washington counties of Island, Mason, Skagit, and Thurston;

(4) Zone 4 shall include the Washington counties of Grays Harbor, Lewis, Pacific, and Whatcom;

(5) Zone 5 shall include:

(i) The Idaho counties of Lewis and Nez Perce;

(ii) The Oregon counties of Gilliam, Morrow, Sherman, and Umatilla; and

(iii) The Washington counties of Adams, Asotin, Benton, Chelan, Columbia, Douglas, Franklin, Garfield, Grant, Kittitas, Klickitat, Okanogan, Walla Walla, and Yakima; and

(6) Zone 6 shall include the Washington counties of Clallam, Jefferson, and San Juan.

(b) For milk received at a plant from producers and which is classified as Class I milk, the price specified in § 1125.50(a) shall be adjusted by the amount stated in paragraphs (b) (1) and (2) of this section for the location of such plant:

(1) For a plant located within one of the zones described in paragraphs (a) (1) through (6) of this section, the adjustment shall be as follows:

	Adjustment per hundredweight
Zone 1	No adjustment
Zone 2	Plus 10 cents
Zone 3	Minus 4 cents
Zone 4	Minus 6 cents
Zone 5	Minus 10 cents
Zone 6	Minus 16 cents

(2) For a plant located outside of one of the zones described in paragraphs (a) (1) through (6) of this section, the adjustment shall be minus 1.5 cents per hundredweight for each 10 miles or fraction thereof by shortest hard-surfaced highway distance that the plant is located from the nearer of the County Courthouse in Spokane or the County-City Building in Seattle.

(c) The Class I price applicable to other source milk shall be adjusted at the rates set forth in paragraph (b) of this section, except that the price when adjusted for location shall not be less than the the Class III price.

(d) For fluid milk products transferred in bulk from a pool plant to another pool plant at which a higher Class I price applies and which is classified as Class I, the price shall be the Class I price applicable at the location of the transferee-plant subject to a location adjustment credit for the transferor-plant determined by the market administrator as follows:

(1) Subtract from the pounds of Class I remaining at the transferee-plant after the computations pursuant to § 1125.44 (a)(13) and (b) the pounds of packaged fluid milk products from other pool plants;

(2) Subtract the pounds of bulk fluid milk products received at the transferee-plant from the following sources:

(i) Producers;

(ii) Handlers described in § 1125.9(c); and

(iii) Pool plants at which the same or a higher Class I price applies;

(3) Assign any pounds remaining to transferor-plants in sequence beginning with the plant at which the least adjustment would apply; and

(4) Multiply the pounds so computed for each transferor-plant by the difference in the Class I prices applicable at the transferee-plant and transferor-plant.

§ 1125.53 Announcement of class prices.

The market administrator shall announce publicly on or before the fifth day of each month the Class I price for the following month, the Class III price for the preceding month and the final Class II price for the preceding month; and on or before the 15th day of each month the tentative Class II price for the following month.

§ 1125.54 Equivalent price.

If for any reason a price or pricing constituent required by this part for

computing class prices or for other purposes is not available as prescribed in this part, the market administrator shall use a price or pricing constituent determined by the Secretary to be equivalent to the pricing constituent that is required.

Uniform Price

§ 1125.60 Handler's value of milk for computing uniform price.

For the purpose of computing the uniform price, the market administrator shall determine for each month the value of milk of each handler with respect to each of his pool plants and of each handler described in § 1125.9 (b) and (c) with respect to milk that was not received at a pool plant as follows:

(a) Multiply the quantity of producer milk in each class, as computed pursuant to § 1125.44(c), by the applicable class prices (adjusted pursuant to § 1125.52) and add together the resulting amounts;

(b) Add the amounts obtained from multiplying the pounds of overage deducted from each class pursuant to § 1125.44(a)(15) and the corresponding step of § 1125.44(b) by the class prices applicable at the location of the pool plant, as adjusted by the butterfat differential specified in § 1125.74. In case overage occurs in a nonpool plant located on the same premises as a pool plant, such overage shall be prorated between the quantity transferred from the pool plant and other source milk in such nonpool plant, add an amount equal to the value of overage allocated to the transferred quantity at the class price applicable at the pool plant;

(c) Add an amount equal to the difference between the value at the Class I price applicable at the pool plant and the value at the Class III price, with respect to skim milk and butterfat in other source milk subtracted from Class I pursuant to § 1125.44(a)(8) (i) through (iv) and (vii) and the corresponding step of § 1125.44(b) excluding receipts of bulk fluid cream products from an other order plant;

(d) Add the amount obtained from multiplying the difference between the Class I price applicable at the location of the transferor-plant and the Class III price by the hundredweight of skim milk and butterfat subtracted from Class I pursuant to § 1125.44(a)(8) (v) and (vi) and the corresponding step of § 1125.44(b);

(e) Add the amount obtained from multiplying the difference between the Class III price for the preceding month and the Class I price adjusted pursuant to § 1125.52, or the Class II price as the case may be, for the current month by the hundredweight of skim milk and butterfat subtracted from Class I and Class II pursuant to § 1125.44(a)(10) and the corresponding step of § 1125.44(b);

(f) Add an amount equal to the value at the Class I price, adjusted for location of the nearest nonpool plant(s) from which an equivalent volume was received, with respect to skim milk and butterfat subtracted from Class I pursuant to § 1125.44(a)(12) and the corresponding step of § 1125.44(b), excluding such skim milk or butterfat in bulk receipts of fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by a handler fully regulated under this or any other order issued pursuant to the Act is classified and priced as Class I milk and is not used as an offset on any payment obligation under this or any other order; and

(g) Add or subtract as the case may be, the amount necessary to correct errors as disclosed by the verification of reports of such handler of his receipts and utilization of skim milk and butterfat in previous months for which payment has not been made.

§ 1125.61 Computation of uniform price.

For each month the market administrator shall compute the "uniform price" per hundredweight for milk of 3.5 percent butterfat content received from producers as follows:

(a) Combine into one total the values computed pursuant to § 1125.60 for all handlers who filed the reports prescribed by § 1125.30 for the month and who made the payments pursuant to § 1125.71 for the preceding month;

(b) Add the aggregate of all minus location adjustments and subtract the aggregate of all plus location adjustments computed pursuant to § 1125.75;

(c) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(d) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(1) The total hundredweight of producer milk; and

(2) The total hundredweight for which a value is computed pursuant to § 1125.60(f); and

(e) Subtract not less than 4 cents nor more than 5 cents per hundredweight. The result shall be the "uniform price" for milk received from producers.

§ 1125.62 Announcement of uniform price and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The fifth day after the end of each month the butterfat differential for such month; and

(b) The 14th day after the end of each month the uniform price for such month.

Payments for Milk

§ 1125.70 Producer-settlement fund.

The market administrator shall establish and maintain a separate fund known as the "producer-settlement fund," into which he shall deposit all payments made by handlers pursuant to §§ 1125.71 and 1125.76 and out of which he shall make all payments to handlers pursuant to § 1125.72. However, the market administrator shall offset the payment due to a handler for such fund against payments due from such handler.

§ 1125.71 Payments to the producer-settlement fund.

(a) On or before the 16th day after the end of the month during which the skim milk and butterfat were received, each handler shall pay to the market administrator the amount, if any, by which the total amount specified in paragraph (a)(1) of this section exceeds the total amount specified in paragraph (a)(2) of this section:

(1) The sum of:

(i) The total value of milk of the handler for such month as determined pursuant to § 1125.60; and

(ii) For a cooperative association handler, the amount due from other handlers pursuant to § 1125.73(d) but without adjustment for butterfat;

(2) The sum of:

(i) The value of milk received by such handler from producers at the applicable uniform price pursuant to § 1125.73(a)(2) but without adjustmentfor butterfat;

(ii) The amount to be paid to cooperative associations pursuant to §11.25.73(d) but without adjustment for butterfat; and

(iii) The value at the uniform price for all skim milk and butterfat applicable at the location of the plants(s) from which received (not to be less than the value at the Class III price) with respect to other source milk for which a value is computed pursuant to §1125.60(f).

(b) On or before the 25th day after the end of the month, each handler operating a plant specified in § 1125.7(c) (2) and (3), if such plant is subject to the classification and pricing provisions of another order which provides for individual handler pooling, shall pay to the market administrator for the producer-settlement fund an amount computed as follows:

(1) Determine the quantity of reconstituted skim milk in filled milk

disposed of as route disposition in the marketing area which was allocated to Class I at such other order plant. If reconstituted skim milk in filled milk is disposed of from such plant as route disposition in the marketing areas regulated by two or more market pool orders, the reconstituted skim milk assigned to Class I shall be prorated according to such disposition in each area; and

(2) Compute the value of the quantity assigned in paragraph (b)(1) of this section to Class I disposition in this area, at the Class I price under this part applicable at the location of the other order plant (but not to be less than the Class III price) and subtract its value at the Class III price.

§ 1125.72 Payments from the producer-settlement fund.

On or before the 18th day after the end of the month during which the skim milk and butterfat were received, the market administrator shall pay to each handler the amount, if any, by which the amount computed pursuant to §1125.71(a)(2) exceeds the amount computed pursuant to §1125.71(a)(1), and less any unpaid obligations of such handler to the market administrator pursuant to §§ 1125.71(a), 1125.77, 1125.85, and 1125.86. However, if the balance in the producer-settlement fund is insufficient to make all payments pursuant to this section, the market administrator shall reduce uniformly such payments and shall complete such payments as soon as the necessary funds are available.

§ 1125.73 Payments to producers and to cooperative associations.

(a) Each handler shall make payments to each producer for milk received from such producer during the month:

(1) On or before the last day of the month to each producer who had not discontinued shipping milk to such handler before the 18th day of the month, at not less than the Class III price for the preceding month per hundredweight of milk received during the first 15 days of the month, less proper deductions authorized in writing by such producer; and

(2) On or before the 19th day after the end of each month for milk received from such producers during such month:

(i) At not less than the uniform price for the quantity of milk received, adjusted by the butterfat differential pursuant to § 1125.74 and by any location adjustments applicable under § 1125.75;

(ii) Minus payments made pursuant to paragraph (a)(1) of this section. However, if by such date such handler has not received full payment for such month pursuant to § 1125.72, he shall not be deemed to be in violation of this paragraph if he reduced uniformly for all producers his payments per hundredweight pursuant to this paragraph by a total amount not in excess of the reduction in payment from the market administrator, however, the handler shall make such balance of payment uniformly to those producers to whom it is due on or before the date for making payments pursuant to this paragraph next following that on which such balance of payments is received from the market administrator.

(b) The payments required in paragraph (a) of this section shall be made, upon request, to a cooperative association qualified under § 1125.18, or its duly authorized agent, with respect to milk received from each producer who has given such association authorization by contract or by other written instrument to collect the proceeds from the sale of his milk, and any payment made pursuant to this paragraph shall be made on or before 2 days prior to the dates specified in paragraph (a) of this section.

(c) Each handler shall pay to each cooperative association or its duly authorized agent which operates a pool plant for skim milk and butterfat received from such plant:

(1) On or before the 2nd day prior to the date specified in paragraph (a)(1) of this section for skim milk and butterfat received during the first 15 days of that month at not less than the Class III price for the preceding month; and

(2) On or before the 17th day after the end of the month, an amount of money computed by multiplying the total pounds of such skim milk and butterfat in each class pursuant to § 1125.42(a) by the class price adjusted by the butterfat differential and taking into account any location adjustments as provided by § 1125.52 applicable at the pool plant of the cooperative association or its agent, minus payment made pursuant to paragraph (c)(1) of this section.

(d) Each handler who received milk for which a cooperative association is the handler pursuant to § 1125.9(c) shall pay such cooperative association for such milk received:

(1) On or before the 2nd day prior to the date specified in paragraph (a)(1) of this section for such milk received during the first 15 days of that month at not less than the Class III price for the preceding month; and

(2) On or before the 18th day after the end of each month, for the milk received at not less than the uniform price for all milk adjusted pursuant to §§ 1125.74 and 1125.75(b), minus payments made pursuant to paragraph (d)(1) of this section.

(e) None of the provisions of this section shall be construed to restrict any cooperative association qualified under section 8c(5)(F) of the Act from making payment for milk to its producers in accordance with such provisions of the Act.

(f) In making payments to producers pursuant to this section, each handler, on or before the 19th day of each month shall furnish each producer with a supporting statement in such form that it may be retained by the producer, which shall show for the preceding month:

(1) The identity of the handler and the producer;

(2) The total pounds of milk delivered by the producer and the average butterfat test thereof and the pounds per shipment if such information is not furnished to the producer each day of delivery;

(3) The minimum rate at which payment to the producer is required under the provisions of this section;

(4) The rate per hundredweight and amount of any premiums or payments above the minimum price provided by the order;

(5) The amount or rate per hundredweight of each deduction claimed by the handler, together with a description of the respective deductions; and

(6) The net amount of payment to the producer.

(g) In making payments to a cooperative association in aggregate pursuant to this section, each handler upon request shall furnish to the cooperative association, with respect to each producer for whom such payment is made, any or all of the above information specified in paragraph (f) of this section.

§ 1125.74 Butterfat differential.

For milk containing more or less than 3.5 percent butterfat, the uniform price shall be increased or decreased, respectively, for each one-tenth percent butterfat variation from 3.5 percent by a butterfat differential, rounded to the nearest one-tenth cent, which shall be 0.115 times the simple average of the wholesale selling prices (using the midpoint of any price range as one price) of Grade A (92-score) bulk butter per pound at Chicago as reported by the Department for the month. § 1125.75 Plant location adjustment for producers and nonpool milk.

(a) In making payment to producers pursuant to § 1125.73(a) subject to the application of § 1125.13(c)(7) appropriate adjustments shall be made per

hundredweight of milk received from producers at respective plant locations at the same rate as specified for Class I milk set forth in § 1125.52.

(b) In making payments to a cooperative association pursuant to § 1125.73(d) appropriate adjustments shall be made at the rates specified for Class I milk in § 1125.52 for the location of the plant at which the milk was received from the cooperative association.

(c) For purposes of computations pursuant to §§ 1125.71(a) and 1125.72 the uniform price for all milk shall be adjusted at the rates set forth in § 1125.52 for Class I milk applicable at the location of the nonpool plant from which the milk or filled milk was received, except that the adjusted uniform price shall not be less than the Class III price.

§ 1125.76 Payments by handler operating a partially regulated distributing plant.

Each handler who operates a partially regulated distributing plant shall pay to the market administrator for the producer-settlement fund on or before the 25th day after the end of the month either of the amounts (at the handler's election) calculated pursuant to paragraph (a) or (b) of this section. If the handler fails to report pursuant to §§ 1125.30(d) and 1125.31(b) the information necessary to compute the amount specified in paragraph (a) of this section, he shall pay the amount computed pursuant to paragraph (b) of this section:

(a) An amount computed as follows:

(1) (i) The obligation that would have been computed pursuant to § 1125.60 at such plant shall be determined as though such plant were a pool plant. For purposes of such computation, receipts at such nonpool plant from a pool plant, or an other order plant shall be assigned to the utilization at which classified at the pool plant or other order plant and transfers from such nonpool plant to a pool plant or an other order plant shall be classifed as Class II or Class III milk if allocated to such class at the pool plant or other order plant and be valued at the uniform price of the respective order if so allocated to Class I milk, except that reconstituted skim milk in filled milk shall be valued at the Class III price. No obligation shall apply to Class I milk transferred to a pool plant or another order plant if such Class I utilization is assigned to receipts at the partially regulated distributing plant from pool plants and other order plants at which an equivalent amount of milk was classified and priced as Class I milk. There shall be included in the obligation so computed a charge in the amount specified in § 1125.60(f) and a credit in the amount specified in § 1125.71(a)(2)(iii) with respect to receipts from an unregulated supply plant, except that the credit for receipts of reconstituted skim milk in filled milk shall be at the Class III price, unless an obligation with respect to such plant is computed as specified in paragraph (a)(1)(ii) of this section; and

(ii) If the operator of the partially regulated distributing plant so requests, and provides with his reports pursuant to §§ 1125.30(d) and 1125.31(b) similar reports with respect to the operations of any other nonpool plant which serves as a supply plant for such partially regulated distributing plant by shipments to such plant during the month equivalent to the requirements of § 1125.7(b), with agreement of the operator of such plant that the market administrator may examine the books and records of such plant for purposes of verification of such reports, there will be added the amount of the obligation computed at such nonpool supply plant in the same manner and subject to the same conditions as for the partially regulated distributing plant.

(2) From this obligation there will be deducted the sum of (i) the gross payments made by such handler for Grade A milk received during the month from dairy farmers at such plant adjusted to a 3.5 percent butterfat basis by the butterfat differential pursuant to § 1125.74, and like payments made by the operator of a supply plant(s) included in the computations pursuant to paragraph (a)(1) of this section and (ii) any payments to the producer-settlement fund of another order under which such plant is also a partially regulated distributing plant.

(b) An amount computed as follows:

(1) Determined the respective amounts of skim milk and butterfat disposed of as route disposition of Class I milk within the marketing area;

(2) Deduct the respective amount of skim milk and butterfat received at the plant:

(i) As Class I milk from pool plants and other order plants, except that deducted under a similar provision of another order issued pursuant to the Act; and

(ii) From a nonpool plant that is not an other order plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such nonpool plant by handlers fully regulated under this or any other order issued pursuant to the Act is classified and priced as Class I milk and is not used as an offset on any payment obligation under this or any other order;

(3) Deduct the quantity of reconstituted skim milk in fluid milk products disposed of as route disposition in the marketing area;

(4) [Reserved].

(5) From the value of such milk at the Class I price applicable at the location of the nonpool plant, subtract its value at the uniform price applicable at such location (not to be less than the Class III price), and add for the quantity of reconstituted skim milk specified in paragraph (b)(3) of this section its value computed at the Class I price applicable at the location of the nonpool plant (but not to be less than the Class III price) less the value of such skim milk at the Class III price.

§ 1125.77 Adjustment of accounts.

Whenever verification by the market administrator of reports or payments of any handler discloses errors resulting in money due:

(a) The market administrator from such handler;

(b) Such handler from the market administrator; or

(c) Any producer or cooperative association from such handler, the market administrator shall promptly notify such handler of any amount so due and payment thereof shall be made on or before the next date for making payments set forth in the provisions under which such error occurred following the 5th day after such notice.

Administrative Assessment and Marketing Service Deduction

§ 1125.85 Assessment for order administration.

As his pro rata share of the expense of administration of the order, each handler shall pay to the market administrator on or before the 16th day after the end of the month 4 cents per hundredweight, or such lesser amount as the Secretary may prescribe, with respect to:

(a) Producer milk (including such handler's own production);

(b) Other source milk allocated to Class I pursuant to § 1125.44(a) (8) and (12) and the corresponding steps of § 1125.44(b), except such other source milk on which no handler obligation applies pursuant to § 1125.60(f); and

(c) Route disposition in the marketing area from a partially regulated distributing plant that exceeds the Class I milk:

(1) Received during the month at such plant from pool plants and other order plants that is not used as an offset under a similar provision of another order issued pursuant to the Act; and

(2) Specified in § 1125.76(b)(2)(ii).

§ 1125.86 Deduction for marketing services.

(a) Except as set forth in paragraph (b) of this section, each handler, in making payments to producers (other than with respect to milk of such handler's own production) pursuant to § 1125.73(a)(2), shall make a deduction of 5 cents per hundredweight of milk or such amount not exceeding 5 cents per hundredweight as the Secretary may prescribe, with respect to the following:

(1) All milk received form producers at a plant not operated by a cooperative association.

(2) [Reserved].

(3) All milk received at a plant operated by a cooperative association from producers for whom the marketing services set forth below in this subparagraph are not being performed by the cooperative association as determined by the market administrator. Such deduction shall be paid by the handler to the market administrator on or before the 16th day after the end of the month. Such moneys shall be expended by the market administrator for the verification of weights, sampling and testing of milk received from producers, and in providing for market information to producers; such services to be performed in whole or in part by the market administrator or by an agent engaged by and responsible to him.

(b) In the case of each producer:

(1) Who is a member of, who has given written authorization for the rendering of marketing service and the taking of deduction therefore to a cooperative association;

(2) Whose milk is received at a plant not operated by such association; and

(3) For whom the market administrator determines that such association is performing the services described in paragraph (a) of this section, each handler shall deduct, in lieu of the deduction specified under paragraph (a) of this section, from the payments made pursuant to § 1125.73(a)(2) the amount per hundredweight on milk authorized by such producer and shall pay, on or before the 18th day after the end of the month, such deduction to the association entitled to receive it under this paragraph.

Effective date: January 1, 1984.

Signed at Washington, D.C. on: November 17, 1983.

C. W. McMillan,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 83-31454 Filed 11-22-83; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 81

[Docket No. 83-123]

Highly Pathogenic Avian Influenza; Expansion of Quarantined Area in Pennsylvania

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: This document amends the "Highly Pathogenic Avian Influenza and Similar Poultry Diseases" interim rule by expanding the quarantined area in Pennsylvania to include additional portions of York and Chester Counties. This action is necessary to help prevent the interstate spread of highly pathogenic avian influenza, a highly contagious and pathogenic viral disease of poultry.

DATES: Effective date is November 21, 1983. Written comments must be received on or before January 23, 1984.

ADDRESS: Written comments should be submitted to Thomas O. Gessel, Director, Regulatory Coordination Staff, APHIS, USDA, Room 728, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Written comments received may be inspected at Room 728 of the Federal Building, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. William W. Buisch, Chief, National Emergency Field Operations Staff, VS, APHIS, USDA, Room 747, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION:

Emergency Action

Dr. John K. Atwell, Deputy Administrator of the Animal and Plant Health Inspection Service for Veterinary Services, has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for public comment. In order to help prevent the spread of highly pathogenic avian influenza, immediate action is necessary to regulate the interstate movement of certain poultry and other items from the areas added to the quarantined area and to provide for the cleaning and disinfection of certain accessories and means of conveyance.

Further, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest; and good cause is found for making this interim rule effective upon signature. Comments are solicited for 60 days after publication of this document. A final document discussing comments received and any amendments required will be published in the **Federal Register.**

Background

Because of the finding of highly pathogenic avian influenza in poultry on premises in Pennsylvania, an interim rule establishing a quarantine and regulations was made effective on November 4, 1983 (48 FR 51422-51423). The interim rule was amended on November 7, 1983, November 10, 1983, and November 16, 1983, as explained in a document published in the **Federal Register** on November 17, 1983 (48 FR 52420-52427).

Highly pathogenic avian influenza is a highly contagious and pathogenic viral disease of poultry. It is defined as a disease of poultry caused by any influenza virus Type A that results in not less than 75 percent mortality within 8 days in at least eight healthy susceptible chickens, 4 to 8 weeks old, inoculated by the intramuscular, intravenous, or caudal airsac route with bacteria-free infectious allantoic or cell culture fluids and using standard laboratory operating procedures to assure specificity. Clinical evidence of the disease includes decreased feed and water consumption, depression, unusual movements or positions, increased mortality, hemorrhage beneath the skin on the lower legs and feet, severe decrease in egg production, post mortem lesions and history of the disease occurrence in the flock.

Prior to the effective date of this document, the quarantined area in Pennsylvania included all of Lancaster County and portions of Berks, Chester, Cumberland, Dauphin, Lebanon, and York Counties.

It had been determined that a quarantined area should have easily understood boundary lines, include the premises where highly pathogenic avian influenza is found, and include at least a five mile buffer zone in every direction from premises where the disease is found. The previous quarantined area was established in accordance with this criteria.

It has now further been determined that if the boundary line under the above criteria would be contiguous to an area containing a high concentration of poultry, the quarantined area should be expanded to include the area containing the high concentration of poultry. Action

is being taken to depopulate poultry and to conduct cleaning and disinfecting operations on premises determined to be infected by highly pathogenic avian influenza. Also, State regulatory measures are in effect to regulate the movement of means of conveyance and other items from quarantined areas to nonquarantined areas within Pennsylvania. However, it is not feasible to regulate all commerce (such as social visits, delivery of services) that could possibly be a means of spreading the disease from premises in quarantined areas to nearby premises in nonquarantined areas. Therefore, as a precautionary measure, it is necessary to include in the quarantined area such contiguous areas where high populations of poultry exist, and thereby require that poultry and other items from the premises in such contiguous areas be subject to the safeguards contained in the interim rule concerning interstate movement.

Based on the finding of clinical evidence of highly pathogenic avian influenza, it has been determined that the disease has spread within Pennsylvania to an area in York County outside of the previously quarantined area. Further, there are high concentrations of poultry being raised in areas contiguous to the previously established quarantine boundary line in the southwestern portion of Chester County.

In accordance with the specified criteria, the regulated area is expanded by adding additional portions of York and Chester Counties and is redescribed as follows:

The following area in Berks, Chester, Cumberland, Dauphin, Lancaster, Lebanon, and York Counties in Pennsylvania beginning at the eastern bank of the Susquehanna River at Interstate Highway 81; then northeasterly along Interstate Highway 81 to its intersection with Interstate Highway 78; then northeasterly along Interstate Highway 78 to its intersection with PA Highway 61; then southerly along PA Highway 61 to its intersection with U.S. Highway 422; then southeasterly along U.S. Highway 422 to its intersection with Interstate Highway 176; then southerly along Interstate Highway 176 to its intersection with Interstate Highway 76; then easterly along Interstate Highway 76 to its intersection with PA Highway 82; then southerly along PA Highway 82 to its intersection with U.S. Highway 1; then southwesterly along U.S. Highway 1 to its intersection with PA Highway 841; then southerly along PA Highway 841 to its intersection with the Pennsylvania/Maryland State Line; then westerly along the Pennsylvania/Maryland State Line to its intersection with PA Highway 516; then northerly along PA Highway 516 to its intersection with PA Highway 116; then northeasterly along PA Highway 116 to its intersection with U.S. Highway 30; then easterly along U.S. Highway 30 to its intersection with Interstate Highway 83; then northerly along Interstate Highway 83 to the eastern bank of the Susquehanna River; then northerly along the eastern bank of the Susquehanna River to Interstate Highway 81.

With certain exceptions, the interim rule provides that the following articles designated as prohibited article are prohibited from being moved interstate from a quarantined area:

(1) Live poultry infected with or exposed to highly pathogenic avian influenza,

(2) Manure from poultry, and

(3) Litter that has been used by poultry.

The interim rule also provides that the following articles designated as restricted articles are allowed to be moved interstate from a quarantined area only in accordance with certain conditions:

(1) Live poultry not infected with or exposed to highly pathogenic avian influenza,

(2) Poultry carcasses or parts thereof,

(3) Eggs from poultry, and

(4) Used coops, containers, troughs or other accessories for use in the handling of poultry or poultry eggs.

The interim rule also contains provisions concerning the cleaning and disinfection of coops, containers, troughs, other accessories, and means of conveyance used in the interstate movement of poultry from quarantined areas.

Executive Order and Regulatory Flexibility Act

The emergency nature of this action makes it impracticable for the Agency to follow the procedures of Executive Order 12291 and Secretary's Memorandum 1512-1 with respect to this interim rule. In order to help prevent the spread of highly pathogenic avian influenza, immediate action is necessary to regulate the interstate movement of certain poultry and other items from the areas added to the quarantined area and to provide for the cleaning and disinfection of certain accessories and means of conveyance.

This emergency situation also makes compliance with section 603 and timely compliance with section 604 of the Regulatory Flexibility act impracticable. Since this action may have a significant economic impact on a substantial number of small entities, the Final Regulatory Impact Analysis, if required, will address the issues required in section 604 of the Regulatory Flexibility Act.

List of Subjects in 9 CFR Part 81

Animal diseases, Poultry and poultry products, Transportation.

PART 81—HIGHLY PATHOGENIC AVIAN INFLUENZA AND SIMILAR POULTRY DISEASES

Under the circumstances referred to above, § 81.4 of 9 CFR Part 81 is revised to read as follows:

§ 81.4 Quarantined areas.

The following area in Berks, Chester, Cumberland, Dauphin, Lancaster, Lebanon, and York Counties in Pennsylvania is designated as a quarantined area: That portion of Pennsylvania beginning at the eastern bank of the Susquehanna River at Interstate Highway 81; then northeasterly along Interstate Highway 81 to its intersection with Interstate Highway 78; then northeasterly along Interstate Highway 78 to its intersection with PA Highway 61; then southerly along PA Highway 61 to its intersection with U.S. Highway 422; then southeasterly along U.S. Highway 422 to its intersection with Interstate Highway 176; then southerly along Interstate Highway 176 to its intersection with Interstate Highway 76; then easterly along Interstate Highway 76 to its intersection with PA Highway 82; then southerly along PA Highway 82 to its intersection with U.S. Highway 1; then southwesterly along U.S. Highway 1 to its intersection with PA Highway 841; then southerly along PA Highway 841 to its intersection with the Pennsylvania/Maryland State Line; then westerly along the Pennsylvania/Maryland State Line to its intersection with PA Highway 516; then northerly along PA Highway 516 to its intersection with PA Highway 116; then northeasterly along PA Highway 116 to its intersection with U.S. Highway 30; then easterly along U.S. Highway 30 to its intersection with Interstate Highway 83; then northerly along Interstate Highway 83 to the eastern bank of the Susquehanna River; then northerly along the eastern bank of the Susquehanna River to Interstate Highway 81.

(Sec. 2, 23 Stat. 31, as amended; secs. 4–8, 23 Stat. 31–33, as amended; secs. 1–3, 32 Stat. 791, 792, as amended; secs. 1–4, 33 Stat. 1264, 1265; 41 Stat. 699; sec. 2, 65 Stat. 693; secs. 3 and 11, 76 Stat. 129, 130 and 132; 76 Stat. 663, 7 U.S.C. 450, 21 U.S.C. 111–113, 114a–1, 115–117, 119–126, 130, 134a, 134b, 134d, 134f; 7 CFR 2.17, 2.51, and 371.2(d))

Done at Washington, D.C. this 21st day of November, 1983.

J. K. Atwell,

Deputy Administrator, Veterinary Services.

[FR Doc. 83-31840 Filed 11-21-83; 3:58 pm]

BILLING CODE 3410-34-M

CIVIL AERONAUTICS BOARD

14 CFR Part 316

[Procedural Reg. Issuance of Part 316 Docket 41660; PR-262]

Collection of Claims Owed the United States

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB is issuing rules to implement the Federal Claims Collection Act and the Debt Collection Act. These rules state the procedures to be used by the CAB to collect debts owed the United States, and how interest will be charged on unpaid claims. The rules further state when interest and penalty changes may be waived and what actions a person must take to respond to a notice of claim. These rules are intended to ensure a fair and expeditious collection of these claims.

DATES: Effective: December 23, 1983.
Adopted: November 1, 1983.

FOR FURTHER INFORMATION CONTACT: Joseph L. Kull, Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428; 202-673-5476.

SUPPLEMENTARY INFORMATION: By notice of proposed rulemaking (PDR-84, 48 FR 39081, August 29, 1983), the Board proposed rules to implement two laws for the collection of debts owed the United States. Those statutes were the Federal Claims Collection Act (Pub. L. 89-508) and the Debt Collection Act, as amended (Pub. L. 97-365). Those laws set the guidelines and general procedures for agencies to pursue claims for the United States. Two comments were received in response to PDR-84: Frontier Airlines and the Regional Airline Association (on behalf of Britt Airways, Chaparral Airlines, Comair, Empire Airlines, PBA Airlines, Pennsylvania Airlines, Precision Airways, Prinair, Rocky Mountain Airways, Scheduled Skyways, and Tennessee Airways). Both comments suggested clarifications or changes in the proposed rules. The Board has decided to adopt the rule with some of those changes.

The rules set simple procedures to implement the laws under the guidelines in rules published jointly by the General Accounting Office and the Department of Justice. Once the amount of a debt is set, the Board will send the debtor a notice of claim. The Regional Airline Association (RAA) commented that it was unclear about what constitutes the notice of claim and whether it would be sent before or after a final Board order or other final disposition setting an overpayment amount. The answer is that a notice of claim is a separate document that would be sent after a final order or other final disposition is adopted. The debt is not owed to the United States until a final order is adopted, so a notice of claim could not be sent until that time. The Board does not believe, therefore, that any change in the rule is needed on this point.

Payment is then due 30 days from the date the notice of claim is sent. The debtor must send the full payment within that period or explain its failure to do so. The Board will make a technical change in the rule suggested by RAA to clarify that the debtor need only respond if full payment is not made within the required 30 days.

Both Frontier and RAA commented on that part of the proposed rule stating how and when interest and penalty charges will be imposed on the debtor. The RAA commented that where the Board is reimbursing a carrier for losses, neither the carrier nor the Board would know that there is an overpayment resulting in a debt until after the fact. RAA argued that a small carrier could be faced with a large debt required to be paid within 30 days that could not have been reasonably anticipated. In such a case, RAA contended, the Board should consider a liberal policy of waiving interest on the debt.

The Board agrees with RAA that proposed § 316.4(c)(3) is broad enough to include such a waiver if found in the best interests of the United States. The Board does not believe any change should be made in the rule to mention specifically that circumstance. The Board and its staff handling these matters are aware of the stain that could be placed on small carriers by a large unanticipated debt, and are prepared to grant waivers where they are found in the public interest.

The Board further believes that Frontier's concern should be handled in the same manner. Frontier stated that waivers of interest and penalties should also be made when claims are challenged by the debtor in the courts. Frontier contended that to threaten a debtor with interest and penalties while a claim is being litigated would be unfair, and would place a roadblock in the way of those debtors exercising their right to judicial review.

The Board does not agree that imposition of interest or penalty charges is unfair in this situation. Any person is free to litigate any claim in our courts, regardless of the merit of the arguments raised. While the litigation is being pursued, the debtor has the use of the money in question. The interest is a measure of the value of that use. The modest (6 percent per year) penalty charge is an additional incentive not to unduly delay payment. If a debtor's claim is sustained, no interest will be owed. If the United States prevails, it should be entitled to interest or other charges, just as are contractors who challenge and win an appeal of a contract claim against the U.S. under the Contract Disputes Act (Pub. L. 96-563). On those occasions where the best interests of the United States would be so served, the Board will waive interest and penalty charges.

Under the rule and applicable statutes, the Board may proceed to collect unpaid claims by offset against payments owed by the United States. RAA contended that under the Debt Collection Act, the Board cannot use offset procedures until "after trying to collect the claim elsewise." The proposed rule states that the Board will collect claims by offset "whenever feasible." RAA implied that this contradicts the statute. We disagree. The statute requires that an agency proceed to collect the claim before using offset measures. An agency is not required to exhaust all other methods. If a debtor does not pay the claim within 30 days or such other period as may be prescribed or arrange for alternative payments, the Board may then proceed with offset. The Board will do so whenever it is practical. The Board recognizes, as RAA pointed out, that offset must be used under the statutory guidelines and those issued by the General Accounting Office and the Department of Justice. The Board will closely follow those guidelines.

No comments were received on the rest of the rule, which establishes procedures for the settlement of claims for less than the principal of the debt and sets forth additional actions the Board may take to collect unpaid claims, such as referral for litigation and notification of credit bureaus.

By a separate rule, the Board is designating its Comptroller as the Claims Agent. That rule gives the Comptroller delegated authority, in accordance with Board policy and precedent, to take action under Part 316.

Final Regulatory Flexibility Analysis

The discussion above is the Board's final regulatory flexibility analysis of the rule under the Regulatory Flexibility Act (5 U.S.C. 604). Copies of this document can be obtained from the Distribution Section, Civil Aeronautics Board, Washington, D.C. 20428, 202-673-5432, by referring to the "PR" number at the top of the document.

Paperwork Reduction Act

The collection-of-information requirements in this proposal are subject to the Paperwork Reduction Act, Pub. L. 96-511, 44 U.S.C. Chapter 35. Those requirements have been submitted to the Office of Management and Budget (OMB) for review and comment. These have been approved by OMB under number 3024-0070.

List of Subjects in 14 CFR Part 316

Administrative practice and procedure, Claims, and Penalties.

Accordingly, the Civil Aeronautics Board amends 14 CFR Chapter II to add a new Part 316, *Collection of Claims Owed the United States*, as follows:

PART 316—COLLECTION OF CLAIMS OWED THE UNITED STATES

Sec.
316.1 Purpose.
316.2 Applicability.
316.3 Notice of claim.
316.4 Interest, penalty charges, and collection fees.
316.5 Collection by offset.
316.6 Settlement of claims.
316.7 Referral for litigation.
316.8 Disclosure to consumer reporting agency.
316.9 Board claims agent.

Authority: Secs. 204, 401, 402, 407, 416, Pub. L. 85-726, as amended, 72 Stat. 740, 754, 757, 758, 771; 49 U.S.C. 1324, 1371, 1372, 1377, 1386. Secs. 3 and 5, Pub. L. 89-308, as amended, 89 Stat. 308, 96 Stat. 1754-1758, 31 U.S.C. 3701-3719.

Note.—The information collection requirements contained in this part have been approved by the Office of Management and Budget under number 3024-0070.

§ 316.1 Purpose.

This part implements the Federal Claims Collection Act, as amended by the Debt Collection Act and interpreted by the General Accounting Office and Department of Justice. It provides procedures under which the Board will collect claims owed to the United States arising from activities under the Board's jurisdiction. The part further sets forth the procedures for the Board to determine and collect interest and other charges on those claims under the Debt Collection Act and for referral of unpaid claims for litigation.

§ 316.2 Applicability.

The part applies to all claims due the United States under the Federal Claims Collection Act as amended by the Debt Collection Act, arising from activities under the jurisdiction of the Board, including amounts due the United States from fees, overpayments, fines, civil penalties, damages, interest, and other sources.

§ 316.3 Notice of claim.

(a) The Board will send a written notice to any person who owes payment to the United States under this part, stating the basis for the claim, the possible interest and penalty charges under this part for non-payment, additional consequences of non-payment, and the date full payment is due. That payment will normally be due 30 days from the date notice under this part is mailed. The notice of claim will be sent return receipt requested.

(b) If the claim is disputed, the debtor shall respond to the notice in writing and state whether and when full payment is to be made, and the reasons for non-payment. If full payment is not made by the date asked in the notice, the debtor shall also state the reasons for the inability to make full payment and how and when payments are to be made.

(c) If no response to the notice is received by the date asked in the notice, the Board may take further action under this part or under 4 CFR Parts 101-105, and the Federal Claims Collection Act, as amended. These actions may include reports to credit bureaus, contracts with collection agencies, revocation of licensing or offset of Federal salary or other administrative offset, as authorized in 31 U.S.C. 3701-3719.

§ 316.4 Interest, penalty fees, and collection charges.

(a) The Board will assess interest on unpaid claims. The interest rate used by the Board is set by the Secretary of the Treasury. The Board will further charge penalty fees of not more than 6 percent per year of the unpaid claim for failure to pay a part of a debt more than 90 days past due. The Board will also impose collection charges to cover the costs of processing and handling overdue claims, based on the costs incurred.

(b) Interest on debts will be charged and will run from the date the notice of claim is mailed if the amount of the debt is not paid within 30 days from that date. The Board may extend the 30-day period when in the public interest. Interest will be calculated only on the principal of the debt. The rate of interest charged is the rate in effect on the date from which interest begins to run. The rate will remain fixed for the duration of the indebtedness.

(c) The Board may waive interest, collection charges or penalty fees if it finds that:

(1) The debtor is unable to pay any significant sum within a reasonable period of time;

(2) Collection of interest or charges jeopardizes collection of the principal of the claim; or

(3) It is otherwise in the best interests of the United States, including, under such circumstances, where an offset or installment payment agreement is in effect.

§ 316.5 Collection by offset.

(a) Whenever feasible, the Board will collect claims under this part by means of administrative offset against obligations of the United States to the debtor. Collection by Federal salary will be under the procedures in 4 CFR Part 102.

(b) The Board will notify the debtor in writing of its intent to use offset procedures to collect the debt unless the debtor agrees to repayment. The Board will ask other Federal agencies to help in the offset whenever possible. The notice to the debtor shall also include the type and amount of the claim and an explanation of the debtor's rights for records and review under 31 U.S.C. 3716(a).

§ 316.6 Settlement of claims.

(a) The Board may not waive the principal of any debt owed the United States.

(b) The Board may settle claims not exceeding $20,000 by compromise at less than the principal of the claim if—

(1) The debtor shows an inability to pay the full amount within a reasonable time;

(2) The Government would be unable to enforce collection in full through litigation or administrative means within a reasonable time;

(3) The cost of collecting the full amount is not justified by the amount of the claim; or

(4) With respect to enforcement debts, the Board's enforcement policy would be served by settlement of the claim for less than the full amount.

§ 316.7 Referral for litigation.

Claims that cannot be settled under § 316.6 or for which collection action cannot be ended or suspended under 4 CFR Parts 103 and 104 will be referred to

the General Accounting Office for litigation.

§ 316.8 Disclosure to consumer reporting agency.

The Board may disclose delinquent debts to consumer reporting agencies under the Federal Claims Collection Act, as amended. If, after a report has been made under this section, the status or amount of the claim substantially changes, the Board will notify the reporting agency in writing within 15 days of the change. Any request for verification information will be given to the reporting agency by the Board within 30 days of receipt of the request. Before disclosure to a reporting agency, the Board will obtain in writing a statement by the agency that it will comply with the Fair Credit Reporting Act and other applicable Federal statutes.

§ 316.9 Board claims agent.

(a) The Board's Comptroller is the Claims Collection Agent for all claims under this part. The Comptroller will take action as delegated under Part 385 of this chapter to carry out this part and the requirements of 4 CFR Parts 101–105.

(b) All action for the collection of claims under this part will be the responsibility of the Comptroller. All Board bureaus and offices shall send documents supporting claims under this part to the Comptroller for action. Delegated waivers or compromise under this part shall be with the concurrence of the General Counsel. Any action taken by the Comptroller under this Part involving air carriers receiving subsidy will be in consultation with the appropriate Bureau or Office director(s).

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 83-31520 Filed 11-22-83; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 385

[Organization Reg. Amdt. No. 134 to Part 385, Docket 41660, OR-212]

Delegations and Review of Action Under Delegation; Nonhearing Matters

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB is delegating authority to its Comptroller to act as its Claims Agent. The Comptroller will take action to collect debts owed the United States, in accordance with Board policy and precedent.

This will ensure an expeditious collection of these claims.

DATES:

Effective: December 23, 1983.

Adopted: November 1, 1983.

FOR FURTHER INFORMATION CONTACT: Joseph L. Kull, Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, 202-673-5225.

SUPPLEMENTARY INFORMATION: For the reasons stated in PR-262, issued contemporaneously, the Board is amending its delegations of authority.

List of Subjects in 14 CFR Part 385

Administrative practice and procedure, Authority delegations (Government Agencies).

PART 385—[AMENDED]

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 385, Delegations and Review of Action Under Delegation: Nonhearing Matters, as follows:

1. The authority for Part 385 is:

Authority: Secs. 102, 104, 401, 402, 403, 407, 416, Pub. L. 85-726, as amended; 72 Stat. 740, 743, 754, 757, 758, 766, 771; 49 U.S.C. 1302, 1324, 1371, 1372, 1373, 1377, 1386. Reorganization Plan No. 3 of 1961, 26 FR 5989.

2. A new paragraph (h) is added to § 385.27 to read:

§ 385.27 Delegation to the Comptroller.

* * * * *

(h) Send notices of claim and other communications to a debtor under Part 316, and to impose and to waive interest and other charges and to settle claims by compromise with the concurrence of those Board officials specified in § 316.9(b) of the chapter, in accordance with Board policy and precedent.

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 83-31519 Filed 11-22-83; 8:45 am]

BILLING CODE 6320-01-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1406

Provision of Performance and Technical Data for Coal and Wood Burning Appliances; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; correction.

SUMMARY: This document corrects a citation contained in final regulations requiring that sales catalogs and other point of sale literature for certain wood and coal burning appliances shall contain information as to minimum safe distances that should be maintained between the appliance and combustibles, which were published May 16, 1983 (48 FR 21893).

FOR FURTHER INFORMATION CONTACT: Wade Anderson, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C. 20207, phone (301) 492-6400.

Accordingly, the Consumer Product Safety Commission is correcting 16 CFR 1406.1(c)(2) to read as follows:

§ 1406.1 Scope, purpose, and effective date.

* * * * *

(c) *Effective date.* * * *

(2) The requirements of § 1406.4(c) apply to sales catalogs and point of sale literature provided by manufacturers after May 16, 1984.

Dated: November 18, 1983.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 83-31470 Filed 11-22-83; 8:45 am]

BILLING CODE 6355-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

[Release Nos. 33-6499; 34-20384; 35-23122; File No. S7-979]

Shelf Registration

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Commission today announced the adoption of a revised shelf registration rule. Rule 415 (17 CFR 230.415) relates to the registration of securities to be offered or sold on a delayed or continuous basis in the future. As revised, the Rule is available for offerings qualified to use short form registration statements and for traditional shelf offerings. These modifications reflect experience with the Rule and the views that have been expressed, particularly those relating to disclosure and due diligence.

EFFECTIVE DATE: December 31, 1983.

FOR FURTHER INFORMATION CONTACT: Prior to the effective date, contact Steven L. Molinari (202) 272-2589, Office of Disclosure Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. After the effective date, contact David B. H.

Martin (202) 272-2573, Office of Chief Counsel, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

In the eighteen months since its adoption on a temporary basis, Rule 415 [1] has operated efficiently and has provided registrants with important benefits in their financings, most notably cost savings. The cost savings are attributable to a number of factors, including flexibility to respond to rapidly changing markets, reduced legal, accounting, printing and other expenses and increased competition among underwriters. At the same time, however, concerns have been raised, including institutionalization of the securities markets, impact on retail distribution, increased concentration in the securities industry, effects on the secondary markets, adequacy of disclosure and due diligence.

The Commission has considered the concerns that have been expressed about Rule 415. Some relate to economic factors, such as volatile interest rates and other market forces, which exist apart from Rule 415 and thus are not appropriate bases on which to take action on the Rule. The Commission believes that the concerns about disclosure and due diligence, however, should be addressed because they may be affected by the manner in which offerings under the Rule may proceed. Accordingly, the Commission has determined to modify the Rule to limit its availability to those offerings where the benefits of shelf registration are most significant and where the disclosure and due diligence concerns are mitigated by other factors. The Commission believes that limiting the Rule to primary offerings of securities qualified to be registered on Form S-3 or F-3[2] and to traditional shelf offerings strikes the appropriate balance.

The integrated disclosure system [3] recognizes that, for companies in the top tier, there is a steady stream of high quality corporate information continually furnished to the market and broadly digested, synthesized and disseminated. In addition, procedures for conducting due diligence investigations of such registrants, including continuous due diligence by means such as designated underwriters' counsel, are being adapted to the intergrated disclosure system and shelf registration. The Commission believes that the widspread market following of such companies and the due diligence procedures being developed serve to address the concerns about the adequacy of disclosure and due diligence and, thus, ensure the protection of investors.

With respect to traditional shelf offerings, the Commission believes that continued use of Rule 415 also is appropriate. First, concerns have not been expressed about these offerings. Second, these offerings may not be feasible on other than a delayed or continuous offering basis.

As to other offerings by non-S-3 or F-3 registrants, however disclosure and due diligence concerns need to be addressed. Accordingly, the Commission has determined not to allow the Rule to be used for such offerings.

As revised, Rule 415 enumerates the securities which are allowed to be offered on a continuous or delayed basis. Unless the securities fall within one of the provisions spelling out the various traditional shelf offerings, they must qualify for registration on Form S-3 or F-3. If they do not, they may not be registered for delayed or continuous offerings.

II. Background

Securities have been registered for continuous and delayed offerings for many years. Some of the instances in which shelf registration was allowed were set forth in Guide 4, which was promulgated in 1968.[4] These included securities to be issued in continuing acquisition programs or those underlying exercisable options, warrants or rights. Administrative practice, however, accommodated traditional shelf offerings beyond those specified in the Guide. Shelf registration was permitted for such diverse offerings as limited partnership tax shelters, employee benefit plans, pools of mortgage backed pass through certificates offered from time to time, and customer purchase plans.

Rule 415 arose in connection with the development of the integrated disclosure system. As part of that effort, the Commission comprehensively reviewed all of the Guides for the Preparation and Filing of Registration Statements and Reports and reorganized them to separate the substantive disclosure and procedural provisions. The shelf rule was the procedural rule which resulted from the reevaluation of Guide 4 and reflected current administrative practice as well as the provisions of the Guide.

The Rule was published for comment twice,[5] before being adopted on a temporary basis in March 1982.[6] Following public hearings and further public comment,[7] the Commission, in September 1982, extended the effective date of the Rule until December 31, 1983.[8] In June 1983, the Commission published the shelf registration rule for comment again in order to provide all interested parties another opportunity to submit their views and experience under the Rule before the Commission made its final determination.[9] Throughout the course of this rulemaking proceeding, the Commission has received almost 400 written and oral submissions from commentators expressing their views on shelf registration.[10]

Two dominant themes emerged from these comments on Rule 415. The majority of commentators, mostly registrants, have been pleased with the Rule and favor its adoption on a permanent basis. Members of the securities industry, on the other hand, have expressed a wide spectrum of views and have reiterated several concerns. In the most recent comment solicitation, they emphasize concerns over the adequacy of disclosure and due diligence. While these commentators voice concerns, only a few of them believe that there should be no shelf registration rule at all. Others with concerns about the Rule recommend that it be retained, either in its present form or in modified form.

The suggested modifications of Rule 415 include: (1) Restricting eligibility for use of the Rule to (a) investment grade debt securities, (b) a combination of investment grade debt securities and

---

[1] 17 CFR 230.415 under the Securities Act of 1933 ("Securities Act") [15 U.S.C. 77a et seq.].

[2] Forms S-3 [17 CFR 239.13] and F-3 [17 CFR 239.33] provide short form registration for a variety of transactions, including primary offerings of investment grade debt and non-convertible preferred securities and primary offerings where the registrant meets certain float requirements designed to ensure widespread market following.

[3] The Commission has adopted an integrated disclosure system for domestic registrants and for foreign private issuers. *See* Release Nos. 33-6383 (March 3, 1982) [47 FR 11380] and 33-6437 (November 19, 1982) [47 FR 54764].

[4] Release No. 33-4936 (December 9, 1968) [33 FR 18617].

[5] *See* Release Nos. 33-6276 (December 23, 1980) [46 FR 78] and 33-6334 (August 6, 1981) [46 FR 42001].

[6] Release No. 33-6383 (March 3, 1982).

[7] The public hearings were announced in Release No. 33-6391 (March 12, 1982) [47 FR 11701].

[8] Release No. 33-6423 (September 2, 1982) [47 FR 39799].

[9] Release No. 33-6470 (June 9, 1983) [48 FR 27768].

[10] The written submissions, transcripts and highlights prepared by the staff are available for public inspection and copying at the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549 *see* File Nos. S7-869, 896, 925 and 979).

limited types of equity securitites or (c) registrants that are widely followed in the marketplace; (2) requiring advance notice to the marketplace of forthcoming offerings; and (3) imposing some form of "cooling off period" between the announcement and sale of securities. Some commentators also suggest providing underwriters relief from liability under the Securities Act.

III. Experience

The Commission, registrants, the securities industry, and others have had over eighteen months of experience with the shelf registration rule. During this time, the Commission has monitored the operation and impact of the Rule, has been provided information concerning actual experience with the Rule and has considered empirical data and studies related to the Rule.[11]

From March 1982 through September 1983, almost 4,600 shelf registration statements relating to $181 billion were filed.[12] These shelf filings represent 52% of the over 8,800 registration statements and 52% of $345 billion of securities registered during this period.

Over 85% of the shelf registrations have been traditional shelf filings.[13] Filings for employee benefit plans and dividend or interest reinvestment plans alone account for 55% of the shelf filings and represent 26% of the $181 billion in shelf registered securities.

Most of the balance have been filings for investment grade debt securities offered and sold from time to time on a delayed basis. These 369 debt filings (registering almost $70 billion) represent 53% of the $133 billion of total debt issues filed from March 1982 through September 1983. Approximately 94% of the 369 delayed debt filings were on Form S-3. Over 35% of the filings were made by companies in the financial industry and over 20% were made by utilities.

The remaining shelf filings related to 195 delayed equity filings (registering $12.5 billion). These filings amounted to about 3% of the over 7,700 equity registration statements and 6% of the $212 billion in equity securities registered. Over half were fixed price syndicated offerings which were filed under Rule 415 largely for the procedural convenience afforded by the Rule.[14] Of the remaining delayed equity filings, 90% were on Form S-3. Aproximately 70% were for common stock and 30% were for preferred stock. Fifteen percent listed an "at the market" distribution as one of the potential distribution methods described. Eleven of these filings were for so-called "dribble-outs" by utility companies, in which common stock is offered through an underwriter into an existing trading market on a regular basis.

IV. Discussion

A. Benefits of Shelf Registration

Virtually all commentators state that shelf registration provides substantial benefits for corporate financings. The principal benefit cited by commentators is that of cost savings. Empirical studies on shelf registration also suggest that securities sold under Rule 415 have lower issuance costs than securities not sold under the Rule.[15]

Cost savings and other benefits are attributed to a number of factors. Flexibility is the Rule's most frequently cited benefit, because it is the source of the greatest cost savings and provides other advantages as well. Commentators stress that flexibility is important in today's volatile markets; that the procedural flexibility afforded by the Rule enables a registrant to time its offering to avail itself of the most advantageous market conditions; that by being able to meet "market windows," registrants are able to obtain lower interest rates on debt and lower dividend rates on preferred stock, thereby benefiting their existing shareholders. The flexibility provided by the Rule also permits variation in the structure and terms of securities on short notice, enabling registrants to match securities with the current demands of the marketplace. Some commentators attributed the success of their offerings to the flexibility provided by the Rule. Empirical studies also support the importance of enhanced financing flexibility in new issue design, market timing and choice of distribution technique.[16] While most discussion of flexibility is in the context of debt offerings, some commentators also assert that flexibility is necessary in the equity markets.

Simplification of the securities registration process also is cited as reducing costs. Legal, accounting, printing and other costs are stated to have been reduced, because only a single registration statement need be filed for a series of offerings, rather than a separate registration statement each time an offering is made. Some commentators also state that simplification of the registration process has given them more flexibility in planning their financing schedules.

Finally, some commentators stress that increased competition among underwriters has resulted in lower underwriting spreads and offering yields, which produce cost savings for registrants and their shareholders. Empirical studies of debt and equity offerings under Rule 415 found lower issuance costs and attributed this primarily to increased competition among investment bankers.[17] Some commentators note that increased competition has spurred the innovation of new financing products.

On the basis of the benefits cited, many commentators, especially registrants, support permanent adoption of Rule 415 as proposed.

---

[11] In particular, in response to the June 1983 comment solicitation, registrants and investment bankers provided data on their actual experience under the Rule. This and other experience with the Rule, including empirical data and studies (*see* note 15 *infra*), are included in the most recent public file of this proceeding and are available for inspection and copying at the Commission's Public Reference Room (*see* File No. S7-979).

[12] These do not include 45 shelf registration statements (registering almost $19 billion of debt securities) filed by 27 foreign government and political subdivisions thereof from September 1980 through October 1983. While Rule 415, by its terms, is not available to foreign government issuers (*see* 17 CFR 230.415(b)), such issuers have been permitted to use a shelf registration procedure since September 1980 (*see* discussion in Part VIII *infra*).

[13] Traditional shelf offerings include those offerings enumerated in former paragraphs (a)(1)(ii) through (a)(1)(vii) of the Rule. These include: (1) Secondary offerings; (2) securities offered pursuant to employee plans and dividend reinvestment plans; (3) securities which are to be issued upon the exercise of outstanding options, warrants or rights; (4) securities which are to be issued upon conversion of other outstanding securities; (5) securities which are to be pledged as collateral; and (6) securities which are registered on Form F-6 [17 CFR 239.36]. Traditional shelf offerings also include some offerings falling within former paragraph (a)(1)(i) of the Rule: commodity fund offerings, mortgage related securities, limited partnership interests, securities registered in connection with a planned series of acquisitions and offerings made on a best efforts basis. As discussed in greater detail in Part VI *infra*, the Commission, in modifying the Rule, has enumerated the permissible traditional shelf offerings.

[14] *See* discussion in Part VI.B *infra*.

[15] *See* Kidwell, Marr, and Thompson, "SEC Rule 415—the Ultimate Competitive Bid," *University of Tennessee and Virginia Polytechnic Institute and State University Working Paper*, 1983 (indicating that debt issues sold under Rule 415 sell between 30 and 40 basis points less than comparable negotiated issues); Rogowski and Sorensen, "Shelf Registration and the Cost of Capital: A Test of Market Efficiency," *Washington State University and University of Arizona Working Paper*, 1983 (evidence of improved efficiency in the securities markets resulting from the flexibility associated with Rule 415); and Bhagat, Marr, and Thompson, "The Rule 415 Experiment: Equity Markets," *University of Utah and Virginia Polytechnic Institute and State University Working Paper*, 1983 (indicating that the issuing cost of equity securities sold under Rule 415 is about 29 percent less than that of comparable equity securities not sold under Rule 415).

[16] *Id.*

[17] *Id.*

B. Concerns

1. *Adequacy of Disclosure.* A number of commentators, especially those from the securities industry, express concerns relating to the adequacy of disclosure. While Rule 415 has been the focal point of these concerns, these commentators question aspects of the Commission's integrated disclosure system, such as short form registration and incorporation by reference. They question the amount and quality of information available, as well as whether investors receive it in time to make investment decisions. These commentators express concern that the Rule contributes to deficiencies in the disclosure provided to investors caused, in great part, by short form registration statements.

The Commission believes that the integrated disclosure system has enhanced the level of disclosure to investors. The basis for the system was the upgrading of the continuous reporting requirements under the Securities Exchange Act of 1934 (the "Exchange Act").[18] This upgrading was designed to ensure that complete and current information is available to all investors on a continuous basis, not only when a registrant makes a public offering of its securities, but for the trading markets as well.[19] This focus recognized that the secondary trading market volume dwarfs the volume of Securities Act offerings.

For Securities Act registration, the integrated disclosure system builds upon the existence of timely and accurate corporate reporting. Thus, registrants that are widely followed in the marketplace may use Forms S-3 and F-3, which allow maximum use of incorporation by reference of Exchange Act reports and generally do not require information contained in those reports to be reiterated in the prospectus and delivered to investors. Forms S-3 and F-3 recognize the applicability of the efficient market theory to those companies which provide a steady stream of high quality corporate information to the marketplace and whose corporate information is broadly disseminated. Information about these companies is constantly digested and synthesized by financial analysts, who act as essential conduits in the continuous flow of information to investors, and is broadly disseminated on a timely basis by the financial press and other participants in the marketplace.[20] Accordingly, at the time S-3/F-3 registrants determine to make an offering of securities, a large amount of information already has been disseminated to and digested by the marketplace.

2. *Due Diligence.* Concerns expressed about the quality of disclosure also relate to underwriters' ability to conduct due diligence investigations.[21] Commentators attribute concerns about due diligence largely to fast time schedules. Under the Rule, any underwriter may be selected to handle a particular offering. Some commentators suggest that no underwriter can afford to devote the time and expense necessary to conduct a due diligence review before knowing whether it will handle an offering and that there may not be sufficient time to do so once it is selected. These commentators also indicate that they may not have the opportunity to apply their independent scrutiny and judgment to documents prepared by registrants many months before an offering

On the other hand, registrants using the Rule indicate that procedures for conducting due diligence investigations have developed and are developing to enable underwriters to adapt to the integrated disclosure system and the shelf registration environment. They note the use of continuous due diligence programs, which employ a number of procedures, including designated underwriters' counsel. These registrants believe that underwriters' ability to conduct adequate due diligence investigations in this environment has not been impaired and, in some cases, has been enhanced.

The Commission recognizes that procedures for conducting due diligence investigations of large, widely followed registrants have changed and are continuing to change. Registrants and the other parties involved in their public offerings—attorneys, accountants, and underwriters—are developing procedures which allow due diligence obligations under Section 11(b) to be met in the most effective and efficient manner possible.[22] The anticipatory and continuous due diligence programs being implemented combine a number of procedures designed both to protect investors by assuring timely and accurate disclosure of corporate information and to recognize the separate legal status of underwriters by providing them the opportunity to perform due diligence.

The trend toward appointment of a single law firm to act as underwriters' counsel is a particularly significant development.[23] Of course, this procedure is not new. Appointing a single law firm to act as underwriters' counsel has been done traditionally by public utility holding companies and their subsidiaries subject to the competitive bid underwriting requirements of Rule 50 (17 CFR 250.50) under the Public Utility Holding Company Act of 1935.[24] This technique is now being followed more broadly in the shelf registration environment and represents what the Commission believes to be a sound practice because it provides for due diligence investigations to be performed continually throughout the effectiveness of the shelf registration statement. Designation of underwriters' counsel facilitates continuous due diligence by ensuring on-going access to the registrant on the underwriters' behalf. Recognizing the independent statutory basis on which underwriters perform

[18] 15 U.S.C. 78a et seq.

[19] *See* Release No. 33-6231 (September 2, 1980) [45 FR 63630], amending Form 10-K [17 CFR 249.310] and Rule 14a-3 [17 CFR 240.14a-3]; Release No. 33-6233 (September 2, 1980) [45 FR 63660], amending Articles 3, 5, and 12 of Regulation S-X [17 CFR Part 210]; Release No. 33-6234 (September 2, 1980) [45 FR 63682], adopting uniform financial statement requirements; and Release No. 33-6288 (February 9, 1981) [46 FR 12480], amending Form 10-Q [17 CFR 249.308a].

[20] In recognition of the important role of research reports in the integrated disclosure system, the Commission recently proposed revisions to Rule 139 [17 CFR 230.139], which provides guidance as to the publication of broker-dealer research reports relating to companies in registration. Release No. 33-6492 (October 5, 1983) [48 FR 46801]. The proposals would increase the research reports that may be issued by reducing substantially the restrictions on research reports concerning registrants eligible to use Form S-3 or F-3.

[21] Section 11 of the Securities Act imposes liability for material misstatements or omissions contained in a registration statement when it goes effective. Section 11(b) provides that each person, other than the issuer, will not be held liable if he can sustain the burden of proof that his conduct, under the circumstances, was reasonable. Specifically, Section 11(b)(3) permits the defendant to prove that he made a reasonable investigation of and had reasonable grounds to believe in the accuracy of the non-expertised portions of the registration statement or, with respect to any part presented upon the authority of an expert other than the defendant, that he had no reasonable ground to believe and did not believe there was a material omission or misstatement. 15 U.S.C. 77k(b)(3). This investigation is known as "due diligence."

[22] *See* Olson, "Spotlight Shines Anew on Statutory Diligence Tasks," *Legal Times* (April 4, 1983), p.14; Hovdesven and Wolfram, "Underwriter Liability in the Integrated Disclosure System," *The National Law Journal* (July 5, 1982), p.13; Landau, "Some Aspects of the Implementation of Shelf Registration Procedures," in *The New Exemptions from SEC Registration*, Law & Business, Inc./Harcourt Brace Jovanovich, p.321; AICPA Exposure Draft, "Amendments to SAS No. 38: Letters for Underwriters" (November 4, 1983), which reflects the accounting profession's adaptation to evolving procedures, including the use of designated underwriters' counsel; and comment letters in File No. S7-879 in response to June 1983 comment solicitation.

[23] Registrants appoint the law firm to act as underwriters' counsel, either with or without consulting with the prospective participating underwriters.

[24] 15 U.S.C. 79-79z-6.

due diligence, registrants cooperate with underwriters and designated counsel in making accommodations necessary for them to perform their due diligence investigation.

Other procedures registrants have developed complement the use of underwriters' counsel by presenting various opportunities for continuous due diligence throughout the shelf process. A number of registrants indicate that they hold Exchange Act report "drafting sessions." This affords prospective underwriters and their counsel an opportunity to participate in the drafting and review of periodic disclosure documents before they are filed.

Another practice is to hold so-called periodic due diligence sessions. Some registrants hold sessions shortly after the release of quarterly earnings to provide prospective underwriters and their counsel an opportunity to discuss with management the most recent financial results and other events of that quarter. Periodic due diligence sessions also include annual meetings with management to review financial trends and business developments. In addition, some registrants indicate that prospective underwriters and underwriters' counsel are able to schedule individual meetings with management at any time.

The Commission believes that the development of anticipatory and continuous due diligence techniques is consistent with the integrated disclosure system and will permit underwriters to perform due diligence in an orderly, efficient manner. Indeed, in adopting Rule 176 as part of that system, [T125] the Commission recognized that, just as different registration forms are appropriate for different companies, the method of due diligence investigation may not be the same for all registrants. Rule 176 sets forth a non-exclusive list of circumstances which the Commission believes bear upon the reasonableness of the investigation and the determination of what constitutes reasonable grounds for belief under Section 11(b) of the Securities Act.[26] Circumstances which may be particularly relevant to an underwriter's due diligence investigation of registrants qualified to use short form registration include the type of registrant, reasonable reliance on management, the type of underwriting arrangement and the underwriter's role, and whether the underwriter participated in the preparation or review of documents incorporated by reference into the registration statement. The Commission expects that the techniques of conducting due diligence investigations of registrants qualified to use short form registration, where documents are incorporated by reference, would differ from due diligence investigations under other circumstances.

3. *Other Concerns.* Securities industry commentators also raise concerns relating to institutionalization of the securities markets, the impact on retail distribution, increased concentration in the securities industry and effects on the secondary markets. Specifically, these commentators believe that Rule 415 is accelerating the trends toward institutionalization of the securities markets and concentration in the securities industry. In their view, the Rule is decreasing the number of syndicated offerings in which regional securities firms participate and excluding individual investors from the new issues market.

While the Commission recognizes the existence of these trends, it believes that they reflect econmic and other factors apart from shelf registration. These factors include volatile interest rates and markets, the growth of mutual and pension funds which act as intermediaries for individual investors, and the homogenization of the financial services industry. These factors are not necessarily affected by Rule 415. Rule 415 is a procedural rule which presents an optional filing technique. It does not mandate any particular method of distribution. Indeed, many offerings of debt and equity securities registered under the Rule have been sold in traditional syndicated offerings. The Commission therefore believes that these concerns transcend Rule 415.

V. Commission Action

The Commission has considered all views and suggestions with respect to Rule 415. There are several reasons why it may be appropriate to adopt the shelf registration rule in substantially its present form. During the eighteen months the Rule has been in effect, it has worked well and has provided registrants with substantial benefits in their financings. Also, most of the concerns raised transcend shelf registration. On the other hand, the Commission believes that concerns raised about the quality and timing of disclosure and due diligence are important to address because they relate to the adequacy of disclosure investors receive in connection with public offerings. Having weighed all considerations, the Commission is modifying Rule 415 to strike an appropriate balance by making it available for offerings eligible to be registered on Form S–3 or F–3 and for traditional shelf offerings.

The Commission believes that shelf registration should continue to be available for registrants eligible to use short form registration. The integrated disclosure system addresses concerns about the quality and timeliness of disclosure by ensuring that the marketplace is provided with a continuous stream of high quality corporate information about registrants widely followed in the marketplace. Similarly, evolving continuous due diligence practices as described above address concerns about due diligence by enhancing the ability of underwriters to conduct due diligence investigations of widely followed registrants.

The Commission also believes that Rule 415 should continue to be available for traditional primary and secondary shelf offerings. Examples of traditional primary shelf offerings include those where securities are sold to employees, customers or existing shareholders; those involving interests in limited partnerships; those related to acquisitions and other business combinations; and those of securities underlying options, warrants, rights or conversions. The Commission is not aware of any disclosure, due diligence or other concerns having been raised about the registration of these securities on a continuous or delayed basis. Moreover, these types of shelf offerings may only be feasible on a traditional shelf basis.

For registrants not eligible to use short form registration, however, the Commission believes that concerns about disclosure and due diligence outweigh the benefits of Rule 415. The Commission also notes that shelf registration may not be as advantageous for such registrants because they cannot rely on subsequently filed Exchange Act reports for certain updating of the information in the shelf registration

[25] 17 CFR 230.176, Release No. 33-6383 (March 3, 1982).

[26] Rule 176 lists the following factors: (1) The type of issuer; (2) the type of security; (3) the type of person; (4) the office held when the person is an officer; (5) the presence or absence of another relationship to the issuer when the person is a director or proposed director; (6) reasonable reliance on officers, employees, and others whose duties should have given them knowledge of the particular facts (in light of the functions and responsibilities of the particular person with respect to the issuer and the filing); (7) when the person is an underwriter, the type of underwriting arrangement, the role of the particular person as underwriter and the availability of information with respect to the registration; and (8) whether, with respect to a fact or document incorporated by reference, the particular person had any responsibility for the fact or document at the time of the filing from which it was incorporated.

statement.[27] Such updating requires the filing of post-effective amendments. Indeed, few non-S-3 or F-3 registrants have used Rule 415 for other than traditional shelf offerings.

VI. Operation of Revised Rule 415

For the reasons stated above, the Commission has determined to limit the availability of Rule 415 to continuous and delayed offerings of securities which may be registered on Form S-3 or F-3 [28] and traditional shelf offerings. Major revisions have been made to paragraph (a)(1)(i) of the Rule, which details those securities which may be registered for an offering to be made on a continuous or delayed basis in the future, to reflect this modification in the scope of the Rule. Corresponding revisions have been made elsewhere in the Rule.

A. Offerings Permitted Under Revised Rule

1. *Traditional Shelf Offerings.* A number of traditional shelf offerings were enumerated in former paragraphs (a)(1) (ii) through (vii). [29] These provisions have been retained and redesignated as paragraphs (a)(1) (i) through (vi).

Other traditional shelf offerings came within former paragraph (a)(1)(i). Because the primary offerings which may be made under Rule 415 are now limited, paragraph (a)(1)(i) has been deleted. That paragraph provided that any securities not falling within one of the categories specifically enumerated in the balance of paragraph (a)(1) could be registered under the Rule, but were limited to an amount reasonably expected to be offered and sold within two years. Those traditional offerings covered by former paragraph (a)(1)(i) are now set forth in paragraphs (a)(1) (vii) through (ix).

Mortgage related securities, such as mortgage backed debt and mortgage participation or pass through certificates, are listed in paragraph (a)(1)(vii). Generally, the securities are registered and then offered from time to time as series of mortgage backed debt are established or pools of mortgages are formed. Shelf registration is essential to sale of these securities. Together with the formation of blind pools, shelf registration allows registrants to match capital demands with portfolio holdings. They can form pools of mortgages as sales of securities backed by those mortgages take place. It is not necessary for the mortgages to be purchased before the securities are priced and sold. With an effective shelf registration statement, pricing and sales can occur contemporaneously with mortgage acquisition.[30]

Paragraph (a)(1)(viii) relates to securities to be issued in connection with business combination transactions. All other traditional shelf offerings are covered by paragraph (a)(i)(ix), which permits offerings that (1) will be commenced promptly, (2) will be made on a continuous basis and (3) may continue for a period in excess of 30 days from the date of initial effectiveness.

Examples of the traditional shelf offerings which come within paragraph (a)(1)(ix) are: customer purchaser plans; exchange, rights, subscription and rescission offers; offers to employees, consultants or independent agents; offerings on a best efforts basis; tax shelter and other limited partnership interests; commodity funds; condominium rental pools; time sharing agreements; real estate investment trusts; farmers' cooperative organizations or others making distributions on a membership basis; and continous debt sales by finance companies to their customers.

2. *Short Form Registration Shelf Offerings.* New paragraph (a)(1)(x) relates to primary delayed or continuous offerings of securities registered, or qualified to be registered, on Form S-3 or F-3. Unless an offering falls within one of the categories of offerings specified in paragraphs (a)(1)(i) through (a)(1)(ix), it must come within paragraph (a)(1)(x) or it cannot be registered pursuant to Rule 415. Thus, only traditional shelf offerings and primary shelf offerings that qualify for short form registration may be offered or sold under the Rule.

Examples of offerings which fall within paragraph (a)(1)(x) are: notes rated as investment grade to be offered from time to time at varying interest rates and maturities; debt or equity securities to be sold from time to time according to a plan of distribution that includes a number of options, such as sales directly to purchasers, through agents, through underwriters and through dealers; debt or equity securities to be sold from time to time pursuant to a plan of distribution that indicates they may be sold in one or more transactions and lists such options as ordinary brokerage transactions, block transactions on an exchange, negotiated transactions, fixed price offerings, or any combination of methods described; and "dribble" programs, in which common stock is offering through an underwriter acting as exclusive sales agent into an existing trading market on a regular basis. Offerings such as these may no longer be made unless the securities are qualified to be registered on Form S-3 or F-3.

B. Shelf Registration Statements Filed for Procedural Convenience

The revised Rule specifically relates only to securities to be offered on a traditional shelf basis or S-3/F-3 securities to be offered on a continuous or delayed basis. It does not relate to any other offerings and, accordingly, nor do the procedures and techniques applicable under the Rule.

In adopting Rule 415, the Commission recognized that offers and sales of securities under the Rule may not be made immediately after the effective

---

[27] Item 512(a) of Regulation S-K [17 CFR 229.512(a)] requires that registrants, in offerings under Rule 415, furnish undertakings to file post-effective amendments: (1) to include updated financial statements as required by Section 10(a)(3) of the Securities Act; (2) to reflect a fundamental change in the information set forth in the registration statement; and (3) to include any new or changed material information with respect to the plan of distribution. Because Forms S-3 and S-8 [17 CFR 239.16b] automatically incorporate by reference all subsequently filed reports pursuant to Sections 13, 14 and 15(d) of the Exchange Act, registrants filing shelf registration statements on these forms may rely on their subsequently filed Exchange Act reports in lieu of post effective amendments for the first two purposes if the Exchange Act reports contain the required information. Other registrants, however, are required to file post-effective amendments in all instances specified in Item 512(a), as well as for purposes of filing required exhibits, such as underwriting agreements, opinions of counsel and supplemental indentures.

[28] These forms may be used if their float tests are met or the securities to be registered are of investment grade. Form S-3 requires that the aggregate market value of stock held by non-affiliates must be either (1) $150 million or more or (2) $100 million or more and the registrant must have had an annual trading volume of such stock of 3 million shares or more. Form F-3 requires that the aggregate market value worldwide of voting stock held by non-affiliates is the equivalent of $300 million or more. Both forms define non-convertible debt or preferred securities as investment grade if, at the time of effectiveness of the registration statement, at least one nationally recognized statistical rating organization (as that term is used in Rule 15c3-1(c)(2)(vi)(F) under the Exchange Act [17 CFR 240.15c3-1(c)(2)(vi)(F)]) has rated the security in one of its generic categories that signifies investment grade. The instructions in both forms note that the four highest rating categories (within which there may be subcategories or gradations indicating relative standing) typically signify investment grade.

[29] These offerings are: secondary offerings; securities offered pursuant to dividend or interest reinvestment or employee benefit plans; securities underlying options, warrants or rights or issuable upon conversions; securities pledged as collateral; and despositary shares evidenced by American Depositary Receipts registered on Form F-6.

[30] Mortgage related securities are the subject of pending legislation. S. 2040 (replaces S. 1821). S. Rep. No. 98-293 (1983). Section 104 of S. 2040 would provide for shelf registration of such securities.

date of the registration statement. Thus, shelf registration statements must be declared effective without certain information such as price, interest rate, maturity and redemption provisions.[31] Post-effective amendments and prospectus supplements[32] serve to ensure that investors are provided with complete, accurate and current information at the time of the offering or sale of securities.

In allowing shelf registration statements to become effective without all required information, however, the Commission did not intend for registrants making offerings on other than a delayed or continuous basis to use the shelf registration rule as a basis for omitting required information from their registration statements when they become effective. Where securities are not to be offered and sold on a delayed or continuous basis, offers and sales generally take place promptly after the effective date and all required information should be included in the registration statement when it becomes effective.

In this regard, the Commission notes that, during the eighteen months that Rule 415 has been in effect, a number of registrants engaged in offerings made other than on a delayed or continuous basis have filed under the Rule for the procedural conveniences it affords prior to effectiveness. In particular, they have used the Rule to avoid the need to file pre-effective amendments reflecting the final terms and conditions of the offering.

As revised, Rule 415 is no longer available for this purpose. Accordingly, the Rule as revised reflects two changes which make clear that Rule 415 techniques are not available for offerings made on other than a delayed or continuous basis. First, the word "only" has been added to the introductory phrase of paragraph (a)(1) to clarify that the Rule pertains exclusively to the offerings enumerated in paragraphs (a)(1) (i) through (x).[33] Second, paragraph (a)(1)(x) is limited to S-3 or F-3 securities to be offered and sold "on a continuous or delayed basis."

C. Other Provisions of Revised Rule

1. *Two Year Amount Limitation.* The two year amount limitation is now contained in a separate provision, new paragraph (a)(2), which specifies that it is applicable to offerings of securities covered by paragraphs (a)(1) (viii) through (x). These are the same offerings which were subject to the two year limit under the former Rule, except for mortgage related securities. The Commission believes that it is no longer necessary to subject these securities to the two year amount limitation.

2. *Undertakings.* Paragraph (a)(2), requiring the registrant to furnish the undertakings in Item 512(a) of Regulation S-K, has been redesignated as paragraph (a)(3). No other change has been made in this provision and the provisions of Item 512(a) remain unchanged as well.

3. *At the Market Equity Offerings.* Paragraph (a)(3), relating to primary at the market offerings of equity securities, has been redesignated as paragraph (a)(4). In addition, the requirement for Form S-3 eligibility has been revised to refer to paragraph (a)(1)(x), in light of the Form S-3 or F-3 limitation now contained in that paragraph.

D. Currently Effective Registration Statements for Offerings Not Permitted Under Revised Rule

When Rule 415 was adopted on a temporary basis, the Commission contemplated that registrants with then-effective shelf registration statements would be subject immediately to the final action taken on the Rule.[34] After December 31, 1983, registrants having effective registration statements pertaining to offerings no longer permitted under the Rule will not be able to offer or sell the securities as registered.[35]

Such registrants have several alternatives. First, securities registered on effective registration statements for types of offerings no longer permissible under the Rule may be removed from registration. Second, if registrants do not wish to deregister the securities, those securities may remain registered but no offerings may be made until the registration statement is post-effectively amended.[36] The post-effective amendment is required to describe the material change to the plan of distribution because the offering may not be made on a shelf basis.[37] Once the offering is commenced, it must be made on a non-Rule 415 basis and any securities then remaining unsold must be deregistered.[38]

VII. Public Utility Holding Companies

Utility companies have been frequent users of Rule 415. Some of these companies are subject to the Public Utility Holding Company Act of 1935 and, as such, are subject to certain additional requirements in connection with their financings. For example, paragraph (b) of Rule 50 requires that offerings of securities by registered holding companies and their subsidiaries be made in accordance with the formal competitive bidding procedures specified therein.

In September 1982, however, the Commission issued a statement of policy concerning the application of Rule 50 in the context of offerings of securities under Rule 415.[39] Determining that the formal competitive bidding procedures specified in paragraph (b) of Rule 50 were inconsistent with those possible under the shelf registration rule, the Commission stated that registered holding companies and their subsidiaries could adopt alternative procedures to those described in paragraph (b) of Rule 50 to develop and procure two or more competitive offers for securities which have been authorized for sale by the Commission. The Commission continues to believe that this policy with respect to Rule 50 is appropriate and it remains in effect.

VIII. Foreign Governments

While Rule 415, by its terms, is not available to foreign governments,[40] foreign governments have been permitted to use a shelf registration

[31] Release No. 6383 (March 3, 1982).

[32] *See* Rule 424 [17 CFR 230.424].

[33] This change does not preclude using a single registration statement to register both securities to be offered and sold on a shelf basis and securities to be offered and sold otherwise than on a shelf basis. Of course, the Rule 415 provisions and techniques apply only to those securities registered for offer and sale on a shelf basis.

[34] Release No. 6383 (March 3, 1982) [47 FR 11380], p. 11395, note 77. *See* Rule 401(f) [17 CFR 230.401(f)].

[35] In a related vein, if registrants with effective S-3 or F-3 shelf registration statements are ineligible to use those Forms at such time as updating for purposes of Section 10(a)(3) of the Securities Act is required, they may not thereafter make shelf offerings. *See* Item 512(a)(1)(i) of Regulation S-K and Rule 401. In such cases, they have the same alternatives as described herein.

[36] *See* Item 512(a)(1)(iii) of Regulation S-K, pursuant to which the registrant will have undertaken to file a post-effective amendment "to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement."

[37] Where a registrant chooses not to deregister and then wishes to make a non-shelf offering of an amount of securities exceeding the remaining registered securities, it may file a new registration statement with respect to the additional securities and use the new registration statement to take the place of the post-effective amendment changing the plan of distribution in the earlier shelf registration statement from a Rule 415 to a non-Rule 415 basis. *See* Rule 429 [17 CFR 230.429].

[38] *See* Item 512(a)(3) of Regulation S-K, pursuant to which the registrant will have undertaken "to remove from registration by means of a post-effective amendment any of the securities . . . which remain unsold at the termination of the offering."

[39] Release No. 35-22623 (September 2, 1982) [47 FR 39810].

[40] Rule 405 defines foreign government as "the government of any foreign country or of any political subdivision of a foreign country."

procedure since September 1980.[41] The Commission revised this staff interpretive position in September 1982 to be consistent with Rule 415 to the extent practicable.[42] Under the revised staff interpretation, seasoned foreign governments [43] are permitted to use shelf registration in a manner substantially similar to that specified in Rule 415. The revised shelf procedure for seasoned foreign government issuers generally has operated well and has not been altered by the granting of any waivers. Accordingly, the Commission affirms the staff position for shelf registration by foreign governments as outlined in September 1982.

IX. Statutory Authority

This rulemaking action is being taken pursuant to Sections 6, 7, 10 and 19(a) of the Securities Act of 1933 [15 U.S.C. 77f, 77g, 77j and 77s(a)].

List of Subjects in 17 CFR Part 230

Reporting and recordkeeping requirements, Securities

X. Text of Rule

In accordance with the foregoing, Title 17, Chapter II, of the Code of Federal Regulations is amended as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. By revising § 230.415 (Rule 415) to read as follows:

§ 230.415 Delayed or continuous offering and sale of securities.

(a) Securities may be registered for an offering to be made on a continuous or delayed basis in the future, *Provided*, That—

(1) The registration statement pertains only to:

(i) Securities which are to be offered or sold solely by or on behalf of a person or persons other than the registrant, a subsidiary of the registrant or a person of which the registrant is a subsidiary;

(ii) Securities which are to be offered and sold pursuant to a dividend or interest reinvestment plan or an employee benefit plan of the registrant;

(iii) Securities which are to be issued upon the exercise of outstanding options, warrants or rights;

(iv) Securities which are to be issued upon conversion of other outstanding securities;

(v) Securities which are pledged as collateral;

(vi) Securities which are registered on Form F-6 (§ 239.36 of this chapter);

(vii) Mortgage related securities, including such securities as mortgage backed debt and mortgage participation or pass through certificates;

(viii) Securities which are to be issued in connection with business combination transactions;

(ix) Securities the offering of which will be commenced promptly, will be made on a continuous basis and may continue for a period in excess of 30 days from the date of initial effectiveness; or

(x) Securities registered (or qualified to be registered) on Form S-3 or Form F-3 (§ 239.13 of 239.33 of this chapter) which are to be offered and sold on a continuous or delayed basis by or on behalf of the registrant, a subsidiary of the registrant or a person of which the registrant is a subsidiary.

(2) Securities in paragraphs (a)(1) (viii) through (x) may only be registered in an amount which, at the time the registration statement becomes effective, is reasonably expected to be offered and sold within two years from the initial effective date of the registration.

(3) The registrant furnishes the undertakings required by Item 512(a) of Regulation S-K (§ 229.512 of this chapter).

(4) In the case of a registration statement pertaining to an at the market offering of equity securities by or on behalf of the registrant:

(i) The offering comes within paragraph (a)(1)(x); (ii) where voting stock is registered, the amount of securities registered for such purposes must not exceed 10% of the aggregate market value of the registrant's outstanding voting stock held by non-affiliates of the registrant (calculated as of a date within 60 days prior to the date of filing); (iii) the securities must be sold through an underwriter or underwriters, acting as principal(s) or as agent(s) for the registrant; and (iv) the underwriter or underwriters must be named in the prospectus which is part of the registration statement. As used in this paragraph, the term "at the market offering" means an offering of securities into an existing trading market for outstanding shares of the same class at other than a fixed price on or through the facilities of a national securities exchange or to or through a market maker otherwise than on an exchange.

(b) This section shall not apply to any registration statement pertaining to securities issued by a face-amount certificate company or redeemable securities issued by an open-end management company or unit investment trust under the Investment Company Act of 1940 or any registration statement filed by any foreign government or political subdivision thereof.

(Secs. 6, 7, 10, 19(a), 48 Stat 78, 81, 85; secs. 205 209, 48 Stat. 906, 908; sec. 8, 68 Stat. 685; sec. 1, 79 Stat. 1051; sec. 308(a)(2), 90 Stat. 57; 15 U.S.C. 77f, 77g, 77j, 77s(a))

By the Commission (Chairman Shad and Commissioners Evans, Longstreth and Treadway); Commissioner Thomas concurring in part and dissenting in part.*

George A. Fitzsimmons,

Secretary.

November 17, 1983.

Special Concurring Opinion of Chairman Shad

The revised shelf rule offers significant advantages to issuers and their shareholders, and mitigates the risks to investors by limiting such offerings to S-3 and F-3 corporations, the largest, most creditworthy and widely followed corporations.

However, concepts suggested under which underwriters might conduct due diligence investigations under the shelf rule are of limited practical value. Issuers can solicit competitive bids from underwriters and effect distributions of securities on the same day. In preparation for shelf offerings, it has been suggested that prospective issuers invite groups of underwriters and their counsel to attend several meetings a year. These would include meetings following release by the companies of their quarterly and annual reports, and when they are preparing their prospectuses, proxies, annual, quarterly and other SEC filing documents.

It would be very expensive for top management executives, underwriters and their counsels to spend hundreds of thousands of hours annually attending such meetings on the speculative possibility that the individual issuer will decide to do a public offering, and that one of the underwriters attending such meetings will be the high bidder for the issue. It therefore seems likely that over time, few top management executives will attend such meetings and that investment bankers will begin sending junior observers, rather than qualified participants.

It has also been suggested that the underwriters rely on due diligence reviews by attorneys hired by the issuer. It is of course the underwriter that is liable for failure to conduct an adequate due diligence investigation, and it is the underwriter's capital and reputation that are at risk if the offering is unsuccessful or performs worse than the general market following the offering.

---

[41] *See* Release No. 33-6240 (September 10, 1982) [45 FR 61609].

[42] Release No. 33-6424 (September 2, 1980) [47 FR 39809].

[43] Foreign governments that have registered their securities (or guarantees of securities of another issuer) under the Securities Act within five years and have not defaulted on any principal or interest are considerd to be seasoned.

* Special Concurring Opinion of Chairman Shad and Opinion of Commissioner Thomas follow.

While due diligence reviews by issuer hired attorneys are useful in defending actions brought by investor-plaintiffs, this is not the principal purpose of such reviews. The principal purpose is to protect investors.

Assessment of the risk of adverse market performance following an offering requires a careful due diligence investigation and the judgment of an experienced underwriter. However, the accelerated time schedules of such offerings limit the opportunity for such assessments.

Issuer hired attorneys have been used in certain utility offerings. While the approach suffers the foregoing infirmities, utilities are the most predictable of corporate enterprises. They are not subject to the vagaries to which industrial and other issuers are subject.

The bulk of shelf offerings to date have occurred during the broadest and strongest stock, bond and new issue markets in history. Investors do not seek rescission or other redress, unless the security declines in price. The test of the shelf rule will come during the next bear market.

The revised shelf rule offers significant advantages to issuers and their shareholders, and mitigates the risks to investors, but the due diligence techniques suggested are of limited practical value. Other due diligence techniques should therefore be reviewed in the light of the shelf rule, as adopted, and the rapidly changing marketplace.

Commissioner Thomas, Concurring in Part and Dissenting in Part

I respectfully dissent from that portion of the Commission's decision today to adopt Rule 415 for offerings qualified to be registered on Forms S-3 and F-3 insofar as it relates to equity securities only. Although I am gratified at the compromise adopted by the Commission and sincerely believe that such a compromise was only reached because of the strong opposition to the Rule voiced by many during the experimental period, I must continue to express my reservations about the Rule on the basis of principle.

I am convinced that the Rule as applied to equities encourages changes in our capital market system substantially in excess of those necessary to facilitate the financings for which it was fashioned. In so doing the Commission risks injuring our capital market system, which is widely regarded as one of our great national assets. As I stated before, I continue to favor, however, adoption of the praiseworthy portion of the Rule that permits major companies rapid access to the markets for the sale of their debt securities.

After studying the comment letters and conferring with issuers, representatives of the securities industry, and institutional and individual investors, I continue to believe that the Rule as applied to equity offerings (1) reduces the quality and timeliness of disclosure available to investors when making their investment decisions, and (2) jeopardizes the liquidity and stability of both our primary and secondary securities markets by encouraging greater concentration of underwriters, market-makers, and other financial intermediaries and by discouraging individual investor participation in the capital market, thereby furthering the trend toward institutionalization of securities holders.

Although I do not believe that it is possible at this time to quantify the various elements of these risks due to the exceptionally strong market we have been experiencing during most of the experimental period and the inactive market experienced at the beginning of the experimental period, I am convinced that many of these risks are real. Incurring these risks is antithetical to the statutory duty of the Commission to protect investors and to maintain the integrity of our capital markets.

[FR Doc. 83-31506 Filed 11-21-83; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 162

[T.D. 83-238]

Boarding and Search of Vessels by Customs Officers

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations relating to the boarding and search of vessels to: (1) permit Customs officers to board and search an American vessel on the high seas without a requirement that there be probable cause to believe that such vessel is violating or has violated the laws of the United States; and (2) provide that Customs officers are authorized to assist any other agency in the enforcement of United States laws on any vessel.

Customs believes that these changes are in the interest of the efficient and effective administration of its enforcement responsibility.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: Stuart P. Seidiel, Assistant Chief Counsel (Enforcement and Operations), U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-2482).

SUPPLEMENTARY INFORMATION:

Background

Section 162.3(a), Customs Regulations (19 CFR 162.3(a)), presently states that a Customs officer, for the purpose of examining the manifest and other documents and papers, and examining, inspecting, and searching a vessel, may at any time go on board:

(1) Any vessel at any place in the United States or within the Customs waters of the United States;

(2) Any American vessel on the high seas, when there is probable cause to believe that such vessel is violating or has violated the laws of the United States; or

(3) Any vessel within a Customs-enforcement area designated such under the provisions of the Anti-Smuggling Act (Act of August 5, 1935, as amended, 49 Stat. 517; 19 U.S.C. 1701, 1703-1711), but Customs officers shall not board a foreign vessel upon the high seas in contravention of any treaty with a foreign government, or in the absence of a special arrangement with the foreign government concerned.

In a notice published in the **Federal Register** on September 14, 1981 (46 FR 45626), Customs proposed to amend § 162.3(a)(2) by eliminating the requirement that there be probable cause to believe that an American vessel is violating or has violated the laws of the United States before it is boarded and searched on the high seas.

The notice also proposed to add a new section 162.3(c) which would state that Customs officers are authorized to assist any other agency in the enforcement of United States laws on any vessel.

Comments

In response to the notice, Customs received four comments, one of which supports the proposed rule.

One commenter simply contends that Customs does not have the authority to make the proposed changes.

Another commenter states that the proposed rule does not present a convincing legal basis for the changes, and that the notice does not adequately address the question of the protection afforded by the Fourth Amendment to the Constitution. The commenter states, with respect to the reference in the notice that Customs authority under 19 U.S.C. 1581(a) is substantially similar to Coast Guard authority under 14 U.S.C. 89(a), that 14 U.S.C. 89(a) specifically authorizes Coast Guard inspections, searches and seizures "upon the high seas," whereas 19 U.S.C. 1581 contains no such general reference to Customs enforcement seaward of Customs waters.

A final commenter maintains that Customs does not have statutory authorization for the proposed rule in that, pursuant to 19 U.S.C. 1581(a), Customs authority with respect to boarding, inspecting, and searching a vessel, is limited to the customs waters. In this regard, *United States* v. *Warren*, 578 F. 2d 1058 (5th Cir. 1978) *(en banc)*, *rev'g* 550 F. 2d 219 and *United States* v. *Williams*, 617 F. 2d 1063 (5th Cir. 1980) are cited. The commenter contrasts the functions of Customs and the Coast

Guard, and concludes that Customs has a well-defined, narrow task compared to the general and pervasive powers of the Coast Guard on the high seas. The commenter further states that, even if Customs did have the statutory authority for the proposed rule, such authority could not be exercised consistently with the Fourth Amendment, particularly with respect to generalized searches, as opposed to stops for documentary checks or safety checks. The commenter contends that the case law indicates that there must be reason to suspect that a border crossing or a violation of law has occurred before even a documentary check or safety check can be made. Thereafter, a generalized search subsequent to an investigatory stop requires probable cause.

Formulation of Final Rule

The comments did not address the proposal to add a new § 162.3(c) to the Customs Regulations. The proposal is being adopted.

After a review of the comments and further consideration of the matter, Customs has decided to adopt the proposal to amend § 162.3(a)(2) to permit Customs officers to board and search an American vessel on the high seas without a requirement that there be probable cause to believe that such vessel is violating or has violated the laws of the United States.

Section 581(a), Tariff Act of 1930, as amended (19 U.S.C. 1581(a)), states as follows:

> Any officer of the customs may at any time go on board of any vessel or vehicle at any place in the United States or within the customs waters or, as he may be authorized, within a customs-enforcement area established under the Anti-Smuggling Act, *or at any other authorized place*, without as well as within his district, and examine the manifest and other documents and papers and examine, inspect, and search the vessel or vehicle and every part thereof and any person, trunk, package, or cargo on board, and to this end may hail and stop such vessel or vehicle, and use all necessary force to compel compliance. (Emphasis supplied.)

Under 14 U.S.C. 89(a), the Coast Guard is authorized to:

> Make inquiries, examinations, inspections, searches, seizures, and arrests upon the high seas and waters over which the United States has jurisdiction, for the prevention, detection, and suppression of violations of laws of the United States. For such purposes, commissioned, warrant, and petty officers may at any time go on board of any vessel subject to the jurisdiction, or to the operation of any law, of the United States, address inquiries to those on board, examine the ship's documents and papers, and examine, inspect, and search the vessel and use all necessary force to compel compliance.

As stated by the court in *Warren, supra* at 1064–65, pursuant to 14 U.S.C. 89(a), the Coast Guard may apprehend and board any vessel of the American flag on the high seas; such authority does not need to be founded upon any particularized suspicion.

In *United States* v. *Freeman*, 579 F. 2d 942, 946 (5th Cir. 1978), the court, in holding that Customs officials had statutory authority pursuant to 19 U.S.C. 1581(a) to detain and board a vessel in customs waters for the purpose of a document check, described 14 U.S.C. 89(a) as being "analogous" to 19 U.S.C. 1581(a), and stated that the language of the two statutes was "nearly identical." The court further stated that "the authority embodied within section 1581 may be traced back to the commencement of the Republic when the First Congress statutorily granted Customs officials *broad powers*." (Emphasis supplied.)

In *United States* v. *Gollwitzer*, 697 F. 2d 1357 (11th Cir. 1983), which involved the boarding and search of a vessel on inland waters by Customs officers, the court spoke of "the broad authority vested in Customs and Coast Guard officers."

Customs believes that the authority for the promulgation of amended section 162.3(a)(2), is as follows:

1. 19 U.S.C. 1581(a), particularly the words "at any other authorized place." 19 U.S.C. 1581(a) authorizes boardings within the United States (internal waters and the territorial sea to the three-mile limit), within the customs waters (generally from the coast to the 12-mile limit of the contiguous zone), or within customs-enforcement areas (50 miles from the limits of customs waters). The only area remaining is international waters beyond the customs waters.

2. The substantial similarity of 19 U.S.C. 1581(a) and 14 U.S.C. 89(a).

3. The fact that the Coast Guard may stop and board any American vessel on the high seas; prior to 1936, the Coast Guard's authority was based upon the predecessor statute to 19 U.S.C. 1581(a). See *Maul* v. *United States*, 274 U.S. 501, 507 (1927).

4. 46 U.S.C. 277 which authorizes customs officers to inspect a vessel's documents at any time.

5. The fact that customs laws clearly contemplate actions beyond the 12-mile limit. See 19 U.S.C. 1581 (g) and (h), 1583, 1586 (b), (c), and (e), and 1587.

6. 19 U.S.C. 66, which states in part that the Secretary of the Treasury "shall give such directions to customs officers and prescribe such rules and forms to be observed by them as may be necessary for the proper execution of the law."

One of the commenters points out language in *United States* v. *Williams, supra* at 1073, which states:

> Section 1581(a) empowers both the Customs Service and the Coast Guard to board vessels and conduct customs searches, but only in customs waters within the twelve-mile limit.

Customs does not believe that this language of *Williams* precludes the amendment to § 162.3(a). The issue of a Customs officer boarding an American vessel on the high seas was not presented in *Williams*, which involved the Coast Guard's seizure of a foreign vessel on the high seas. Further, Customs believes that the court in *Williams*, in writing of section 1581(a), merely repeated the limitations recognized by the court in *Warren*, which were based on the restrictive language of § 162.3(a)(2). Customs does not believe that the court in *Williams* considered the "at any other authorized place" language of 19 U.S.C. 1581(a).

Customs believes that § 162.3(a) should be consistent with the language of the corresponding statute, 19 U.S.C. 1581(a). If additional interpretation of the statute or regulation is necessary, it should be done by the courts. Over the last few years, there have been numerous cases in several circuits involving vessel searches and seizures.

Customs believes that the amendment to § 162.3(a) is constitutional. In *Williams, supra* at 1081–82, the court spoke of:

> * * * The cases holding that section 89(a) constitutionally authorizes the Coast Guard to stop American vessels beyond the twelve-mile limit for routine safety and documentary checks. E.g. *United States* v. *Warren*, 578 F. 2d 1058; *United States* v. *One (1) 43 Foot Sailing Vessel*, 538 F. 2d 694; *United States* v. *Odom*, 526 F. 2d 339. These cases reconfirm the notion that the fourth amendment does not necessarily require any sort of suspicion of criminal activity before a vessel may be stopped at sea; in addition, they imply that Congress's authority to enact statutes providing for "groundless" searches of vessels is not limited by the Constitution to United States customs waters.

The *Williams* court, *supra* at 1083, also stated that:

> The United States obviously has a vital interest in preventing the smuggling of illegal narcotics into the country and in apprehending those who may reasonably be suspected of violating the criminal narcotics laws.
>
> Furthermore, the seizure of a nautical vessel is a very limited and foreseeable intrusion.

In *Freeman, supra* at 946, the court stated:

[No] case holds that the stop of a vessel on the seas for a document or safety check is constitutionally proscribed by the Fourth Amendment. Indeed, our cases have upheld the right of government agents to stop vessels for routine safety and document checks under the analogous statutory authority granted to the Coast Guard by 14 U.S.C. 89(a).

In *Gollwitzer, supra* at 1657, the court recognized that ocean going vessels have a diminished expectation of privacy:

The potential for provoking fear by randomly stopping vessels capable of ocean travel is therefore less onerous than that in the context of random automobile stops or airport seizures.

The United States Supreme Court in *U.S.* v. *Villamonte-Marquez*,—U.S.—(1983) recognized the constitutionality of 19 U.S.C. 1581 and held that the standards which govern vessel boardings are different than those governing land vehicles.

The proposal to amend § 162.3 will improve the effectiveness of maritime interdiction activities. Operations on the high seas will continue to be governed by the 1978 interagency agreement between the Coast Guard and Customs which sets forth the framework for such activities.

The Fourth Amendment prohibits searches and seizures which are unreasonable. The actions authorized by the amendment to § 162.3(a) are not unreasonable in view of the role of Customs; the fact that Customs frequently acts in concert with the Coast Guard; and the fact that no case holds that the stop and search of a vessel on the high seas is constitutionally prohibited by the Fourth Amendment.

Executive Order 12291

These amendments will not result in a "major rule" as defined in section 1(b) of E.O. 12291. Accordingly, a regulatory impact analysis is not required.

Regulatory Flexibility Act

It is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that these amendments will not have a significant economic impact on a substantial number of small entities. The amendments are an enforcement measure which is not expected to have incidental effects on a substantial number of small entities.

Drafting Information

The principal author of this document was Gerard J. O'Brien, Jr., Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 162

Law enforcement, Customs duties and inspection, Imports.

Amendments to the Regulations

Part 162, Customs Regulations (19 CFR Part 162), is amended as set forth below.

William von Raab,

Commissioner of Customs.

Approved: November 2, 1983.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

PART 162—RECORDKEEPING, INSPECTION, SEARCH, AND SEIZURE

Section 162.3 is revised to read as follows:

§ 162.3 Boarding and search of vessels.

(a) *General authority.* A Customs officer, for the purpose of examining the manifest and other documents and papers and examining, inspecting and searching the vessel, may at any time go on board:

(1) Any vessel at any place in the United States or within the Customs waters of the United States;

(2) Any American vessel on the high seas;

(3) Any vessel within a Customs-enforcement area designated such under the provisions of the Anti-Smuggling Act (Act of August 5, 1935, as amended, 49 Stat. 517; 19 U.S.C. 1701, 1703–1711), but Customs officers shall not board a foreign vessel upon the high seas in contravention of any treaty with a foreign government, or in the absence of a special arrangement with the foreign government concerned.

(b) *Search of army or navy vessel.* If the district director or special agent in charge believes that sufficient grounds exist to justify a search of any army or navy vessel, the facts shall be reported to the commanding officer or master of the vessel with a request that he cause a full search to be made, and advise the district director or special agent in charge of the result of such search. If, after the cargo has been discharged, passengers and their baggage landed, and the baggage of officers and crewmembers examined and passed, the district director or special agent in charge believes that sufficient grounds exist to justify the continuance of Customs supervision of the vessel, the commanding officer or master of the vessel shall be advised accordingly.

(c) *Assistance of other agencies.* Customs officers are authorized to assist any other agency in the enforcement of United States laws on any vessel.

(R.S. 251, as amended, sec. 581, 46 Stat. 747, as amended, sec. 624, 46 Stat. 759 (19 U.S.C. 66, 1581, 1624))

[FR Doc. 83-31495 Filed 11-22-83; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 75F-0355 and 82F-0305]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule; denial of request for stay of effective date; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is denying requests to stay the amendment to the food additive regulations that provides for the safe use of aspartame in carbonated beverages and carbonated beverage syrup bases. After reviewing a request for a stay submitted with objections to the amendment and requests for a hearing, FDA has concluded that the public interest would not be served by a stay of the amendment while the agency analyzes the objections and makes a decision whether to grant a hearing.

DATE: This document confirms July 8, 1983, as the effective date of the regulation authorizing the use of aspartame in carbonated beverages and carbonated syrup bases (21 CFR 172.804).

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

Aspartame is the methyl ester of a digestible dipeptide, which has a nutritive value of four calories per gram. G. D. Searle & Co., Skokie, IL, originally petitioned in 1973 for approval of its use as a sweetener and flavor enhancer. FDA approved the petition in a final regulation published in the **Federal Register** of July 26, 1974 (39 FR 27317), and codified at 21 CFR 172.804.

FDA received formal objections to this regulation and requests for a hearing to investigate certain alleged toxic effects of aspartame. FDA granted the request for a hearing and

established a Public Board of Inquiry (the Board) to evaluate the scientific issues.

Subsequently, FDA stayed the regulation (40 FR 56907; Dec. 5, 1975) while an audit of the authenticity of certain toxicological studies on aspartame was carried out. Following this evaluation, the Board convened a public hearing; it completed the hearing and issued its report in 1980 (Aspartame, Decision of the Public Board of Inquiry, Docket No. 75F-0355) (Board's decision).

In the **Federal Register** of July 24, 1981 (46 FR 38285), the Commissioner of Food and Drugs reviewed the safety issues debated at the hearing and announced his final decision that aspartame was safe within the meaning of section 409(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)). He specifically determined that, on the basis of available data, aspartame consumption would not cause brain damage resulting in mental retardation or endocrine dysfunction, nor would it cause brain tumors. FDA approved aspartame for the following uses as a sweetener: dry sugar substitutes in free-flowing and tablet form; cold cereals; chewing gum; and dry bases for beverages, instant coffees and teas, puddings and gelatins, and dairy analog toppings (21 CFR 172.804(c)).

II. Aspartame for Use in Carbonated Beverages

A. Regulations Approving Use

On July 8, 1983 (48 FR 31376), FDA issued a final rule amending the regulation authorizing the use of aspartame to permit its use as a sweetener in carbonated beverages and carbonated beverage syrup bases. That regulation responded to a petition filed by G. D. Searle & Co. (47 FR 46140; Oct. 15, 1982). Before approving this new use, the agency reviewed, among other safety issues, the potential neurotoxicity of the components and decomposition products of aspartame, the stability of aspartame in carbonated beverages, and the potential impact on health of increased consumption of aspartame resulting from its additional use in carbonated beverages.

In reaching his decision that aspartame is safe as a food additive in carbonated beverages at projected consumption levels, the Commissioner determined that there was no evidence that aspartame's component amino acids adversely alter brain levels of neurotransmitters. Based on all the evidence before him, the Commissioner also concluded that there was no cause for concern about the safety of aspartame's decomposition products, diketopiperazine (DKP) and methanol, even at dosages of aspartame well above the 99 percent consumption level.

FDA based its determination on the evaluation of additional studies submitted by the petitioner, data from other relevant scientific studies, and data furnished in comments responding to the notice of the filing of the petition. These data are included in the administrative record for Docket No. 82F-0305.

B. Objections and Requests for a Hearing and a Stay

Two objections were filed to the July 8, 1983 regulation. The objections argued that numerous safety issues had not been adequately considered by the agency prior to promulgation of the regulation, and requested that the regulation be stayed or revoked pending examination of those issues in a public hearing. The two parties objecting to the regulation on the basis of unresolved safety issue were James S. Turner, 1424 16th St. NW., Washington, DC 20036, objecting on behalf of himself and the Community Nutrition Institute, 1146 19th St. NW., Washington, DC 20036 (hereinafter referred to as Turner objection); and Woodrow C. Monte, Director, Food Science and Nutrition Laboratories, Arizona State University, Tempe, AZ (hereinafter referred to as Monte objection). In addition, Richard J. Wurtman, M.D., Massachusetts Institute of Technology, Cambridge, Mass., commented on the regulation, but did not request a hearing or a stay of the regulation. Prior to publication of the final rule approving the use of aspartame in soft drinks, Dr. Wurtman wrote a number of letters to FDA in which he expressed his concern about certain alleged adverse effects of aspartame on brain function. Dr. Wurtman's letters and FDA's responses are in Docket No. 82F-0305. Because Dr. Wurtman's comment and the two objections raise that same issue, this document is also responsive to his comment. (See discussion in Section D.1. below.)

C. Standard for Granting a Discretionary Stay

Under section 409(e) of the act, a petition for a hearing or a stay of a food additive regulation does not operate automatically to stay or delay the effectiveness of that regulation. FDA regulations provide that the Commissioner may grant a stay of a challenged regulation in those situations where the public interest so warrants (21 CFR 10.35(d)(1)).

Promulgation of the regulation approving aspartame's additional use as a beverage sweetener was preceded by the Commissioner's determination, based on all available evidence, that aspartame is safe for human consumption, including this use. Because adoption of the regulation constitutes a finding by the Commissioner that the regulation is in the public interest, a substantial showing to the contrary must be made to justify a stay (40 FR 40682, 40687; Sept. 3, 1975). Under these circumstances, a stay of the regulation would be appropriate only upon a determination by the Commissioner that the objections create significant doubt as to the soundness of the initial finding of safety. If that were the case, the Commissioner could find that a stay would be in the public interest because the possibility of a risk to public health and safety would exist.

D. Scientific Issues Raised in Objections

This section discusses the specific issues identified by Dr. Monte and Mr. Turner in their objections to the regulation approving the use of aspartame in carbonated beverages. Citations are included to relevant **Federal Register** discussions of these issues, and to portions of the administrative record (Docket No. 75F-0355 or 82F-0305) where these points have been discussed or reviewed. Wherever issues raised by the two objections are similar, they have been combined for ease of discussion and analysis. In responding to the various issues raised by the objections, the agency incorporates by reference all materials in the administrative record (Docket Nos. 75F-0355 and 82F-0305).

For ease of discussion, each topic of an objection is listed below as a heading, followed by the agency's analysis of the topic.

1. *Brain Damage:* Mental retardation, brain lesions, potential changes in important brain chemicals leading to possible behaviorial modification, and the related need to test for this effect prior to approval of use in beverages.

The potential for brain damage resulting from aspartame-derived amino acids was one of the main safety concerns addressed in the hearing before the Public Board of Inquiry. The Board evaluated objections received in response to the publication of the original regulation authorizing aspartame for use in certain dry foods (39 FR 27317; July 26, 1974) and heard extensive testimony on the issue in its public hearing. With regard to aspartame's potential for causing mental retardation, brain lesions, or

undesirable effects on the neuroendocrine regulatory systems, the Board rejected the position of the objectors and concluded that aspartame did not cause brain lesions (Board's Decision, p. 38). The Commissioner's final decision discussed the matter in detail, and concurred with the Board's findings (46 FR 38285; July 24, 1981).

One of the present objections alleged that ingestion of combined high levels of aspartame and carbohydrates may result in nontoxic, but adverse, changes in the brain levels of important neurotransmitters. The preamble to the regulation authorizing the use of aspartame in carbonated beverage discussed that issue (48 FR 31376, 31378–31380). The relevance of specific experimental data submitted to the agency in support of this hypothesis was addressed in detail in a letter from the Director of the Bureau of Foods to Dr. Richard Wurtman, dated August 12, 1983. The agency sent Dr. Wurtman a letter, dated September 8, 1983, responding specifically to his comment. Those letters are in the administrative record (Docket No. 82F–0305).

2. *Decomposition Products:* Toxicity of diketopiperazine, methyl alcohol; detection of nitrosation products with modern methods; possible toxic, unidentified decomposition products.

The administrative record (Docket No. 75F–0355) contains the results of bioassays, including tests for fetal toxicity, which demonstrate the safety of DKP, a known decomposition product of aspartame. The validity of the DKP bioassay results was reviewed by the Commissioner in his decision (46 FR 38285, 38302). The safety aspects of DKP, methyl alcohol, and other decomposition products that may be present in carbonated beverages were reviewed in the preamble to the carbonated beverage regulation (48 FR 31376). That discussion contains citations to specific studies in the administrative record as well as to the scientific literature. Searle submitted data bearing on the formation of nitrosamines in support of its petition for approval of the use of aspartame in dry food. The results of these studies and the agency's evaluation of them are part of the administrative record (Docket No. 75F–0355).

3. *Cancer:* Brain tumors in rats, cancer in two human clinical participants, precancerous uterine polyps in rats, cancer from aspartame-derived methyl alcohol or its formaldehyde metabolite.

A possible association between aspartame ingestion and increased incidence of brain neoplasms in the rat was the second issue reviewed by the Public Board of Inquiry. The Board's decision on this issue (Board's decision, p. 39), as well as the Commissioner's detailed review of and decision on this point (46 FR 38285), are discussed again in the preamble to the carbonated beverage regulation (48 FR 31376).

The occurrence of a breast and a stomach cancer in two subjects participating in clinical testing of aspartame was evaluated in a pathology report contained in the administrative record supporting the approval of aspartame for use as a table top sweetener and for dry drink mixes (Docket No. 75F–0355, entry E–65, March 6, 1973). FDA determined that the tumors were unrelated to aspartame ingestion. The formation of uterine polyps in test animals treated with diketopiperazine was fully evaluated and resolved prior to the convening of the Board. (See Docket No. 75F–0355, memoranda, June–August 1975.)

4. *Consumption:* Improper or inadequate estimates of human exposure to aspartame from carbonated beverage consumption.

The highest likely level of daily aspartame consumption has been repeatedly considered: By the Board (Board's Decision, pp. 13–14); by the Commissioner in his decision on aspartame in dry foods (46 FR 38285, 38289); by the agency in promulgating the carbonated beverage rule (48 FR 31376, 31377). The regulation requires Searle to submit quarterly survey results of consumption, as well as production reports to the agency. (See 46 FR 38285, 38303.)

5. *Quality of data:* Flawed or inadequate test results.

Prior to the convening of the Board, the petitioner contracted with Universities Associated for Research and Education in Pathology, Inc. (UAREP), to review and evaluate the authenticity of certain animal studies with aspartame and DKP (44 FR 31716). A report prepared by UAREP verified the reliability of the studies. Other studies were authenticated after review by an agency task force. Only after FDA had concurred with the UAREP authentication of the test results did the agency proceed with the Board's hearing (Aspartame; Ruling on Objections and Notice of Hearing; 44 FR 31716, 31717). The Commissioner's decision discussed the issue in detail and reviewed all the evidence relied upon by the agency in reaching its conclusion (46 FR 38285, 38286).

6. *Labeling:* Inadequate notice to the public of potential harm; no requirement for notice in restaurants.

The original aspartame regulation requires a label notice on foods containing aspartame to alert individuals with phenylketonuria that the product contains phenylalanine (21 CFR 172.804(e)(1)). The Commissioner reviewed the need for additional label information in response to the earlier objection (46 FR 38285, 38303), and addressed this question again in the preamble to the carbonated beverage rule (48 FR 31376, 31381).

III. Evaluation of the Objections and Request for a Stay

After a careful review of the specific safety issues raised in the current objections, the agency has concluded that the objections do not provide evidence that potential public harm may result from the use of aspartame in carbonated beverages, and therefore the safety issues raised in the objections do not warrant a stay of § 172.804(c)(6).

The physiological and neurological effects of aspartame have been comprehensively studied over the past 10 years. The agency has subjected the data from these studies to exhaustive and searching analysis, and most of the issues raised in the objections currently under review are substantially identical to issues that FDA has already examined and resolved in its prior determinations of aspartame's safety. (See 46 FR 38285, July 24, 1981; and 48 FR 31376, July 8, 1983.) Those points which purport to raise new issues or novel interpretations of issues previously considered by FDA do not present public health questions that, even if resolved in favor of the persons filing the objections, are serious enough to warrant a stay of the regulation. Accordingly, the request for a stay is denied.

The agency is carefully reviewing the objections and requests for a hearing but has not yet completed this review. The Commissioner will publish the agency's decision on this matter in a future issue of the **Federal Register.**

Dated: November 16, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31451 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

21 CFR Parts 193 and 561

[FAP 2H5349/R626; FAP 2H5349/R627; PH-FRL 2476-2]

Tolerances for Pesticides in Food and Animal Feeds Administered by the Environmental Protection Agency; Propetamphos

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: These rules establish a food and a feed additive regulation to permit residues of the insecticide propetamphos in or on food and feed resulting from application in food-handling establishments of the insecticide propetamphos containing a maximum of 1.0 percent active ingredient. These regulations to establish maximum permissible levels for residues of the insecticide were requested pursuant to a petition by Sandoz, Inc., Crop Protection.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

By mail: William Miller, Product Manager (PM) 16, Registration Division (TS-767C), Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 211, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-2600).

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of June 30, 1982 (47 FR 28453), which announced that Sandoz, Inc., Crop Protection, 480 Camino Del Rio South, San Diego, CA 92108, had submitted a food additive petition (FAP 2H5349) proposing to amend 21 CFR Part 193 by permitting residues of .01 part per million (ppm) of the insecticide propetamphos ([(e)]-methylethyl 3-[[(ethylamino)methoxyphosphinothioyl]-oxy]-2-butenoate]) in food-handling establishments.

In the **Federal Register** of December 22, 1982 (47 FR 57129), EPA gave notice that Sandoz, Inc., had amended the petition. This amendment proposed amending 21 CFR Part 561 by establishing a regulation permitting residues of the insecticide propetamphos in or on animal feed exposed to the insecticide during treatment of animal feed-handling establishments with a tolerance limitation of 0.1 ppm and by amending 21 CFR Part 193 by permitting residues of 0.1ppm of propetamphos in or on food resulting from application of the insecticide in food-handling establishments.

There were no comments received in response to the notices of filing.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the regulation include a rabbit teratology study with a no-observed-effect level (NOEL) of 10.0 mg/kg (highest dose tested); a neurotoxicity study with a NOEL of 147 mg/kg (highest dose tested); a 6-month dog-feeding study with a NOEL of 2 ppm (0.05 mg/kg); a 13-week rat-feeding study with a NOEL of 4 ppm (0.2 mg/kg); a 2-year rat oncogenic/feeding study with a NOEL of 6 ppm (0.3 mg/kg); a mouse lifetime oral feeding study with a NOEL of 0.05 mg/kg/day; no oncogenic effects observed under the conditions of the studies at 6, 12, or 120 ppm (0.3, 0.6, or 3 mg/kg/day) in rats or mice at doses of 0.05, 1, 6, or 21 mg/kg/day; and the reproduction phase of a 3-generation rat reproduction/teratology study with a NOEL of 20 ppm (1.05 mg/kg).

Based on the chronic mouse-feeding study with a NOEL of 0.05 mg/kg/day, using a safety factor of 10, the acceptable daily intake (ADI) for humans is 0.005 mg/kg/day, and the maximum permissible intake (MPI) is 0.3000 mg/day for a 60-kg human.

The theoretical maximum residue contribution (TMRC) in the human diet from this regulation is 0.1500 mg/day per 1.5 kilograms of diet. There are no permanent tolerances established currently for this pesticide. This regulation uses 50.00 percent of the ADI.

Desirable data currently lacking include a rat teratology study that uses a maximum tolerated dose which would cause toxicity in addition to cholinesterase depression.

There are no regulatory actions pending against continued registration of the insecticide, and no other considerations are involved in establishing these food and feed additive regulations. The metabolism of the insecticide is adequately understood, and an adequate analytical method, gas chromatography using a flame photometric detector (P-mode) or an alkali flame ionization detector, is available.

The pesticide is considered useful for the purpose for which the regulations are sought. It is concluded that the pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 751, 7 U.S.C. 135(a) et seq.). Therefore, the regulations are established set forth below.

Any person adversely affected by these regulations may, within 30 days after publication of this notice in the **Federal Register** file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

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

Pursuant to the requirements of the Regulatory Flexiblility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new food or feed additive levels or conditions for safe use of additives, or raising such food or feed additive levels, do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24945).

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))

List of Subjects in 21 CFR Parts 193 and 561

Food additives, Animal feeds, Pesticides and pests.

Dated: November 9, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 193—[AMENDED]

Therefore 21 CFR, Chapter I, is amended as follows:

1. In Part 193, § 193.375 is revised to read as follows:

§ 193.375 Propetamphos.

A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos ([(e)-]-methylethyl 3-[[(ethylamino)

methoxyphosphinothioyl]oxy]-2-butenoate]) in food commodities exposed to the insecticide during treatment of food-handling establishments.

(a) Direct application shall be limited solely to spot and/or crack and crevice treatment in food-handling establishments where food and food products are held, processed, prepared, or served. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pin-stream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of food or food-contact surfaces.

(b) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

PART 561—[AMENDED]

2. In Part 561, new § 561.434 is added to read as follows:

§ 561.434 Propetamphos.

A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos ([e]-]-methylethyl 3-[[(ethylamino) methoxyphosphinothioyl]oxy]-2-butenoate]) in animal feed exposed to the insecticide during treatment of animal feed-handling establishments.

(a) Direct application shall be limited soley to spot and/or crack and crevice treatment in feed-handling establishments where feed and feed products are held, processed, prepared, or sold. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pinstream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of feed or feed-contact surfaces.

(b) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[FR Doc. 83-31489 Filed 11-22-83; 8:45 am]
BILLING CODE 6560-50-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 5

[T.D. 7921]

Income Tax; Credit for Employment of Certain New Employees

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations under sections 44B, 52, 53, and 381 of the Internal Revenue Code of 1954 relating to a credit for the employment of certain new employees. It reflects certain changes made by the Revenue Act of 1978, the Technical Corrections Act of 1979, and the Economic Recovery Tax Act of 1981. These final regulations provide taxpayers desiring to qualify for the credit with the guidance needed to comply with the law.

EFFECTIVE DATE: The amendments are effective, generally, with respect to wages paid or incurred after December 31, 1978.

FOR FURTHER INFORMATION CONTACT: John G. Schmalz of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Ave. NW., Washington, D.C. 20224. Attention: CC:LR:T, 202-566-3516.

SUPPLEMENTARY INFORMATION:

Background

On December 28, 1979 (44 FR 76817), the **Federal Register** published proposed amendments to the Income Tax Regulations (26 CFR Part 1) under sections 44B, 51, 52, 53, 280C, and 381 of the Internal Revenue Code of 1954. The amendments were proposed to conform the regulations to section 202(d)(3)(A) of the Tax Reduction and Simplification Act of 1977 (91 Stat. 148), and section 321 of the Revenue Act of 1978 (92 Stat. 2830). The proposed amendments were issued under the authority contained in sections 44B, 381(c)(26), and 7805 of the Internal Revenue Code of 1954 (92 Stat. 2834, 26 U.S.C. 44B; 91 Stat. 148, 26 U.S.C. 381(c)(26); 68A Stat. 917, 26 U.S.C. 7805). A public hearing was held on April 24, 1980 (45 FR 16500). After consideration of all comments regarding the proposed amendments, these amendments are adopted as revised by this Treasury decision. The proposed amendments, as published by the notice of proposed rulemaking, included § 1.51-1 dealing with the amount of credit. Section 1.51-1 is reserved in this Treasury decision and is being reproposed with additional rules to reflect the changes made by the Economic Recovery Tax Act of 1981. The new notice of proposed rulemaking appears in the same issue of the **Federal Register** as this Treasury decision.

The final regulations in this document also reflect the amendments made by section 103(a)(6)(B) of the Technical Corrections Act of 1979 (94 Stat. 209), and sections 207 and 261(e) of the Economic Recovery Tax Act of 1981 (95 Stat. 225, 262).

The amendments to the regulations create no new recordkeeping or reporting requirements. Evaluation of the effectiveness of the regulations after issuance will be based on comments received from offices within the Treasury Department, other government agencies, state and local governments, and the public.

Explanation of the Provisions

Section 321 of the Revenue Act of 1978 provides a targeted jobs credit for the employment of individuals qualifying as members of a targeted group. The targeted jobs credit replaces the new jobs credit allowable under section 44B (as in effect prior to enactment of the Revenue Act of 1978). In general, a taxpayer may elect to claim a credit under section 44B for amounts paid or incurred after December 31, 1978, for taxable years ending after that date, to members of a targeted group. Generally, to qualify for the credit, the amounts must be paid or incurred to members of a targeted group first hired after September 26, 1978. However, amounts paid or incurred after December 31, 1978, to a vocational rehabilitation referral hired before September 27, 1978, may qualify for the credit if a credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978) was claimed for the individual by the taxpayer for a taxable year beginning before January 1, 1979.

Section 53 of the Code relating to the amount of tax liability that can be eliminated by the credit for a taxable year is also amended by the Revenue Act of 1978. As amended, the amount of the credit may not exceed 90 percent of a taxpayer's tax liability reduced by certain credits. Prior to the amendment, a taxpayer could eliminate 100 percent of tax liability. The Revenue Act of 1978 also repealed section 53(b) which limited the amount of the credit that is passed through to a partner, a beneficiary of an estate or trust, or a shareholder of a subchapter S corporation to a limitation separately computed with respect to the partner's,

beneficiary's or shareholder's interest in the entity. This repeal was made effective for taxable years beginning after December 31, 1978.

Public Comments and Changes in Response to Public Comments

Comments were received concerning the repeal of section 53(b) stating that the regulations should provide that a credit earned in a taxable year beginning before January 1, 1979 (*i.e.*, before the effective date of the repeal of section 53(b)) and carried over to a taxable year beginning after December 31, 1978, should not be subject to the requirement of separate computation of the limitation in the carryover year. The final regulations adopt this rule and provide other rules clarifying the repeal of section 53(b).

Drafting Information

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

Special Analysis

The Commissioner of Internal Revenue has determined that this final rule is not a major rule as defined in Executive Order 12291. Accordingly, a Regulatory Impact Analysis is not required. Pursuant to 5 U.S.C. 605(b), the Secretary of the Treasury has certified that the requirements of the Regulatory Flexibility Act do not apply to this final rule because it will not have a significant economic impact on a substantial number of small entities.

List of Subjects

26 CFR 1.0–1 through 1.58–8

Income taxes, Tax liability, Tax rates, Cedits.

26 CFR Part 5

Income taxes, Revenue Act of 1978.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR Part 1 is amended as follows:

PART 1—[AMENDED]

Paragraph 1. There is inserted immediately after § 1.44A–4 the following new section.

§ 1.44 B–1 Credit for employment of certain new employees.

(a) *In general*—(1) *Targeted jobs credit.* Under section 44B a taxpayer may elect to claim a credit for wages (as defined in section 51(c) paid or incurred to members of a targeted group (as defined in section 51(d)). Generally, to qualify for the credit, the wages must be paid or incurred to members of a targeted group first hired after September 26, 1978. However, wages paid of incurred to a vocational rehabilitation referral (as defined in section 51(d)(2)) hired before September 27, 1978, may qualify for the credit if a credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978) was claimed for the individual by the taxpayer for a taxable year beginning before January 1, 1979. The amount of the credit shall be determined under section 51. Section 280C(b) (relating to the requirement that the deduction for wages be reduced by the amount of the credit) and the regulations thereunder will not apply to taxpayers who do not elect to claim the credit.

(2) *New jobs credit.* Under section 44B (as in effect prior to enactment of the Revenue Act of 1978) a taxpayer may elect to claim as a credit the amount determined under sections 51, 52, and 53 (as in effect prior to enactment of the Revenue Act of 1978). Section 280C(b) (relating to the requirement that the deduction for wages be reduced by the amount of the credit) and the regulations thereunder will not apply to taxpayers who do not elect to claim the credit.

(b) *Time and manner of making election.* The election to claim the targeted jobs credit and the new jobs credit is made by claiming the credit on an original return, or on an amended return, at any time before the expiration of the 3-year period beginning on the last date prescribed by law for filing the return for the taxable year (determined without regard to extensions). The election may be revoked within the above-described 3-year period by filing an amended return on which the credit is not claimed.

(c) *Election by partnership, electing small business corporation, and members of a controlled group.* In the case of a partnership, the election shall be made by the partnership. In the case of an electing small business corporation (as defined in section 1371(a)), the election shall be made by the corporation. In the case of a controlled group of corporations (within the meaning of section 52(a) and the regulations issued thereunder) not filing a consolidlated return under section 1501, the election shall be made by each member of the group. In the case of an affiliated group filing a consolidated return under section 1501, the election shall be made by the group.

Par. 2. Section 1.51–1 is removed.

Par. 3. There is inserted immediately after § 1.50B–5 the following new section:

§ 1.51–1 Amount of Credit. [Reserved]

Par. 4. Section 1.52–1 is amended by revising paragraph (a) to read as follows:

§ 1.52–1 Trades or businesses that are under common control.

(a) *Apportionment of jobs credit among members of a group of trades or businesses that are under common control*—(1) *Targeted jobs credit.* (i) In the case of a group of trades or businesses that are under common control (within the meaning of paragraph (b) of this section) at any time during the calendar year, the amount of the targeted jobs credit (computed under section 51 as if all the organizations that are under common control are one trade or business) under section 4–1B must be apportioned among the members of the group on the basis of each member's proportionate share of the wages giving rise to such credit. If the group of trades or businesses that are under common control have different taxable years, the credit shall be computed as if all the organizations have the same taxable year as the organization for which a determination of the proportionate share of the credit is being made. For taxable years beginning before January 1, 1982, the amount of the qualified first-year wages cannot exceed 30 percent of the aggregate unemployment insurance wages paid by the group of trades or businesses under common control during the calendar year ending in the taxable year of the organization for which a determination of the proportionate share of the credit is being made. The limitations in section 53 and the regulations thereunder apply to each organization individually (although, in applying these limitations, an affiliated group of corporations electing to make a consolidated return shall be treated as one organization).

(ii) The application of the subparagraph may be illustrated by the following examples:

Example (1). (a) Corporation M and its three subsidiaries, Corporations N, O, and P, are a group of businesses that are under common control and each uses the cash receipts and disbursements method of accounting and has a calendar year taxable year. Corporations M, N, O, and P paid out the following amounts in unemployment insurance wages, qualified first-year wages and qualified second-year wages during 1980.

	Unemployment insurance wages	Qualified 1st-Year wages	Qualified 2d-year wages
Corporation:			
M	$600,000	$184,000	$75,000
N	300,000	85,000	90,000
O	360,000	120,000	115,000
P	24,000	24,000	0
Total	1,284,000	413,000	280,000

(b) Since Corporations M, N, O, and P are under common control, the amount of qualified first-year wages paid by the group is limited to 30 percent of the aggregate unemployment insurance wages paid by the group in the calendar year ending in the group's taxable year. Since the qualified first-year wages of $413,000 exceeds 30% of the aggregate unemployment insurance wages, the group is limited to qualified first-year wages of $385,200 (30% of $1,284,000). The amount of the targeted jobs credit attributable to qualified first-year wages is equal to $192,600 (50% of $385,200). The amount of the credit attributable to qualified second-year wages is equal to $70,000 (25% of $280,000).

(c) The credit is apportioned among Corporations M, N, O, and P on the basis of their proportionate share of the qualified first-year wages or qualified second-year wages giving rise to the credit. Each corporation's share of the credit attributable to qualified first-year wages would be computed as follows:

Corporation:		Amount of credit
M	$192,600 × $\frac{\$184,000}{\$413,000}$	= $85,807.26
N	$192,600 × $\frac{\$85,000}{\$413,000}$	= $39,639.23
O	$192,600 × $\frac{\$120,000}{\$413,000}$	= $55,961.26
P	$192,600 × $\frac{\$24,000}{\$413,000}$	= $11,192.25

Each corporation's share of the credit attributable to qualified second-year wages is computed as follows:

Corporation:		Amount of credit
M	$70,000 × $\frac{\$75,000}{\$280,00}$	= $18,750
N	$70,000 × $\frac{\$90,000}{\$280,000}$	= $22,500
O	$70,000 × $\frac{\$115,000}{\$280,000}$	= $28,750
P	$70,000 × $\frac{0}{\$280,000}$	= 0

Example (2). Assume the facts in example (1) with these additional facts. A, a member of a targeted group, worked for more than one of the members of the controlled group in the taxable year. A first began work for Corporation M on January 1, 1980, and later worked for Corporations N and O during 1980. For services rendered by A during 1980, the following wages were paid to A: Corporation M paid A $2,500 of qualified first-year wages; Corporation N paid A $1,500 of qualified first-year wages; Corporation O paid A $3,000 of qualified first-year wages. Corporations M, N, and O paid A a total of $7,000 of wages during 1980. Only $6,000 of qualified first-year wages per year per employee may be taken into account for purposes of the credit. See § 1.51-1(d)(1). Since Corporations M, N, and O are treated as a single employer under section 52(a), the maximum $6,000 of qualified first-year wages paid A by the group must be apportioned among Corporations M, N, and O as follows:

Corporation:		Qualified 1st-Year wages
M	$6,000 × $\frac{\$2,500}{\$7,000}$	= $2,142.86
N	$6,000 × $\frac{\$1,500}{\$7,000}$	= $1,285.71
O	$6,000 × $\frac{\$3,000}{\$7,000}$	= $2,571.43

Example (3). (a) Corporation Q and its two subsidiaries, Corporations R and S, are a group of businesses that are under common control and each uses the cash receipts and disbursements method of accounting. Corporation Q has a calendar year taxable year. Corporation R has a July 1 through June 30 taxable year. Corporation S has an October 1 through September 30 taxable year. For purposes of determining Corporation R's proportionate share of the credit, the credit is computed as if Corporations Q and S have the same taxable year as Corporation R. Accordingly, Corporation R would compute its share of the credit for its 1979–1980 taxable year as set forth below.

	Unemployment insurance wages, 1979	Qualified wages paid from July 1, 1979, to June 30, 1980	
		1st year wages	2d year wages
Corporation:			
Q	$500,000	$150,000	$80,000
R	300,000	110,000	50,000
S	100,000	25,000	10,000
Total	900,000	285,000	140,000

(b) Since Corporations Q, R, and S are under common control, the amount of qualified first-year wages is limited to 30 percent of the aggregate unemployment insurance wages paid by the group during the calendar year ending in Corporation R's taxable year. Since the qualified first-year wages of $285,000 exceeds 30 percent of the aggregate unemployment insurance wages, the group is limited to qualified first-year wages of $270,000 (30% of $900,000). The amount of the targeted jobs credit attributable to qualified first-year wages paid by members of the group during the period of the taxpayer's taxable year is $135,000 (50% of $270,000). The amount of the credit attributable to qualified second-year wages paid or incurred by members of the group during the period of the taxpayer's taxable year is $35,000 (25% of $140,000).

(c) The credit is apportioned to Corporation R on the basis of its proportionate share of the qualified first-year wages and qualified second-year wages giving rise to the credit. Corporation R's share of the credit attributable to qualified first-year wages is $52,105.26

$$\$135,000 \times \frac{\$110,000}{\$285,000}$$

Corporation R's share of the credit attributable to qualified second-year wages is $12,500

$$\$35,000 \times \frac{\$50,000}{\$140,000}$$

Corporation R's share of the credit for its 1979–1980 taxable year is $64,605.26 ($52,105.26 + $12,500).

(2) *New jobs credit.* In the case of a group of trades or businesses that are under common control at any time during the calendar year, the amount of the new jobs credit (computed under section 51 as if all the organizations that are under common control are one trade or business) under section 44B (as in effect prior to enactment of the Revenue Act of 1978) must be apportioned among the members of the group on the basis of each member's proportionate contribution to the increase in unemployment insurance wages for the entire group. The limitations in section 53 (as in effect prior to enactment of the Revenue Act of 1978) and the regulations thereunder apply to each organization individually (although, in applying these limitations, an affiliated group of corporations electing to make a consolidated return shall be treated as one organization). The application of this subparagraph may be illustrated by the following example:

Example. (a) Corporation T and its three subsidiaries, U, V, and W, are a group of businesses that are under common control and each has a calendar year taxable year. Corporations T, U, V, and W have paid out the following amounts in unemployment insurance wages during 1976 and 1977:

	1976	1977	Increase in FUTA wages in 1977 over 1976
Corporation.			
T	$1,000,000	$1,015,000	+$15,000
U	500,000	650,000	+150,000
V	600,000	580,000	−20,000
W	40,000	100,000	+60,000
Total	2,140,000	2,345,000	205,000

(b) Since all employees of trades or, businesses that are under common control are treated as employed by a single employer, the computations in section 51 are performed as if all the organizations which are under common control are one trade or business. Consequently, the amounts of the total unemployment insurance wages of the group in 1976 (*i.e.*, $2,140,000) and 1977 (*i.e.*,

$2,345,000) are used to determine the increase in unemployment insurance wages in 1977 over the 1976 wage base. Since the amount equal to 102 percent of the 1976 unemployment insurance wages ($2,182,800) is greater than the amount equal to 50 percent of the 1977 unemployment insurance wages ($1,172,500), the increase in unemployment insurance wages in 1977 over the 1976 wage base is $162,200 ($2,345,000–$2,182,800). The limitations in section 51(c), (d), and (g) (as in effect prior to enactment of the Revenue Act of 1978) must also be computed as though all the organizations under common control are one trade or business. For purposes of this example, it is assumed that none of those limitations reduce the amount of increase in unemployment insurance wages. As a result, the amount of the new jobs credit allowed to the group of business is $81,100 (50% of $162,200).

(c) The credit is apportioned among Corporations T, U, and W on the basis of their proportionate contributions to the increase in unemployment insurance wages. No credit would be allowed to Corporation V because it did not contribute to the increase in the group's unemployment insurance wages. Corporation T's share of the credit would be $5,406.66 ($81,100×($15,000÷$225,000 (*i.e.*, $15,000+$150,000+$60,000))). Corporation U's share would be $54,066.67 ($81,100×($150,000÷225,000)), and Corporation W's share would be $21,626.67 ($81,100×($60,000÷$225,000)).

* * * * *

Par. 5. Section 1.52–2 is amended by revising paragraph (a) to read as follows:

§ 1.52–2 Adjustments for acquisitions and dispositions.

(a) *General rule.* The provisions in this section only apply to the computation of the new jobs credit. If, after December 31, 1975, an employer acquires the major portion of a trade or business or the major portion of a separate unit of a trade or business, then, for purposes of computing the new jobs credit for any calendar year ending after the acquisition, both the amount of unemployment insurance wages and the amount of total wages considered to have been paid by the acquiring employer, for both the year in which the acquisition occurred and the preceding year, must be increased, respectively, by the amount of unemployment insurance wages and the amount of total wages paid by the predecessor employer that are attributable to the acquired portion of the trade or business or separate unit. If the predecessor employer informs the acquiring employer in writing of the amount of unemployment insurance wages and the amount of total wages attributable to the acquired portion of the trade or business that have been paid during the periods preceding the acquisition, then, for purposes of computing the credit for any calendar year ending after the acquisition the amount of unemployment insurance wages and the amount of total wages considered paid by the predecessor employer shall be decreased by those amounts. Regardless of whether the predecessor employer so informs the acquiring employer, the predecessor employer shall not be allowed a credit for the amount of any increase in the employment insurance wages or the total wages in the calendar year of the acquisition attributable to the acquired portion of the trade or business over the amount of such wages in the calendar year preceding the acquisition.

* * * * *

Par. 6. Section 1.52–3 is revised to read as follows:

§ 1.52–3 Limitation with respect to certain persons.

(a) *Mutual savings institutions.* In the case of an organization to which section 593 applies (that is, a mutual savings bank, a cooperative bank or a domestic building and loan association), the amount of the targeted jobs credit (new jobs credit in the case of wages paid before 1979) allowable under section 44B shall be 50 percent of the amount otherwise determined under section 51, or, in the case of an organization under common control, under § 1.52–1 (a) and (b).

(b) *Regulated investment companies and real estate investment trusts.* In the case of a regulated investment company or a real estate investment trust subject to taxation under subchapter M, chapter 1 of the Code, the amount of the targeted jobs credit (new jobs credit in the case of wages paid before 1979) allowable under section 44B shall be reduced to the company's or trust's ratable share of the credit. The ratable share shall be determined in accordance with rules similar to the rules provided in section 46(e)(2)(B) and the regulations thereunder. For purposes of computing the ratable share, the reduction of the deduction for wage or salary expenses under § 1.280C–1 shall not be taken into account.

(c) *Cooperatives*—(1) *Taxable years ending after October 31, 1978.* For taxable years ending after October 31, 1978, in the case of a cooperative organization described in section 1381(a), rules similar to rules provided in section 46(h) and the regulations thereunder shall apply in determining the distribution of the amount of the targeted jobs credit (new jobs credit in the case of wages paid before 1979) allowable to the cooperative organization and its patrons under section 44B.

(2) *Taxable years ending before November 1, 1978.* For taxable years ending before November 1, 1978, in the case of a cooperative organization described in section 1381(a), the amount of new jobs credit allowable under section 44B shall be reduced to the cooperative's ratable share of the credit. The ratable share shall be the ratio which the taxable income of the cooperative for the taxable year bears to its taxable income increased by the amount of the deductions allowed under section 1382 (b) and (c). For purposes of computing the ratable share, the reduction of the deduction for wage or salary expenses under § 1.280C–1 shall not be taken into account.

Par. 7. Section 1.53–1 is redesignated as § 1.53–3 and new §§ 1.53–1 and 1.53–2 are added immediately after § 1.52–3 to read as follows:

§ 1.53–1 Limitation based on amount of tax.

(a) *General rule*—(1) *Targeted jobs credit.* For taxable years beginning after December 31, 1978, the amount of the targeted jobs credit allowed by section 44B (as amended by the Revenue Act of 1978) shall not exceed 90 percent of the tax imposed by chapter 1, reduced by the credits enumerated in section 53(a).

(2) *New jobs credit.* For taxable years beginning before January 1, 1979, the amount of the new jobs credit allowed by section 44B (as in effect prior to enactment of the Revenue Act of 1978) shall not exceed the tax imposed by chapter 1, reduced by the credits enumerated in section 53(a).

(b) *Special rule for 1978–79 fiscal year.* In the case of a taxable year beginning before January 1, 1979, and ending after that date, the sum of the targeted jobs credit (determined without regard to the tax liability limitation in paragraph (a)(1) of this section) and the new jobs credit (determined without regard to the tax liability limitation in (a)(2) of this section) shall not exceed the tax imposed by chapter 1, reduced by the credits enumerated in section 53(a).

§ 1.53–2 Carryback and carryover of unused credit.

(a) *Allowance of unused credit as a carryback or carryover*—(1) *In general.* Section 53(b) (formerly designated as section 53(c) for taxable years beginning before 1979) provides for carrybacks and carryovers of unused targeted jobs credit (new jobs credit in the case of wages paid before 1979). An unused credit is the excess of the credit determined under section 51 for the taxable year over the limitation

provided by § 1.53–1 for such taxable year. Subject to the limitations contained in paragraph (b) of this section and paragraph (f) of § 1.53–3, an unused credit shall be added to the amount allowable as a credit under section 44B for the years to which an unused credit can be carried. The year with respect to which an unused credit arises shall be referred to in this section as the "unused credit year."

(2) *Taxable years to which unused credit may be carried.* An unused targeted jobs credit (new jobs credit in the case of wages paid before 1979) shall be a new employee credit carryback to each of the 3 taxable years preceding the unused credit year and a new employee credit carryover to each of the 15 taxable years succeeding the unused credit year. An unused credit must be carried first to the earliest of the taxable years to which it may be carried, and then to each of the other taxable years (in order of time) to the extent that the unused credit may not be added (because of the limitation contained in paragraph (b) of this section) to the amount allowable as a credit under section 44B for a prior taxable year.

(b) *Limitations on allowance of unused credit*—(1) *In general.* The amount of the unused targeted jobs credit (new jobs credit in the case of wages paid before 1979) from any particular unused credit year which may be added under section 53(b)(1) (section 53(c)(1) in the case of a new jobs credit) to the amount allowable as a credit under section 44B for any of the preceding or succeeding taxable years to which such credit may be carried shall not exceed the amount by which the limitation in § 1.53–1 for such preceding or succeeding taxable year exceeds the sum of (i) the credit allowable under section 44B for such preceding or succeeding taxable year, and (ii) other unused credits carried to such preceding or succeeding taxable year which are attributable to unused credit years prior to the particular unused credit year. Thus, in determining the amount, if any, of an unused credit from a particular unused credit year which shall be added to the amount allowable as a credit for any preceding or succeeding taxable year, the credit earned for such preceding or succeeding taxable year, plus any unused credits originating in taxable years prior to the particular unused credit year, shall first be applied against the limitation based on amount of tax for such preceding or succeeding taxable year. To the extent the limitation based on amount of tax for the preceding or succeeding year exceeds the sum of the credit earned for such year and other unused credits attributable to years prior to the particular unused credit year, the unused credit from the particular unused credit year shall be added to the amount allowable as a credit under section 44B for such preceding or succeeding year. If any portion of the unused credit is a carryback to a taxable year beginning before January 1, 1977, section 44B shall be deemed to have been in effect for such taxable year for purposes of allowing such carryback as a credit under section 44B. To the extent that an unused credit cannot be added for a particular preceding or succeeding taxable year because of the limitation contained in this paragraph, such unused credit shall be available as a carryback or carryover to the next succeeding taxable year to which it may be carried.

(2) *Special rules for an electing small business corporation.* An unused targeted jobs credit (new jobs credit in the case of wages paid before 1979) under section 44B of a corporation which arises in an unused credit year for which the corporation is not an electing small business corporation (as defined in section 1371(b)) and which is a carryback or carryover to a taxable year for which the corporation is an electing small business corporation shall not be added to the amount allowable as a credit under section 44B to the shareholders of such corporation for any taxable year. However, a taxable year for which the corporation is an electing small business corporation shall be counted as a taxable year for purposes of determining the taxable years to which such unused credit may be carried.

(3) *Corporate acquisitions.* For the carryover of unused credits under section 44B in the case of certain corporate acquisitions, see section 381(c)(26) and § 1.381(c)(26)–1.

(4) *Examples.* This paragraph may be illustrated by the following examples.

Example (1). In 1978, A, a calendar year taxpayer, had an unused new jobs credit of $2,000. In 1979, A has a targeted jobs credit of $2,000 and a tax liability imposed by chapter 1 of the Code of $4,000 after all credits listed in section 53(a) have been taken into account. The amount of A's targeted jobs credit allowable under section 44B for 1979 is 90 percent of A's tax liability. The amount of the new jobs credit that may be carried to 1979 is limited to $1,600 ($3,600 [90% of $4,000]—$2,000).

Example (2). In 1979, B, a calendar year taxpayer, has a tax liability imposed by chapter 1 of the Code of $10,000 after all credits listed in section 53(a) have been taken. B's targeted jobs credit for that taxable year is limited to 90 percent of his income tax liability or $9,000. B had a $15,000 targeted jobs credit in 1979 resulting in an unused targeted jobs credit of $5,000 for that year. In 1976 and 1977 B had tax liabilities imposed by chapter 1 of the Code of $3,000 and $4,000 respectively after all credits listed in section 53(a) had been taken. For purposes of carrying back an unused targeted jobs credit to a taxable year beginning before January 1, 1977, section 44B as amended by the Revenue Act of 1978 is deemed to have been in effect for such taxable year. Accordingly, the applicable tax liability limitation for 1976 would be governed by section 53(a) (as amended by the Revenue Act of 1978) which limits the amount of targeted jobs credit allowed to 90 percent of the tax imposed by chapter 1 of the Code after all credits listed in section 53(a) have been taken. B may carry back $2,700 (90% of $3,000) of the 1979 unused targeted jobs credit to 1976. B may carry back $4,000 of the unused targeted jobs credit to 1977 because section 53(a) as it applied to the 1977 taxable year limited the amount of the credit to 100 percent of the taxpayer's tax liability imposed by chapter 1 of the Code after all credits listed in section 53(a) had been taken.

Par. 8. Section 1.53–3, as redesignated in Paragraph 7, is amended as follows:

1. Paragraph (a) is amended to read as set forth below.

2. Paragraph (f) is revised to read as set forth below.

§ 1.53–3 Separate rule for pass-through of jobs credit.

(a) *In general.* Under section 53(b), in the case of a new jobs credit or targeted jobs credit earned under section 44B by a partnership, estate or trust, or subchapter S corporation, the amount of the credit that may be taken into account by a partner, beneficiary, or shareholder may not exceed a limitation under section 53(b) separately computed with respect to the partner's, beneficiary's, or shareholder's interest in the entity. A credit is subject to the limitation of section 53(b) with respect to a partner, beneficiary, or shareholder if it is earned by a partnership, estate or trust, or subchapter S corporation in a taxable year ending within, or ending before, a taxable year beginning before January 1, 1979 of the partner, beneficiary, or shareholder. See paragraph (f) of this section for rules on carryback or carryover of a credit subject to separate limitation. This section prescribes rules, under the authority of section 44B(b), relating to the computation of the separate limitation. For purposes of this section, references to section 53(a) and (b) are to that section as it existed before it was amended by the Revenue Act of 1978. This paragraph may be illustrated by the following examples:

Example (1). A, a calendar year taxpayer, is a partner in P, a calendar year partnership.

A's pro rata portion of the credit earned by P in 1978 is $200. The $200 credit to be claimed on A's 1978 return is subject to the separate limitation in section 53(b) because the limitation applies to taxable years of the taxpayer beginning before January 1, 1979.

Example (2). B, a calendar year taxpayer, is a shareholder in Corporation M, a subchapter S corporation with a July to June fiscal year. B's pro rata portion of the credit earned by Corporation M in its taxable year beginning in 1978 is $100. The $100 credit to be claimed on B's 1979 return is not subject to the separate limitation requirement of section 53(b) because the limitation only applies to taxable years of the taxpayer beginning before 1979, notwithstanding the credit was earned by Corporation M before 1979.

* * * * *

(f) *Carryback or carryover of credit subject to separate limitation.* A credit subject to the separate limitation under section 53(b) that is carried back or carried over to a taxable year beginning before January 1, 1979, is also subject to the separate limitation in the carryback or carryover year. For purposes of the preceding sentence, a credit that is earned by a partnership, a trust, or estate, or a subchapter S corporation in a taxable year of such entity ending within, or after, the taxable year of a partner beneficiary or shareholder beginning after December 31, 1978, will not be subject to the separate limitation in section 53(b) with respect to such partner, beneficiary, or shareholder. The taxpayer to whom the credit has been passed through shall not be prevented from applying the unused portion in a carryback or carryover year merely because the entity that earned the credit changes its form of conducting business if the nature of its trade or business essentially remains the same. The computation of the separate limitation in such a case shall reflect the income attributable to the taxpayer's interest in the entity in its revised form. Thus, a shareholder carrying over a credit from a subchapter S corporation may include dividends declared by that corporation after the subchapter S election had been terminated as income attributable to that person's interest in the entity. Similarly, if a partnership incorporates in a carryover year, any income attributable to an interest in the corporation will be regarded, for purposes of computing the separate limitation under section 53(b), as income attributable to an interest in the entity. This paragraph may be illustrated by the following examples:

Example (1). A, a calendar year taxpayer, is a shareholder in Corporation M, a subchapter S corporation. In 1977, A's pro rata share of the new jobs credit earned by Corporation M was $10,000. A could only use $2,000 of the credit in 1977 because of the separate limitation under section 53(b). In 1978, A carries the unused credit over from 1977. The carryover credit is subject to the separate limitation under section 53(b).

Example (2). Assume the same facts as in example (1) except that the unused credit is carried over to 1979. The carryover credit is not subject to the separate limitation under section 53(b) because that limitation does not apply to taxable years of a taxpayer beginning after December 31, 1978.

Example (3). B, a calendar year taxpayer, is a shareholder in Corporation W, a subchapter S corporation. In 1979, B's pro rata share of the targeted jobs credit covered by Corporation W was $5,000 but B could only use $3,000 of the credit in 1979. B carries back the unused credit to 1978. The carryback credit is not subject to the separate limitation under section 53(b).

Par. 9. Section 1.280C–1 is amended to read as follows:

§ 1.280C–1 Disallowance of certain deductions for wage or salary expenses.

If an employer elects to claim the targeted jobs credit under section 44B (as amended by the Revenue Act of 1978), or elects to claim the new jobs credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978), the employer must reduce its deduction for wage or salary expenses paid or incurred in the year the credit is earned by the amount allowable as credit (determined without regard to the provisions of section 53). In the case in which wages and salaries are capitalized the amount subject to depreciation must be reduced by an amount equal to the amount of the credit (determined without regard to the provisions of section 53) in determining the depreciation deduction. In the case of an employer who uses the full absorption method of inventory costing under § 1.471–11, the portion of the basis of the inventory attributable to the wage or salary expenses giving rise to the credit and paid or incurred in the year the credit is earned must be reduced by the amount of the credit allowable (determined without regard to the provisions of section 53). If the employer is an organization that is under common control (as described in § 1.52–1), it must reduce its deduction for wage or salary expenses by the amount of the credit apportioned to it under § 1.52–1 (a) or (b). The deduction for wage and salary expenses must be reduced in the year the credit is earned, even if the employer is unable to use the credit in that year because of the limitations imposed by section 53.

Par. 10. There is inserted immediately after § 1.381(c)(25)–1 the following new section:

§ 1.381(c)(26)–1 Credit for employment of certain new employees.

The computation of carryovers and carrybacks of unused targeted jobs credit (new jobs credit in the case of wages paid before 1979) under section 44B in a transaction to which section 381 applies shall be made under the principles of § 1.381(c)(23)–1 (relating to the computation of carryovers and carrybacks of unused investment credit), except that provisions of paragraph (c)(4) and paragraph (e) (6), (7), and (8) of such section shall not apply.

PART 5—[AMENDED]

§ 5.44B–1 [Removed]

Par. 11. Section 5.44B–1 is hereby removed.

This Treasury decision also conforms the regulations to the amendments made to sections 44B, 52 and 53 by the Technical Corrections Act of 1979 and the Economic Recovery Tax of 1981. To this extent, this Treasury decision is issued solely under the authority contained in section 7805 of Internal Revenue Code of 1954. The rules prescribed reflecting these changes are favorable to taxpayers. For this reason and because these rules are interpretative regulation, the requirement for notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code and the effective date limitation of subsection (d) of that section are found to be inapplicable.

This Treasury decision is issued under the authority contained in sections 44B, 381, and 7805 of the Internal Revenue Code of 1954 (92 Stat. 2834, 26 U.S.C. 44B; 91 Stat. 148, 26 U.S.C. 381(c)(26); 68A Stat. 917, 26 U.S.C. 7805).

James I. Owens,

Acting Commissioner of Internal Revenue.

Approved: November 5, 1983.

John E. Chapoton,

Assistant Secretary of the Treasury.

[FR Doc. 83-31461 Filed 11-18-83; 12:31 pm]

BILLING CODE 4830-01-M

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 178

[T. D. ATF-160]

State Laws and Published Ordinances; Incorporation by Reference

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

ACTION: Final rule (Treasury decision).

SUMMARY: This final rule incorporates by reference the compiled list of State laws and published ordinances, entitled "State Laws and Published Ordinances—Firearms (ATF Publication 5300.5 (12-82))." This compiled list is annually revised and is developed from State firearms laws obtained from federal libraries, and from copies of firearms ordinances published by political subdivisions and furnished ATF. The published ordinances are those which the Director determines to be relevant to the enforcements of 18 U.S.C. Chapter 44—firearms.

DATES: Effective date: November 23, 1983. Approval for Incorporation by Reference in this document by the Director of the Federal Register is effective on November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Gary D. Caplan, Firearms and Explosives Operations Branch (202) 566-7591.

SUPPLEMENTARY INFORMATION:

Reason for Incorporation by Reference

Historically, the list of State laws and published ordinances, pursuant to 18 U.S.C. 921(a)(19), has been annually published in the **Federal Register** in its entirety.

ATF seeks to reduce operating costs by no longer publishing in the **Federal Register** the list in its entirety but rather incorporate it by reference under 5 U.S.C. 552(a)(1). The list, however, will continue to be revised annually and furnished to Federal firearms licensees in accordance with the law and regulations.

"State Laws and Published Ordinances—Firearms (ATF Publication 5300.5)" is eligible for incorporation by reference under 1 CFR Part 51 since the incorporation will help reduce the volume of matter printed in the **Federal Register**, will not reduce the usefulness of the publication system of the Office of the Federal Register, and will continue to be easily available to the public for purchase and inspection. The use of the term "incorporation by reference" was authorized by Congress in 5 U.S.C. 552 to reduce the volume of material published in both the **Federal Register** and the Code of Federal Regulations. The legal effect of an incorporation by reference is that the material is treated as if it actually were published in full text in the **Federal Register** and in the Code of Federal Regulations.

Amendments

The definition of "published ordinance" in § 178.11 is amended and § 178.24 is revised to reflect the incorporation by reference of the list of State laws and published ordinances.

Executive Order 12291

It has been determined that this final rule is not a "major rule" within the meaning of Executive Order 12291 of February 17, 1981 (46 FR 13193), because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State or local agencies, or geographic regions; and it will not have 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 a regulatory flexibility analysis, are not applicable because neither 5 U.S.C. 553 nor any other law requires the publication of a general notice of proposed rulemaking for this final rule.

List of Subjects in 27 CFR Part 178

Administrative practice and procedure, Arms and ammunition, Authority delegations, Customs duties and inspection, Exports, Imports, Military personnel, Penalties, Reporting and recordkeeping requirements, Research, Seizures and forfeitures, and Transportation.

Drafting Information

The principal author of this final rule is Lori D. Weins of the Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms. Other personnel of the Bureau of Alcohol, Tobacco and Firearms and offices of the Department of the Treasury participated in developing this final rule both as to matters of substance and style.

Authority and Issuance

Because this final rule merely makes procedural changes authorized by the Office of the Federal Register and editorial changes to improve the clarity of the regulations, it is unnecessary and impractical to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly, it is unnecessary and impractical to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Accordingly, this final rule is issued under the authority contained in 5 U.S.C. 552(a) (80 Stat. 383, as amended). As amended, 27 CFR Part 178 reads as follows:

PART 178—COMMERCE IN FIREARMS AND AMMUNITION

1. The Table of Sections is amended to revise the heading of § 178.24 to read as follows:

Sec.

* * * * *

178.24 List of State laws and published ordinances.

* * * * *

2. Section 178.11 is amended by revising the definition listed to read as follows:

§ 178.11 Meaning of terms.

* * * * *

Published ordinance. A published law of any political subdivision of a State which the Director determines to be relevant to the enforcement of this part and which is contained on a list compiled by the Director, which list is incorporated by reference in the **Federal Register**, revised annually, and furnished to licensees under this part.

* * * * *

3. Section 178.24 is revised to read as follow:

§ 178.24 List of State laws and published ordinances.

(a) The Director is authorized to compile, annually revise, and furnish to Federal fireamrs licensees a list of State laws and published ordinances which are relevant to the enforcement of this part.

The Director annually revises the list and publishes it as "State Laws and Published Ordinances—Firearms" which is furnished free of charge to licensees under this part.

(b) "State Laws and Published Ordinances—Firearms" is incorporated by reference in this part. It is ATF Publication 5300.5, 1982 ed. and is for sale from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Room 8401, 1100 L Street, NW, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register. A notice of any change in the publication will be published in the **Federal Register**.

Signed: January 13, 1983.

Stephen E. Higgins,

Director.

Approved: October 25, 1983.

John M. Walker, Jr.,

Assistant Secretary, (Enforcement and Operations).

October 25, 1983.

[FR Doc. 83-31475 Filed 11-22-83; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R, Amdt. No. 23]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Hearing Impairment Critieria Under the Program for the Handicapped

AGENCY: Office of the Secretary, DoD.

ACTION: Amendment of final rule.

SUMMARY: This amends the CHAMPUS Regulation by revising the criteria for determining when a hearing impairment is a serious handicap. The revised criteria reflect current professional opinion regarding the handicapping effects of hearing impairments. The amendment will make benefits available to a greater number of handicapped beneficiaries.

EFFECTIVE DATE: This amendment is effective November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Rose M. Sabo, Health Care Policy Specialist, Policy Branch, OCHAMPUS, Aurora, CO 80045; telephone (303) 361-4014.

SUPPLEMENTARY INFORMATION: We published our proposed amendment on pages 38538 and 38539 of the **Federal Register** on July 28, 1981, and invited the public to comment for 30 days. We received eight comments from individuals and five from professional organizations and interested agencies. The following summarizes the comments, suggestions and actions taken:

1. All the comments endorsed the proposal; however, a few people requested we make the amendment retroactive to the effective date of the CHAMPUS Regulation, which is June 1, 1977. Going back 6 years and authorizing benefits would create numerous administrative problems and increased Program costs, precluding adoption of the suggestion. Alternatively, the amendment will be effective the date the final rule is published in the **Federal Register.**

2. One comment recommended that we use the Veterans Administration's Schedule of Rating Disabilities instead of the proposed criteria. Adopting the VA criteria would not be appropriate. The Veterans Administration's Schedule of Rating Disabilities is used primarily to evaluate disabilities in veterans for monetary entitlement. It is not used as a basis for determining whether the veteran is entitled to a hearing aid or associated medical services, whereas the CHAMPUS criteria were specifically developed for that purpose.

3. Another comment requested we clarify that the criteria represent hearing threshold levels without amplification. We have accepted this suggestion and clarified the criteria.

4. One person requested that we modify the rule for preauthorization under the Program for the Handicapped. While this request is outside the scope of this amendment, the issue is under separate consideration.

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance and military personnel.

PART 199—[AMENDED]

Accordingly, 32 CFR, Chapter I, is amended as follows:

§ 199.11 is amended by revising paragraph (e)(2) (iii) and (iv) to read as follows:

§ 199.11 Program for the Handicapped.

* * * * *

(e) *Serious Physical Handicap.* * * *

(2) *Examples of conditions which may cause serious physical handicaps.* * * *

(iii) *Hearing Impairment—Testable Patients.* A hearing impairment is a serious physical handicap when, unaided by amplification, it is manifested by:

(*a*) A 45 decibel Hearing Threshold Level (HL) or poorer in either ear tested at 1,000; 2,000; or 3,000 Hz frequencies; or by

(*b*) A 30 decibel HL or poorer in *each* ear tested at 1,000; 2,000; or 3,000 Hz frequencies; or by

(*c*) Speech discrimination of 60% or poorer with either ear.

(iv) *Hearing Impairment—Nontestable Patients.* Where pure tone audiometry or speech discrimination testing is not available or not reliable because of the patient's age or condition, the attending physician must submit documentation which demonstrates the patient is unable to engage in basic productive activities of daily living expected of unimpaired persons of the same age group. An example of acceptable documentation would be electrophysiological tests of hearing such as auditory evoked potential testing or a behavioral assessment which shows that, without special help, and infant with a hearing impairment will not develop normal language. Each case will be reviewed on its own merits.

* * * * *

Note.—We have determined that this amendment only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It is not, therefore, a "major rule" under Executive Order 12291. We certify that this amendment will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

[10 U.S.C. 1079, 1086; 5 U.S.C. 301]

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

November 18, 1983.

[FR Doc. 83-31457 Filed 11-22-83; 8:45 am]

BILLING CODE 3810-01-M

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1151

General Statement of Policy

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Final rule.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (ATBCB) occasionally receives requests to participate in litigation as *amicus curiae* (friend of the court). Such requests were previously dealt with pursuant to the procedures in 36 CFR 1151.2—Amicus Curiae Policies. When the ATBCB adopted Authorities and Delegations at its July 12, 1983, meeting, published separately as 36 CFR Part 1153, 36 CFR § 1151.2 (c) and (d) of the above policy were amended. The amendment rescinds the prior authority of the General Counsel to reject requests to the ATBCB to participate as *amicus curiae* in litigation and of the ATBCB Executive Committee to approve such requests. The amended *amicus* policy delegates to the ATBCB Executive Committee the authority to disapprove *amicus* requests, to recommend to the Board that it approve such requests and to request that the Chairperson special ATBCB meetings to consider such requests. The section requires ATBCB

approval prior to any petition to participate as *amicus curiae*.

EFFECTIVE DATE: July 12, 1983.

FOR FURTHER INFORMATION CONTACT: Ms. Laurinda Steele, Office of Administration and Management, Architectural and Transportation Barriers Compliance Board, 330 C Street, SW., Washington, D.C. 20202, Phone (202) 245-1801 voice or TDD.

Authority: 29 U.S.C. 792, Pub. L. 93-112, as amended by Pub. L. 95-602.

PART 1151—[AMENDED]

For the reasons set out in the Summary, 36 CFR 1151.2 (c) and (d) are amended as set forth below.

§ 1151.2 [Amended]

1. By revising 36 CFR 1151.2(c) to read as follows:

* * * * *

(c) The Executive Committee of the ATBCB has the duty and responsibility to review requests to the Board to enter litigation as *amicus curiae*. In carrying out these responsibilities, the Executive Committee is delegated the authority to disapprove such requests and make recommendations to the ATBCB to approve such requests. ATBCB approval shall be required prior to any *amicus* filing. The Executive Committee may request the Chairperson of the ATBCB to call a special meeting of the ATBCB to expedite ATBCB to call a special meeting of the ATBCB to expedite ATBCB action on the Executive Committee's recommendations.

* * * * *

2. By removing 36 CFR 1151.2(d).

Dated: October 27, 1983.

Wm. Bradford Reynolds,

Chairperson.

[FR Doc. 83-29806 Filed 11-22-83; 8:45 am]

BILLING CODE 6820-BP-M

---

36 CFR Part 1151

Federal Contracting Policies; General Statement

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Final rule.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (ATBCB) amends its regulations relating to Federal contracts. The regulations were originally published as a policy statement at 46 FR 37045 (1981), 36 CFR 1151.4, effective May 5, 1981. The procurement process is a highly detailed one, requiring actions on a regular basis and a clear delineation of authorities to key officials. The general policy designates the officials responsible for procurement activity for purposes of the Federal Property and Administrative Services Act. The amended policy adds a requirement for ATBCB approval of the objective of every contract which has major policy implications. The amended policy retains the requirement for ATBCB approval of the objective of every contract over $10,000 that is not a basic administrative procurement, and the requirement for approval of the ATBCB Planning and Budget Committee before a sole source procurement can be entered. The amended policy also sets out specifically other procurement authorities and requirements of the ATBCB and Executive Director that were not contained in the May 5, 1981, policy statement.

EFFECTIVE DATE: July 12, 1983.

FOR FURTHER INFORMATION CONTACT: Ms. Laurinda Steele, Office of Administration and Management, Architectural and Transportation Barriers Compliance Board, 330 C Street, SW., Washington, D.C. 20202. Phone: (202) 245-1591 voice or TDD.

SUPPLEMENTARY INFORMATION:

List of Subjects in 36 CFR Part 1151

Authority delegations, Consultants, Government contracts, Government procurement, Organization and functions.

Pursuant to Section 502 of the Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 391, as amended, the Architectural and Transportation Barriers Compliance Board (ATBCB) established at its meeting on May 5, 1981, policies relating to procurement by Federal contracts and grants. At its July 12, 1983, meeting, the ATBCB amended that general policy statement.

The Federal Property and Administrative Services Act, 40 U.S.C. 471 *et seq.*, 41 U.S.C. 251-260, established contract policies applicable to Federal civilian agencies. The statute authorizes two methods of procurement: formal advertising and negotiation. Competition is to be strived for in both methods. The procurement process is a highly detailed one, requiring actions on a regular basis and a clear delineation of authorities to key officials.

Due to its institutional structure and location, as well as resource limitations, the ATBCB receives procurement administrative support services from the agency through which ATBCB funds are disbursed. Under the existing policy statement, the Chairperson is the "Head of the Agency" and the Executive Director is the "Head of the Procurement Activity" for procurement purposes. The amended policy statement continues those designations.

Sections (a) and (d) contain no substantive changes. Sections (b)(2) and (b)(3) give the Executive Director authority to direct suspension or termination of contracts under his or her procuring authority, and of contracts under the delegated authority of designated subordinate officials; and the authority to process unsolicited proposals. Neither of these sections alters any provision of the existing policy statement. The previous policy provided that prior ATBCB approval of procurements was required only for single procurements in excess of $10,000. The amended policy retains that requirement and in addition requires prior ATBCB approval of all procurements having major policy implications. It also provides that the ATBCB may ratify unauthorized procurements and direct suspension or termination of contracts under its procuring authority.

The existing policy statement provides that the Executive Director can enter into "basis Administrative procurements," regardless of amount, without prior ATBCB approval. The amended policy statement defines in more detail a "basic Administrative procurement" but does not change the substantive content of the existing provision, with one exception: Any printing procurement over $10,000 must have prior ATBCB approval.

Section (g) is a new section which requires the Executive Director to report semi-annually to the ATBCB on procurement activities. The section does not alter any provisions of the existing policy statement.

Authority: 29 U.S.C. 792; Pub. L. 93-112, as amended by Pub. L. 95-602.

PART 1151—[AMENDED]

For the reasons set out in the preamble, 36 CFR Part 1151 is amended as shown.

1. By revising paragraphs (b) and (c) to read as follows:

§ 1151.4 Federal procurement policies.

* * * * *

(b) Except as otherwise provided in this § 1151.4, for purposes of the Federal Property and Administrative Services Act and implementing regulations and circulars, the Executive Director is delegated authority to act as "Head of the Procuring Activity" and to designate appropriate subordinate officials. The Executive Director may (1) enter all contracts on behalf of the ATBCB in accordance with the provisions of this

§ 1151.4 or may delegate that responsibility, (2) to the extent authorized by law, direct suspension or termination of contracts under his or her procuring authority, and of contracts under the delegated authority of designated subordinate officials, and (3) process unsolicited proposals.

(c) The ATBCB will approve the specific objective of each procurement (1) in excess of $10,000, or (2) which has a major policy implication before any such procurement is awarded and reserves the right, as warranted, to impose limitations applicable to particular procurements.

* * * * *

2. By removing the word "Board" and inserting "ATBCB" so that paragraph (d) reads as follows:

* * * * *

(d) The ATBCB will enter into a sole source procurement only after approval to do so has been given by a majority vote of the members of the Planning and Budget Committee of the ATBCB and the Chairperson.

* * * * *

3. By adding a new paragraph (e) to read as follows:

* * * * *

(e) To the extent authorized by law, the ATBCB may:

(1) ratify unauthorized procurements, and

(2) direct suspension or termination of contracts under its procuring authority.

* * * * *

4. By redesignating paragraph (e) as paragraph (f) and revising it to read as follows:

* * * * *

(f) Paragraphs (c)(1) and (d) of this § 1151.4 do not apply to basic Administrative procurements, regardless of amount of said procurements, except as otherwise provided in (2), below. The term basic Administrative procurement shall mean procurements for:

(1) Purchase or rental of equipment, including data processing equipment, and related services.

(2) Printing. (However, each printing procurement in excess of $10,000 shall be approved in advance by the ATBCB.)

(3) Stenographic services.

(4) Office supplies.

(5) Furniture and furnishings.

(6) Services of administrative law judges and expert witnesses in connection with compliance proceedings.

(7) Administrative support services of another Federal agency.

(8) Consultants and related expenses to perform staff functions when appropriate staff has not been hired.

(9) Space acquisition.

(10) Accommodating the known physical handicaps of employees.

(11) Appropriate training of employees.

(12) Meeting other administrative needs of the office.

* * * * *

5. By adding a new paragraph (g) to read as follows:

* * * * *

(g) The Executive Director will report semi-annually in writing to the ATBCB on each procurement, regardless of amount, entered into to date in the fiscal year, listing each procurement separately with its amount and date. In addition, the report shall list all procurements then in progress that have not been awarded and any procurements being considered for any future time.

Dated: October 27, 1983.

Wm. Bradford Reynolds,

Chairperson.

[FR Doc. 83-29807 Filed 11-22-83; 8:45 am]

BILLING CODE 6820-BP-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300075A; PH-FRL 2475-6]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Certain Primary Alkyl Amines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for primary *n*-alkylamines, where the alkyl group (C_8–C_{18}) is derived from coconut, cottonseed, soya, or tallow acids when used as surfactants in pesticide formulations. This regulation was requested by the Armak Co.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Rm. 3708, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

N. Bhushan Mandava, Registration Support and Emergency Response Branch, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7700).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of September 14, 1983 (48 FR 41186) that Armak Co., 8401 West 47th St., McCook, IL 60525, had submitted a request that 40 CFR 180.1001(d) be amended by establishing an exemption from the requirement of a tolerance for primary *n*-alkylamines, where the alkyl group (C_8–C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as water; baits such as sugar, starches, and meat scraps; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The pesticide is considered useful for the purpose for which the exemption is sought. It is concluded that the exemption from the requirement of a tolerance will protect the public health and is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this notice in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

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

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 9, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR 180.1001(d) is amended by adding and alphabetically inserting the inert ingredient primary *n*-alkylamines, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * *		
Primary *n*-alkylamines, where the alkyl group (C_8–C_{18}) is derived from coconut, cottonseed, soya, or tallow acids		Surfactant
* * * * *		

* * * * *

[FR Doc. 83-31483 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[PP 3F2806/R623; PH-FRL-2476-3]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Flucythrinate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for residues of the insecticide flucythrinate in or on certain raw agricultural commodities. This regulation to establish maximum permissible levels for residues of the insecticide was requested by the American Cyanamid Co.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

By mail: Timothy A. Gardner, Product Manager (PM) 17, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 207, CM No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703-557-2690).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of February 9, 1983 (45 FR 6018), which announced that the American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, had submitted a pesticide petitition (PP 3F2806) to EPA proposing that 40 CFR 180.400 be amended by establishing a tolerance for residues of the insecticide flucythrinate [(±) cyano(3-phenoxyphenyl)methyl(+)-4-difluoromethoxy)-alpha-(1-methylethyl)benzeneacetate] in or on the raw agricultural commodities apples at 1.0 part per million (ppm), meat and meat by-products (mbyp) of cattle at 0.1 ppm, cattle fat at 1.0 ppm, milk at 0.3 ppm, and milk fat at 6.0 ppm.

No comments were received in response to the notice of filing.

The petition was subsequently amended as follows: meat and meat by-products of cattle, goats, hogs, horses, and sheep at 0.1 ppm; fat of cattle, goats, hogs, horses, and sheep at 1.0 ppm; whole milk at 0.1 ppm and milk fat at 2.0 ppm.

The data submitted in the petition and other relevant material have been evaluated. The data considered in support of the proposed tolerance included an acute oral rat toxicity study with a median lethal dose (LD_{50}) of 81 milligrams (mg)/kilogram (kg) for male rats and 67 mg/kg for female rats; a 21-day delayed hen neurotoxicity study with a no-observed-effect level (NOEL) of 5,000 mg/kg, the highest dose tested (HDT); teratology studies (in rats and rabbits), with a NOEL of 8.0 mg/kg/day (HDT) for rats and a NOEL of 60 mg/kg/day (HDT) for rabbits; a 3-generation rat reproduction study with a NOEL of 30 ppm; 90-day subchronic rat and dog feeding studies with a NOEL of 60 ppm for rats and 150 ppm (HDT) for dogs (HDT); a 24-month rat chronic-feeding/oncogenicity study that resulted in a systemic NOEL of 60 ppm in which no oncogenic effects were noted at dosage levels of 30, 60, and 120 ppm (120 ppm being the highest dosage level tested); an 18-month mouse oncogenic study in which no oncogenic effects were noted at dosage levels of 30, 60, and 120 ppm (120 ppm being the highest dosage level tested); and the following mutagenicity studies: an Ames test at 1,000 micrograms (μg)/Plate (HDT) and a rat dominant-lethal test at 10.0 mg/kg (HDT), both negative.

Data considered desirable but currently lacking are the following: (1) A 1-year or longer dog-feeding study; (2) a second neurotoxicity study in hens at higher dosage levels.

Actions being taken to obtain the lacking information are as follows:

1. The 1-year or longer dog study is in progress and will be submitted to the Agency in the third quarter of 1984.

2. Rationale as to why the neurotoxicity study need not be repeated has been submitted and is undergoing review. If the Agency does not accept the rationale as to why the study should not be repeated, the company will be required to repeat the 21-day delayed neurotoxicity study in hens at higher dose levels and submit the results to the Agency.

The acceptable daily intake (ADI) is calculated to be 0.0150 mg/kg/day based on the 3-generation rat reproduction study and its NOEL of 30 ppm (150 mg/kg) using a 100-fold safety factor. The maximum permissible intake (MPI) is calculated to be 0.900 mg/day for a 60-kg person. Published and pending tolerances result in a theoretical maximum residue contribution (TMRC) of 0.0384 mg/day and utilize 4.27 percent of the ADI. The establishment of these tolerances will increase the TMRC to 0.1003 mg/day resulting in a total utilization of 11.15 percent of the ADI.

The nature of the residue is adequately understood for this tolerance. An adequate analytical method, gas chromatography, is available for enforcement purposes. There are currently no regulatory actions pending against the registration of this pesticide, and there are no other relevant considerations in establishing this tolerance.

A related document (PP 3H5381/R624) establishing a regulation permitting residues of this chemical in or on the commodity apple pomace (dry) appears elsewhere in this issue of the **Federal Register.**

The pesticide is considered useful for the purpose for which the tolerances are sought. Based on the information cited above, the Agency has determined that the establishment of the tolerances for residues of the insecticide flucythrinate in or on the commodities will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register,** file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the

requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, pesticides and pests.

Dated: November 14, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR 180.400 is amended by adding, and alphabetically inserting, the following raw agricultural commodities, to read as follows:

§ 180.400 Flucythrinate; tolerances for residues.

* * * * *

Commodities	Parts per million
Apples	1.0
Cattle, fat	1.0
Cattle, mbyp	0.1
Cattle, meat	0.1
* * * * *	
Goats, fat	1.0
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	1.0
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	1.0
Horses, mbyp	0.1
Horses, meat	0.1
Milk	0.1
Milk, fat	2.0
* * * * *	
Sheep, fat	1.0
Sheep, mbyp	0.1
Sheep, meat	0.1

[FR Doc. 83-31488 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[OPP-300076A; PH-FRL 2475-8]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Sulfuric Acid

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for sulfuric acid that meets the Food Chemicals Codex specifications when used as an inert ingredient pH control agent in pesticide formulations. This proposed regulation was requested by Dow Corning Corp.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written comments to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

N. Bhushan Mandava, Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Registration Support and Emergency Response Branch, Rm. 716, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703-557-7700).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of August 30, 1983 (48 FR 39244) that Dow Corning Corp., Midland, MI 48640, had submitted a request that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for sulfuric acid that meets the Food Chemicals Codex specifications and is used as an inert ingredient pH control agent.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as water; baits such as sugar, starches, and meat scraps; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellants in aersol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The pesticide is considered useful for the purpose for which the exemption is sought. It is concluded that the exemption from the requirement of a tolerance will protect the public health and is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this notice in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulations deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

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

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 9, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR 180.1001(c) is amended by adding and alphabetically inserting the inert ingredient sulfuric acid, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* *	* *	*
Sulfuric acid (CAS Registry No. 7664-93-9) that meets the Food Chemicals Codex specifications.	0.1% of pesticide formulation.	pH control agent.
* *	* *	*

* * * * *

[FR Doc. 83-31481 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[PP 3E2766/R613; PH-FRL 2476-5]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Chlorpyrifos

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for the combined residues of the insecticide chlorpyrifos and its metabolite in or on the raw agricultural commodity kiwifruit. This regulation to

establish a maximum permissible level for residues of chlorpyrifos in or on the commodity was requested, pursuant to a petition, by Dow Chemical Company.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

By mail: Jay Ellenberger, Product Manager (PM) 12, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 202, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703-557-2386).

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule published in the **Federal Register** of September 14, 1983 (48 FR 41184), which announced that the Dow Chemical Company, PO Box 1706, Midland, MI 48640, had submitted pesticide petition 3E2766 to EPA proposing to amend 40 CFR 180.342 by establishing a tolerance for the combined residues of the insecticide chlorpyrifos [*O,O*-diethyl*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] and its metabolite 3,5,6-trichloro-2-pyridinol in or on the raw agricultural commodity kiwifruit imported from New Zealand at 2.0 parts per million (ppm).

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The scientific data submitted in the petition and other relevant material have been evaluated and discussed in the notice of proposed rulemaking.

The pesticide is considered useful for the purpose for which the tolerance is sought. It is concluded that the tolerance would protect the public health and is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this notice in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

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

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 9, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR 180.342 is amended by adding alphabetically the raw agricultural commodity kiwifruit to read as follows:

§ 180.342 Chlorpyrifos; tolerances for residues.

* * * * *

Commodities	Parts per million
* * * * *	
Kiwifruit	2.0
* * * * *	

[FR Doc. 83-31486 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 271

[SW-3-FRL 2476-7]

Maryland; Phase II, Component A Interim Authorization of the State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Approval of State program.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act of 1976 (RCRA), the State of Maryland has applied for Interim Authorization Phase II, Component A. The Environmental Protection Agency (EPA) has reviewed Maryland's application for Phase II, Component A Interim Authorization and has determined that Maryland's hazardous waste program is substantially equivalent to the Federal program covered by Phase II, Component A.

The State of Maryland is hereby granted Interim Authorization for Phase II, Component A to operate the State's hazardous waste program in lieu of the Federal program for facilities which treat or store hazardous waste in containers, tanks, surface impoundments and waste piles.

EFFECTIVE DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Anthony J. Donatoni, Chief, State Programs Section, Waste Management Branch, U.S. EPA Region III, 6th and Walnut Streets, Philadelphia, PA 19106, (215) 597-7937.

SUPPLEMENTARY INFORMATION:

Background

In the May 19, 1980 **Federal Register** (45 FR 33063) the Environmental Protection Agency promulgated regulations, pursuant to Subtitle C of the Resource Conservation and Recovery Act of 1976 (RCRA) as amended, to protect human health and the environment from the improper management of hazardous waste. Included in these regulations, which became effective November 19, 1980, were provisions for a transitional stage in which States would be granted interim program authorization. The Interim Authorization program is being implemented in two phases corresponding to the two stages in which the underlying Federal program has taken effect. Phase I of the Federal program, published in the May 19, 1980 **Federal Register** (45 FR 33063), includes regulations pertaining to the identification and listing of hazardous wastes; standards applicable to generators and transporters of hazardous waste, including a manifest system; and the "interim status" standards applicable to existing hazardous waste management facilities before they receive permits. The State of Maryland received Interim Authorization for Phase I on July 8, 1981. In the January 26, 1981 **Federal Register** (26 FR 7965), the Environmental Protection Agency announced the availability of portions of the second phase of Interim Authorization. Phase II of the Federal program includes permitting procedures and standards for hazardous waste management facilities. EPA made the second phase of Interim Authorization available in components, in order to authorize State programs as expeditiously as possible and because some of the standards for hazardous waste treatment, storage, and disposal facilities (40 CFR Part 264) have been promulgated at different times. Component A, published in the **Federal Register** January 12, 1981 (46 FR 2802), contains standards for permitting containers, tanks, surface impoundments, and waste piles. Component B, published in the **Federal Register** January 23, 1981 (46 FR 7666), contains standards for permitting hazardous waste incinerators. Component C, published in the **Federal Register** July 26, 1982 (47 FR 32274),

contains standards for permitting surface impoundments, waste piles, land treatment facilities and landfills. These Component C standards for permitting surface impoundments and waste piles superseded the Component A standards for permitting storage and treatment in surface impoundments and waste piles published on January 12, 1981. However, States that submitted a complete application for Component A to EPA and for which EPA had published a notice of public hearing prior to the effective date of the Component C standards (January 26, 1983) could receive Interim Authorization for Component A based upon the standards promulgated on January 12, 1981 (see 47 FR 32379). The State of Maryland applied for Phase II, Component A Interim Authorization, which would enable them to permit the storage and treatment of hazardous waste in containers, tanks, surface impoundments and waste piles.

A notice of public comment period and hearing was published in the State's major newspapers and was sent to those persons on the State and EPA mailing list at least 30 days prior to the hearing. A **Federal Register** notice announcing the public comment period and the public hearing was published on January 25, 1983 (48 FR 3383) and the public hearing was held on March 9, 1983. The comment period was held open until March 16, 1983.

Discussion

The State of Maryland submitted its complete application for Phase II, Component A on January 19, 1983. EPA reviewed that State's application and prepared comments. The issues which EPA identified for the State to address included: (1) more detail about certain program areas described in the Program Description, (2) a commitment in the Memorandum of Agreement to announce permit actions over the radio and also notify local government officials, (3) clarification of citations and explanations in the Attorney General's Statement, and (4) correcting numerous regulatory inaccuracies.

Through letters dated March 4, 1983, April 14, 1983, June 2 and 23, 1983, and an amendment to the Attorney General's Statement received by EPA on October 20, 1983, the State of Maryland satisfactorily responded to the issues raised by EPA. In those letters, the State clarified certain issues and amended portions of the State's application. The amended Program Description now more clearly explains how new permit standards, established to support Component A, will interface with existing State permits and permit conditions. In addition, a more detailed explanation of the use of an "Operations Manual" as part of a facility permit is provided in the amended Program Description.

The amended Memorandum of Agreement now contains provisions requiring the State to pay for radio announcements of permit actions and to notify local government officials of the same.

A supplemental Attorney General's Certification adequately addressed EPA's concerns regarding specific items like the adoption of Federal regulations by reference, the imposition of financial responsibility on permittees, a ban on constructing facilities without permits, and binding owners of facilities to permit conditions. The supplemental certification also incorporated numerous other items previously considered by the Assistant Attorney General.

Lastly, the State modified its Authorization Plan describing a procedure to correct minor regulatory deficiencies in response to EPA comments. On May 27, 1983 the State published a regulatory errata in the Maryland Register. In Addition, the amended Authorization Plan commits the State to correcting the more substantive elements of its regulations in a formal regulation proposal under a specific schedule.

Responsiveness Summary

EPA Region III conducted a public hearing on the Maryland complete application for Phase II Component A Interim Authorization on March 9, 1983, in Baltimore, Maryland.

The hearing was attended by twelve (12) members of the public in addition to EPA Region III and Maryland agency representatives. Three people provided testimony. Two of the three people testifying at the hearing also provided written comments. Two additional written comments were received during the public comment period. All comments were reviewed and considered by EPA in reaching the decision on Maryland's application. The public comment period closed on March 16, 1983.

One of the five persons who submitted comments favored the delegation of regulatory authority to the State of Maryland unconditionally. Two commenters favored delegation, but provided comments. The two remaining commenters neither supported nor opposed interim authorization, but identified their concerns about the State's program application.

One commenter was concerned that the State might not have enough health and science professionals on its staff to appreciate the public health and toxicologic aspects of a hazardous waste management program. EPA has assessed the classification and quantity of resources available to implement Phase I and Phase II Component A of the RCRA program and has determined they are adequate.

Two commenters raised concerns about the State's regulations, COMAR 10.51.01–.09. One issue involved the uncertainties about the requirement for, and contents of, a facility Operations Manual. The State amended its Program Description to explain how the Operations Manual is part of the permit and what information is contained within. General comments on the regulations fell into three categories. The first included comments related to the editorial errors identified within the State's regulations. Although the errors in the regulations may affect their clarity, EPA has determined the regulations are substantially equivalent to the federal regulations. Where specific legal clarifications were necessary, the State has provided them to EPA. In addition, the State prepared a regulatory errata for editorial errors which was published in the Maryland Register on May 27, 1983 and has committed, in an amended Authorization Plan, to correct other parts of the regulations through an official regulation proposal/adoption procedure. The two other categories of regulation comments included concerns about State provisions being more stringent than EPA's and the fact that Maryland adopted additional regulations which had only been proposed by EPA. Federal regulations clearly allow State programs to be more stringent than the Federal program (40 CFR Part 271.121(i)) and, as mentioned earlier, EPA has determined the State's regulations for Phase II Component A are at least substantially equivalent to the federal program.

One commenter had a particular concern about the State basing its regulations for storage surface impoundments and waste piles on EPA's original Component A regulations promulgated January 12, 1981. The issue involves the fact that EPA superseded the January 12, 1981 regulations when the Component C regulations for surface impoundments and waste piles were promulgated on July 26, 1983 and subsequently took effect on January 26,

1983. The Component C regulations provided more flexibility for permitting storage surface impoundments and waste piles, especially for existing facilities. However, Mayland elected to adopt EPA's original January 12, 1981 Component A regulations to permit storage surface impoundments and waste piles. In addition, the State remained eligible to apply for Component A, to permit these facilities, based on EPA's original promulgation, as long as two conditions were met (See 47 FR 32379). EPA regulations allowed Maryland to receive interim authorization for the original Component A to permit storage surface impoundments and waste piles since: (1) a complete application for Component A was submitted to EPA and (2) EPA published its public hearing notice before January 26, 1983. EPA's regulations also clearly explain, in a clarifying footnote, that the Agency will consider State programs based on the January 12, 1981 standards for storage surface impoundments and waste piles substantially equivalent to the amended analogous provisions of Component C.

Several commenters also provided suggestions on ways to possibly improve the administration of the State's program, but these comments were beyond the scope of the RCRA program authorization requirements and deemed to be inappropriate for consideration by EPA.

One of Maryland's regulations requires Federal facilities to comply with the financial responsibility requirements for owners and operators of treatment, storage, and disposal facilities. Federal facilities are exempted from this requirement in the Federal program (40 CFR 264.140(c)).

State programs are allowed to be more stringent or more extensive in scope than the Federal program (40 CFR 271.121(1)). More stringent or more extensive programs are reviewed as part of the final authorization process to determine whether they are consistent with the Federal program and other authorized State programs. See 40 CFR 271.4 (42 U.S.C. 6926(b)). The consistency review involves an examination of the basis for the State requirement. However, there is no interim authorization provision analogous to the consistency requirement of 40 CFR 271.4 for final authorization. Consequently, the Maryland financial responsibility requirement is not a barrier to interim authorization.

EPA's decision to grant Maryland interim authorization does not mean that EPA agrees with the factual or legal basis for Maryland's decision to require Federal facilities to comply with its financial responsibility regulations. However, under our regulations and statute, consistency with the Federal program is an issue with respect to final, not interim, authorization. The Agency may reexamine this issue during final authorization.

Decision

I have determined that the State of Maryland's program is substantially equivalent to the Federal program for Phase II, Component A Interim Authorization as defined in 40 CFR Part 271, Subpart B (formerly 40 CFR 123, Subpart F). In accordance with Section 3006(c) of RCRA, the State of Maryland is hereby granted Interim Authorization to operate its hazardous waste program in lieu of Phase II, Component A of the Federal hazardous waste program.

Compliance With Executive Order 12291

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

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. The authorization effectively suspends the applicability of certain Federal regulations in favor of Maryland's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Hazardous materials, Indian-lands, Reporting and recordkeeping requirements, Waste treatment and disposal, Intergovernmental relations, Penalties, Confidential business information.

Authority

This notice is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926 and 6974(b).

Thomas P. Eichler,

Regional Administrator.

[FR Doc. 83-31460 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

21 CFR Part 561

[FAP 3H5381/R6245 PH-FRL-2476-4]

Tolerances for Pesticides in Animal Feeds Administered by the Environmental Protection Agency; Flucythrinate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a food additive regulation to permit residues of the insecticide flucythrinate in apple pomace (dry). This regulation to establish the maximum permissible level for residues of the insecticide in apple pomace was requested by the American Cyanamid Co.

EFFECTIVE DATE: Effective on November 23, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Timothy A. Gardner, Product Manager (PM) 17, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 207, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-2690).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of February 9, 1983 (48 FR 6018), that announced that the American Cyanamid Co., PO Box 400, Princeton, NJ 08540, had submitted food additive petition FAP 3H5381 to the Agency proposing to amend 21 CFR Part 561 by establishing a regulation permitting residues of the insecticide (±)cyano(3-phenoxy-phenyl)methyl(±)-4-(difluoromethoxy)-alpha-(1-methylethyl) benzeneacetate in the food commodity apple pomace (dry at 10.0 parts per million (ppm).

The American National Standards Institute (ANSI) has adapted the common name "flucythrinate" for the above chemical name.

There were no comments recieved in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicity and other relevant data pertaining to this insecticide are included in a related document [PP 3F2806/R623] establishing tolerances in or on various raw agricultural commodities which appears

elsewhere in this issue of the **Federal Register**.

The pesticide is considered useful for the purpose for which the regulation is sought. It is concluded that the pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973, 89 Stat. 751, 7 U.S.C. 1235(a) *et seq.)*, and is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this regulation in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objection should specify the provisions of the regulation deemed objectionable and the grounds for the objections. A hearing will be granted if the objections are suported by grounds legally sufficient to justify the relief sought.

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–534, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new food or feed additive levels, or conditions for safe use of additives, or raising such food or feed additive levels, do not have a significant economic impact of a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24945).

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 346(c)(1)))

List of Subjects in 21 CFR Part 561

Animal feeds, Pesticides and pests.

Dated: November 14, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

PART 561—[AMENDED]

Therefore, 21 CFR 561.435 is added, to read as follows:

§ 561.435 Flucythrinate.

A regulation is established permitting residues of the insecticide flucythrinate ((±)cyano(3-phenoxyphenyl)methyl(±)-4-(difluoromethoxy)-alpha-(1-methylethy)benzeneacetate) in or on the following food commodity:

Food	Parts per million
Apple pomace (dry)	10.0

[FR Doc. 83-31487 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1033

[Fifty-Second Rev. S.O. No. 1473]

Various Railroads Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Fifty-Second Revised Service Order No. 1473.

SUMMARY: Pursuant to Section 122 of the Rock Island Railroad Transition and Employee Assistance Act, Pub. L. 96–254, this order authorizes various railroads to provide interim service over the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., November 30, 1983, and continuing in effect until 11:59 p.m., March 31, 1984, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275–7840 or 275–1559.

SUPPLEMENTARY INFORMATION:

Decided November 17, 1983.

Pursuant to Section 122 of the Rock Island Railroad Transition and Employee Assistance Act, Pub. L. 96–254 (RITEA), the Commission is authorizing various railroads to provide interim service over Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), (RI) and to use such tracks and facilities as are necessary for those operations.

In view of the urgent need for continued rail service over RI's lines pending the implementation of long-range solutions, this order permits carriers to provide service to shippers which may otherwise be deprived of essential rail transportation.

Appendix A, to the previous order, is revised by deleting at Item 20.B., the authority for the Burlington Northern Railroad Company (BN), to operate at North Fort Worth, Texas, and at Item 23., the authority for the Colorado and Eastern Railway (COE), to operate between Colorado Springs and Limon, Colorado. These authorities were deleted at the request of the involved carriers and the Rock Island Trustee. Item 24., in Appendix A is renumbered accordingly.

This order is further revised, by extending its expiration date until March 31, 1984.

Appendix B of Forty-Third Revised Service Order No. 1473 is unchanged and is incorporated into this order by reference.

It is the opinion of the Commission that an emergency exists requiring that the railroads named in the appendices be authorized to conduct operations using RI tracks and/or facilities; that notice and public procedure are impracticable and contrary to the public interest; and good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033.1473 Revised Service Order 1473.

(a) *Various railroads aurhorized to use tracks and/or facilities of the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee).* Various railroads are authorized to use tracks and/or facilities of the Chicago, Rock Island and Pacific Railroad Company (RI), as listed in Appendix A to this order, in order to provide interim service over the RI; and as listed in Appendix B to this order, to provide for continuation of joint or common use facility agreements essential to the operations of these carriers as previously authorized in Service Order No. 1435.

(b) The Trustee shall permit the affected carriers to enter upon the property of the RI to conduct service as authorized in paragraph (a).

(c) The Trustee will be compensated on terms established between the Trustee and the affected carrier(s); or upon failure of the parties to agree as hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by Section 122(a) Pub. L. 96–254.

(d) Interim operators, authorized in Appendix A to this order, shall, within fifteen (15) days of its effective date, notify the Railroad Service Board of the date on which interim operations were commenced or the expected commencement date of those

operations. Termination of interim operations will require at least (30) thirty days notice to the Railroad Service Board and affected shippers.

(e) Interim operators, authorized in Appendix A to this order, shall, within thirty days of commencing operations under authority of this order, notify the RI Trustee of those facilities they believe are necessary or reasonably related to the authorized operations.

(f) During the period of the operations over the RI lines authorized in paragraph (a), operators shall be responsible for preserving the value of the lines, associated with each operation, to the RI estate, and for performing necessary maintenance to avoid undue deterioration of lines and associated facilities.

1. In those instances where more than one railroad is involved in the joint use of RI tracks and/or facilities described in Appendix B, one of the affected carriers will perform the maintenance and have supervision over the operations in behalf of all the carriers as may be agreed to among themselves, or in the absence of such agreement, as may be decided by the Commission.

(g) Any operational or other difficulty associated with the authorized operations shall be resolved through agreement between the affected parties or, failing agreement, by the Commission's Railroad Service Board.

(h) Any rehabilitation, operational, or other costs related to authorized operations shall be the sole responsibility of the interim operator incurring the costs, and shall not in any way be deemed a liability of the United States Government.

(i) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(j) *Rate applicable.* Inasmuch as the operations described in Appendix A by interim operators over tracks previously operated by the RI are deemed to be due to carrier's disability, the rates applicable to traffic moved over these lines shall be the rates applicable to traffic routed to, from, or via these lines which were formerly in effect on such traffic when routed via RI, until tariffs naming rates and routes specifically applicable become effective.

(k) In transporting traffic over these lines, all interim operators described in Appendix A shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of rates of transportation applicable to that traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between the carriers; or upon failure of the carriers to so agree, the divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(l) To the maximum extent practicable, carriers providing service under this order shall use the employees who normally would have performed the work in connection with traffic moving over the lines subject to this Order.

(m) *Effective date.* This order shall become effective at 11:59 p.m., November 30, 1983.

(n) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., March 31, 1984, unless otherwise modified, amended, or vacated by order of this Commission.

This action is taken under the authority of 49 U.S.C. 10304, 10305, and Section 122, Public Law 96–254

List of Subjects in 49 CFR Part 1033

Railroads.

This order shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission., Railroad Service Board, members J. Warren McFarland, Bernard Gaillard, and John H. O'Brien.

Agatha L. Mergenovich,

Secretary.

Appendix A—RI Lines Authorized To Be Operated by Interim Operators

1. *Peoria and Pekin Union Railway Company (PPU):*

A. Mossville, Illinois (milepost 148.23) to Peoria, Illinois (milepost 161.0) including the Keller Branch (milepost 1.55 to 6.15).

2. *Union Pacific Railroad Company (UP):*

A. Beatrice, Nebraska.

B. Approximately 36.5 miles of trackage extending from Fairbury, Nebraska, to RI Milepost 581.5 north of Hallam, Nebraska.

3. *Toledo, Peoria and Western Railroad Company (TPW):*

A. Peoria Terminal Company trackage from Hollis to Iowa Junction, Illinois.

4. *Chicago and North Western Transportation Company (CNW):*

A. At Omaha, Nebraska, 0.1 mile of industrial trackage in the vicinity of 19th and Pierce Streets.

5. *Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW):*

A. From Newport, Minnesota to a point near the east bank of the Mississippi River, sufficient to serve Northwest Oil Refinery, at St. Paul Park, Minnesota.

B. From Davenport (milepost 182.35) to Iowa City, Iowa (milepost 237.01).

6. *Missouri Pacific Railroad Company (MP):*

A. From Little Rock, Arkansas (milepost 135.2) to Hazen, Arkansas (milepost 91.5).

B. From Litte Rock, Arkansas (milepost 135.2) to Pulaski, Arkansas (milepost 141.0).

C. From Hot Springs Junction (milepost 0.0) to and including Rock Island milepost 4.7.

7. *Norfolk and Western Railway Company (NW):* Is authorized to operate over tracks of the Chicago, Rock Island and Pacific Railroad Company running southerly from Pullman Junction, Chicago, Illinois, along the western shore of Lake Calumet approximately four plus miles to the point, approximately 2,500 feet beyond the railroad bridge over the Calumet Expressway, at which point the RI track connects to Chicago Regional Port District track, for the purpose of serving industries located adjacent to such tracks. Any trackage rights arrangements which existed between the Chicago, Rock Island and Pacific Railroad Company and other carriers, and which extend to the Chicago Regional Port District Lake Calumet Harbor, West Side, will be continued so that shippers at the port can have NW rates and routes regardless of which carrier performs switching services.

8. *Cadillac and Lake City Railway Company (CLK):*

A. From Limon, Colorado (milepost 530.75) to Caruso, Kansas (milepost 430.0) a distance of 100.75 miles.

B. Over-head rights from Caruso, Kansas (milepost 430.0) to Colby, Kansas (milepost 387.0), a distance of approximately 43 miles, in order to effect interchange with the Union Pacific Railroad.

9. *Baltimore and Ohio Railroad Company (BO):*

A. From Blue Island, Illinois (milepost 15.7) to Bureau, Illinois (milepost 114.2), a distance of 98.5 miles.

B. From Bureau, Illinois (milepost 114.12) to Henry, Illinois (milepost 126.94) a distance of approximately 12.8 miles.

10. *Keota Washington Transportation Company (KWTR):*

A. From Keota to Washington, Iowa; to effect interchange with the Chicago, Milwaukee, St. Paul and Pacific Railroad Company at Washington, Iowa, and to serve any industries on the former RI which are not being served presently.

B. At Vinton, Iowa (milepost 120.0 to 123.0).

C. From Vinton Junction, Iowa (milepost 23.4) to Iowa Falls, Iowa (milepost 97.4).

11. *The La Salle and Bureau County Railroad Company (LSBC):*

A. From Chicago (milepost 0.60) to Blue Island, Illinois (milepost 16.61), and yard tracks 6, 9 and 10; and crossover 115 to effect interchange at Blue Island, Illinois.

B. From Blue Island, Illinois (milepost 16.61), to Mokena, Illinois (milepost 29.6).

C. From Western Avenue (Subdivision 1A, milepost 16.6) to 119th Street (Subdivision 1A, milepost 14.8), at Blue Island, Illinois.

D. From Gresham (subdivision 1, milepost 10.0) to South Chicago (subdivision 1B, milepost 14.5) at Chicago, Illinois.

E. From Pullman Junction, Chicago, Illinois, (milepost 13.2) running southerly to the entrance of the Chicago International Port, a distance of approximately five miles, for the purpose of bridge rights and to effect interchange at the Kensington and Eastern Yard.

12. *The Atchison, Topeka and Santa Fe Railway Company (ATSF):*

A. At Alva, Oklahoma.

B. At St. Joseph, Missouri.

13. *Iowa Northern Railroad Company (IANR):*

A. From Cedar Rapids, Iowa (milepost 100.5), to Manly, Iowa (milepost 225.1).

B. At Vinton, Iowa (milepost 23.4), and west on the Iowa Falls Line to Dysart, Iowa (milepost 40.37).

14. *Iowa Railroad Company (IRRC):*

A. From Council Bluffs (milepost 490.15) to West Des Moines, Iowa (milepost 364.34) a distance of approximately 126.81 miles.

B. From Audubon Junction (milepost 440.7) to Audubon, Iowa (milepost 465.1) a distance of approximately 24.4 miles.

C. From Hancock, Iowa (milepost 6.4) to Oakland, Iowa (milepost 12.3) a distance of approximately 5.9 miles.

D. Overhead rights from West Des Moines, Iowa (milepost 364.34) to East Des Moines, Iowa (milepost 350.8). (This trackage was sold to CNW, however, the RI trustee holds rights for overhead use.)

E. From East Des Moines, Iowa (milepost 350.8) to Iowa City, Iowa (milepost 237.01) a distance 113.79 miles.

F. Overhead rights from Iowa City, Iowa (milepost 237.01) to Davenport, Iowa (milepost 182.35), including interchange with the Cedar Rapids and Iowa City Railway. (This trackage is currently leased to the MILW, see Item 5.B.)

G. From Bureau, Illinois (milepost 114.2) to Davenport, Iowa (milepost 182.35)

H. From Rock Island, Illinois through Milan, Illinois, to a point west of Milan sufficient to serve the Rock Island Industrial Complex.

I. At Rock Island, Illinois including 26th Street Yard.

J. From Altoona to Pella, Iowa.

15. *Missouri-Kansas-Texas Railroad Company (MKT):*

A. From Oklahoma City, Oklahoma (milepost 496.4) to McAlester, Oklahoma (milepost 365.0), a distance of approximately 131.4 miles.

16. *Chicago Short Line Railway Company (CSL):*

A. From Pullman Junction easterly for approximately 1000 feet to serve Clear-View Plastics, Inc., all in the vicinity of the Calumet switching district.

B. From Rock Island Junction westerly for approximately 3000 feet to Irondale Wye.

17. *Kyle Railroad Company (Kyle:*

A. From Belleville (milepost 187.0) to Caruso, Kansas (milepost 430.0), a distance of approximately 243 miles. Kyle will be responsible for the maintenace of the jointly used track between Colby and Caruso as mutually agreed upon with CLK, and for coordinating operations.

B. From Belleville (milepost 187.0) to Mahaska, Kansas (milepost 170.0) a distance of approximately 17 miles.

C. From Belleville (milepost 225.34) to Clay Center, Kansas (milepost 178.37) a distance of approximately 47 miles.

18. *North Central Oklahoma Railway, Inc. (NCOK):*

A. From Mangum, Oklahoma (milepost 97.2) to Anadarko, Oklahoma (milepost 18.14).

B. From El Reno, Oklahoma (milepost 515.0) to Hydro, Oklahoma (milepost 553.0) a distance of approximately 38 miles.

C. From Geary, Oklahoma (milepost 0.0) to Homestead, Oklahoma (milepost 42.8) a distance of approximately 43 miles.

D. From North Enid, Oklahoma (milepost 0.30) to Ponca City, Oklahoma (milepost 54.8) a distance of approximately 54.5 miles.

19. *South Central Arkansas Railway, Inc. (SCK):*

A. From El Dorado, Arkansas (milepost 99) to Dubach, Louisiana (milepost 142.3).

20. *Burlington Northern Railroad Company (BN):*

A. At Burlington, Iowa (milepost 0 to milepost 2.06).

21. *Omaha, Lincoln and Beatrice Railway Company (OLB):*

A. At Lincoln, Nebraska (milepost 559.16 to milepost 561.37).

22. *Texas North Western Railway Company (TNW):*

A. From Hardesty, Oklahoma (milepost 119.20) to Liberal, Kansas (milepost 152.35) a distance of approximately 33.15 miles.

*23. *Farmrail Corporation (FMRC):*

A. From west of Elk City (milepost 615.0) to west of Erick, Oklahoma (milepost 642.0), a distance of approximately 27 miles.

*Changed.

[FR Doc. 83-31467 Filed 11-22-83; 8:45 am]

BILLING CODE 7035-01-M

---

49 CFR Part 1180

[Ex Parte No. 282 (Sub-4a)]

Forced Sale Procedures for Bankrupt Railroad Lines

AGENCY: Interstate Commerce Commission.

ACTION: Notice of final rules.

SUMMARY: Section 213 of the Rail Safety and Service Improvement Act of 1982, Pub. L. 97-468, amended section 17(b) of the Milwaukee Railroad Restructuring Act [45 U.S.C. 915(b)] which deals with the sale or transfer of lines of bankrupt railroads. Specifically, the Commission is empowered to prescribe terms, including compensation, for the sale of lines over which no service is being provided by the owner, upon the request of a financially responsible offeror whose offer to purchase has been rejected by the trustee. When more than one offeror participates in a proceeding, the Commission is authorized to select an offeror based on a public interest standard.

On February 28, 1983, the Commission published interim rules to effectuate these statutory changes and requested public comment on them (48 FR 8281, Feb. 28, 1983).

After reviewing the comments the Commission has decided to adopt the interim rules as final with certain minor changes (*see* appendix). Most significantly, the final rules provide that if a trustee has not acted on a purchase offer within 120 days, this inaction may be deemed a rejection for the purpose of these proceedings. Also, the final rules provide that once an offer has been rejected by the trustee the offeror has a 30-day time limit for filing its application to institute these proceedings.

DATE: These regulations are effective on December 23, 1983.

FOR FURTHER INFORMATION CONTACT:

Louis E. Gitomer, (202) 275-7245

or

Wayne A. Michel, (202) 275-7657

SUPPLEMENTARY INFORMATION: Additional information concerning the specifics of section 213 of the Rail Safety and Service Improvement Act of 1982 and these final rules, as modified in light of public comment, is in the Commission decision. To purchase a copy of the decision, write to T.S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, DC 20423 or call 289-4357 (in the DC Metropolitan area) or toll free (800) 424-5403.

This action will not significantly effect the quality of the human environment, energy consumption, or a substantial number of small entities.

This action is taken under the authority of 49 U.S.C. 10321 and 5 U.S.C. 553.

List of Subjects in 49 CFR Part 1180

Railroads, Transportation, Bankruptcy procedures.

Decided: November 9, 1983.

By the Commission, Chairman Taylor, Vice Chairman Sterrett, Commissioners Andre and Gradison.

Agatha L. Mergenovich,

Secretary.

Appendix

PART 1180—[AMENDED]

49 CFR Part 1180 is amended by adopting the interim rules (48 FR 8281) as final rules with certain changes. Accordingly, Subpart C is revised to read as follows:

Subpart C—Forced Sale Procedures for Bankrupt Railroad Lines

Sec.

1180.40 Purpose and scope.

1180.41 Submission and contents of offer.

1180.42 Commission's 15 day determination.

1180.43 Agreement between the parties.

Sec.
1180.44 Failure to reach an acquisition agreement.
1180.45 Requests to set the terms.
1180.46 Multiple offer proceedings.
1180.47 Transmission of the Commission's prescribed terms to the court.
1180.48 Special provisions concerning these forced sale proceedings.
1180.49 Definitions for Subpart C.

Authority: 49 U.S.C. 10321 and 5 U.S.C. 553.

Subpart C—Forced Sale Procedures for Bankrupt Railroad Lines

§ 1180.40 Purpose and scope.

Under 45 U.S.C. 915, the Commission can require the sale of certain rail lines to a financially responsible person. To be eligible for such sale the line must be owned by a carrier in liquidation, and the owner must not be providing service. Further, the offeror must first have made an offer to the trustee in bankruptcy and the trustee must have rejected that offer. If the trustee and the offeror fail to reach a voluntary agreement within 120 days after the date the offer was made and the trustee has not rejected the offer, the offeror may, at any time following the expiration of the 120-day period, notify the trustee that the offeror deems the failure to reach an agreement as a rejection of the offer by the trustee for the purposes of this subpart.

§ 1180.41 Submission and contents of offer.

(a) Before an application is filed, the applicant must obtain a docket number from the Commission's Office of the Secretary.

(b) Applications must be filed within 30 days of the trustee's rejection of the offer or within 30 days of the date the offeror notifies the trustee that the offeror has deemed the offer to be rejected because the trustee failed to act on it within 120 days of the date the offer was made.

(c) An offeror shall serve its application (an original and 10 copies) upon the Commission (with a copy to the Deputy Director, Rail Section, Room 5417), the trustee, and the court. In addition, the offeror shall make a good faith effort to determine whether any other offers for all or part of the line(s) in question have been made to the trustee. If other offers have been made, the offeror shall, concurrent with its filing at the Commission, serve copies of its application upon those other offerors, including persons whose offers are still pending with the trustee.

(d) Applications shall be accompanied by a $300.00 filing fee.

(e) The initial offeror shall (1) identify the line(s) question; (2) certify that the trustee has rejected its offer or certify that the trustee failed to act on the offer within 120 days of the date the offer was made and that the offeror has deemed the offer to be rejected, and indicate what that offer was; (3) certify that it has concurrently served copies on the trustee, court, and all other known offerors; (4) state its offering price; (5) offer evidence indicating that it is financially responsible; and (6) certify that the trustee has not accepted another offer for the line(s) in question.

§ 1180.42 Commission's 15 day determination.

(a) The Commission (Director, Office of Proceedings) shall, within 15 days of the filing of the application, determine whether the applicant is a financially responsible person and has made a *bona fide* offer to acquire the line or lines under reasonable terms. If the Commission makes these findings, the offeror and the trustee shall enter into negotiations. If the Commission fails to make either of these findings, the application shall be dismissed.

(b) Appeals to dismissal of an application pursuant to the preceding paragraph will be governed by the rule set forth in 49 CFR 1011.7(b)(1), pertaining to appeals from decisions of employees under delegated authority. An original and 10 copies of all appeals, and replies to appeals should be filed with the Commission.

§ 1180.43 Agreement between the parties.

If at any time the parties reach a voluntary agreement, a request for approval shall be filed with the Commission and the court, and the parties must comply with the regulations governing the acquisition of lines of railroads in reorganization which are set forth in Subpart B of this part.

§ 1180.44 Failure to reach an acquisition agreement.

(a) If the trustee and any financially responsible offeror fail to agree on the amount of compensation or terms of acquisition within 30 days of the commencement of negotiations, either party may, within 60 days after the conclusion of the unsuccessful negotiations, request the Commission to prescribe terms for acquisition, including reasonable compensation, for the line or lines to be acquired. Requests for prescription of terms shall be served on all other parties.

(b) If no request for prescription of terms of acquisition is received by the Commission within 60 days of the unsuccessful conclusion of negotiations, the proceeding shall be terminated, and the application dismissed.

§ 1180.45 Requests to set the terms.

(a) If the Commission is requested to prescribe conditions and compensation, it shall issue its decision setting the terms and conditions within 60 days of the request.

(b) Any party filing a request shall set forth in detail in its request information showing the value of the line and any other information necessary to support the request for conditions, and serve the request on all parties of record.

(c) Other parties have 30 days to submit their supporting or opposing views to the Commission and the initial offeror.

(d) The party filing the initial request has 10 days to respond to any pleadings submitted pursuant to paragraph (c) of this section.

(e) In its decision, the Commission will establish the amount of reasonable compensation (which in no case will be less than the constitutional minimum value of the line as defined in 49 U.S.C. 10910) and set other conditions as needed. This decision will be binding on both parties except that the offeror may withdraw its offer no later than 10 days after the date the Commission's decision is served, by notifying, in writing, the Commission and all other parties to the proceeding. If there are no other offerors who are parties to the proceeding and are willing to accept the terms, the proceeding shall be terminated, and the application dismissed.

§ 1180.46 Multiple offer proceedings.

(a) Concurrent with the filing of the application, the initial offeror is required to make a good faith effort to identify and serve all other persons who either had previously made offers for all or part of the line or have offers currently pending with the trustee.

(b) Within 10 days of the filing of the application, any other party interested in making an offer for all or part of this line must file an application (an original and 10 copies) with the Commission (with a copy to the Deputy Director, Rail Section, Room 5417), the trustee, the initial offeror, and the court. That application must: (1) Identify the line; (2) indicate whether an offer had ever been made to the trustee and, if so, the status of the offer; (3) state the offering price and show why it is reasonable; (4) contain evidence indicating that the offeror is financially responsible; and (5) contain a statement certifying that the offeror has complied with the service requirements.

(c) Within 15 days of the filing of the first application, the Commission (Director, Office of Proceedings) shall determine whether any other offeror is

financially responsible. Any offeror who is found financially responsible may negotiate with the trustee and has the same right to reach an agreement with the trustee as the first offeror. Any offeror who is not found to be financially responsible may not further participate in the proceeding, and its application will be dismissed.

(d) Appeals to dismissal of an application pursuant to the preceding paragraph will be handled in the manner indicated in § 1180.42(b).

(e) If an agreement is reached between the trustee and any offeror, the provisions of § 1180.43 apply.

(f) If no offeror reaches an agreement with the trustee during the negotiation period, any offeror or the trustee may request the Commission to prescribe the terms of and set conditions for acquisition. If no request is made, the proceeding will be terminated, and all applications dismissed.

(g) If more than one offeror is participating in a proceeding under these regulations, the Commission's decision setting terms and conditions will select the offeror and be based on which offer best serves the public interest.

(h) Within 10 days of the service of the Commission's decision setting the terms, all offerors, even those not initially chosen by the Commission, shall notify the Commission in writing of their willingness to accept the terms. An offeror's failure to notify the Commission of its acceptance of the terms or its refusal to accept the prescribed terms will result in that offeror being excluded from further consideration as a potential purchaser.

(i) If the originally selected offeror refuses to accept the terms, the Commission will immediately choose a purchaser among those *bona fide*, financially responsible offerors who have accepted the terms. That choice will also be based on an analysis of the public interest.

(j) If there are no such offerors willing to accept the terms, the proceeding shall be terminated, and all applications dismissed.

§ 1180.47 Transmission of the Commission's prescribed terms to the court.

Within 15 days after the Commission prescribes conditions and compensation for acquisition, the Commission shall transmit such terms to the court, unless the offer is withdrawn.

§ 1180.48 Special provisions concerning these forced sale proceedings.

(a) Any person acquiring a line or lines under these regulations shall use, to the maximum extent practicable, employees or former employees of the carrier subject to liquidation in the operation of service on such line or lines.

(b) No person acquiring a line under these regulations may transfer or discontinue service on the line for 4 years after acquisition.

(c) Commission approval of acquisition under these regulations obviates any need for the parties to seek further Commission approval under 49 U.S.C. 10901 or 11343 to consummate the transaction or institute service.

(d) If a party to an acquisition agreement approved under these regulations defaults on the obligations thereunder, then the other party to the agreement shall promptly inform the Commission. Upon notification, the Commission will take approprate action.

(e) The Commission's prescription of conditions and compensation, once accepted by an offeror, is final. Administrative appeals will not be entertained.

§ 1180.49 Definitions for Subpart C.

(a) Carrier subject to liquidation. A carrier which on January 14, 1983 was the subject of a proceeding pending under section 77 of the Bankruptcy Act or under subchapter IV of Chapter 11 of Title 11, United States Code, and which has been ordered by the court to liquidate its properties.

(b) The court. The court having bankruptcy jurisdiction over the carrier subject to liquidation.

(c) Financially responsible person. A person capable of compensating the carrier subject to liquidation for the acquisition of the line or lines proposed to be acquired and able to cover expenses associated with providing service over such line or lines for at least four years.

[FR Doc. 83-31466 Filed 11-22-83; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 681

[Docket No. 31103-217]

Western Pacific Spiny Lobster Fisheries

AGENCY: National Oceanic and Atmospheric Administrator (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NOAA issues a final rule to implement Amendment 1 to the Fishery Management Plan for the Spiny Lobster Fisheries of the Western Pacific Region (FMP). Five of the six proposed measures in the amendment have been approved; one has been disapproved. Implementation of the approved measures will establish complementary regulations for the spiny lobster fisheries within the fishery conservation zone (FCZ) and the territorial sea off the main Hawaiian Islands. This rule is necessary to protect the resource as the commercial fishery expands.

Two technical and clarifying changes also were in the proposed rules issued for that action. These measures make the management of the spiny lobster fishery more effective.

EFFECTIVE DATE: December 20, 1983.

FOR FURTHER INFORMATION CONTACT: James J. Morgan (NMFS, Southwest Region), 213-548-2518.

SUPPLEMENTARY INFORMATION: The FMP for the spiny lobster fishery (February 7, 1983, at 48 FR 5560) established Federal regulations for the management of the commercial fishery in the Northwestern Hawaiian Islands (NWHI). Federal management measures for the NWHI include conservation and reporting requirements; however, the FMP only established reporting requirements for the FCZ off the main Hawaiian Islands.

On September 30, 1981, the Hawaii Department of Planning and Economic Development notified the Western Pacific Fisheries Management Council (Council) that the FMP was not consistent with Hawaii's Coastal Zone Management Plan "to the maximum extent practicable" as required by subsection 307(c)(1) of the Coastal Zone Management Act. The Council then reached an agreement with the State of Hawaii by which the State would implement State regulations for the NWHI territorial sea identical to Federal regulations for the FCZ, and the Council would prepare an amendment to the FMP adopting management measures for the FCZ off the main Hawaiian Islands that are identical to State regulations.

By the time the FMP received final approval by the Assistant Administrator for Fisheries, NOAA had notified the State of Hawaii that the FMP was consistent with Hawaii's Coastal Zone Management Plan to the maximum extent practicable, and regulations implementing the FMP were published in the **Federal Register** on February 7, 1983. Nevertheless, the State of Hawaii's position continued to be that the FMP needed to be amended. The State argued the failure to adopt regulations in the

FCZ that are identical to its regulations would impair its ability to enforce its regulations. Because differences on the consistency issue persisted, the Council decided to proceed with Amendment 1 and a hearing was held on the amendment in Honolulu, Hawaii on March 14, 1983 (48 FR 7608). A notice of availability of the amendment was published in the **Federal Register** on August 4, 1983 (48 FR 35475). Proposed rules were published on September 1, 1983 (48 FR 39685).

It was proposed in Amendment 1 to establish federal regulations for the spiny lobster fisheries in the FCZ off the main Hawaiian Islands which would be identical to State regulations for the fishery in the territorial sea around the main islands. This action would reduce confusion for fishermen, reduce conflicts that may arise, and simplify enforcement throughout the main island's fishery. To make federal management identical to State management, six State measures were proposed for the FCZ. These measures are (1) all spiny lobsters with a carapace length less than 8.26 cm must be released; (2) all spiny lobsters carrying eggs be released; (3) no spiny lobsters may be taken during June, July, and August; (4) no spiny lobsters may be taken using spears, chemicals, poisons, or explosives; (5) traps must not exceed 6 feet × 6 feet × 10 in size; and (6) spiny lobsters must be landed whole.

The individual measures were discussed in the preamble to the proposed rule. Public comments on the proposed rule were invited until October 14, 1983. No public comments were received. Following a review of the amendment and supporting documentation, the Regional Director determined that all of the proposed measures, except the measure regulating the size of fish traps, should be implemented in the FCZ in order to establish complementary management for the spiny lobster fisheries. The measure regulating the size of fish traps was not approved because fish traps only catch lobsters incidentally and the size of the trap has no influence on the incidental catch; therefore the measure can be regulated by the State of Hawaii requirements for the multi-species trap fishery.

The carapace length of 8.26 cm is adopted for the FCZ and all lobsters less than 8.26 cm must be released. This measure is identical to the State regulation and it will afford protection for the resource as the fishery expands. The necessary attendant regulations to the size limit of prohibiting the use of spears, chemicals, poisons, and explosives, and requiring that lobsters be landed whole so that they can be measured also are adopted.

As in the case of the NWHI, the measure requiring the release of lobsters carrying eggs is adopted for the FCZ off the main islands. A closed season for the months of June, July, and August is adopted for the FCZ off the main islands. The adoption of the closed season will simplify enforecement in the fishery which has been predominantly a recreational fishery within the territorial sea.

Classification

The Secretary of Commerce has determined that the FMP Amendment 1, excluding the measure regulating the size of fish traps, is necessary for the conservation and management of the spiny lobster fishery and that it is consistent with the Magnuson Fishery Conservation and Management Act and other applicable law. The Council prepared an environmental assessment of this amendment and concluded that there will be no significant impact on the environment as a result of this rule. You may obtain a copy of the environmental assessment from the Council at the address listed above.

Based upon the analysis in the regulatory impact review, the Administrator of NOAA has determined that the regulations implementing this amendment are not major under Executive Order 12291 and that they do not require a regulatory impact analysis. The main reason for this is that while the commercial fishery extends into the FCZ, this area accounts for only a small portion of the total catch, and the regulations therefore will have a limited economic impact. This rule will have the following economic effects:

1. Economic and social benefits will improve for the recreational fishery because the resource will receive additional protection.

2. The incomes, costs and profits of the commercial fishery will not be affected.

3. The employment impacts will be negligible.

You may obtain a copy of this regulatory impact review from the Council at the address listed above.

The General Counsel of the Department of Commerce certified to the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities because the amendment adopts existing State regulations and therefore imposes no additional regulatory impact. As a result, a regulatory flexibility analysis was not prepared.

This rule contains collection of information requirememts subject to the Paperwork Reduction Act. A request for approval to collect this information has been submitted to the Office of Management and Budget. This action merges the requirements of § 681.4 Permits and § 681.5 Recordkeeping and Reporting into approved collections 0648-0013, 0648-0016 and 0648-0097.

In response to a letter from the Council stating that this proposed rule will be implemented in a manner consistent to the maximum extent practicable with the approved coastal zone management programs of Hawaii, in accordance with section 307 of the Coastal Zone Management Act, the Hawaii Department of Planning and Economic Development, on June 24, 1983, informed the Council that Amendment 1 is consistent with the Hawaii Coastal Zone Management Plan.

Implementation of Amendment 1 will not constitute an action that "may affect" endangered or threatened species within the meaning of regulations implementng the Endangered Species Act of 1973. Furthermore, implementation of the amendment will not affect marine mammal populations within the meaning of the Marine Mammal Protection Act of 1972.

List of Subjects in 50 CFR Part 681

Fish, Fisheries, Reporting and recordkeeping requirements.

Anthony J. Calio,

Deputy Administrator, NOAA.

For the reasons stated in the preamble, 50 CFR Part 681 is proposed to be amended as follows:

PART 681—WESTERN PACIFIC SPINY LOBSTER FISHERIES

1. The authority citation of 50 CFR Part 681 reads as follows:

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

2. The table of contents for this part is amended by adding the sections for a new Subpart C and by placing the existing authority line after this new subpart to read as follows:

* * * * *

2. The table of contents for this part is amended by adding the sections for a new Subpart C and by placing the existing authority line after this new subpart to read as follows:

* * * * *

Subpart C—Management Measures for Permit Area 2 (the main Hawaiian Islands)

Sec.

681.30 General.

681.31 Size restrictions.

Sec.
681.32 Reproductive condition restrictions.
681.33 Closed season.
681.34 Gear restrictions.
681.35 Lobster condition.

* * * * *

(3) In § 681.1, paragraph (b) is amended to read as follows:

§ 681.1 Purpose and scope.

* * * * *

(b) These regulations govern commercial fishing for spiny lobsters by fishing vessels of the United States, within the U.S. fishery conservation zone (FCZ) seaward of American Samoa, Guam, and Hawaii. The management measures specified in Subpart B apply only in the FCZ seaward of the Northwestern Hawaiian Islands (Permit Area 1). The management measures specified in Subpart C apply only in the FCZ seaward of the main Hawaiian Islands (Permit Area 2).

* * * * *

(4) In § 681.2, the definition of Permit Area 2 is revised and three new definitions, one for *Permit Number*, one for *Permit Area 3*, and one for *Processor* are added in appropriate alphabetical order to read as follows:

§ 681.2 Definitions.

Permit Area 2 means the FCZ of the Hawaiian Islands Archipelago lying to the east of 161°00′ W. longitude, commonly known as the main Hawaiian Islands;

Permit Area 3 means the FCZ of the Territory of Guam and the FCZ of the Territory of American Samoa.

Permit Number means the number issued to a vessel under this part by the NMFS.

Processor means any person that changes the form of a lobster through such methods as freezing, cleaning, or removing tails. It does not include a person that only boxes or packages lobster or lobster parts. It also does not include a person that catches lobsters and processes them at sea.

5. In § 681.4, paragraphs (a)(2) and (b)(2)(ix) are revised to read as follows:

§ 681.4 Permits.

(a) * * *

(2) Each permit is valid for fishing only in the area specified in the permit. Permit areas are defined in § 681.2.

(b) * * *

(2) * * *

(ix) The approximate fish-hold capacity of the vessel;

* * * * *

6. Section 681.5 is amended by revising paragraphs (a), (b) (1) and (2), and (c) and by adding new paragraph (d) to read as follows:

§ 681.5 Recordkeeping and reporting.

(a) *Reports.* The operator of any vessel engaged in commercial fishing for spiny lobster subject to this part must—

(1) Maintain on board the fishing vessel, while fishing for spiny lobster, an accurate and complete NMFS Daily Lobster Catch Report in English. All information specified in paragraph (b) of this section must be recorded within 24 hours after the completion of the fishing day.

(2) Within 72 hours of each landing of spiny lobsters, submit to the Regional Director the NMFS Daily Lobster Catch Report for that fishing trip.

(3) Maintain an accurate and complete NMFS Trip Processing and Sales Report in which is recorded the information specified in paragraph (c) of this section.

(4) Within 72 hours of each landing of spiny lobsters, submit to the Regional Director the NMFS Trip Processing and Sales Report covering all lobsters that have been sold. For any lobsters that have not been sold within 72 hours of landing, the operator must submit a supplemental NMFS Trip Processing and Sales Report within 72 hours of each subsequent sale of the remaining lobsters.

(5) Make the Daily Lobster Catch Report and the Trip Processing and Sales Report available for inspection by an authorized officer or any employee of NMFS designated by the Regional Director to make such an inspection.

(b) *Daily Lobster Catch Report.* The Daily Lobster Catch Report must contain the following information for all spiny lobsters taken under this part:

Vessel information—

(i) Name of vessel;

(ii) Call sign of vessel;

(iii) Permit number of vessel;

(iv) Size of crew; and

(v) Number of traps.

(2) Fishing information—

(i) Location of lobster catch by statistical area as depicted in the NMFS Daily Lobster Catch Report form;

(ii) Date and time of trap deployment and number of traps deployed;

(iii) Date and time of trap retrieval and number of traps retrieved;

(iv) Number and species of legal spiny lobsters per trap deployment;

(v) Number and species of sublegal spiny lobsters per trap deployment;

(vi) Number and species of berried female spiny lobsters per trap deployment; and

(vii) Number of slipper lobsters and Kona crabs per trap deployment.

(3) * * *

(c) *Trip Processing and Sales Report.* The Trip Processing and Sales Report must contain the following information for all spiny lobsters taken under this part:

(1) Vessel information—

(i) Name of vessel; and

(ii) Permit number.

(2) Landing information—

(i) Date of landing; and

(ii) Port of landing.

(3) Processing information—

(i) Weight of whole lobsters frozen at sea;

(ii) Weight of lobster tails frozen at sea;

(iii) Weight of whole lobsters to be frozen on land; and

(iv) Weight of lobster tails to be frozen on land.

(4) Sales information—

(i) Number, weight, and revenue from sale of live lobsters;

(ii) Number, weight, and revenue from sale of whole, frozen lobsters;

(iii) Number, weight, and revenue from sale of frozen lobster tails; and

(iv) Weight and revenue from sale of lobster byproducts.

(d) *Processor annual report.* Processors of lobster products harvested in the management area must submit an annual report covering the period January 1 to December 31 to the Regional Director on a form which can be obtained from the Regional Director. This report is due by April 1 of the following year and must specify the following:

(1) Source (by FCZ surrounding each State) of lobsters processed;

(2) Poundage of lobsters processed by species;

(3) Number of individual lobsters processed by species;

(4) Method of processing;

(5) Form of final product; and

(6) Current actual lobster-processing capacity.

7. Section 681.6 is revised to read as follows:

§ 681.6 Vessel identification.

(a) *Permit number.* Each fishing vessel subject to this part must display its permit number on the port and starboard sides of the deckhouse or hull, and on an appropriate weather deck so as to be visible from enforcement vessels and aircraft.

(b) *Numerals.* The permit number must be affixed to each vessel subject to this part in block Arabic numerals at least 18 inches in height for fishing vessels of 65 feet in length or longer, and at least ten inches in height for other vessels. Markings must be legible and of a color that contrasts with the background.

(c) *Duties of operator.* The operator of each fishing vessel subject to this part must—

(1) Keep the displayed permit number clearly legible and in good repair; and

(2) Ensure that no part of the vessel, its rigging, or its fishing gear obstructs the view of the permit number from an enforcement vessel or aircraft.

8. In § 681.7, a new paragraph (c) is added to read as follows:

§ 681.7 Prohibitions.

* * * * *

(c) In permit Area 2, in addition to the prohibitions in paragraph (a) of this section, it is unlawful for any person to—

(1) Fish for, take, or retain spiny lobsters—

(i) By methods other than lobster traps or by hand, as specified in § 681.34; or

(ii) In the months of June, July, and August, as specified in § 681.33.

(2) Retain or possess on a fishing vessel any spiny lobster taken in Permit Area 2 which is less than the minimum size specified in § 681.31;

(3) Possess on a fishing vessel any spiny lobster or spiny lobster part taken in Permit Area 2 in a condition where the lobster is not whole and undamaged as specified in § 681.35; or

(4) Retain or possess on a fishing vessel, or remove the eggs from, any egg-bearing spiny lobster, as specified in § 681.32.

9. In § 681.8, paragraphs (a) and (b)(3) are revised to read as follows:

§ 681.8 Enforcement.

(a) *General.* The owner or operator of any fishing vessel subject to this part must immediately comply with instructions issued by an authorized officer to facilitate safe boarding and inspection of the vessel, its gear, equipment, logbook, reports, permit, and catch, for purposes of enforcing the Magnuson Act and this part.

(b) * * *

(3) "AA AA AA etc." is the call to an unknown station, to which the signaled vessel should respond by identifying his vessel by radio, visual signals, or by lighting his permit number; and

* * * * *

10. A new Subpart C is added to read as follows:

Subpart C—Management Measures for Permit Area 2 (the Main Hawaiian Islands)

§ 681.30 General.

The management measures specified in this subpart govern fishing for spiny lobster in the FCZ seaward of the main Hawaiian Islands (Permit Area 2).

§ 681.31 Size restrictions.

Only spiny lobsters with a carapace length of 8.26 cm or greater may be retained.

§ 681.32 Reproductive condition restrictions.

A female spiny lobster of any size may not be retained if it is carrying eggs externally. Eggs may not be removed from female spiny lobsters.

§ 681.33 Closed season.

Spiny lobster fishing is not allowed in Permit Area 2 during the months of June, July, and August.

§ 681.34 Gear restrictions.

Spiny lobsters may be taken only with lobster traps or by hand. Lobsters may not be taken by means of poisons, drugs, other chemicals, spears, nets, hooks, or explosives.

§ 681.35 Lobster condition.

Any spiny lobster with a punctured or mutilated body, or a separated carapace and tail, may not be retained.

[FR Doc. 83-31409 Filed 11-22-83; 8:45 am]
BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

7 CFR Part 6

Licenses for Importation/Transfer of Sugar To Be Re-Exported in Sugar Containing Products

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule establishes procedures and conditions for the issuance of licenses which will permit the importation/transfer of sugar exempt from quotas on sugars, sirups and molasses as modified by Presidential Proclamation 4941 of May 5, 1982, as amended. A quantity of sugar equal to the sugar imported/transferred under such a license must be exported in a sugar containing product.

DATES: Comments received before December 8, 1983, will be considered.

ADDRESS: Mail comments to Chief, Sugar Group, Horticultural and Tropical Products Division, Foreign Agricultural Service, USDA, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Carol Brick-Turin, Agricultural Economist, Sugar Group, Foreign Agricultural Service, U.S. Department of Agriculture, 12th & Independence Avenue, SW., Washington, D.C. 20250 Tel: (202) 447-6939.

SUPPLEMENTARY INFORMATION:

Background

Presidential Proclamation 4941 of May 5, 1982, modified the import quota for sugar, sirups and molasses described in items 155.20 and 155.30 of the Tariff Schedules of the United States (TSUS) in order to carry out a provision in the Geneva (1967) Protocol of the General Agreement on Tariffs and Trade (Note 1 of Unit A, Chapter 10, Part I of Schedule XX; 19 U.S.T., Part II, 1282) and the International Sugar Agreement, 1977 (T.I.A.S. 9664, 31 U.S.T. 5135). Presidential Proclamation 5002 of November 30, 1982, amended Proclamation 4941 to read, in part, as follows:

> The Secretary may exempt the entry of articles described in items 155.20 and 155.30 from the requirements or limitations established pursuant to this headnote on the condition that such articles . . . be re-exported . . . in sugar containing products. Such articles shall be entered under licenses issued pursuant to regulations promulgated by the Secretary * * *.

Under the proposed rule licenses will be issued for importation/transfer of sugar exempt from quota to be exported in sugar containing products. The certificate of eligibility requirements contained in 15 CFR 201 would not apply to this sugar.

License System For Importation/Transfer of Sugar To Be Re-Exported in Sugar Containing Products

Under the proposed rule, manufacturers of sugar containing products will be issued either import licenses for the importation of quota-exempt raw sugar or user licenses for the transfer of refined sugar to a manufacturer from a refiner in the United States. The amount of sugar transferred from a refiner to a licensed manufacturer under this program may be credited to the refiner's license pursuant to 7 CFR 6.108(b)(2). Manufacturers will be required to export the imported/transferred sugar in a sugar containing product and will post a bond to ensure such export. However, if it can be proven that the manufacturer exported sugar in containing products before importing the corresponding sugar, no bond will be required.

The applicant for a license will be asked to provide certain information to the Licensing Authority. Upon receipt of the required information, a license either to import sugar, exempt from quota, or to transfer imported quota-exempt sugar will be established in favor of the applicant in the amount requested, not to exceed 10,000 short tons, raw value. All imports/transfers of sugar will be charged to the import/user license amount. Licenses will not be assignable unless specifically authorized; however, a license may employ an agent to import or transfer sugar on his/her behalf.

A quantity of sugar in a sugar containing product, equivalent to the quantity of sugar imported/transferred under license (after allowance for refining and manufacturing losses), must be exported within 15 months of the date of entry or within 12 months of the date of transfer. License holders must present to the Licensing Authority an exporter's statement certifying that export has occurred, along with proof of export, within 90 days of export.

As proof of export of sugar is received the Licensing Authority will, if requested, credit the quantity exported to the license, adjusted on the basis of sugar content, and the license holder's bond obligations will be reduced accordingly. At no time may charges or credits exceed the license amount.

The public is invited to submit written comments and suggestions on the proposed rule to the above address. Each person submitting comments and suggestions should include his/her name and address and reasons for suggested changes. Copies of all written communications will be available for examination by interested persons in Room 6091, South Building, United States Department of Agriculture, during regular business hours.

Rulemaking Matters

This proposed rule has been reviewed under USDA procedures required by Executive Order 12291 and Secretary's Memorandum 1512-1 and has been classified as "not major" since the proposed rule, if made final, would not have any of the effects specified in those documents.

The Administrator, Foreign Agricultural Service (FAS), certifies that this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Consequently, no regulatory flexibility analysis is required under the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The public is invited to comment on the impact of this proposed rule on small entities, and the Administrator, FAS, will review this determination in light of those comments.

The proposed rule should yield benefits to the public by increasing employment in the field of manufacturing of sugar containing products and related industries and by improving the balance of trade. Currently, because of the import quotas on sugars, sirups and molasses, U.S. manufacturers must pay a significantly higher price for sugar than the world

price available to manufacturers overseas. This rule will permit an equalization of the raw material cost and will make U.S. sugar containing products more competitive in the world market. Costs should be minimal since the licensing system has been designed to conform as closely as possible to current commercial practices.

An assessment of the impact on the environment of this proposed rule, if promulgated, has been completed. It has been determined that this action will have no foreseeable significant effects on the quality of the human environment. Consequently, no environmental impact statement is necessary for this proposed rule. An environmental assessment is available for review in Room 6091, South Building, USDA during normal business hours.

The paperwork requirements imposed by this rule will not become effective until they have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

Discussion of Comments Received on Advance Notice of Proposed Rulemaking

An "Advance Notice of Proposed Rulemaking" was published in the **Federal Register** on April 25, 1983 (48 FR 17600). Twenty-six written comments were submitted in response to that "Advance Notice of Proposed Rulemaking." These comments, as well as a summary of oral comments received, are available for inspection. All of the comments were considered in preparing the proposed rule. The comments unanimously supported the promulgation of a regulation to establish a re-export licensing program. Comments focused on the following questions:

(1) To whom should a license be issued? (2) How long should a license be effective? (3) Can an agent be used by a manufacturer? (4) What quantity should be assigned to each license? (5) How should processing losses be accounted for in the disposition of license quantities? (6) As bonding is envisioned, how should the monetary obligation of the bond be handled? (7) What documentation should be required to constitute proof of re-export? (8) Should the proposed rule allow importation of quota-exempt sugar in order to replace sugar already exported in sugar containing products? (9) What should be the effective date of the proposed rule? and (10) Should substitution be permitted?

Specific comments on issues raised in the Advance Notice of Proposed Rulemaking are discussed below

(1) To whom should a license be issued?

Numerous comments suggested that manufacturers of sugar containing products should be issued licenses. Others suggested that refiners and agents should also be issued licenses.

After review of these comments it is proposed that manufacturers be issued licenses. An import license will be issued for importation of raw sugar and a user license will be issued for transfer of refined sugar from a U.S. refiner.

(2) How long should a license be effective?

Comments suggesting the length of time a license should be effective ranged from one to three years. Many comments also suggested that the Licensing Authority should have discretionary authority to provide for an extension of the effective period of a license.

Owing to the diverse needs of potential participants and the need for adequate administrative control over the program, it is proposed that export of a sugar containing product take place within 12 months from the date of transfer of refined sugar transferred under a user license, or within 15 months from the date of entry of raw sugar imported under an import license. Because refiners are given three months from the date of entry to process and export or otherwise dispose of sugar imported under 7 CFR 6.100–6.112, manufacturers importing sugar directly under this program are given the same three month period to allow for processing. Provisions for license extension are provided for under section 6.212.

(3) Can an agent be used by manufacturers?

All those commenting on this issue suggested that provisions should be made for the use of agents. The Licensing Authority has provided for the use of agents in Section 6.205.

(4) What quantity should be assigned to each license?

Suggested license size ranged from 5 to 28,000 short tons. Several comments also suggested that licensees should be permitted to import whatever amount of non-quota sugar is deemed adequate to support anticipated business needs.

Given the Licensing Authority's current knowledge of the potential market for the re-export of sugar containing products as well as the need to maintain adequate administrative control of non-quota sugar entering the United States, the maximum license size is proposed at 10,000 short tons, raw value. We have, however, provided that the Licensing Authority may modify this limit by publishing a notice in the Federal Register.

(5) How should processing losses be accounted for in the disposition of license quantities?

All comments that focused on this issue suggested that sugar processing losses should be accounted for in the manufacturing process according to the provisions currently acceptable to the U.S. Customs Service under the duty drawback program and, provided that the lost sugar has no recovery value, be credited to exports.

Product loss provisions, similar to those currently acceptable to the U.S. Customs Service for duty drawback, have been provided for in section 6.208(b)(2).

(6) As bonding is envisioned, how should the monetary obligation of the bond be handled?

Comments on the bonding issue stressed the need for as uncomplicated and inexpensive a procedure as possible. One comment suggested that a general entry bond with a revolving balance be used. Another suggested that the performance bond be required before license issuance and the value of such bond be the quantity of the license times the current market stabilization price (MSP) for sugar. Two other comments recommended that either refiners provide certificates of transfer to product exporters against a general term import bond provided by the exporter, or that refiners provide certificates of transfer to the agent of the product exporter against a general term bond provided by the agent. In both cases it was suggested that the bond be based on the average difference between the equivalent world and domestic value of raw sugar for some agreed period.

After careful review, it is proposed that a single entry bond or term bond be permitted. Bonds for importation will be posted with the U.S. Customs Service, and bonds for transfers will be posted with the Licensing Authority. The value of the bond will be the license quantity multiplied by one and one half times the difference between the Number 11 contract price and the Number 12 contract price or Market Stabilization Price, whichever is greater (Section 6.207(e)). However, if export before import could be proven, no bond would be required.

(7) What documentation should be required to constitute proof of re-export?

Several comments suggested that submission of a copy of the appropriate

U.S. Customs form be used as the primary proof of re-export. Others suggested that an affidavit certifying the claim on this form as true and correct also be provided.

Section 6.206 provides that the appropriate U.S. Customs form acceptable under 19 CFR Part 191 or an export bill of lading (accompanied by a certifying document) will serve as sufficient proof of re-export. The Licensing Authority will accept alternate proof if established to his/her satisfaction.

(8) Should the proposed rule allow importation of quota exempt sugar to replace sugar already exported in sugar containing products?

All comments stressed that, in order to make the program commercially viable, it should include the privilege of replacement which would allow imports of non-quota sugar to replace sugar already exported in products. Provision for export before import (replacement of sugars) after issuance of a license has been provided for in section 6.209.

(9) What should be the effective date of the proposed rule?

A number of comments suggested that the rule be made retroactive to the effective date of Presidential Proclamation 5002 (November 30, 1982). One comment suggested retroactivity to June 28, 1983, the effective date of the re-export program for refined sugar, while another suggested retroactivity to May 5, 1982, the date Presidential Proclamation 4941 modified the sugar import quotas.

After careful review it has been determined that while Presidential Proclamation 5002 gave the Department of Agriculture legal authority to promulgate rules, it cannot be used as a basis for retroactivity. The Presidential Proclamation allows for exemptions from import quotas of articles entered under license. Retroactivity would mean allowing import/export before the attainment of a license and would therefore not conform with the requirements of the Presidential Proclamation.

(10) Should substitution be permitted?

Several comments suggested that manufacturers be permitted to receive non-quota sugar at one plant location and satisfy export criteria through production and export of product from another plant using different sugar (substitution of sugars). Provisions to allow for substitution are set forth in section 6.209.

List of Subjects in 7 CFR Part 6

Foreign trade, Imports, Licenses, Quotas, Sugar.

In accordance with the above, it is proposed to amend 7 CFR Part 6 by adding to the subpart titled "Subpart-Importation of Sugar Free From Quota" the following:

Subpart—Sugar To Be Re-Exported in Sugar Containing Products

Sec.
6.200 Definitions.
6.201 Issuance of a license.
6.202 Application for a license.
6.203 Import of sugar.
6.204 Transfer of sugar.
6.205 Import/transfer of sugar by an agent.
6.206 Proof of export.
6.207 Bond requirements.
6.208 Charges and credits to licenses.
6.209 Replacement of sugars; substitution of sugars.
6.210 Records.
6.211 Enforcement.
6.212 Waiver.
6.213 Expiration.

Authority: Presidential Proclamation No. 5002, 47 FR 54269.

§ 6.200 Definitions:

(a) "Agent" means customs house broker, freight forwarder, sugar refiner or other designeee of the licensee.

(b) "Appropriate customs official" means the district or area Director of the U.S. Customs Service, his/her designee, or any other customs officer of similar authority and responsibility for the customs district in which the port of entry is located.

(c) "Date of entry" is the date when the specified U.S. Customs Service entry form is properly executed and deposited, together with any estimated duties and special import fees and any related documents required by law or regulation to be filled with such form at the time of entry with the appropriate customs official.

(d) "Date of export" means the date of exporation as shown on an export bill of lading, Customs Form 7511 (Notice of Exportation), or such other proof of export as is accepted by the Licensing Authority for the particular shipment.

(e) "Date of License" means the day when the license is issued by the Licensing Authority.

(f) "Date of Transfer" means the date of transfer of refined sugar from a refiner to a manufacturer as indicated on a Notice of Transfer.

(g) "Department" means the U.S. Department of Agriculture.

(h) "License" means either: (1) An import license issued by the Secretary through the Licensing Authority permitting the importation of sugar not chargeable to the import quota for sugar as modified by Presidential Proclamation 4941, as amended, for articles covered by item numbers 155.20 or 155.30 of the Tariff Schedules of the United States; or (2) a user license issued by the Secretary through the Licensing Authority permitting the transfer, in accordance with the provisions of this program, of refined sugar corresponding to sugar imported under 7 CFR 6.100–6.112 from a refiner to a manufacturer.

(i) "Licensing Authority" means the Chief, Sugar Group, Foreign Agricultural Service, U.S. Department of Agriculture, or his/her designee.

(j) "Manufacturer" means a person that produces a sugar containing product in the United States and exports some or all of that product.

(k) "Notice of Transfer" means a document, in form and substance satisfactory to the Licensing Authority, that is signed by both a refiner and licensed manufacturer certifying delivery of a specified amount of refined sugar corresponding to sugar imported under 7 CFR 6.100–6.112 from the refiner to the manufacturer.

(l) "Person" means any individual, partnership, corporation, association, estate, trust or any other business entity, and, whenever applicable, any unit, instrumentality or agency of a government, domestic or foreign.

(m) "Program" means the licensing program provided for in these regulations (7CFR 6.200–6.213).

(n) "Quota" means any quota on imports of sugar, sirups or molasses as covered by items 155.20 or 155.30 of the Tariff Schedules of the United States under Presidential Proclamation 4941 of May 5, 1982, 47 FR 19661, and any modifications thereto.

(o) "Raw value" means, for a given quantity of sugar, the equivalent of that quantity of sugar in terms of ordinary commercial raw sugar testing 96 degrees by the polariscope as determined in accordance with regulations issued by the Secretary of the Treasurey.

(p) "Refiner" means any person in the United States who engages in the processing (refining) of sugar to further improve the quality of such sugar.

(q) "Secretary" means the Secretary of Agriculture or any officer or employee of the Department to whom the Secretary has delegated the authority or to whom the authority hereafter may be delegated to act in the Secretary's place.

(r) "Sugar" means sugars, sirups and molasses derived from sugarcane or sugar beets as defined in items 155.20 and 155.30 of the Tariff Schedules of the United States.

(s) "Sugar containing product" means any product to which sugar has been added that does not fall under items 155.20 or 155.30 of the Tariff Schedules of the United States.

(t) "Tolling contract" means an agreement between a licensed manufacturer and a U.S. refiner for the processing of a specific amount of sugar owned throughout the processing operation by the manufacturer.

§ 6.201 Issuance of a license.

(a) The Secretary, through the Licensing Authority, may issue a license to a manufacturer in accordance with the provisions of this program. The license may contain such conditions, limitations or restrictions as the Licensing Authority determines to be appropriate for the purposes of this program. The Licensing Authority may add or modify such conditions, limitations or restrictions at such time and in such manner as the Licensing Authority, in his/her discretion, determines to be necessary or appropriate for the purposes of this program.

(b) A quantity of sugar equivalent to the quantity of sugar, raw value, imported under an import license, adjusted in accordance with section 6.208(c), must be exported in a sugar containing product within 15 months of the date of entry. A quantity of sugar equivalent to the quantity of sugar, raw value, transferred under a user license must be exported in a sugar containing product within 12 months of the date of transfer. However, the Licensing Authority may credit a license for valueless sugar lost in normal product manufacture.

(c) The license amount may not exceed 10,000 short tons of sugar, raw value. Quantities of sugar imported/transferred under the license will be charged to the license and quantities of sugar contained in sugar containing products exported will be credited to the license as provided in § 6.208. At no time may the outstanding balance of charges or credits exceed the maximum license amount except as a result of adjustments for polarization made pursuant to § 6.208(c).

(d) No more than one license may be issued and outstanding at any one time to any licensee. A license may be surrendered in whole or in part to the Licensing Authority.

(e) The Secretary may change the quantitative limit in paragraph (c) of this section through the publication of a notice in the **Federal Register** if he/she determines that such a change is appropriate within the purposes of this program.

§ 6.202 Application for a license.

An applicant for a license must apply in writing to the Licensing Authority. The letter of application shall contain as a minimum the following information:

(a) Name and address of the applicant;

(b) License amount requested, not to exceed 10,000 short tons of sugar, raw value;

(c) Type of license requested (import or user license);

(d) The TSUS item number and description of the sugar to be imported or transferred, if known;

(e) Name of the firm that will establish a performance bond in favor of the United States Government on behalf of the applicant, if known;

(f) Name of anticipated refiner from which processed non-quota sugar will be received, if known at time of application, or copy of valid tolling contract;

(g) Description of sugar containing products to be exported, if known, and estimated sugar content of such products.

The Licensing Authority may waive any provisions of this section for good cause if it is determined that such a waiver will not adversely affect the implementation of this program.

§ 6.203 Import of sugar.

(a) Import of sugar exempt from the quotas on items 155.20 and 155.30 of the Tariff Schedules of the United States will be allowed only in conformity with the conditions of the license, the provisions of this program, and any other procedures specified by the Licensing Authority.

(b) The import license holder shall submit to the Licensing Authority a statement, certified as true and accurate, of the polarization and weight of the imported sugar to be charged to the license. This statement must adequately identify the imported sugar and state the basis for the determination of the polarization of the sugar. The basis must be either the settlement polarization or some other means approved by the Licensing Authority.

§ 6.204 Transfer of sugar.

(a) Transfer of refined sugar imported under 7 CFR 6.100–6.112 will be allowed only in conformity with the conditions of the license, the provisions of this program, and any other procedures specified by the Licensing Authority.

(b) The holder of a user license shall submit to the Licensing Authority, within 10 working days of transfer of sugar, a Notice of Transfer which must adequately identify the non-quota sugar received from a U.S. refiner, including polarization and weight of the transferred sugar to be charged to the license.

§ 6.205 Import/transfer of sugar by an agent.

The licensee may utilize an agent to import or transfer non-quota sugar. The agent must, upon request, produce for inspection by the appropriate U.S. Customs official a written authorization designating such person to act as an agent for the purpose of entering sugar or must, upon request, produce for inspection by the Licensing Authority written authorization designating such person to act as an agent for the purpose of transferring sugar.

§ 6.206 Proof of export.

(a) The proof of export will consist of:

(1) *Certification.* A written certification by the license holder that he/she has exported a specified quantity of sugar in sugar containing products. The certification shall include:

(i) The license holder's name and address;

(ii) An identification of the license to which the quantity of sugar in the sugar containing product that is exported is to be credited;

(iii) The weight of sugar, raw value, contained in the sugar containing product exported, and the amount of valueless sugar, raw value, actually lost in the manufacture of that product;

(iv) The percentage of valueless sugar lost in normal product manufacture;

(v) The date of export, point of export, and an identification of the export carrier;

(vi) The intended destination; and

(vii) For sugar imported or transferred before the export of the corresponding sugar containing product, an identification of the imported or transferred sugar to which the sugar in the exported sugar containing product corresponds, including the quantity and polarization of the imported/transferred sugar.

(2) *Documentation.* A copy of a certified Customs Form 7511 (Notice of Exportation) or an original bill of lading, or copy thereof with indication of the U.S. Customs Office at which the original is filed, with drawback claim number. A copy of a Chronological Summary of Exports pursuant to 19 CFR 191.53 with indication of the U.S. Customs office at which the original is filed, with drawback claim number, will also serve as acceptable documentation.

(b) The certification must accompany the documentation submitted to the Licensing Authority. The certification and documentation must be submitted to the Licensing Authority within 90 days from the date of export. The Licensing Authority will not credit the license for sugar in exported sugar

containing products until satisfactory proof of export is received.

(c) The Licensing Authority may waive the provisions of this section if exportation is otherwise established to the Licensing Authority's satisfaction.

(d) The Licensing Authority may, for good cause, extend the period for submitting proof of export upon written application of the license holder.

§ 6.207 Bond requirements.

(a) Sugar imported under an import license must meet all applicable Customs bond requirements (see 19 CFR Parts 113, 141–144) and be subject to a U.S. Customs performance bond ("bond") posted with the appropriate Customs official meeting the requirements of this section. Sugar transferred under license shall be subject to a bond posted with the Licensing Authority, meeting the requirements of this section. However, no bond will be required for the quantity of any sugar imported or transferred under license that corresponds to a quantity of sugar that has been exported prior to the import or transfer of such sugar and credited to the license in accordance with § 6.208.

(b) A bond may cover imports or transfers made either during the period of time specified in the bond (term bond) or for a specified import or transfer (single entry bond).

(c) Only an importer may be the principal on a bond to cover sugar to be imported. Only a manufacturer may be the principal on a bond to cover sugar to be transferred. The surety or sureties shall be among those listed by the Secretary of the Treasury as acceptable on Federal bonds.

(d) The obligation under the bond shall be made effective as of the date of entry/transfer.

(e) The amount of the bond for the import or transfer of sugar under a license will be equal to one and one half times the difference between the daily "spot" price per pound of raw sugar as reported in the Number 12 contract of the New York Coffee, Sugar and Cocoa Exchange or the Market Stabilization Price (MSP) established pursuant to Presidential Proclamation 4940 of May 5, 1982, as amended (or any successor proclamation), whichever is greater, and the daily "spot" price of the Number 11 contract of the New York Coffee, Sugar and Cocoa Exchange, multiplied by the weight of the sugar imported or transferred, raw value, under the license. In the case of a single entry bond, the Number 12 and Number 11 contract prices and the MSP shall be computed as of the last market day before the execution of the bond. In the case of a term bond, the Number 12 and Number 11 contract prices and the MSP shall be computed quarterly, based on the average price difference during the 20 consecutive market days preceding the 20th day of the month preceding the calendar quarter. If the New York Coffee, Sugar and Cocoa Exchange does not report a Number 11 or 12 contract price for one or more of these market days, then the Licensing Authority may use such price as he/she deems appropriate.

(f) The appropriate Customs official will release the obligation under the U.S. Customs bond for imported sugar by an amount computed in accordance with § 6.207(e) for a corresponding quantity of sugar credited to the license in accordance with section 6.208(b), as determined by the Licensing Authority. The Licensing Authority will release the obligation under the bond for transferred sugar by an amount computed in accordance with § 6.207(e) for a corresponding quantity of sugar credited to the license in accordance with § 6.208(b), as determined by the Licensing Authority.

(g) If the license holder fails to obtain a credit to the license within 15 months of the date of entry or within 12 months of the date of transfer of corresponding sugar in an amount sufficient to offset the charge to the license for that corresponding sugar, payment will be made to the United States of America under the bond of the monetary amount corresponding sugar not offset by timely exportation. Payment for non-performance under U.S. Customs bonds will be handled pursuant to 19 CFR 172. Payment for non-performance under bonds will be handled pursuant to provisions established by the Licensing Authority.

§ 6.208 Charges and credits to licenses.

(a) Charges will be made to an import license for quantities of sugar imported under the license. This charge will be adjusted on the basis set forth in paragraph (c) of this section when the license holder submits the information required by section 6.203; or to a user license for quantities of sugar, raw value, transferred under the license, when the license holder submits the information required by section 6.204.

(b) At the request of the license holder, the Licensing Authority will credit a license for:

(1) quantities of sugar in the sugar containing products, raw value, for which proof of export has been submitted in accordance with the provisions of this program;

(2) quantities of sugar charged to license which the Licensing Authority determines have been destroyed, lost in the production process, or otherwise disposed of so as to render the use or exportation of a corresponding quantity of sugar in sugar containing products impossible or unnecessary; and

(3) for sugar charged to an import license, the quantity of sugar lost in the refining process. This shall be computed by dividing the quantity of sugar imported, expressed in raw value, by 1.07.

(c) To obtain the raw value for sugar with a polarization of 92 degrees or above, the formula to be used is [(Polarization × .0175) − 0.68] × weight. For sugar of less than 92 degrees polarization the total sugar content shall be divided by 0.972.

§ 6.209 Replacement of sugars; substitution of sugars.

(a) The sugar exported in sugar containing products does not have to be identical to the sugar imported or transferred.

(b) Exportation of sugar in sugar containing products may occur any time after the date of the license, including prior to the date of entry or transfer of the corresponding quantity of sugar charged to the license. Any quantity of sugar exported in sugar containing products prior to the entry or transfer of the corresponding sugar will be treated as having been exported within 15 months of entry, or 12 months of transfer, of the corresponding sugar for purposes of sections 6.201(b) and 6.207(g).

§ 6.210 Records.

(a) Each manufacturer requesting credit for valueless sugar lost in normal product manufacture in accordance with section 6.208(b) shall keep records to establish for all sugar containing products exported under the provisions of this program:

(1) The date or inclusive dates of manufacture;

(2) The quantity and identity of the sugar, raw value, imported or transferred under the provisions of this program;

(3) The quantity and description of the articles manfactured;

(4) The quantity of loss incurred.

(b) All records required to be kept by a manufacturer under this program concerning particular sugar shall be retained for at least 3 years after a license is credited for that sugar in accordance with § 6.208(b).

(c) The manufacturer must, upon request, make these records available to the Licensing Authority for inspection.

§ 6.211 Enforcement.

(a) If at any time after receiving the proof of export described in § 6.206 and release of the bond under § 6.207 the Licensing Authority determines that the export of sugar in the form of sugar containing products corresponding to the amount of sugar imported/transferred under the license did not occur, the Licensing Authority may hold the license holder liable for up to one and one half times the difference between the daily "spot" price per pound as reported in the Number 12 contract of the New York Coffee, Sugar and Cocoa Exchange or the Market Stabilization Price, whichever is greater, and the daily "spot" price of the Number 11 contract of the New York Coffee, Sugar and Cocoa Exchange in effect on the last market day before the date of entry/transfer of the corresponding sugar or the last market day before the end of the period during which export was required, whichever is greater, times the amount of sugar, raw value, that should have been, but was not, exported in sugar containing products. In the event no Number 11 or Number 12 price is reported by the New York Coffee, Sugar and Cocoa Exchange for the relevant market day, then the Licensing Authority may use such price as he/she deems appropriate.

(b) If at any time the Licensing Authority determines that a license holder has failed to comply with the requirements of this program, the Licensing Authority may, after notice to the license holder, suspend or revoke the license issued to the license holder under this program and/or refuse to issue future licenses to that manufacturer. The Licensing Authority reserves the right to revoke a license if claims filed under 19 CFR Part 191 are denied.

(c) The determination of the Licensing Authority under paragraphs (a) and (b) of this section may be appealed to the Director, Horticultural and Tropical Products Division, Foreign Agricultural Service (FAS), within 30 days from the date of notification. The request for reconsideration shall be presented in writing specifically stating any reason as to why such determination should not stand. The Director, Horticultural and Tropical Products Division, FAS, will provide such person with an opportunity for an informal hearing on such matter. A further appeal may be made to the Administrator, FAS, within five working days of the notification of the decision of the Director, Horticultural and Tropical Products Division, FAS.

§ 6.212 Waiver.

Under unusual, unforeseen or extraordinary circumstances, the Licensing Authority may extend the period for the export of sugar in sugar containing products or may temporarily increase the maximum amount of the license.

§ 6.213 Expiration

The licenses issued under this program shall expire upon written notice to the license hodlers by the Licensing Authority. The notice will state the expiration date of the licenses and any other details applicable to the expiration of the licenses.

Signed at Washington, D.C. on November 21, 1983.

Richard A. Smith,

Administrator, Foreign Agricultural Service.

[FR Doc. 83-31648 Filed 11-21-83; 4:16 pm]

BILLING CODE 3410-10-M

Farmers Home Administration

7 CFR Parts 1910, 1924, 1930, 1941, and 1945

Implementation of Coordinated Financial Statements

Correction

In FR Doc. 83-30101 beginning on page 51312 of the issue of Tuesday, November 8, 1983, make the following correction. On page 51312, first column, in the **DATES:** section, "January 9, 1983" should read "January 9, 1984".

BILLING CODE 1505-01-M

NUCLEAR REGULATORY COMMISSION

10 CFR Ch. I

Issuance of Quarterly Report on the Regulatory Agenda

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Regulatory Agenda.

SUMMARY: The Nuclear Regulatory Commission has issued the September 1983 Regulatory Agenda. The Agenda, which is a quarterly summary of all rules on which the NRC has proposed or is planning action and all petitions for rulemaking which have been received and are pending disposition by the Commission is issued to provide the public with information regarding NRC's rulemaking activities.

ADDRESS: A copy of this report, designated NRC Regulatory Agenda (NUREG-0936) Vol. 2, No. 3 is available for inspection and copying at a cost of five cents per page at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

Single copies of the report may be obtained at a cost of $6.00, payable in advance from the NRC/GPO Sales Program, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, Telephone (301) 492-7086, Toll free number (800) 368-5642.

Dated at Bethesda, Maryland this 17th day of November 1983.

For the Nuclear Regulatory Commission.

J. M. Felton,

Director, Division of Rules and Records, Office of Administration.

[FR Doc. 83-31507 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 202

[Docket No. R-83-1112; FR-1713]

Property Improvement and Mobile Home Programs; Approval of Lending Institutions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish a new part that sets out the requirements for HUD approval in granting a contract of insurance to new eligible financial institutions to participate in the Title I (National Housing Act) program. The proposed rule prescribes requirements for approval, enumerates eligible lenders, provides for "user" fees to participate in the program, and provides for the termination of the insurance contract or appropriate administrative sanctions.

DATES: Comments must be received by December 23, 1983.

ADDRESS: Interested persons are invited to submit written comments, suggestions, or data regarding the proposed rule to the Office of the General Counsel, Rules Docket Clerk, Room 10278, Department of Housing and

Urban Development, 451 Seventh Street SW., Washington, D.C. 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection during regular business hours at the above address. The rule may be changed on the basis of comments received.

FOR FURTHER INFORMATION CONTACT: Andrew Zirneklis, Office of Lender Certification, Room 9154, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410 (202) 426-3976 (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 2 of Title I of the National Housing Act provides that the Secretary is authorized and empowered, upon such terms and conditions as he may prescribe, to insure banks, trust companies, personal finance companies, mortgage companies, building and loan associations, installment lending companies, and other such financial institutions which the Secretary finds to be qualified by experience or facilities and approves as eligible for credit insurance against losses which they may sustain as a result of loans and advances of credit made in connection with the financing of improvements to real and personal property and the purchase of manufactured homes with or without lots. Therefore, the Department believes that it would be in the best interest of the public to set forth in a regulation the approval requirements for lending institutions interested in being granted insurance contracts under the Title I Program, as well as the procedures for termination of such contracts.

These regulations are substantially similar to our regulations for Title II mortgage insurance at 24 CFR Part 203. Many of the provisions of the proposed regulations have been followed by HUD and approved lenders for many years under HUD Handbook 4700.1, Title I Property Improvement Loan Operating Handbook. That handbook sets forth, in certain detail, the types of eligible lenders under the Title I program, the qualifications and requirements for HUD approval of these lenders, and the methods for temination of Title I contracts of insurance.

It is the Department's belief that participants in its programs should be responsible institutions in a postition to offer adequate lending services and facilities to loan applicants who seek to participate in HUD programs. The regulations proposed in this document fill out certain gaps in the handbook and parallel similar regulations for Title II mortgage insurance. The regulations require that eligible lenders receive HUD approval and hold contracts of insurance to participate in the Title I program. This is provided for under present HUD procedures in the granting of an insurance contract between HUD and the lender, and this practice is continued. These regulations do not establish extensive new standards for lender approval. They represent minimum uniform standards for assuring that lenders approved for participation in the Title I program are responsible institutions.

The regulations define several categories of eligible lenders: Government Institutions and National Mortgage Associations, Supervised Lenders (those subject to the periodic inspection and supervision of a governmental agency as required by law), and Nonsupervised Lenders. This parallels the categories of eligible lenders that have been granted Contracts of Insurance by HUD in the past.

The regulations also set forth a number of general requirements for the approval of all eligible lenders which very closely parallel our regulations at 24 CFR 203.2; and, further, they set forth a number of specific requirements for particular categories of eligible lenders to ensure their viability and stability (i.e., relating to minimum net worth and minimum available credit resources, as well as certain reporting requirements).

Finally, the regulations provide for termination of the Contract of Insurance pursuant to its terms and for a variety of administrative sanctions against the future approval of a lender to hold a Contract of Insurance. These regulations specifically incorporate the procedures of 24 CFR Part 25 (Mortgagee Review Board) with respect to the administrative sanctions. The Board will be delegated the responsibility to impose these sanctions. The specific grounds for the imposition of administrative sanctions intended to bring a lender into compliance with applicable statutes and regulations are specified in our proposals and generally involve instances where the lender's viability, stability, or integrity have been jeopardized.

Certain requirements in the proposed regulations are new for Title I lenders. They are as follows:

1. Section 202.4(a)(6) requires that each approved financial institution shall file a yearly verification report on a form prescribed by the Secretary. This provision is necessary to maintain HUD's computerized list of all approved lenders from which HUD mails publications and other issuances required by Title I lenders. It also serves as the vehicle by which lenders will pay their annual "user" fees to HUD.

2. Section 202.4(a)(9) requires each financial institution, other than an eligible governmental lender or such other institutions designated by the Secretary as being exempted, to pay an application and an annual "user" fee in such amount, and at such time, as the Secretary may require. This provision is intended to assist the Department in defraying the cost of approving and supervising financial institutions for participation in the Title I programs. A schedule of such fees will be separately announced to the industry.

3. Section 202.4(a)(10)(ii) provides that lender approval may be rejected by the Department if the applicant or any officer, Director, principal or employee has been indicted for, or has been convicted of, an offense which reflects upon the responsibility, integrity or ability of the lender to participate in HUD Programs as an approved lender.

4. Section 202.5 provides that approval of a financial institution to enter into a Contract of Insurance may be terminated or otherwise sanctioned by the Department's Mortgagee Review Board pursuant to the procedural requirements set forth at 24 CFR 25.4. Both the Department and the lender, in accordance with the terms of the Contract of Insurance, have always had the option to terminate the contract upon five days written notice. The administrative sanctions relate to HUD approval of the lender as an entity capable of participating in the Title I program.

The collection of information requirements contained in this proposed rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act of 1980 (Pub. L. 96-511). The assigned OMB control number is 2502-0017.

A 30 rather than a 60 day period is being provided for public comment in order to provide the Department with sufficient lead time to notify financial institutions of the amount of the fee, program the computers, and implement a billing system so that the program, if implemented, can begin in the first half of 1984.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50 which implement Section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours in the

Office of the Rules Docket Clerk at the above address.

This rule does not constitute a "major rule" as that term is defined in § 1(b) of Executive Order 12291 on Federal Regulations. Analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) have 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.

Pursuant to the provisions of 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the Undersigned hereby certifies that this rule would not have a singificant economic impact on a substantial number of small entities because the majority of financial institutions participating in the Title I program are large depository institutions and none of the proposed changes pose undue burdens for small entities seeking approval to loan funds.

This proposed rule is listed at 48 FR 47432 as item H-90-82 in the Department's Semi-annual Agenda of Regulations published on October 17, 1983 (48 FR 47418) pursuant to Executive Order 12291 and the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance Program numbers are:

14.110, Manufactured (Mobile) Home Insurance—Financing Purchases of Mobile Homes as Principal Residences of Borrowers;
14.142, Property Improvement Loan Insurance for Improving All Existing Structures and Building of New Nonresidential Structures; and
14.162, Mortgage Insurance—Combination and Mobile Home Lot Loans.

List of Subjects in 24 CFR Part 202

Approval of lending institutions, Mortgage insurance, Administrative practice and procedure, Government contracts.

Accordingly, HUD proposes to add a new part to the Code of Federal Regulations, 24 CFR Part 202, as follows:

PART 202—APPROVAL OF LENDING INSTITUTIONS UNDER TITLE I

Sec.
202.1 Purpose.
202.2 Approval of lending institutions.
202.3 Eligible lenders.
202.4 Approval requirements.
202.5 Termination of insurance contract and administrative sanctions.

Authority: Sec. 7(d) Department of Housing and Urban Development, 42 U.S.C. 3535(d); Title I, sec. 2, 48 Stat. 1248, 12 U.S.C. 1703.

§ 202.1 Purpose.

The purpose of this part is to establish uniform standards for the approval or disapproval of lending institutions which apply for or hold Contracts of Insurance under Title I of the National Housing Act and HUD regulations at 24 CFR Part 201.

§ 202.2 Approval of lending institutions.

A lender may be approved for participation in the program under Title I of the National Housing Act upon filing a request for approval on a form prescribed by the Secretary. The granting of an insurance contact by the Secretary shall constitute an agreement between the lender and the Secretary which shall govern the lender's continued approval subject to the provisions of this Part. Approval for eligibility does not grant separate rights in the applicant apart from the Contract of Insurance.

(Approved by the Office of Management and Budget under control number 2502-0017)

§ 202.3 Eligible lenders.

A chartered institution, a permanent organization having succession, or a trust, in the following forms is eligible for approval:

(a) *Government Institutions and National Mortgage Associations.* A Federal, State or municipal governmental agency, a Federal Reserve Bank, a Federal Home Loan Bank, and a National Mortgage Association which is empowered to participate in a consumer installment lending operation;

(b) *Supervised Institutions.* A member of the Federal Reserve System, a lender whose accounts are insured by the Federal Savings and Loan Insurance Corporation (FSLIC), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), or an institution which is subject to the inspection and supervision of a governmental agency which is required by law to make periodic examinations of its books and accounts;

(c) *Nonsupervised Institutions.* An institution which has as its principal activity the lending or investment of funds in mortgages, consumer installment notes or similar advances of credit, or the purchase of consumer installment contracts and which is not subject to the inspection and supervision of a governmental agency as required by law.

§ 202.4 Approval requirements.

(a) An eligible lender shall establish to the satisfaction of the Secretary that it meets and will continue to meet the following general requirements:

(1) It shall employ trained personnel competent to perform their assigned responsibilities in consumer lending activities and shall have adequate staff and facilities to originate and service Title I loans;

(2) It shall comply with Title VIII of the Civil Rights Act of 1968, as amended, Executive Order 11063, as amended, the Equal Credit Opportunity Act, and other Federal laws relating to consumer lending activities;

(3) It shall provide prompt notification, on a form prescribed by the Secretary, of all corporate changes, including, but not limited to: mergers, terminations, name, location, control, ownership, and character of business;

(4) It shall ensure that all employees who will sign applications for insurance on behalf of the lender shall be corporate officers or will otherwise be authorized to bind the lender in matters involving the origination of Title I loans;

(5) It shall not use escrow funds for any purpose other than that for which they were received;

(6) It shall file a yearly verification report on a form prescribed by the Secretary;

(7) It shall, upon request, submit a copy of its latest financial statement or such other information as the Secretary may request, and submit to an examination of that portion of its records which relate to its consumer lending activities;

(8) It shall remain responsible to the Secretary for the actions of its lending and servicing branches;

(9) Except for those eligible governmental lenders described in § 202.3(a) or for others which the Secretary may exempt, it shall pay an application and an annual fee in such amount, and at such time, as the Secretary may require to assist in defraying the cost of approving and supervising approved lenders for participation in the Title I Program;

(10) Neither the applicant lender, nor any officer, director, principal or employee of the applicant lender shall:

(i) Be under suspension, debarment, or other restriction under Part 24 or Part 25 of this title or under similar procedures of any other Federal agency, or

(ii) Be or become indicted for, or convicted of, an offense which adversely affects the lender's integrity

or its ability to participate in HUD programs as an approved lender.

(b) In addition to the general requirements applicable to all eligible lenders in paragraph (a) of this section, a supervised institution shall promptly notify the Secretary in the event of termination of its supervision by its supervising agency and, as to supervised institutions which are not members of the Federal Reserve System or whose accounts are not insured by the FSLIC, FDIC, or NCUA, shall have and maintain a net worth of not less than $100,000 in assets acceptable to the Secretary.

(c) In addition to the general requirements applicable to all eligible lenders in paragraph (a) of this section, a nonsupervised institution shall:

(1) Have and maintain a net worth of not less than $100,000 in assets acceptable to the Secretary;

(2) Have and maintain a reliable warehouse line of credit or other funding program acceptable to the Secretary in an amount of not less than $250,000 for use in Title I loan financing;

(3) Within 75 days of the close of its fiscal year and at such other times as may be requested, file with the Secretary an audit report (a financial statement in a form acceptable to the Secretary consisting of a balance sheet, a statement of operations and retained earnings, an analysis of the lender's net worth adjusted to reflect only assets acceptable to the Secretary, and an analysis of escrow funds) based on an audit performed by a Certified Public Accountant or by a qualified Independent Public Accountant (as defined by the Comptroller General of the United States) licensed by a State or other political subdivision of the United States.

(Approved by the Office of Management and Budget under control number 2502-0017.)

§ 202.5 Termination of insurance contract and administrative sanctions.

(a) *Termination of insurance contract.* A Contract of Insurance may be terminated in accordance with its terms at any time by the Secretary or designee upon giving the lender at least 5 days prior written notice.

(b) *Administrative sanctions.* Administrative sanctions may be applied to prevent a lender from entering into a Contract of Insurance, in accordance with the procedures established in 24 CFR 25.4, and may include the following:

(1) A letter of reprimand informing the lender of the existence or occurrence of a violation and directing the lender to bring and maintain its activities in conformity with all HUD requirements. Failure to comply with a directive in a letter of reprimand may result in other sanctions as set forth in this section;

(2) Probation for a specified period of time for the purpose of evaluating the lender's compliance with HUD requirements. During a period of probation, additional reasonable requirements may be imposed on the lender as an aid in evaluating the lender. Such additional requirements may include supervision of the lender's activities by HUD, periodic reporting to HUD, or submission to HUD of internal audits, audits by an Independent Public Accountant, or other audits;

(3) Temporary suspension, if there exists adequate evidence that continuation of approval pending completion of any audit, investigation, or other review, or such administrative or legal proceedings as may ensue, would not be in the public interest or in the best interest of the Department;

(4) Termination for a specified period of time or, in cases involving egregious circumstances, for an indefinite period.

(c) *Grounds for administrative sanctions.* Administrative sanctions shall be based upon one or more of the following grounds:

(1) Failure to remain in continuing compliance with the requirements for approval of lenders at 24 CFR 202.4;

(2) Submission of false information to HUD in connection with a loan;

(3) Failure properly to supervise and monitor dealers under the provisions of 24 CFR Part 201;

(4) Exhaustion of the general insurance reserve established under 24 CFR Part 201;

(5) Maintenance of a claim/loan ratio representing an unacceptable risk to the Department;

(6) Failure to cooperate with HUD audit, investigation or request for information as to the conduct of the lender's HUD or FHA insured business;

(7) Such other reason as the Mortgagee Review Board, Secretary, Under Secretary or Hearing Officer, as appropriate, determines to be justified. Such reasons include, but are not limited to, failure to exercise prudent credit judgment, business practices, or servicing procedures or failure or refusal to comply with HUD requirements or other requirements of law or regulation.

(d) *Settlement Agreements.* The Department may at any time enter into a settlement agreement with a lender to resolve any outstanding grounds for any sanction provided for by this section. Such agreements may provide for cessation of any violation; correction or mitigation of the effects of any violation; repayment of sums of money wrongfully or incorrectly paid to the lender by a borrower or by HUD; actions to collect sums of money wrongfully or incorrectly paid by the lender to a third party; indemnification of HUD for insurance claims on Title I loans originated in violation of HUD requirements; or implementation of a Quality Control Plan or other corrective measures acceptable to HUD. Failure of a lender to comply with a settlement agreement may result in suspension or termination of HUD approval.

Dated: October 28, 1983.

Philip Abrams,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 83-31498 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-27-M

Office of the Secretary

24 CFR Part 868

[Docket No. R-83-1118]

Comprehensive Improvement Assistance Program

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: This rule would revise the Comprehensive Improvement Assistance Program (CIAP) regulations by replacing the defined term "major repairs" with the defined term "non-routine maintenance." "Major repairs" has been used to identify those CIAP-eligible work items that are subject to HUD-determined prevailing wage rates rather than to Davis-Bacon prevailing wage rates. The Department has been concerned that the term "major repairs" could be interpreted by PHAs to include developmental work items that properly should be subject to Davis-Bacon prevailing wage rates. The Department accordingly proposes to substitute the term "non-routine maintenance" and to revise the definition to emphasize that work items subject to HUD-determined wage rates must be operational in nature. The new definition also would specify particular types of work that are not "non-routine maintenance."

DATE: Comments must be received on or before January 23, 1984.

ADDRESS: Interested persons are invited to submit comments regarding this rule to the Office of General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410. Comments should refer to the above docket number and title. A copy of each set of comments submitted will be available for public inspection and

copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Pris Buckler, Room 4224, Office of Public Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410, (202) 755-5595. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

"Major Repairs" Replaced by "Non-Routine Maintenance"

Section 12 of the United States Housing Act of 1937 (USHA of 1937) (42 U.S.C. 1437j) provides in part that all laborers and mechanics employed in the development of a lower income housing project must be paid "not less than the wages prevailing in the locality, as predetermined by the Secretary of Labor pursuant to the Davis-Bacon Act (49 Stat. 1101) * * *." Section 12 also provides that all maintenance laborers and mechanics employed in the operation of a lower income housing project must be paid "not less than the wages prevailing in the locality, as determined or adopted * * * by the Secretary * * *."

The provisions of section 12 of the USHA of 1937 apply to work funded under CIAP, which was established by section 14 of the USHA of 1937 (42 U.S.C. 1437*l*). CIAP provides assistance to Public Housing Agencies to improve the physical condition of existing public housing projects, and to upgrade the management and operation of such projects.

Most work items funded under CIAP are developmental for purposes of the wage rate requirements in section 12 of the USHA of 1937. However, since the inception of CIAP, the Department has recognized that certain eligible work items are operational for purposes of section 12. Section 868.9(h)(1) of the interim rule which initially implemented CIAP provided that HUD-determined wages would be paid to, among others, "all laborers and mechanics employed by the PHA itself or by a contractor engaged by the PHA in carrying out major repairs as defined in § 868.3" (46 FR 21940, April 14, 1981).

Section 868.3 of the interim rule defined "major repairs" to mean "work items that are usually not recurrent, are substantial in scope, involve expenditures that would otherwise materially distort the level trend of maintenance expense and may include replacement of structural elements and nonexpendable equipment due to normal wear and tear by items of substantially the same kind."

The final rule (47 FR 22312, May 21, 1982) made no change in the definition of "major repairs" or in the requirement to pay HUD-determined prevailing wages to laborers and mechanics carrying out major repairs.

The Department is concerned that the use of the term "major repairs" may itself create confusion for PHAs in distinguishing developmental work items from operational work items in order to determine whether to apply Davis-Bacon prevailing wage rates or to apply HUD-determined prevailing wage rates. In order to minimize the risk that the wrong wage rule is applied, the Department proposes to replace the term "major repairs" with the term "non-routine maintenance", which is more descriptive of operational work. The Department would also revise the definition to (1) delete the description of the work items as being "not recurrent" and instead refer to work items that ordinarily would be performed in the course of upkeep but have become substantial because they have been put off, (2) describe replacement items within the coverage of the definition as "equipment and materials" rather than "structural elements and non-expendable equipment." The definition would also provide expressly that work that constitutes reconstruction, a substantial improvement in the quality or kind of original equipment and materials, or remodeling which alters the nature or type of housing units is not "non-routine maintenance."

The Department will issue guidance to its field offices and to PHAs that will list typical eligible work items under CIAP and indicate whether they are subject to Davis-bacon or to HUD-determined prevailing wage rates.

Other Matters

A finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50 which implement Section 102(2)(C) of the National Environmental Policy Act of 1969. The finding is available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, D.C. 20410.

This rule does not constitute a "major rule" as that term is defined in Section 1(b) of Executive Order 12291 on Federal Regulation issued by the President on February 17, 1981. Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) have 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.

Pursuant to 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the Undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule may have some economic impact on small entities since it may result in certain PHAs and contractors of PHAs paying different wages to laborers and mechanics than may have been paid in the absence of the revision. The difference, however, would result only from the fact that this rule should minimize the risk of an erroneous application of the wage rate provisions already required by section 12 of the USHA of 1937.

This rule was listed as Item No. H-40-83 at 48 FR 47444 in the Department's Semiannual Agenda of Regulations published on October 17, 1983 (48 FR 18054), pursuant to Executive Order 12291 and the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance program number and title is 14.158—Public Housing—Modernization of Projects.

List of Subjects in 24 CFR Part 868

Loan programs—housing and community development, Public housing, Reporting and recordkeeping requirements.

Accordingly, the Department proposes to amend 24 CFR Part 868 as follows:

1. In § 868.3, the definition "major repairs" would be removed and a new definition "non-routine maintenance" would be added, to read as follows:

§ 868.3 Definitions.

* * * * *

"Non-routine maintenance" means work items that ordinarily would be performed on a regular basis in the course of upkeep of a property, but become substantial in scope because they have been put off, and that involve expenditures that would otherwise materially distort the level trend of maintenance expenses. Non-routine maintenance may include replacement (by items of substantially the same kind) of equipment and materials rendered unsatisfactory because of normal wear and tear. Work that constitutes reconstruction, a substantial improvement in the quality or kind of original equipment and materials, or remodeling that alters the nature or type

of housing units is not nonroutine maintenance.

* * * * *

§§ 868.4; 868.9 and 868.18 [Amended]

2. In addition to the amendment set forth above, 24 CFR Part 868 would be amended to remove the words "major repairs" and insert, in their place, the words "non-routine maintenance" in the following places:

a. 24 CFR 868.4(a);
b. 24 CFR 868.4(g);
c. 24 CFR 868.9(h)(1) and (2); and
d. 24 CFR 868.18(a).

(Secs. 12, 14, United States Housing Act of 1937 (42 U.S.C. 1437j, l,) sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)))

Dated: November 1, 1983.

Samuel R. Pierce, Jr.,

Secretary of Housing and Urban Development.

[FR Doc. 83-31397 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-32-M

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 880, 881, 883, 884, 886, 888 and 899

[Docket No. R-83-1079]

Section 8 Housing Assistance Payments Program for New Construction or Substantial Rehabilitation Projects; Contract Rent Adjustments

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: The Department proposes to amend its contract rent adjustment regulations to provide more accurate rent adjustments for newly constructed and substantially rehabilitated projects assisted under Section 8 of the United States Housing Act of 1937. The Department has been concerned that the current method for computing contract rents for these projects may result in excessive contract rent increases and inequitable treatment of projects based on the type of financing used. In addition, Congress has enacted a new limitation on contract rent adjustments applicable to those projects that have contracts executed on or after October 1, 1981. The new limitation would restrict contract rent adjustments to the amount of operating cost increases for comparable rental dwelling units in the same market area which are suitable for occupancy by families assisted under the Section 8 Housing Assistance Payments Program. This rule would amend the method for determining and applying annual adjustment factors for all projects involving new construction and substantial rehabilitation in a manner consistent with the new statutory limitation. The proposed rule would provide that the annual adjustment factor (1) Would be derived from operating cost data rather than from market rent data and (2) would not be applied to the portion of the contract rent attributed to debt service.

DATE: Comments must be received by: January 23, 1984.

ADDRESS: Comments should be sent to the Rules Docket Clerk, Office of General Counsel, Room 10278, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410. Each comment should include the commenter's name and address and must refer to the docket number indicated in the heading of this document. A copy of each comment will be available for public inspection during regular business hours at the above address. The Department will evaluate the comments received on this proposed rule before formulating its final regulation.

FOR FURTHER INFORMATION CONTACT: James J. Tahash, Director, Program Planning Division, Office of Multifamily Housing Management, Room 6178, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410, telephone (202) 755-5654; or Steven Silvert, Acting Director, Office of State Agency and Bond Financed Programs, Room 6122, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410, telephone (202) 755-8135. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: Under the Section 8 Housing Assistance Payments Program, HUD or Public Housing Agencies (PHAs) make housing assistance payments on behalf of eligible tenants to project owners. The payments are equal to the difference between the contract rent and the tenant's contribution based upon income. The initial contract rents are set forth in the Housing Assistance Payments Contract (HAP Contract) and are determined in accordance with the appropriate programmatic regulations.

Section 8(c)(2) of the United States Housing Act of 1937 (the Act), as amended, (42 U.S. 1437f(c)(2)) requires that the HAP Contract provide for adjustments in the contract rents. Section 8(c)(2)(A) of the Act provides for annual or more frequent adjustment in the maximum monthly rents for units covered by HAP Contracts to reflect changes in the fair market rentals established in the area for similar types and sizes of dwelling units or on the basis of a reasonable formula devised by the Secretary of HUD. Section (8)(c)(2)(B) of the Act permits additional adjustments in the maximum monthly rent where necessary to reflect changes in the actual and necessary expenses of owning and maintaining the units which have resulted from substantial general increases in real property taxes, utility rates, or similar costs, and which are not adequately compensated for by the adjustment in the maximum monthly rent permitted under section 8(c)(2)(A). Section 8(c)(2)(C) provides that neither of the two above adjustments in the maximum rents may result in material differences between the rents charged for assisted and comparable unassisted units.

These three sections apply both to newly constructed or substantially rehabilitated projects and to existing housing and moderately rehabilitated projects assisted under the Section 8 Housing Assistance Payments Program. Section 324(2) of the Housing and Community Development Amendments of 1981 (HCD Amendments of 1981) added section 8(c)(2)(D) to the Act. This provision requires the Secretary to limit increases in contract rents for newly constructed or substantially rehabilitated projects to the amount of operating cost increases for comparable rental dwelling units in the same market area which are suitable for occupancy by families assisted under Section 8. Where no comparable dwelling units exist in the same market area, the Secretary has authority to approve such increases in accordance with the best available data regarding operating cost increases in rental dwelling units.

Except for section 8(c)(2)(D), the Department has implemented its statutory authority under section 8(c)(2) through the provisions of 24 CFR Part 888 and other regulations pertaining to the specific Section 8 program involved, and through the provisions of the HAP Contracts. Under Part 888 the Department implements section 8(c)(2)(A) by publishing Annual Adjustment Factors (Factors) at least annually in the **Federal Register**. The Factors are developed for the appropriate Census Region or Metropolitan Statistical Area. In addition, HUD field offices are authorized under § 888.204 to establish separate or revised Factors if the published Factors applicable to a particular area result in rents that are substantially lower than rents charged

for comparable units not receiving assistance under the Act.

The methodology for computing the Factors has been revised from time to time. The current methodology involves generating (1) a single gross rent adjustment factor for each area based on the changes in the rent and utility components of the Consumer Price Index for the most recent 12-month period and (2) separate matrices of adjustment factors by rent ranges for contract rent including and excluding utilities, based on data obtained from The Annual Housing Survey. (See Notice of publication of annual adjustment factors pursuant to 24 CFR 888, 48 FR 2595, January 20, 1983.)

The adjusted contract rent is determined by multiplying the total contract rent in effect on the anniversary date of the HAP Contract by the appropriate Factor.

The provisions of section 8(c)(2)(B) permitting additional adjustments are implemented in the regulations relating to the specific Section 8 programs (see 24 CFR 880.609 (b), 881–609(b), 883.710(b), 884.109(c), and 886–312(c)). In general, these regulations allow for special additional adjustment of the contract rent when an owner demonstrates that there have been increases in the actual and necessary expenses of owning and maintaining assisted units which have resulted from general increases in real property taxes, assessments, and utility rates, and which are not adequately compensated for by annual adjustments based on the Factors.

The overall limitation on contract rent adjustments contained in section 8(c)(2)(C) is contained in the following programmatic regulations: 24 CFR 880.609(c), 881.609(c), 883.710(c), 884.109(d), and 886.312(d).

Each HAP Contract contains provisions required by sections 8(c)(2)(A), (B) and (C). For example, the following are the applicable provisions contained in the current form of the HAP Contract, HUD–52522 D (8–80):

2.7 *Rent Adjustments.*

(a) *Funding of Adjustments.* Housing assistance payments will be made in amounts commensurate with Contract Rent Adjustments under this section up to the maximum [annual contract commitment available under the Contract].

(b) *Annual Adjustments*

(1) Upon request from the Owner to the [Contract Administrator], Contract Rents will be adjusted on the anniversary date of the contract in accordance with 24 CFR 888 and this Contract. See, however, paragraph (d).

(2) In the case of previously HUD-owned projects, the Contract Rents shall be adjusted in accordance with 24 CFR 886, Subpart C and this Contract.

(3) Contract Rents may be adjusted upward or downward, as may be appropriate; however, in no case shall the annual adjustment result in Contract Rents less than the Contract Rents on the effective date of the Contract.

(c) *Special Additional Adjustments.* Special additional adjustments shall be granted, when approved by HUD, to reflect increases in the actual and necessary expenses of owning and maintaining the Contract Units which have resulted from substantial general increases in real property taxes, utility rates, assessments and utilities not covered by regulated rates. The Owner must demonstrate that such general increases have caused increases in the Owner's operating costs which are not adequately compensated for by annual adjustments. The Owner shall submit to HUD supporting data, financial statements and certifications which clearly support the increase. See, however, paragraph (d).

(d) *Overall Limitation.* Notwithstanding any other provision of this Contract, adjustments after Contract execution or cost certification, where applicable, shall not result in material differences between the rents charged for assisted and comparable unassisted units, as determined by HUD; except to the extent that the differences existed with respect to the Contract Rents set at Contract execution or cost certification, where applicable.

As indicated in the above discussion, contract rent adjustments are computed by applying the Factor to the entire contract rent. The Department, for a considerable time, has been concerned that this method may cause unnecessary escalation of contract rents. The concern stems from the fact that the adjustments are intended to compensate owners for increases in operating expenses. By applying the Factor to the full rent, it is applied not only to the portion which would pay operating expenses but also to the portion attributable to debt service, which is a fixed expense. Under this methodology, projects that have a comparatively high ratio of debt service to operating expenses would receive disproportionately high contract rent adjustments.

The Department addressed this problem in an interim rule amending Part 888, Subpart B (44 FR 3908, January 18, 1979). This interim rule revised the way the Department computed contract rent adjustments under section 8(c)(2)(A) in three significant ways:

1. Actual operating expenses had to be determined for the project based on submission of an audited financial statement to HUD;

2. The Factor was applied to the portion of the contract rent attributed to operating expenses; and

3. Operating expenses could not exceed 45 percent of total operating revenue.

All 60 comments received by HUD on the interim rule were adverse. The objections were primarily directed against: (1) The use of a ceiling of 45 percent of total operating revenue in computing contract rent increases, and (2) the requirement that owners submit audited financial statements supporting each increase. The commenters contended as follows:

1. The 45 percent ceiling on operating expenses is arbitrary and unfair. In the initial years, operating expenses should be less than 45 percent of total revenue. However, with operating costs increasing yearly but with the debt service remaining constant, the 45 percent ceiling would be exceeded in the overwhelming majority of cases.

2. The 45 percent ceiling is too rigid because it fails to allow for (a) Variations based upon the type of project (for example, scattered site, high density, inner city, family versus elderly), (b) inclusion or non-inclusion of utilities in the rents, (c) the presence of subsidized financing under which debt service is less than the norm, (d) variations in equity, and (e) the presence of special financing provisions which could cause changes in debt service.

3. Using actual expenses as the base (even with a ceiling amount) tends to reward inefficiency and penalize efficiency.

4. Applying the Factor to only the operating expenses portion of the contract rent would result in too low an adjustment, since the rate of increase in the Consumer Price Index for rent and utilities, on which the Factor is based, is lower than the rate of increase in operating expenses.

5. The provision in the interim rule requiring that the rent adjustments be supported by an audited statement submitted to HUD is objectionable because:

a. The requirement would violate the concept of an "automatic" annual adjustment.

b. The cost of the audit would add to project expenses, and on small projects, the cost of the audit might outweigh the amount of the rent adjustment.

c. Special audits would have to be obtained, at extra cost, when the anniversary date of the contract does not coincide with the end of the project's fiscal year.

d. The requirement would add to HUD's administrative workload.

e. Insofar as the requirement would result in uncertainty or delay in effectuating the annual adjustment, it would cause financial problems for the projects.

The Department agreed with the commenters that the 45 percent ceiling appeared to be arbitrary and tended to penalize efficient project operators. The Department also decided to consider further whether to require that audited financial statements be submitted to support each contract rent adjustment. For these reasons, the Department on April 12, 1979 rescinded the interim rule (44 FR 21768). The rescission was effective May 14, 1979, but applied retroactively to all contracts adjusted since November 8, 1978.

Congress, with a similar concern that contract rent adjustments may be excessive, amended section 8(c)(2) by adding subparagraph (D) through enactment of section 324 of the HCD Amendments of 1981. Section 8(c)(2)(D) provides:

> Notwithstanding the foregoing, the Secretary shall limit increases in contract rents for newly constructed or substantially rehabilitated projects assisted under this section to the amount of operating cost increases incurred with respect to comparable rental dwelling units of various sizes and types in the same market area which are suitable for occupancy by families assisted under this section. Where no comparable dwelling units exist in the same market area, the Secretary shall have authority to approve such increases in accordance with the best available data regarding operating cost increases in rental dwelling units.

Congress also provided, in section 371(b) of the HCD Amendments of 1981, that this provision "shall apply only with respect to contracts entered into on and after October 1, 1981." The obvious purpose of section 371(b) was to avoid the possibility that section 8(c)(2)(D) could be construed as a taking of a preexisting contractual right.

In developing a rule to implement section 8(c)(2)(D), the Department first considered developing an operating cost factor which would represent the amount of operating cost increases incurred by comparable rental dwelling units of various sizes and types which are suitable for occupancy by families assisted under the Section 8 Program. The contract rent adjustment for new construction and substantial rehabilitation projects under contract on or after October 1, 1981 would be computed using the current methodology for determining annual adjustment factors, but the adjustment could not exceed an amount determined by multiplying the operating expense portion of the contract rent by the operating cost factor.

This approach, while fully implementing section 8(c)(2)(D), would not correct the continuing problem that annual adjustments computed for projects with contracts entered into before October 1, 1981 can be excessive. Section 8(c)(2)(D) did not address this problem; however, nothing in the text of sections 324(2) and 371(b) of the HCD Amendments of 1981 or in their legislative history suggests that section 8(c)(2)(D) was intended to prevent the Secretary from using his authority under section 8(c)(2)(A) to adjust the methodology for determining and applying annual adjustment factors in order to obtain more reasonable contract rent adjustments. Indeed, section 8(c)(2)(D) suggests a methodology which should provide more reasonable contract rent adjustments than are obtained under current methodology.

Therefore, the Department is proposing, with respect to all contracts involving new construction or substantial rehabilitation, to amend its regulations concerning the development and application of annual adjustment factors in a manner which is consistent with the requirements of section 8(c)(2)(D). Specifically, the proposed rule would make it clear that, for contracts involving newly constructed or substantially rehabilitated units, the annual adjustment factor would be derived from operating cost data rather than from market rent data. In addition, this factor would not be applied to that portion of the contract rent which would be attributed to debt service.

Revising the methodology for computing annual adjustments under section 8(c)(2)(A) does not pose the problem of retroactive application of a statute which Congress was addressing in section 371(b) of the HCD Amendments of 1981. As noted above in the excerpt from current HAP Contracts, outstanding Contracts give project owners no greater right to a particular contract rent adjustment than is provided by section 8(c)(2). Project owners are entitled to at least annual adjustments in contract rents to reflect changes in fair market rentals or based on a reasonable formula, if those adjustments do not result in a material difference in rents between assisted and comparable unassisted units. Project owners are similarly entitled to special adjustments to reflect increases in the actual and necessary expenses of owning and maintaining the units resulting from general increases in real property taxes, utility rates, or similar costs which are not adequately compensated for by the annual adjustment. This proposed rule would not adversely affect these rights.

In addition, this proposed rule would meet the principal objections to the interim rule. It would not establish any percentage ceiling on operating expenses. It would not require submission of audited financial statements. Instead, the operating expense portion of the contract rents would be determined by subtracting monthly debt service from contract rent. It would not apply a market rent generated annual adjustment factor to the operating expense portion of the contract rent. Rather, it would use an annual adjustment factor derived from operating expense data. Moreover, by focusing on area rather than individual project cost increases, the proposed rule would not reward inefficient operation or penalize efficient operation.

To effect these changes, the Department proposes to amend 24 CFR Part 888 to revise subpart B and to add a new subpart C which would govern the development and application of annual adjustment factors for Section 8-assisted projects involving new construction and substantial rehabilitation. Subpart B would be amended to make it apply only to Section 8-assisted projects involving existing housing and moderate rehabilitition. Section 888.203 would be revised to provide a more accurate description of the use of contract rent annual adjustment factors.

In the new Subpart C, § 888.301, Purpose, would identify the specific Section 8 Housing Assistance Payment Programs subject to the annual adjustment factors developed under that subpart. They would be: New Construction (24 CFR Part 880), Substantial Rehabilitation (24 CFR Part 881), State Housing Agencies (24 CFR Part 883), New Construction Set-Aside for Section 515 Rural Rental Housing Projects (24 CFR Part 884) and the substantial rehabilitation component of the Program for Disposition of HUD-Owned Projects (24 CFR Part 886, Subpart C).

Section 888.302, Manner of publication, would provide for the same type of publication of annual adjustment factors as provided under current § 888.202, except that the authority to publish revised factors would not be limited to HUD Field Offices.

In § 888.303, Use of contract rent automatic annual adjustment factors, paragraph (a) would provide instruction on determining the appropriate annual adjustment factor. To permit more flexibility in defining the area covered by a specific schedule of annual adjustment factors, the term "market area" would be substituted for "Census Region or Standard Metropolitan Statistical Area." This is consistent with the change proposed in § 888.203 for

existing and moderately rehabilitated housing.

Section 888.303(b) contains guidance on how to compute contract rent adjustments. It would provide that the annual adjustment factor be applied to contract rent less debt service. "Debt service" for noninsured projects would be defined to be the lesser of principal and interest on which the initial contract rents were based or the actual cost of permanent financing plus an assumed annual distribution of 6 percent on equity and any fixed annual deposit to the reserve for replacement. For insured projects, the rule would adopt the formula for computing debt service currently used in the computation of initial rent determinations. Under 24 CFR 207.19(e)(1)(i), debt service is computed by applying a debt service factor (covering debt service requirements and a rate of return to the owner) to the sum of the replacement cost and working capital. The rule would also include reserve for replacement deposits in debt service for those pre-October 1, 1979 project owners whose reserve for replacements deposits are not adjusted annually. Reserve for replacement deposits would not be considered debt service when the project owner opts to have reserve for replacement deposits adjusted annually by the amount of the annual adjustment factor.

Section 888.303(c) would provide that the annual adjustment factor under subpart C represents operating cost increases incurred by comparable dwelling units of various sizes and types in the same market area which are suitable for occupancy by families assisted under the Section 8 Program. It also would provide that, if no comparable dwelling units exist in the same market area, the annual adjustment factor would be determined in accordance with the best available data regarding operating cost increases in rental dwelling units.

Section 888.304, Revision to the annual adjustment factors, would provide HUD with the authority (comparable to that in § 888.204) to publish separate or revised adjustment factors for a particular area if HUD determines that the costs of operating comparable rental housing have increased at a substantially greater rate than the annual adjustment factors.

The Department also proposes to make technical amendments to the regulations concerning special additional adjustments authorized by section 8(c)(2)(B) of the Act. This rule would amend §§ 880.609(b), 881.609(b), 883.710(b), 884.109(c) and 886.312(c) to follow more closely the statutory description of the types of costs that can justify a special additional adjustment. The term "other similar costs" would be inserted into these sections and "assessments and utilities not covered by regulated rates" would be given as examples of "other similar costs".

Finally, the proposed rule would remove the word "Automatic" from the term "Automatic Annual Adjustment Factors". Use of the word "Automatic" can be misleading since annual adjustment factors are not automatically applied to adjust contract rents. Adjustments must be sought by the project owner and, in general, Adjustments cannot result in material differences between the rents charged for assisted units and comparable unassisted units.

A finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implement Section 102(2)(C) of the National Environmental Policy Act of 1969. The finding is available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Room 10278, 451 Seventh Street, S.W., Washington, D.C. 20410.

This rule does not consitute a "major rule" as that term is defined in Section 1(b) of Executive Order 12291 on Federal Regulation Issued by the President on February 17, 1981. Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, state or local government agencies, or geographic regions; or (3) have 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.

Pursuant to 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the Undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The Changes to be effected by this rule would have some economic impact on small entities, but are intended to provide a more accurate measure of contract rent adjustments needed to meet increases in operating expenses.

The rule was listed at 48 FR 47445 as item H-132-82 in the Department's Semiannual Agenda of Regulations published on October 17, 1983 (48 FR 47418), pursuant to Executive Order 12291 and the Regulatory Flexibility Act.

The collection of information requirements contained in this rule have been submitted to the Office of Management and Budget for review under Section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. § 3504(h)). Please send any comments regarding the collection of information requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, Attention: Desk Officer for HUD.

The Catalog of Federal Domestic Assistance program number and title is 14.156 Lower Income Housing Assistance Program.

List of Subjects

24 CFR Part 880

Grant programs—housing and community development, Rent subsidies, Low and moderate income housing.

24 CFR Part 881

Grant programs—housing and community development, Rent subsidies, Low and moderate income housing.

24 CFR Part 883

Grant programs—housing and community development, Rent subsidies, New construction and substantial rehabilitation.

24 CFR Part 884

Grant programs—housing and community development, Rent subsidies, Rural areas, Low and moderate income housing.

24 CFR Part 886

Grant programs—housing and community development, Low and moderate income housing, Rent subsidies.

24 CFR Part 888

Rent subsidies.

Accordingly, the Department proposes to amend Chapter VIII of title 24 CFR, as follows:

PART 880—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR NEW CONSTRUCTION

§ 880.609 [Amended]

1. In § 880.609, paragraph (b) is proposed to be revised to read as follows:

* * * * *

(b) *Special additional adjustments.* Special additional adjustments will be granted, to the extent determined

necessary by HUD, to reflect increases in the actual and necessary expenses of owning and maintaining the assisted units, where such increases have resulted from substantial general increases in real property taxes, utility rates, or similar costs (*e.g.*, assessments and utilities not covered by regulated rates), and which are not adequately compensated for by the annual adjustment under paragraph (a) of this section. Requests for special additional adjustments must be accompanied by required supporting data, financial statements and certifications.

* * * * *

PART 881—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR SUBSTANTIAL REHABILITATION

§ 881.609 [Amended]

2. In § 881.609, paragraph (b) is proposed to be revised to read as follows:

* * * * *

(b) *Special additional adjustments.* Special additional adjustments will be granted, to the extent determined necessary by HUD, to reflect increases in the actual and necessary expenses of owning and maintaining the assisted units, where such increases have resulted from substantial general increases in real property taxes, utility rates, or similar costs (*e.g.*, assessments and utilities not covered by regulated rates), and which are not adequately compensated for by the annual adjustment under paragraph (a) of this section. Requests for special additional adjustments must be accompanied by required supporting data, financial statements and certifications.

PART 883—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—STATE HOUSING AGENCIES

§ 883.710 [Amended]

3. In § 883.710, paragraph (b) is proposed to be revised to read as follows:

* * * * *

(b) *Special additional adjustments.* Special additional adjustments will be granted, to the extent determined necessary by HUD and the Agency, to reflect increases in the actual and necessary expenses of owning and maintaining the assisted units, where such increases have resulted from substantial general increases in real property taxes, utility rates, or similar costs (*e.g.*, assessments and utilities not covered by regulated rates), and which are not adequately compensated for by the annual adjustment under paragraph (a) of this section. Requests to the Agency for special additional adjustments must be accompanied by requiring supporting data, financial statements and certifications.

* * * * *

PART 884—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM, NEW CONSTRUCTION SET-ASIDE FOR SECTION 515 RURAL RENTAL HOUSING PROJECT

§ 884.109 [Amended]

4. In § 884.109, paragraph (c) is proposed to be revised to read as follows:

* * * * *

(c) *Special additional adjustments.* Special additional adjustments will be granted, to the extent determined necessary by HUD, to reflect increases in the actual and necessary expenses of owning and maintaining the assisted units, where such increases have resulted from substantial general increases in real property taxes, utility rates, or similar costs (*e.g.*, assessments and utilities not covered by regulated rates), and which are not adequately compensated for by the annual adjustment under paragraph (b) of this section. Requests for special additional adjustments must be accompanied by required supporting data, financial statements and certifications.

* * * * *

PART 886—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—SPECIAL ALLOCATIONS

§ 886.312 [Amended]

5. In § 886.312, paragraph (c) is proposed to be revised to read as follows:

* * * * *

(c) *Special additional adjustments.* Special additional adjustments will be granted, to the extent determined necessary by HUD, to reflect increases in the actual and necessary expenses of owning and maintaining the assisted units, where such increases have resulted from substantial general increases in real property taxes, utility rates or similar costs (*e.g.*, assessments and utilities not covered by regulated rates), and which are not adequately compensated for by the annual adjustment under paragraph (b) of this section. Requests for special additional adjustments must be accompanied by required supporting data, financial statements and certifications.

* * * * *

PART 888—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—FAIR MARKET RENTS AND CONTRACT RENT ANNUAL ADJUSTMENT FACTORS

6. In Part 888, the heading to Subpart B is proposed to be revised to read as follows:

* * * * *

Subpart B—Contract Rent Annual Adjustment Factors—Existing Housing and Moderate Rehabilitation

* * * * *

7. In Part 888, § 888.201 is proposed to be revised to read as follows:

§ 888.201 Purpose.

The Annual Adjustment Factors published under this subpart are used to adjust rents under all Section 8 Housing Assistance Payments Programs for Existing Housing and for Moderate Rehabilitation (24 CFR Part 882).

8. In Part 888, § 888.203 is proposed to be revised to read as follows:

§ 888.203 Use of contract rent annual adjustment factors.

(a) The adjustment monthly amount of the Contract Rent for a dwelling unit is determined by multiplying the Contract Rent (or Moderate Rehabilitation Base Rent) in effect on the anniversity date of the contract by the applicable Annual Adjustment Factor (see paragraph (b) of this section) and rounding the result to the nearest whole dollar amount.

(b) Two sets of Annual Adjustment Factors are provided, one for Contract Rents Including Highest Cost Utility and one for Contract Rents Excluding Highest Cost Utility. Use the Annual Adjustment Factor, appropriate to the Contract Rent to be adjusted, for the market area where the project is located.

9. In Part 888, a new Subpart C is proposed to be added to read as follows.

Subpart C—Contract Rent Annual Adjustment Factors—New Construction and Substantial Rehabilitation

Sec.

888.301 Purpose.
888.302 Manner of publication.
888.303 Use of contract rent annual adjustment factors.
888.304 Revision to the annual adjustment factors.

Authority: Sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C.

3535(d), secs. 5(b) and 8, U.S. Housing Act of 1937 (42 U.S.C. 1437c(b) and 1437f)).

Subpart C—Contract Rent Annual Adjustment Factors—New Construction and Substantial Rehabilitation

§ 888.301 Purpose.

The Annual Adjustment Factors published under this subpart are used to adjust rents under the following Section 8 Housing Assistance Payments Programs: New Construction (24 CFR Part 880), Substantial Rehabilitation (24 CFR Part 881), State Housing Agencies (24 CFR Part 883), New Construction Set-Aside for Section 515 Rural Rental Housing Projects (24 CFR Part 884), and the substantial rehabilitation component of the Program for Disposition of HUD-Owned Projects (24 CFR Part 886, Subpart C).

§ 888.302 Manner of publications.

Adjustment Factors will be published in the **Federal Register** at least annually by Notice. Interim revisions may be published as market conditions indicate. In the case of revised factors applicable only to specific areas, HUD will publish a notice appropriate to the limited scope of the revised factors (see § 888.304).

§ 888.303 Use of contract rent annual adjustment factors.

(a) Two sets of Annual Adjustment Factors are provided, one for Contract Rents Including Highest Cost Utility and one for Contract Rents Excluding Highest Cost Utility. To compute an adjustment to a Contract Rent, find the set of Annual Adjustment Factors appropriate to the Contract Rent to be adjusted, find the adjustment factors applicable to the market area where the project is located, and select the adjustment factor.

(b) The adjusted amount of the Contract Rent is equal to the sum of: (1) The Contract Rents in effect on the anniversary date of the Contract less debt service, multiplied by the Annual Adjustment Factor selected in paragraph (a), plus (2) debt service. "Debt service" means (1) For noninsured projects, principal and interest on which the initial Contract Rents were based or the actual cost of financing, whichever is less, and an assumed annual distribution of 6 percent on equity and any fixed annual deposit to the reserve for replacement, and (2) for insured projects, an amount determined by applying the formula contained in § 207.19(e)(1)(i) of this title. For an insured project that was insured before October 1, 1979, if the owner has not opted to adjust annual deposits to the reserve for replacement account by the amount of the Annual Adjustment Factor, debt service also includes the amount of the annual deposit to the reserve for replacement account.

(c) The Annual Adjustment Factor referred to in paragraph (a) of this section is determined by HUD, using operating cost information including any information provided by a State Agency (as defined in 24 CFR 883.302). The Annual Adjustment Factors represent the operating cost increases incurred by comparable rental dwelling units of various sizes and types in the same market area which are suitable for occupancy by families assisted under the Section 8 Program. Where no comparable dwelling units exist in the same market area, HUD determines the Annual Adjustment Factor in accordance with the best available data regarding operating cost increases in rental dwelling units.

§ 888.304 Revision to the annual adjustment factors.

If the application of the Annual Adjustment Factors results in rents that are substantially lower than rents charged for comparable units not receiving assistance under the U.S. Housing Act of 1937, in the area for which the factor was published or a portion thereof, and HUD determines that the costs of operating comparable rental housing have increased at a substantially greater rate than the Adjustment Factors, HUD will consider establishing separate or revised Annual Adjustment Factors for that particular area. HUD will publish appropriate notice of the establishment of any such revised Annual Adjustment Factors. These factors will remain in effect until superseded by the subsequent publication of Annual Adjustment Factors pursuant to § 888.302.

§ 880.602, 880.609, 881.602, 881.609, 883.703, 883.710, 884.109, 886.112, 899.201 [Amended].

10. In addition to the amendments set forth above, Chapter VIII of title 24 is proposed to be revised by removing the word "Automatic" in the following places:

(a) 24 CFR 880.602(a)(1).
(b) 24 CFR 880.609(a).
(c) 24 CFR 881.602(a)(1).
(d) 24 CFR 881.609(a).
(e) 24 CFR 883.703(a)(1).
(f) 24 CFR 884.109(b) (1) and (2).
(g) 24 CFR 886.112(b).
(h) 24 CFR 888.204.
(i) 24 CFR 899.201 in the cross reference to Part 888.

Authority: Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)); secs. 5(b) and 8, U.S. Housing Act of 1937 (42 U.S.C. 1437c(b) and 1437f).

Dated: November 1, 1983.

W. Calvert Brand,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. 83-31390 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-01-M

---

24 CFR Part 885

[Docket No. R-83-1124]

Payment and Performance Bond Requirement: Loans for Housing for the Elderly or Handicapped

AGENCY: Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend HUD's regulations governing the direct loan program for elderly or handicapped housing (24 CFR Part 885) to increase the amount of payment and performance bond coverage serving as assurance of completion of construction or rehabilitation from 50 percent to 100 percent of the total cost of construction or rehabilitation for each bond. This change would bring these regulations into line with recently published policy for HUD's multifamily mortgage insurance programs and would provide the Department with additional security and protection at no additional cost for borrowers or construction contractors.

DATE: Comments must be received by January 23, 1984.

ADDRESS: Interested persons are invited to submit comments regarding this rule to Office of the General Counsel, Rules Docket Clerk, Room 10278, Department of Housing and Urban Development, 451 Seventh St., SW., Washington, D.C. 20410. Comments should refer to the above docket number and title. A copy of each comment submitted will be available for public inspection and copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Robert W. Wilden, Director, Elderly, Congregate and Health Facilities Division, Office of Multifamily Housing Development, Office of Housing, Department of Housing and Urban Development, 451 Seventh St., SW., Washington, D.C. 20410, telephone (202)

426-7830. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: 24 CFR Part 885 establishes a direct loan program for the purposes of providing Federal loans, in accordance with Section 202 of the Housing Act of 1959 (12 U.S.C. 1701q), for construction and permanent financing of housing projects serving elderly or handicapped families and individuals. This proposed rule would amend Part 885 to increase the bond amount for corporate surety bonds for payment and performance serving as assurance of completion of construction or rehabilitation.

Section 885.415(n) requires that before the initial loan closing, a borrower must provide the appropriate HUD Field Office with assurance of completion of construction or moderate or substantial rehabilitation. Currently, the assurance may be in the form of a performance and payment bond in the amount of 50 percent of the total construction or rehabilitation costs. This proposed rule would modify § 885.415(n) to increase the size of each bond from 50 percent to 100 percent of total rehabilitation or construction costs. This amendment would conform Section 202 with performance and payment bond requirements for HUD's multifamily mortgage insurance programs published in the **Federal Register** (48 FR 44068) on September 27, 1983, which also require that the amount of each payment or performance bonds equal 100 percent of the construction contract amount. Public comment received in response to the multifamily mortgage insurance program amendment indicated a concern that increasing the required amount for payment and performance bonds would make it both more difficult and more costly to obtain these bonds. The preamble for the final rule addressed these concerns and explained why the increased bond amount requirement neither affects a surety's decision to issue a bond nor the cost of a bond. Since these matters clearly are of concern to those involved in constructing or rehabilitating Section 202 financed projects, the Department is providing its position on these matters.

First, an increase in the percentage of coverage of a bond does not affect a surety company's decision to bond a contractor. The bonding decision is based on the surety company's assessment of whether the contractor has the ability to complete the construction contract. This assessment involves doing a complete financial and credit analysis of the contractor. If the contractor is found to have the ability to complete construction, the surety company will generally issue a bond. The percentage coverage of the bond simply is not relevant to this issue.

Second, increasing the bond coverage from 50 to 100 percent should have no significant effect on the cost of the bond. An informal survey of bonding companies showed that, except where a bond is for less than 20 percent of the contract price, bond premiums are determined solely on the basis of contract price (as adjusted according to the duration of the contract) and are in no way affected by the percentage amount of a bond. An examination of the fixed rates published by The Surety Association of America reveals the same fact: contractors pay $12.00 a month per $1,000 for the first $500,000 of a contract, $7.25 a month per $1,000 for the next $2,000,000 of contract price, $5.75 a month per $1,000 for the next $2,500,000, etc., without regard to the amount of the bond. For contracts of a given duration, contract price is the sole determinant of the premium charged, and an increase in HUD's bond requirements would not affect the price of bonds for contractors.

The proposed rule also would add a provision to § 885.415(h) requiring that the surety company be acceptable to the Assistant Secretary. Current multifamily mortgage insurance regulations contain a similar requirement. (See 24 CFR 207.19(c)(6).)

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implements Section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the Rules Docket Clerk at the address set forth above.

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulations. Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of one hundred million dollars or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or (3) have 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.

Pursuant to Section 605(b) of the Regulatory Flexibility Act, the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The additional protection afforded HUD by 100 percent bonds should not involve significant increases in costs, nor affect a contractor's ability to furnish bonds.

The rule was listed at 48 FR 47447 as Item No. H-57-83 in the Department's most recent Semiannual Agenda of Regulations published on Ocotber 17, 1983 (48 FR 47418) pursuant to Executive Order 12291 and the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance program number is 14.157.

List of Subjects in 24 CFR Part 885

Aged, Grant programs—housing and community development, Handicapped, Loan programs—housing and community development, Low and moderate income housing.

Accordingly, 24 CFR Part 885, Subpart D, is amended as follows:

PART 885—LOANS FOR HOUSING FOR THE ELDERLY OR HANDICAPPED

In § 885.415, paragraph (n) is revised to read as follows:

§ 885.415 Requirements prior to initial loan closing.

* * * * *

(n) Assurance of Completion of Construction or Moderate or Substantial Rehabilitation Contract in the form of corporate surety bonds for payment and performance, each in the amount of 100 percent of the amount of the HUD-estimated construction or rehabilitation cost, or a cash escrow in the amount of 25 percent of the HUD-estimated construction or rehabilitation cost. All surety companies issuing bonds must be satisfactory to the Assistant Secretary.

* * * * *

(Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d))

Dated: November 1, 1983.

W. Calvert Brand,

General Deputy Assistant Secretary for Housing, Deputy Federal Housing Commissioner.

[FR Doc. 83-31395 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 5

[LR-218-81]

Credit for Employment of Certain New Employees

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the credit for employment of individuals qualifying as members of a targeted group. Changes to the applicable tax law were made by the Revenue Act of 1978, the Technical Corrections Act of 1979, the Economic Recovery Tax Act of 1981, the Tax Equity and Fiscal Responsibility Act of 1982, and the Technical Corrections Act of 1982. The regulations would provide the public with the guidance needed to comply with the law as amended by these acts.

DATES: Written comments and requests to comment orally at the public hearing must be delivered or mailed by January 23, 1984. The amendments are proposed to be generally effective for certain wages paid or incurred after December 31, 1978 to an individual who begins work for the employer before January 1, 1985.

ADDRESSES: Send comments and requests to comment orally at the public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-218-81), Washington D.C. 20224.

FOR FURTHER INFORMATION CONTACT: John G. Schmalz of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3516).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 51 and 381 of the Internal Revenue Code of 19954. This document also contains proposed amendments to the Temporary Income Tax Regulations under the Revenue act of 1978 (26 CFR Part 5) under section 51 of the Internal Revenue Code of 1954. Generally these amendments are proposed to conform the regulations to section 321 of the Revenue Act of 1978 (92 Stat. 2830), section 103(a)(6) of the Technical Corrections Act of 1979 (94 Stat. 209), section 261 of the Economic Recovery Tax Act of 1981 (95 Stat. 260), section 233 of the Tax Equity and Fiscal Responsibility Act of 1982 (96 Stat. 501), and section 102(l) of the Technical Corrections Act of 1982 (96 Stat. 2374) and are to be issed under the authority contained in sections 44B, 381, and 7805 of the Internal Revenue Code of 1954 (91 Stat. 141, 26 U.S.C. 44B; 91 Stat. 148, 26 U.S.C. 381(c)(26); 68A Stat. 917, 26 U.S.C. 7805).

In General

Section 321 of the Revenue Act of 1978 provides a targeted jobs credit for the employment of individuals qualifying as members of a targeted group. The targeted jobs credit replaces the new jobs credit allowable under section 44B (as in effect prior to enactment of the Revenue Act of 1978). In general, a taxpayer may elect to claim a credit under section 44B for amounts paid or incurred after December 31, 1978, for taxable years ending after that date, to members of a targeted group. Generally, to qualify for the credit, the amounts must be paid or incurred to members of a targeted group first hired after September 26, 1978. However, amounts paid or incurred after December 31, 1978, to a vocational rehabilitation referral hired before September 27, 1978, may qualify for the credit if a credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978) was claimed for the individual by the taxpayer for a taxable year beginning before January 1, 1979.

Amount of Credit

Except in the case of a qualified summer youth employee, the amount of the credit allowable by section 44B for the taxable year is 50 percent of the qualified first-year wages plus 25 percent of the qualified second-year wages. Generally, qualified first-year wages are the first $6,000 of wages paid or incurred by the employer during the taxable year to an individual who is a member of a targeted group for services rendered during the 1-year period beginning with the day the individual begins work for the employer. Qualified second-year wages are the first $6,000 of wages paid or incurred by the employer during the taxable year to an individual who is a member of a targeted group for services rendered during the 1-year period beginning on the day after the last day of the qualified first-year wages period. For taxable years of the employer beginning before January 1, 1982, qualified first-year wages are further limited to 30 percent of the aggregate unemployment insurance wages paid by the employer during the calendar year ending in such taxable year.

Special rules apply to wages that are paid to employees who are qualified summer youths. In general, an employer is entitled to a credit equal to 85 percent of not more than $3,000 of wages paid to a qualified summer youth employee during a 90 day period between May 1 and September 15.

Members of a Targeted Group

An individual is a member of a targeted group if the individual is certified as a qualified summer youth employee, a vocational rehabilitation referral, an economically disadvantaged youth, an economically disadvantaged Vietnam-era veteran, an SSI recipient, a general assistance recipient, a youth participating in a cooperative education program, an economically disadvantaged ex-convict, an eligible work incentive employee, or an involuntarily terminated CETA employee. The first category was added by the Tax Equity and Fiscal Responsibility Act of 1982. The last two categories were added by the Economic Recovery Tax Act of 1981. The Economic Recovery Tax Act also amended the definition of a youth participating in a cooperative education program to require the individual to be also a member of an economically disadvantaged family.

The proposed regulations provide rules and definitions relating to the eligibility requirements for several of the targeted groups. In the case of youths participating in a cooperative education program, the proposed regulations define the term "program of vocational education" (a component in the definition of qualified cooperative education program) in accordance with the definition of that term in the Vocational Education Act of 1963 and the Department of Education regulations thereunder because the legislative history of the Revenue Act of 1978 indicates that the term "qualified cooperative education program" in section 51(d)(8) is similar to that term as used in the Vocational Education Act.

The proposed regulations also provide guidance on the issue of second certifications with respect to employees who continue to work for the same employer after the employee no longer meets the requirements for membership in the targeted group for which the employee was originally certified. For example, a qualified summer youth employee may continue to work for the same employer after the end of the ninety day period described in section 51(d)(12)(B)((iii) and may then qualify as an economically disadvantaged youth. Similarly, a youth certified as

participating in a qualified cooperative education program may no longer be actively participating in the program, but may then qualify as an economically disadvantaged youth. The proposed regulations provide that the timely certification rules do not apply to the second certification if the first certification was timely. The proposed regulations also provide that for purposes of eligibility requirements, the "hiring date" will be defined as the day the individual is certified for the second targeted group. Thus, whether an individual meets an age requirement for the second targeted group will be determined as of the date of certification rather than the original hiring date. In addition, in the case of a qualified summer youth employee, the proposed regulations clarify that a second economic eligibility determination must be made on the basis of the six months immediately preceding the month in which the second certification is made. In the case of a recertification of an individual who was originally certified as a member of any targeted group, other than a qualified summer youth employee, however, the proposed regulations provide that no second economic eligibility determination need be made.

In general, the State employment security agency is the agency responsible for certifying an individual as a member of a targeted group. In the case of youths participating in a qualified cooperative education program, the school offering the program must certify the individual as a member of that targeted group. A school may satisfy the certification requirement by using Form 6199. In either case, a certificate may be revoked if it is discovered that the information supplied by the individual for purposes of issuing the certificate was incorrect or false.

Furthermore, the amendments made by the Economic Recovery Tax Act have the effect of making so-called retroactive certifications invalid unless the employer has requested in writing a certification before the employee began work. Therefore, an individual will not be treated as a member of a targeted group unless, before the day the individual begins work for the employer, the employer receives a certification from the designated local agency or school, or has requested in writing a certification. However, the Tax Equity and Fiscal Responsibility Act of 1982 amended this rule with respect to individuals who begin work for the employer after May 11, 1982 so that certifications will be valid if requested or received on or before the day the individual begins work for the employer. Transitional rules apply with respect to certain employees.

Comments and Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably seven copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held. Notice of the time and place for the public hearing is published in this issue of 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 OMB, Attention: Desk Officer of Internal Revenue Service, New Executive Office Building, Washington, D.C. 20503. The Internal Revenue Service requests that persons submitting comments on these requirements to OMB also send copies of those comments to the Service.

Regulatory Flexibility Act and Executive Order 12291

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 comment, the Internal Revenue Service has concluded that the regulations proposed herein are interpretative and that the notice and public procedures requirements of 5 U.S.C. 553 do not apply. Accordingly, these proposed regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these proposed regulations is John G. Schmalz 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

26 CFR Part 1.0–1 through 1.58–8

Income taxes, Tax Liability, Tax Rates, Credits.

26 CFR Part 5

Income taxes, Revenue Act of 1978.

Proposed Amendments to the Regulations

The proposed amendments to the Income Tax Regulations (26 CFR Part 1) and the Temporary Income Tax Regulations under the Revenue Act of 1978 (26 CFR Part 5) are as follows:

PART 1—[AMENDED]

Paragraph 1. There is inserted immediately after § 1.50B–1 the following new section:

§ 1.51–1 Amount of credit.

(a) *Determination of amount*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, the amount of the targeted jobs credit allowable by section 44B for the taxable year equals 50 percent of the qualified first-year wages (minus any qualified first-year wages paid to individuals while such individuals are qualified summer youth employees) plus 25 percent of the qualified second-year wages.

(2) *Special rule for employment of qualified summer youth employees.* In the case of an employer who pays or incurs qualified wages after April 30, 1983, to a qualified summer youth employee beginning work for the employer after such date, the amount of the targeted jobs credit allowed by section 44B for the taxable year is equal to the amount determined under paragraph (a)(1) of this section plus an amount equal to 85 percent of the first $3,000 of qualified wages paid to each qualified summer youth employee during the taxable year. Such wages must be attributable to services rendered by the qualified summer youth employee during any 90 day period between May 1 and September 15.

(3) *Limitation.* See section 53 and the regulations thereunder for rules limiting the amount of the credit to a percentage of the amount of the tax imposed by chapter 1 of the Code.

(b) *Definitions*—(1) *Qualified wages.* The term "qualified wages" means wages (as defined in paragraph (b)(4)) paid or incurred by the employer during the taxable year to individuals who are members of a targeted group (within the meaning of section 51(d)).

(2) *Qualified first-year wages*—(i) *General rule.* Except in the case of

qualified summer youth employees, the term "qualified first-year wages" means the first $6,000 of wages (as defined in paragraph (b)(4)) attributable to services rendered by a member of a targeted group during the 1-year period beginning with the day the individual first begins works for the employer. In the case of a vocational rehabilitation referral, as defined in section 51(d)(2), the one year period begins with the day the individual begins work for the employer on or after the beginning of such individual's rehabilitation plan. However, with the exception of vocational rehabilitation referrals for whom the employer claimed a credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978) for a taxable year beginning before January 1, 1979, members of a targeted group who are first hired after September 26, 1978, and before January 1, 1979, will be treated as if they first began work for the employer on January 1, 1979. The date on which the wages are paid does not determine whether the wages are first-year wages; rather, the wages must be attributed to the period during which the work was performed. See paragraph (f)(1) of this section for an additional limitation on the term qualified first-year wages. (See examples (1), (2), (3), (4), (5), and (6) in paragraph (g) of this section for examples illustrating the application of the rules in this paragraph (b)(2)).

(ii) *Special rule for qualified summer youth employees.* In the case of a qualified summer youth employee, qualified first-year wages for the purposes of the 85 percent credit referred to in paragraph (a)(2) of this section include only wages attributable to services rendered by a qualified summer youth employee during any 90-day period between May 1 and September 15. If the individual is retained by the employer after the 90-day period and recertified as a member of another targeted group, the term "qualified first-year wages" for the purposes of the 50 percent credit described by section 51(a)(1) has the meaning given that term in paragraph (b)(2)(i) of this section except that the $6,000 limitation for qualified first-year wages shall be reduced by wages up to, but not more than, $3,000 attributable to services rendered during the 90-day period.

(3) *Qualified second-year wages.* The term "qualified second-year wages" means the first $6,000 of wages attributable to services rendered by a member of a targeted group, other than a qualified summer youth employee, during the 1-year period beginning on the day after the last day of the period for qualified first-year wages. The date on which the wages are paid does not determine whether the wages are second-year wages; rather, the wages must be attributed to the period during which the work was performed.

(4) *Wages*—(i) *General rule.* Except as otherwise provided in paragraph (b)(4)(ii) and (iii) of this section, the term "wages" shall only include amounts paid or incurred after December 31, 1978, for taxable years ending after December 31, 1978. For purposes of this section, the term "wages" has the meaning given to such term by section 3306(b) (determined without regard to any dollar limitation contained in such subsection).

(ii) *Special rules.* In the case of agricultural labor or railway labor, the term "wages" means unemployment insurance wages within the meaning of subparagraph (A) or (B) of section 51(h)(1). The term "wages" shall not include any amounts paid or incurred by an employer for any pay period to any individual for whom the employer receives federally funded payments for on-the-job training for such individual for such pay period. (See example (7) in paragraph (g) of this section). In addition, the term "wages" shall not include any amount paid or incurred by the employer in a taxable year beginning before January 1, 1982, to an individual with respect to whom the employer claims a credit under section 40 (relating to expenses of work incentive programs). For youths participating in a qualified cooperative education program:

(A) Section 3306 (c)(10)(C) (relating to the definition of employment for certain students) does not apply in determining wages under this section; and

(B) The term "wages" shall include only those amounts paid or incurred by the employer that are attributable to services rendered by the individual while he or she meets the conditions specified in section 51(d)(8)(A). For purposes of the preceding sentence, an employee who met the requirement in section 51(d)(8)(A)(iv), dealing with economically disadvantaged status, when hired, shall be deemed to continuously meet the requirement in section 51(d)(8)(A)(iv) during the time the employee is in the cooperative education program. See also paragraph (e) of this section for rules relating to the exclusion of wages paid to certain individuals.

(iii) *Termination.* The term "wages" shall not include any amount paid or incurred to an individual who begins work for the employer after December 31, 1984.

(5) *Special rule for eligible work incentive employees.* In the case of an eligible work incentive employee (as defined in § 1.51-1(c)(4)), this paragraph (b) shall be applied for taxable years beginning after December 31, 1981, as if such employee had been a member of a targeted group for taxable years beginning before January 1, 1982. (See example (B) in paragraph (g) of this section.)

(c) *Members of targeted groups*—(1) *In general.* An individual is a member of a targeted group if the individual is certified as (i) a vocational rehabilitation referral, (ii) an economically disadvantaged youth, (iii) an economically disadvantaged Vietnam-era veteran, (iv) an SSI recipient, (v) a general assistance recipient, (vi) a youth participating in a cooperative education program, (vii) an economically disadvantaged ex-convict, (viii) an eligible work incentive employee, (ix) a qualified summer youth employee, or (x) an involuntarily terminated CETA employee. Except as provided below, see section 51(d) for a definition of these groups. See paragraph (d) of this section for rules concerning the certification of individuals as members of one of these targeted groups.

(2) *Youths participating in a qualified cooperative education program*—(i) *Student requirements.* For an individual to qualify as a youth participating in a qualified cooperative education program, the individual must meet each of the following conditions (A) through (D)—

(A) The youth must have attained the age of 16 but not 20. (An individual reaching 19 will be treated as a youth participating in a qualified cooperative education program only for wages paid or incurred after November 26, 1979.)

(B) The youth must not have graduated from a high school or vocational shool.

(C) The youth must be enrolled in and actively pursuing a qualified cooperative education program (as defined in paragraph (c)(2)(iii) of this section).

(D) With respect to wages paid or incurred after December 31, 1981, the youth must be a member of an economically disadvantaged family when initially hired.

(ii) *Economically disadvantaged family.* See section 51(d)(11) for the rules relating to the determination of whether an individual is a member of an economically disadvantaged family.

(iii) *Qualified cooperative education program.* The term "qualified

cooperative education program" means a program of vocational education for individuals who (through written cooperative arrangements between a qualified school and one or more employers) receive instruction (including required academic instruction) by alternation of study in school with a job in any occupational field (but only if these two experiences are planned by the school and employer so that each contributes to the student's education and employability). See section 51(d)(8)(C) for a definition of a "qualified school." For purposes of this paragraph, the term "program of vocational education" means an organized educational program which is directly related to the preparation of individuals for employment, or for additional preparation for a career requiring other than a baccalaureate or advanced degree. An "organized educational program" means only instruction related to the occupation or occupations for which the students are in training or instruction necessary for students to benefit from such training. The student's employment contributes to his education and employability only if it is related to the occupation for which the student is in training in school. However, the student's employment need not be directly related to or in the same technical field as the training the student receives in school. For example, a student studying carpentry does not have to work as a carpenter for the program to constitute a "qualified cooperative education program." The progpam will qualify if, for example, the student works at a hardware store because the student's work would familiarize the student with the materials and tools used by carpenters. The program would not qualify, however, if the student works at a restaurant and generally performs tasks in such employment not related to carpentry.

(3) *General assistance recipients.* In order for an individual to qualify as a general assistance recipient, the individual must receive assistance for a period of not less than 30 days ending within the preemployment period (as defined in section 51(d)(13)) from a qualified general assistance program. A qualified general assistance program is a program of a State or a political subdivision of a State that the Secretary has designated as providing general assistance (or similar assistance) which is based on need and consists of money payments or voucher or scrip. For purposes of the preceding sentences, a program qualifying as a general assistance program by reason of non-cash assistance (*i.e.*, voucher or scrip) shall be so treated only with respect to amounts paid or incurred after July 1, 1982, to individuals beginning work for the employer after such date. For purposes of this subparagraph, the term "money" means cash or an instrument convertible into cash (*e.g.*, a check).

(4) *Eligible work incentive employees.* An eligible work incentive employee means an individual who has been certified by the designated local agency (as defined in paragraph (d)(10) of this section) as—

(i) being eligible for financial assistance under part A of title IV of the Social Security Act and as having continuously received such financial assistance during the 90-day period which immediately precedes the date on which such individual is hired by the employer, or

(ii) having been placed in employment under a work incentive program established under section 432(b)(1) or 445 of the Social Security Act.

The provisions of this paragraph (c)(4) are effective with respect to taxable years of the employer beginning after December 31, 1981. (See paragraph (b)(5) of this section for a special rule relating eligible work incentive employees).

(5) *Involuntarily terminated CETA employees*—(i) *In general.* An involuntarily terminated CETA employee is an individual who first began work for an employer after August 13, 1981, in taxable years of the employer ending after August 13, 1981, and is certified by the designated local agency (as defined in paragraph (d)(10) of this section) as having been involuntarily terminated after December 31, 1980, from employment financed in whole, or in part, under a program under part D or title II or title VI of the Comprehensive Employment and Training Act.

(ii) *Termination.* Section 51(d)(10) and this paragraph (c)(5) shall not apply to any individual who begins work for the employer after December 31, 1982.

(d) *Certification*—(1) *General rule.* Except as otherwise provided in this paragraph, an individual shall not be treated as a member of a targeted group unless, on or before the day on which such individual begins work for the employer, the employer has received, or has requested in writing, a certification that the individual is a member of a targeted group from the designated local agency (as defined in paragraph (d)(10) of this section). In addition, the employer must receive a certification before the credit under section 44B can be claimed. However, with respect to individuals who began work for the employer on or before May 11, 1982, the certification will be timely only if requested or received before the day the individual began work for the employer. In the case of a request in writing mailed via the United States Postal Service, the request shall be deemed to be made on the date of the postmark stamped on the cover in which such request was mailed to the designated local agency provided the request is mailed in accordance with the mailing requirements in § 301.7502-1(c) and delivered in accordance with the delivery requirements in § 301.7502-1(d). In the case of an employee who begins work on a Saturday, Sunday, or a legal holiday, the deadline for making a timely request in writing for a cerification or receiving a timely certification shall be the next succeeding day which is not a Saturday, Sunday, or legal holiday. (See section 7503 for a definition of "legal holdiday.") See paragraph (d)(2) of this section for transitional rules applicable to certain employees who began work for the employer before September 26, 1981. See paragraph (d)(3) of this section for special rules applicable to cooperative education students, and paragraph (d)(4) of this section for special rules applicable to eligible work incentive employees.

(2) *Transitional rules for certain employees who began work for the employer on or before September 26, 1981.* In the case of an individual, other than a cooperative education student, who began work for the employer before June 29, 1981, the employer must either receive, or request in writing, a certification before July 23, 1981. In the case of an individual, other than a cooperative education student, who began work for the employer after June 28, 1981, and on or before September 26, 1981, the employer must either receive, or request in writing, a certification before September 26, 1981.

(3) *Cooperative education students.* In the case of cooperative education students, the school administering the cooperative education program must issue the certification. Form 6199 is provided for this purpose. If the student begins work for the employer after September 26, 1981, see the general rule in § 1.51-1(d)(1) for the date when this certification must be received or requested. If the student begins work for the employer on or before September 26, 1981, the employer must receive the certification or request it in writing before September 26, 1981. In order for an employer to claim a credit on wages paid or incurred to a cooperative education student after December 31, 1981, the employer must receive or

request in writing a determination that the student is a member of an economically disadvantaged family. A request for economic eligibility determination for a cooperative education student must be made in writing by the employer to the participating school. If the student begins work for the employer on or before September 26, 1981, the employer must receive or request in writing such determination at any time before September 26, 1981. However, a request in writing on or after August 13, 1981, to a participating school for certification will be deemed to include a request for an economic eligibility determination. In addition, any certification issued by a school after August 13, 1981, will be deemed to be issued in response to a request for certification which includes a request for an economic eligibility determination. The rule in the preceding sentence does not eliminate the requirement that the employer receive a certification that includes an economic eligibility determination in order to claim a credit for wages paid or incurred after December 31, 1981. If a certification issued by a school after August 13, 1981, does not contain an economic eligibility determination and the employer wishes to claim a credit for wages paid or incurred after December 31, 1981, the employer must receive a completed certification before the date on which the credit is claimed.

(4) *Eligible work incentive employees.* In the case of eligible work incentive employees, the employer must either receive, or request in writing, a certification within the time requirements of paragraph (d) (1) or (2) of this section, whichever is applicable. Before October 12, 1981 (the date the Economic Recovery Tax Act of 1981 codified the State employment security agency as the designated local agency for certifying targeted groups), a certificate may be received or requested in writing from either the designated local agency (as defined in paragraph (d)(10) of this section) or the offfice or agency that properly issued certifications under section 50B(h)(1) relating to the work incentive credit.

(5) *Certifications that are not timely.* Any certification that is not timely received or requested by the employer in accordance with the rules of this paragraph will be treated as invalid. Thus, the employer will not be allowed to claim a credit under section 51 with respect to any wages paid or incurred to an employee whose certification or request for certification is not timely. A timely request for certification does not eliminate the need for the employer to receive a certification before claiming the credit.

(6) *Incorrect certification.* If an individual has been certified as a member of a targeted group, and such certification is incorrect because it was based on false information provided by such individual, the certification shall be revoked and wages paid by the employer after the date on which notice of revocation is received by the employer shall not be treated as qualified wages. For purposes of this paragraph, a certification will be considered to be incorrect only if the individual would not have been certified had correct information been provided to the issuer of the certification. Thus, false information that is not material to the issue of an individual's eligibility as a member of a targeted group will not invalidate an otherwise valid certification.

(7) *Certifications issued to certain rehires.* This paragraph (d)(7) applies in the case of an employee who first began work for the employer before October 13, 1981, and was dismissed and rehired by the employee. A certification received or requested by an employer with respect to such an employer will be considered timely only if there was a valid business reason, unrelated to the availability of the credit, for the dismissal and rehire and if the employer did not dismiss and then rehire the employee in order to meet the timing requirement with respect to certification. An individual who is dismissed and then rehired for the purpose described in the preceding sentence will be considered for purposes of section 51(d)(16) and this paragraph to have been continuously employed by the employer during the time between the dismissal and the rehire. Whether the employer was motivated by reason of the certification rules in section 51(d)(16) and this paragraph to dismiss and then rehire an employee is a question of fact to be determined from all the circumstances surrounding the dismissal and rehire. (See paragraph (e)(2) of this section for a separate rule disallowing the credit in the case of nonqualifying rehires).

(8) *Individuals who continue to be employed by the same employer but as a member of another targeted group*—(i) *In general.* This paragraph (d)(8) applies in the case of an employee who continues to be employed by the same employer but no longer qualifies as a member of the targeted group for which such employee was first certified (*e.g.*, the employee was originally certified as a qualified summer youth employee with respect to a ninety-day period between May 1 and September 15, but such ninety-day period has ended). In such case, the employer may request a certification that the employee is a memmber of another targeted group, and if any wages paid to such individual are qualified first-year wages or are qualified second-year wages, the employer may be entitled to a credit under section 44B with respect to such wages. The second certification will not be invalid merely because it was requested or received after the individual began work for the employer; only the first certification (for example, the certification with respect to an individual hired first as a qualified summer youth employee) must meet the requirement of section 51(d)(16) that a certification must be requested or received by an employer on or before the day on which the individual begins work for the employer.

(ii) *Qualified summer youth employees.* In the case of a former qualified summer youth employee, the term "hiring date" means not the day the individual is hired by the employer but means the day the individual is certified as a member of the new targeted group. Accordingly, the age requirements of section 51(d)(3)(B) shall be applied as of the day the individual is certified as a member of the second targeted group. In addition, if a second economic eligibility determination is required because the 45-day period referred to in section 51(d)(11) has lapsed, section 51(d)(11) shall be applied by taking into consideration the income during the 6 months immediately preceding the month in which the second determination occurs.

(iii) *Other employees.* In the case of an individual originally certified as a member of a targeted group (other than a qualified summer youth employee) such as a youth participating in a qualified cooperative education program, who is sought to be recertified as a member of another targeted group, the eligibility requirements for the recertification shall generally be applied with reference to the date of recertification, rather than the hiring date. However, this rule will not alter the determination described in section 51(d)(11), which is to be made with reference to the hiring date. Accordingly, if the individual was determined to be a member of an economically disadvantaged family when certified for the first targeted group, no second determination of this status need be made.

(9) *Certification where a trade or business has been transferred to a new employer.* In the case of the transfer of a

trade or business in which an individual who is a member of a targeted group is retained as an employee in the trade or business, the certification obtained for such employee by the transferor-employer will apply with respect to the transferee-employer. For purposes of determining the amount of the credit allowable to the transferee-employer, the 1-year period referred to in § 1.51-1(b)(2)(i) will be considered to begin with the day the employee first began work for the transferor-employer, and the amount of qualified first-year wages and qualified second-year wages paid or incurred to the employee must be reduced by the amount of any such wages paid or incurred by the transferor-employer. See examples (10) and (11) in paragraph (g) of this section.

(10) *Designated local agency*—(i) *In general.* For the period before October 12, 1981, the term "designated local agency" means the agency for any locality designated jointly by the Secretary and the Secretary of Labor to perform certifications of employees for employers in that locality. On or after October 12, 1981, the term "designated local agency" means a State employment security agency established in accordance with the Act of June 6, 1933, as ameneded (29 U.S.C. 49-49n).

(ii) *Jurisdiction.* The designated local agency is the agency that has, pursuant to its charter, jurisdiction over the individual that is sought to be certified. Thus, any certification that is issued with respect to an individual who is not within the jurisdiction of the designated local agency that issued the certification will be invalid. Notwithstanding any other provision of this section, a request in writing for certification to the appropriate designated local agency that is made before January 23, 1984 will be considered to be timely if it is made after an otherwise timely request in writing for certification was made to a designated local agency that does not have jurisdiction over the individual sought to be certified.

(e) *Certain ineligible individuals*—(1) *Related individuals.* For the purpose of section 51(a), "qualified wages" does not include any amounts paid or incurred by a taxpayer to any of the following individuals:

(i) An individual who is related (within the meaning of any of paragraphs (1) through (8) of section 152(a)) to the taxpayer;

(ii) An individual who is a dependent (within the meaning of section 152(a)(9)) of the taxpayer;

(iii) An individual who is related (within the meaning of any of paragraphs (1) through (8) of section 152(a)) to a shareholder who owns (within the meaning of section 267(c)) more than 50 percent in value of the outstanding stock of the taxpayer, if the taxpayer is a corporation;

(iv) An individual who is a dependent (within the meaning of section 152(a)(9)) of a shareholder described in paragraph (e)(1)(iii) of this section;

(v) An individual who is a grantor, beneficiary or fiduciary of the taxpayer, if the taxpayer is an estate or trust;

(vi) An individual who is a dependent (within the meaning of section 152(a)(9)) of an individual described in paragraph (e)(1)(v) of this section; or

(vii) An individual who is related (within the meaning of any of paragraphs (1) through (8) of section 152(a)) to an individual described in paragraph (e)(1)(v) of this section.

(2) *Nonqualifying rehires.* For purposes of section 51(a), "qualified wages" does not include wages paid to an employee who had been employed by the employer prior to the current hiring date of the employee if at any time during such prior employment the employee was not a member of a targeted group. The preceding sentence shall not apply to an employee who was previously timely certified as a member of a targeted group with respect to the same employer. An employee shall be treated as not having been a member of a targeted group if the certification requirements of section 51(d)(16) were not met. (See example (8) in paragraph (g) of this section).

(3) *Effective date.* The provisions of this paragraph (e) are effective with respect to employees first beginning work for an employer after October 12, 1981.

(f) *Limitations—(1) Limitation on qualified first-year wages.* With respect to taxable years beginning before January 1, 1982, the amount of the qualified first-year wages which may be taken into account for purposes of the targeted jobs credit for any taxable year shall not exceed 30 percent of the aggregate unemployment insurance wages paid by the employer during the calendar year ending in such taxable year. In the case of a group of trades or businesses under common control (as defined in § 1.52-1(b)), the qualified first-year wages cannot exceed 30 percent of the aggregate unemployment insurance wages paid to all employees of that group of trades or businesses under common control during the calendar year ending in such taxable year. For this purpose the term "unemployment insurance wages" has the same meaning given to the term "wages" as defined in § 1.51-1(b)(4). In the case of agricultural or railway labor, see section 51(h)(1) for the applicable definition of unemployment insurance wages. (See examples (13) and (14) in paragraph (g) of this section.)

(2) *Remuneration must be for trade or business employment.* Remuneration paid by an employer to an employee during any taxable year shall be taken into account only if more than one half of the remuneration paid by the employer to an employee is for services in a trade or business of the employer. This determination shall be made by each employer without regard to section 52 (a) or (b). Accordingly, employees of corporations that are members of a controlled group or all employees of partnerships, proprietorships, and other trades or businesses (whether or not incorporated) which are under common control will be treated as being employed by each separate employer for this purpose. For this purpose, the term "year" means the taxable year of the employer. (See example (15) in paragraph (g) of this section.)

(g) *Examples.* The application of this section may be illustrated by the following examples which, except as otherwise stated, assume that the limitations imposed by §§ 1.51-1(f)(2) and 1.53-3 are inapplicable:

Example (1). Corporation M is a calendar year, cash receipts and disbursements method taxpayer. A, an econimically disadvantaged youth, first began work for Corporation M on October 1, 1978. Qualified first-year wages with respect to A are wages attributable to the period beginning on January 1, 1979 (since A was first hired after September 26, 1978, he is treated as having begun work on January 1, 1979) and ending on December 31, 1979. In the 1979 taxable year, Corporation M pays A $5,000 of qualified first-year wages attributable to services performed in 1979. Corporation M's allowable credit is equal to $2,500 (50 percent of $5,000).

Example (2). Assume the same facts as in example (1), except that in 1980 Corporation M pays to A $100 of wages attributable to services rendered in 1979. These wages will still be considered as qualified first-year wages, but the credit may not be claimed until the 1980 taxable year.

Example (3). Corporation O is a calendar year, cash receipts and disbursements method taxpayer. C, a vocational rehabilitation referral, first began work for Corporation O on July 1, 1978. Corporation O claimed a credit under section 44B (as in effect prior to enactment of the Revenue Act of 1978) for $3,000 of wages paid to C in the 1978 taxable year. Corporation O paid C $6,000 for services performed from January 1, 1979, to June 30, 1979. The period during which qualified first-year wages are determined begins on July 1, 1978, and ends on June 30, 1979. Amounts paid before January 1, 1979, however, are not taken into consideration in determining the amount of qualified first-year wages. Accordingly, only

the wages attributable to services performed from January 1, 1979, through June 30, 1979, are considered as qualified first-year wages. Corporation O's allowable credit is equal to $3,000 (50 percent of $6,000).

Example (4). I first began work for Corporation Q, a cash receipts and disbursements method taxpayer, on January 1, 1981, and was not a member of a targeted group. On March 1, 1981, I was convicted of a felony and sentenced to prison. I quit working for Corporation Q, and served the prison sentence. On November 1, 1981, I again was hired by Corporation Q, and began work on that date. On the November 1, 1981, hiring date, I was an economically disadvantaged ex-convict for whom Corporation Q received a certificate. Corporation Q paid I $500 of wages for services performed from November 1, 1981, to December 31, 1981, and $6,000 of wages for services performed during 1982. The $500 of wages paid for services performed from November 1, 1981, to December 31, 1981, would be qualified first-year wages because these qualified wages were paid for services performed during the 1-year period beginning on the date I first began work for Corporation Q (January 1, 1981). The $6,000 of wages paid for services performed during 1982 would be qualified second-year wages because these qualified wages were paid for services performed during the 1-year period beginning on the day after the first 1-year period. Accordingly, Corporation Q has an allowable credit of $250 attributable to qualified first-year wages and $1,500 attributable to qualified second-year wages.

Example (5). Assume the same facts as in example (4), except that all dates are 1 year later. Thus, I first began work for Corporation Q on January 1, 1982, was convicted on March 1, 1982, and was rehired on November 1, 1982. Under these facts, Q is not entitled to take a targeted jobs credit with respect to I's wages because I is a nonqualifying rehire.

Example (6). J, an economically disadvantaged youth, first began work for Corporation R, a calendar year cash receipts and disbursements method taxpayer, on December 1, 1979. On July 1, 1980, J was laid off by Corporation R and began work for Corporation S, which is unrelated to Corporation R, on July 2, 1980. On November 1, 1980, J again began work for Corporation R and continued working for Corporation R until January 1, 1982. At the time J first began work for Corporation S, J no longer met the qualifications of an economically disadvantaged youth. Corporation S may not claim a credit for wages paid to J because J was not a member of a targeted group at the time he began work for Corporation S. Corporation R, however, may claim a credit for wages paid to J because J was a member of a targeted group when he was hired by Corporation R. Corporation R's qualified first-year wages paid to J are the wages paid for services performed by J from December 1, 1979, to July 1, 1980, and from November 1, 1980, to November 30, 1980. Corporation R's qualified second-year wages paid to J are the wages paid for services performed by J from December 1, 1980, to November 30, 1981. Corporation R may not claim a credit for wages paid for services performed by J after November 30, 1981

Example (7). K, a member of a targeted group, first began work for Corporation T on January 1, 1979. For the pay periods from January 1, 1979, to March 31, 1979, Corporation T received federally funded payments for on-the-job training for K and paid wages of $2,000 to K. During the remainder of 1979 Corporation T paid wages of $7,000 to K. Corporation T may claim a credit on $6,000 of qualified first-year wages. Amounts paid to K by Corporation T during the pay periods for which Corporation T received federally funded payments for on-the-job training for K are not considered wages for purposes of the credit. However, corporation T may consider $6,000 of the total $7,000 of wages paid after March 31, 1979, as qualified first-year wages.

Example (8). P first began work for Corporation X on January 1, 1981, as an individual who was certified to be an eligible employee for purposes of the WIN credit provided in section 40. Corporation X paid P $6,000 of wages during its taxable year beginning on January 1, 1981, and $6,000 of wages during its taxable year beginning on January 1, 1982. X can claim a credit under section 44B for the wages paid in 1982 if the requirements of section 51 are met. For purposes of section 51(a), P's qualified first-year wages are the wages paid from January 1, 1981, to December 31, 1981, and P's qualified second-year wages are the wages paid from January 1, 1982, to December 31, 1982. Thus, Corporation X is only entitled to claim a credit under section 44B based on P's qualified second-year wages.

Example (9). (i) L, 15 years of age, first began work for Corporation U on August 1, 1979. On September 3, 1979, L began her junior year in high school and enrolled in a qualified cooperative education program that was to run for her junior and senior years. On October 1, 1979, when L turned 16, she met all the requirements of § 1.51-1(c)(2)(i) and qualified as a youth participating in a qualified cooperative education program. Corporation U is entitled to claim a credit on wages paid or incurred for services performed by L after September 30, 1979, so long as L meets the requisite requirements. L's summer vacation began on June 1, 1980. The cooperative education program L was enrolled in did not continue during the summer vacation. Thus, during her summer vacation, L did not meet the requirement of actively pursuing a qualified Cooperative education program. Accordingly, corporation U may not claim a credit on wages paid for services performed by L during L's summer vacation. On September 2, 1980, L began her senior year, and again met all the requirements of § 1.51-1(c)(2)(i). She continued to meet these requirements until June 5, 1981, when she graduated from high school. Accordingly, Corporation U may claim a credit on wages paid for services performed after September 1, 1980, and before June 5, 1981.

(ii) Assume the same facts as in (i), above, except that all dates are 3 years later. Under these facts, V is not entitled to claim a targeted jobs credit with respect to L's wages because L has not been timely certified under section 51(d)(16) and § 1.51-1(d)(3).

Example (10). D, began work for a drugstore owned by E as a sole proprietor on January 1, 1979 and was certified as a member of a targeted group with respect to E. On June 1, 1979, E sold the drugstore where D worked to F, who continued to operate the drugstore with D as an employee. D's qualification as a member or a targeted group is not required to be redetermined in order for F to qualify for the targeted jobs credit. F will take into account the certification of D's eligibility that was provided to E. F will have qualified first-year wages consisting of the first $6,000 of wages paid or incurred to D by E and F from January 1, 1979, to December 31 1979 (reduced by any qualified wages paid or incurred by E to D from January 1, to May 31, 1979). F's qualified second-year wages will consist of the first $6,000 of wages paid or incurred to D by F from January 1, 1980, to December 31, 1980.

Example (11). G began work in a machine shop owned by H as a sole proprietor on January 1, 1979, and was certified as a member of a targeted group with respect to H. On June 1, 1980, H transferred all the assets of the machine shop to newly formed Corporation P. Corporation P retained G as an employee in the machine shop. G's qualification as a member of a targeted group is not required to be redetermined in order for P to qualify for the targeted jobs credit. H has qualified first-year wages in the amount of the first $6,000 of wages paid or incurred to G by H from January 1, 1979, to December 31, 1979. Corporation P has qualified second-year wages in the amount of the first $6,000 of wages paid or incurred to G by H and Corporation P from January 1, 1980, to December 31, 1980 (reduced by any qualified second-year wages paid by H to G.)

Example (12). W operates a retail store as a sole proprietor. On June 1, 1982, W hires S after receiving a written determination from a local community organization that S meets the requirements as an economically disadvantaged youth. W does not request a certification from the State employment security agency as to S's eligibility. W is not entitled to claim a credit with respect to wages paid to S because W did not receive, or request in writing, a certification from the State employment security agency as to S's eligibility on or before the day on which S began work for W.

Example (13). Corporation V is a cash receipts and disbursement method taxpayer with a July 1 through June 30 taxable year. In the taxable year ending June 30, 1980, the aggregate unemployment insurance wages paid by V were $150,000. In calendar 1979 the aggregate unemployment insurance wages paid by corporation V were $110,000. Corporation V's qualified first-year wages are limited to 30 percent of the aggregate unemployment insurance wages paid by it in calendar year 1979 or $33,000 (30 percent of $110,000), even though the aggregate unemployment insurance wages paid by it in the taxable year ending June 30, 1980, were 150,000.

Example (145). Assume the same facts as in example (13), except that all dates are 3 years later. Since the limitation on qualified first-year wages does not apply to taxable years beginning after December 31, 1981,

Corporation V's qualified first-year wages are $150,000.

Example (15). M operates a retail store as a sole proprietor. N and O, both members of a targeted group, first began work for M on January 1, 1979. M paid N total qualified first-year wages of $6,000 in 1979. Three thousand one hundred dollars of those wages were for services in M's retail store, and $2,900 of those wages were for services as M's maid. M paid O total qualified first-year wages of $6,000 in 1979. Three thousand dollars of those wages were for services in M's store, and $3,000 of those wages were for services as M's chauffeur. M has an allowable credit of $3,000 in 1979 of all $6,000 of qualified first-year wages paid to N because more than one-half of the remuneration paid by M to N was for services in M's trade or business. M may not take into account the wages paid to O because not more than one-half of the remuneration paid by M to O was for services in M's trade or business. Accordingly, M any not claim a credit on wages paid to O.

Par. 2. Section 1.381(c)(26)–1 is amended to read as set forth below:

§ 1.381(c)(26)–1 Credit for employment of certain new employees.

(c) *Carryovers and carrybacks.* The computation of carryovers and carrybacks of unused targeted jobs credit (new jobs credit in the case of wages paid before 1979) under section 44B in a transaction to which section 381(a) applies shall be made under the principles of § 1.381(c)(23)–1 (relating to the computation of carryovers and carrybacks of unused investment credit), except that the provisions of paragraph (c)(4) and paragraph (e)(6), (7), and (8) of such section shall not apply.

(b) *Other items.* See § 1.51–1(d)(9) for a rule that applies to certain transfers of a trade or business in which members of a targeted group are employed.

PART 5—[AMENDED]

§ 5.51–1 [Removed]

Par. 3. Section 5.51–1 is removed.

James I. Owens,

Acting Commissioner of Internal Revenue.

[FR Doc. 83-31462 Filed 11-18-83; 12:31 pm]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300082; PH-FRL 2472-7]

Sodium Dihydrogen Phosphate; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that sodium dihydrogen phosphate be exempted from the requirement of a tolerance when used as an inert ingredient in pesticide formulations. This proposed regulation was requested by E. I du Pont de Nemours and Co.

DATE: Written comments must be received on or before December 23, 1983.

ADDRESS: By mail, submit comments to: Program Management and Support Division (TS–757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, deliver comments to: Registration Support and Emergency Response Branch, Registration Division (TS–767), Environmental Protection Agency, Rm. 724A, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT:

By mail: N. Bhushan Mandava, Registration Support and Emergency Response Branch, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Registration Support and Emergency Response Branch, Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–557–7700).

SUPPLEMENTARY INFORMATION: At the request of E. I. du Pont de Nemours and Co., the Administrator proposes to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for sodium dihydrogen phosphate as a buffering agent in pesticide formulations applied to growing crops only.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(d), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as water; baits such as sugar, starches, and meat scraps; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

Preambles to proposed rulemaking documents of this nature include the common or chemical name of the substance under consideration, the name and address of the firm making the request for the exemption, and toxicological and other scientific bases used in arriving at a conclusion of safety in support of the exemption.

Name of inert ingredient: Sodium dihydrogen phosphate.

Name and address of requester: E. I. du Pont de Nemours and Co., Wilmington, DE 19898.

Bases for approval: Potassium dihydrogen phosphate is listed under 40 CFR 180.1001(d) as exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formations applied to growing crops. Sodium dihydrogen phosphate is the identical molecule with sodium rather than potassium as the cationic moiety. Sodium dihydrogen phosphate is cleared under 21 CFR 182.6778 as a generally recognized as safe (GRAS) chemical for use as a general purpose food additive.

Based on the above information, and review of its use, it has been found that, when used in accordance with good agricultural practices, this ingredient is useful and does not pose a hazard to humans or the environment. It is concluded, therefore, that the proposed amendment to 40 CFR Part 180 will protect the public health, and it is proposed that the regulation be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains this inert ingredient, may request within 30 days after publication of this notice in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating both the subject and the petition and document control number [OPP–300082]. All written comments filed in response to this notice of proposed rulemaking will be available for public inspection in the Registration Support and Emergency Response Branch at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–534, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in

the **Federal Register** of May 4, 1981 (46 FR 24950).

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 9, 1983.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, it is proposed that 40 CFR 180.1001(d) be amended by adding and alphabetically inserting the inert ingredient as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * *	*	*
Sodium dihydrogen phosphate (CAS Reg. No. 7558-80-7) conforming to 21 CFR 182.6778.		Buffering agent.
* * *	*	*

* * * * *

[FR Doc. 83-31102 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[PP 3E2890/P316; PH-FRL 2475-7]

Dimethoate; Proposed Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that a tolerance be established for the combined residues of the insecticide dimethoate and its oxygen analog in or on the raw agricultural commodity lentils. The proposed regulation to establish a maximum permissible level for the combined residues of dimethoate in or on the commodity was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATE: Comments must be received on or before December 23, 1983.

ADDRESS: Written comments by mail to:

Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring comments to: Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Donald Stubbs (703-557-1192).

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition 3E2890 to EPA on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of Idaho.

This petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for the combined residues of the insecticide dimethoate (*O, O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate) including its oxygen analog (*O,O*)-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate in or on the raw agricultural commodity lentils at 2.0 parts per million (ppm).

The data submitted in the petition and other relevant materials have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicological data considered in support of the proposed tolerance include: a hen delayed neurotoxiocity study with a no-observed-effect level (NOEL) of 130 parts per million (ppm) (16.3 milligrams per kilogram (mg/kg) of body weight) dimethoate and 240 ppm (30 mg/kg) of the dimethoate oxygen analog; a dog 90-day feeding study with a cholinesterase (ChE) inhibition NOEL of 9 ppm (0.2 mg/kg) dimethoate; a rat 90-day feeding study with a ChE inhibition NOEL of 32 ppm (1.6 mg/kg) dimethoate; a human volunteer feeding study with a ChE inhibition NOEL of 0.2 mg/kg/day and a lowest-effect level (LEL) of 30 mg/day; a rat 2-year feeding study with a NOEL of 1 ppm (0.05 mg/kg for brain, blood, and plasma ChE inhibition; two teratogenicity studies (cat and rat), each with a NOEL of 2.8 mg/kg/day; and a mouse reproduction study with a NOEL of 50 ppm (7.5 mg/kg).

The acceptable daily intake (ADI), based on the human volunteer study (NOEL of 0.2 mg/kg/day for ChE inhibition) and using a ten-fold safety factor, is calculated to be 0.02 mg/kg of body weight (bw)/day. The maximum permitted intake (MPI) for a 60-kg human is calculated to be 1.2 mg/day. The theoretical maximum residue contribution (TMRC) from existing tolerances for a 1.5-kg daily diet is calculated to be 0.5138 mg/day; the current action will increase the TMRC by 0.00123 mg/day (0.23 percent). Published tolerances utilize 42.82 percent of the ADI; the current action will utilize an additional 0.10 percent.

The Agency has concluded that the residues of dimethoate including its oxygen analog added to the human diet from the proposed use will not significantly increase dietary exposure in humans. Thus, the tolerance that will be established by this proposed rule is considered to pose a negligible increment in risk.

Although there are currently no actions pending against the continued registration of dimethoate, the Agency published a Rebuttable Presumption Against Registration (RPAR) notice in the **Federal Register** of September 12, 1977 (42 FR 45086) for all pesticide products containing dimethoate. The presumptions were based on information indicating potential oncogenic, mutagenic, and reproductive and fetotoxic effects in test animals (teratogenicity was subsequently concluded to be an additional risk of concern). In a Preliminary Notice of Determination published in the **Federal Register** of November 19, 1979 (44 FR 66558), the Agency concluded that the information submitted in response to the RPAR notice was insufficient to overcome the presumption against dimethoate and that the risks arising from certain uses of dimethoate were greater than the benefits of use unless risks were reduced by modifications in the terms and conditions of registrations. After considering the comments of the Scientific Advisory Panel, the Secretary of Agriculture, and other interested persons, the Agency issued a Final Notice of Determination in the **Federal Register** on January 19, 1981 (46 FR 5364). In this Notice, the Agency initiated a regulatory action to deny the applications for registration of dimethoate products for use in dust formulations, and to require that the labels of dimethoate products be modified to include certain protective clothing and equipment requirements. The Agency concluded that risk from dietary exposure was not an issue of concern at current tolerance levels.

In order to fill certain data gaps, the Agency issued a Data Call-In Notice (November 25, 1981), under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act. The terms of the Call-In Notice indicate scheduled completion dates for the following toxicological studies: oncogenicity, to be completed by November of 1984; mutagenicity and teratology, to be completed by May of 1983. Several of these studies have been received by the Agency and are being reviewed.

The nature of the residues is adequately understood, and an adequate analytical method (gas-liquid chromatography using a flame photometric detector set for the phosphorous mode) is available for enforcement purposes. Since the grazing and feeding of treated lentil vines by livestock is prohibited, there should be no problem with secondary residues in meat and milk.

Based on the above information considered by the Agency, the tolerance established by amending 40 CFR 180.204 would protect the public health. It is proposed, therefore, that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 3E2890/P316]. All written comments filed in response to this petition will be available in the Program Management and Support Division, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: November 14, 1983.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, it is proposed that 40 CFR 180.204 be amended by adding alphabetically the raw agricultural commodity lentils to read as follows:

§ 180.204 Dimethoate including its oxygen analog; tolerances for residues.

* * * * *

Commodities	Parts per million
* * * * *	
Lentils	2.0
* * * * *	

[FR Doc. 83-31482 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 271

[SW-4-FRL 2475-8]

Hazardous Waste Management Program; Florida; Application for Interim Authorization, Phase II, Component C

AGENCY: Environmental Protection Agency.

ACTION: Notice of public comment period and of a public hearing.

SUMMARY: Today EPA is announcing the availability for public review of the Florida application of Phase II, Component C, Interim Authorization, Hazardous Waste Management Program, inviting public comment, and giving notice that if significant public interest is expressed, EPA will hold a public hearing on the application. This is in accordance with agency regulations to protect human health and the environment from improper management of hazardous waste, including the provisions for authorization of State programs to operate in lieu of the Federal program and for a transitional stage in which States can be granted interim program authorization.

DATE: If significant public interest is expressed in holding a hearing, a public hearing is scheduled for Thursday, December 29, 1983, at 7:00 p.m. EPA reserves the right to cancel the public hearing if significant public interest in holding a hearing is not communicated to EPA by telephone or in writing by December 12, 1983. EPA will determine by December 14, 1983, whether there is significant interest to hold the public hearing. All written comments on the Florida interim authorization application must be received by the close of business on December 12, 1983.

ADDRESSES: If significant public interest is expressed, EPA will hold a public hearing on Florida's application for interim authorization on Thursday December 29, 1983, at 7:00 p.m. at the Flamenco Room, Holiday Inn-Parkway, 1302 Apalachee Parkway, Tallahassee, FL, 32301, Telephone: 901/877-3141.

Written comments on the application and written or telephoned communication of interest in EPA's holding a public hearing on the Florida application must be sent to: James H. Scarbrough, Chief, Residuals Management Branch, U.S. EPA, 345 Courtland St., NE., Altanta, Georgia 30365, 404/881-3016.

If you wish to find out whether or not EPA will hold a public hearing on the Florida application based upon EPA's decision that there was significant public interest in such a hearing, write or telephone after December 14, 1983, the EPA contact person listed below or telephone Mr. Robert W. McVety, Administrator, Solid/Hazardous Waste Section, Florida Department of Environmental Regulation, Twin Towers Office Building, 2600 Blair Stone Rd., Tallahassee, Florida 32301, 904/488-0300.

Copies of the Florida interim authorization application for Phase II Component C, are available during normal business hours at the following addresses for inspection and copying:

Florida Department of Environmental Regulation, Solid/Hazardous Waste Section, Twin Towers Office Building, Room 421, Tallahassee, Florida 32301. Telephone: 904/488-0300

Environmental Protection Agency, Regional Office Library, Room 121, 345 Courtland Street, NE., Atlanta, Georgia 30365. Telephone: 404/881-4216

Environmental Protection Agency, Headquarters Library, 401 M Street, SW., Washington, DC 20460

Written comments should be sent to: James H. Scarbrough, Chief, Residuals Management Branch, U.S. Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365. Telephone: 404/881-3016.

The public hearing will be held at: Holiday Inn-Parkway, Flamenco Room, 1302 Apalachee Parkway, Tallahassee, FL, 32301. Telephone: 901/877-3141.

FOR FURTHER INFORMATION CONTACT: James H. Scarbrough, Chief, Residuals Management Branch, Environmental

Protection Agency, 345 Courtland Street, NE. Telephone: 404/881-3016.

SUPPLEMENTARY INFORMATION: In the May 19, 1980, **Federal Register** (45 FR 33063) the Environmental Protection Agency promulgated regulations, pursuant to the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976, as amended, to protect human health and the environment from the improper management of hazardous waste. These regulations included provisions under which EPA can authorize qualified State hazardous waste management programs to operate in lieu of the Federal program. The regulations provide for a transitional stage in which qualified State programs can granted interim authorization. The interim authorization program is being implemented in two phases corresponding to the two stages in which the underlying Federal program will take effect.

The State of Florida received interim authorization for Phase I on May 19, 1982.

In the January 26, 1981 **Federal Register** (46 FR 7965), the Environmental Protection Agency announced the availability of portions or components of Phase II of interim authorization. Component A, published in the **Federal Register** January 12, 1981 (46 FR 2802), contains standards for permitting containers, tanks, surface impoundments and waste piles. Component B, published in the **Federal Register** January 23, 1981 (46 FR 7666), contains standards for permitting hazardous waste incinerators.

In the July 26, 1982 **Federal Register** (47 FR 32378), the Environmental Protection Agency announced that states with qualified programs can be authorized for Phase II Interim Authorization, Component C. Component C published in the **Federal Register** includes standards for permitting of land disposal facilities.

A full description of the requirements and procedures for State interim authorization is included in 40 CFR Part 271, Subpart B (48 FR 14249). As noted in the May 19, 1980 **Federal Register**, copies of complete State submittals for Phase II interim authorization are to be made available for public inspection and comment. In addition, a public hearing is to be held on the submittal.

List of Subjects in 40 CFR Part 271

Hazardous materials, Indians-lands, Reporting and recordkeeping requirements, Waste treatment and disposal, Intergovernmental relations, Penalties, Confidential business information.

Dated: November 15, 1983.

Charles R. Jeter,

Regional Administrator.

[FR Doc. 83-31350 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

---

40 CFR Part 415

[FRL-2476-1]

Effluent Guidelines and Standards; Inorganic Chemicals Manufacturing Point Source Category

AGENCY: Environmental Protection Agency.

ACTION: Public hearing.

SUMMARY: Notice is hereby given of a hearing open to the public to discuss and receive comments on pretreatment standards recently proposed in the **Federal Register** relating to the Inorganic Chemicals Manufacturing Point Source Category (October 25, 1983; 48 FR 49408). The hearing will be held to elicit additional comments on the regulation. These comments will be used to further assist the Agency in developing the final regulation.

DATE: The public hearing has been scheduled for December 15, 1983.

ADDRESS: The public hearing will be held at the following address: L'Enfant Plaza Hotel, 480 L'Enfant Plaza East, SW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Harold B. Coughlin, Effluent Guidelines Division (WH-552), (202) 382-7115, Evironmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION: Registration for the hearing will be held from 8:30 to 9:00 a.m. The hearing will start at 9:00 a.m. opportunity will be given throughout the hearing for the audience to submit written questions to the Presiding Officer. These questions will be addressed during a question and answer session at the conclusion of the oral testimony presentations.

For those persons making an oral presentation, it is requested that a written transcript of their presentation, as well as correct spelling of names, affiliations and addresses, be submitted to the court recorder. Official transcripts of the hearing will be available upon request.

Dated: November 10, 1983.

Rebecca W. Hanmer,

Acting Assistant Administrator for Water

[FR Doc. 83-31490 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

---

40 CFR Part 761

[OPTS-66008; TSH FRL 2389-7]

Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, and Distribution in Commerce Exemptions

Correction

In FR Doc. 83-29573 beginning on page 50486 in the issue of Tuesday, November 1, 1983, make the following corrections:

1. On page 50491, column three, paragraph one, line twenty-three, "TACA" should read "TSCA".

2. On page 50496, column one, paragraph two, line five, "DOE" should read "Dow".

BILLING CODE 1505-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6535]

National Flood Insurance Program; Proposed Flood Elevation Determinations; Iowa

Correction

In FR Doc. 83-15921, beginning on page 27555, in the issue of Thursday, June 16, 1983, on page 27557, in the table, in the entry for "Iowa", in the "Elevation" column, the third line down "* 381" should read "* 881".

BILLING CODE 1505-01-M

---

44 CFR Part 67

[Docket No. FEMA-6541]

National Flood Insurance Program; Proposed Flood Elevation Determination; Wisconsin

Correction

In FR Doc. 83-17729, beginning on page 30706, in the issue of Tuesday July 5, 1983, on page 30712, in the table, in the entry for "Wisconsin", in the "Elevation" column, in the fifth line "*73" should read "*873".

BILLING CODE 1505-01-M

Notices

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

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

Forms Under Review by Office of Management and Budget

November 18, 1983.

The Department of Agriculture has submitted to OBM for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extensions, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection; (2) Title of the information collection; (3) Form number(s), if applicable; (4) How often the information is requested; (5) Who will be required or asked to report; (6) An estimate of the number of responses; (7) An estimate of the total number of hours needed to provide the information; (8) An indication of whether section 3504(h) of Pub. L. 96-511 applies; (9) Name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, Room 108-W, Admin. Bldg., Washington, D.C. 20250, (202) 447-4414.

Comments on any of the items listed should be submitted directly to: Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503; ATTN: Desk Officer for USDA.

If you anticipate commenting on a submission but find that preparation time will prevent you from doing so promptly, you should advise the OMB Desk Officer of your intent as early as possible.

New

• Federal Grain Inspection Service
Disposition of Excess Grain—Records
Recordkeeping
Businesses, State or Local Governments: 203 responses; 31 hours; not applicable under 3504(h)
Lewis Lebakken, (202) 382-1738

• -Foreign Agricultural Service
Licenses for Importation/Transfer of Sugar to be Re-exported in Sugar Containing Products
On Occasion
Businesses or Other for-Profit: 60 responses; 30 hours; not applicable under 3504(h)
Carol Brick-Turin, (202) 447-6939

• Foreign Agricultural Service
Licensing of Sugar Exempt from Quotas for Purpose of Production of Polyhydric Alcohol
Monthly
Businesses or other for-Profit: 3 responses; 36 hours; not applicable under 3504(h)
Gordon Patty, (202) 447-2579

Reinstatement

• Rural Electrification Administration
Checklist for Review of Supplemental Loan Proposal or Area Coverage Design
REA 567
On Occasion
Small Businesses: 200 responses: 200 hours; not applicable under 3504(h)
John Soma, (202) 382-8529

• Rural Electrification Administration
Report of Progress of Construction and Engineering Services
REA-178
Monthly
Small Businesses: 1080 responses; 540 hours; not applicable under 3504(h)
Archie Caill, (202) 382-9082

Larry Roberson,
Acting Department Clearance Officer.

[FR Doc. 83-31300 Filed 11-22-83; 8:45 am]
BILLING CODE 3410-01-M

Office of International Cooperation and Development, Agribusiness Promotion Council; Meeting

Notice is hereby given that the USDA Agribusiness Promotion Council will meet on November 29, 1983 from 1:00 to 5:00 p.m. and November 30, 1983 from 7:30 to 10:00 a.m. at the Hyatt Regency Miami, 400 S.E. Second Avenue, City of Miami, Florida. The Council will meet to report accomplishments to Secretary Block and to formulate plans for the second year. The meeting will be open to the public. Written statements may be submitted to Joan S. Wallace, Administrator, USDA/OICD, Room 3047, South Building, Washington, D.C. 20250 until November 25, 1983. Additional information and agendas may be obtained by contacting Dr. Joan S. Wallace at the above address.

Robert P. Scherle,
Acting Administrator.

[FR Doc. 83-31455 Filed 11-22-83; 8:45 am]
BILLING CODE 3410-DP-M

Forest Service

Modoc National Forest Grazing Advisory Board; Meeting

The Modoc National Forest Grazing Advisory Board will meet at 10:00 a.m., December 16, 1983, at the Rancho Steak House, 404 W. 12th St., Alturas, California.

The purpose of this meeting is to discuss expenditures of Range Betterment Funds and Allotment Management Plans.

The meeting will be open to the public. Persons who wish to attend or who would like further information should notify William E. Britton, Modoc Supervisor's Office, telephone 916-233-5811. Written statements may be filed with the Board before or after the meeting.

Dated: November November 15, 1983.

Michael Alaux,
Acting Forest Supervisor.

[FR Doc. 83-31442 Filed 11-22-83; 8:45 am]
BILLING CODE 3410-11-M

CIVIL AERONAUTICS BOARD

Fitness Determination of Executive Express, Ltd.

AGENCY: Civil Aeronautics Board.

ACTION: Notice of Commuter Air Carrier Fitness Determination—Order 83-11-65, Order to Show Cause.

SUMMARY: The Board is proposing to find that Executive Express, Ltd. is fit, willing, and able to provide commuter air carrier service under section 419(c)(2) of the Federal Aviation Act, as amended, and that the aircraft used in this service conform to applicable safety standards. The complete text of this order is available, as noted below.

DATE: Responses: All interested persons wishing to respond to the Board's tentative fitness determination shall serve their responses on all persons listed below no later than December 6, 1983, together with a summary of the testimony, statistical data, and other material relied upon to support the allegations.

ADDRESSES: Responses or additional data should be filed with the Special Authorities Division, Room 915, Civil Aeronautics Board, Washington, D.C. 20428, and with all persons listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Timothy E. Carmody, Bureau of Domestic Aviation, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428, (202) 673-5121.

SUPPLEMENTARY INFORMATION: The complete text of Order 83-11-65 is available from the Distribution Section, Room 100, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Persons outside the metropolitan area may send a postcard request for Order 83-11-65 to that address.

By the Civil Aeronautics Board: November 16, 1983.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 83-31521 Filed 11-22-83; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Full Council Meeting President's Export Council; Partially Closed Meeting

A meeting of the PEC will be held December 8, 1983, 11:00 a.m., Indian Treaty Room, the White House, Washington, D.C. The Council's purpose is to advise the President on matters relating to United States export trade.

General Session: 11:00 a.m.-1:00 p.m. and 2:30-5:00 p.m. Opening remarks; discussion of previous PEC recommendations; reports by subcommittees on their recommendations, projects and issues; discussion of the organizational issues; and a roundtable discussion on industrial competitiveness issues.

Executive Session: 4:00-5:00 p.m. Discussion of matters properly classified under Executive Order 12356, dealing with trade administration and controls.

Because of White House security, the general session will be open to the public on a limited basis. Anyone wishing to attend must submit full name, address, social security number, date and place of birth, and affiliation, at least 10 days in advance of the meeting. A Notice of Determination to close meetings or portions of meetings of the Council to the public on the basis of 5 U.S.C. 552b(c)(1) was approved on February 3, 1983, in accordance with the Federal Advisory Committee Act. A copy of the Notice is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce, (202) 377-4217.

For further information, reservations to attend the open session, or copies of the minutes contact Angi Knapp (202) 377-1125.

Dated: November 21, 1983.

Henry P. Misisco,

Acting Director, Office of Planning and Coordination.

[FR Doc. 83-31612 Filed 11-22-83; 8:45 am]

BILLING CODE 3510-DR-M

President's Export Council; Open Meeting

A meeting of the President's Export Council's Export Promotion Subcommittee will be held December 8, 1983, 9:00 a.m., at the Herbert C. Hoover Building, Room 4830, 14th Street and Constitution Avenue, NW., Washington, D.C. The Council's purpose is to advise the President on matters relating to United States export trade.

Agenda: Opening remarks; trade development reorganization; status report on Foreign Sales Corporation Act; trade missions; and discussion of future meeting plans.

The meeting will be open to the public with a limited number of seats available. For further information or copies of the minutes contact Angi Knapp (202) 377-1125, Room 3213, U.S. Department of Commerce, Washington, D.C. 20230.

Dated: November 21, 1983.

Henry Misisco,

Acting Director, Office of Planning and Coordination.

[FR Doc. 83-31613 Filed 11-22-83; 8:45 am]

BILLING CODE 3510-DR-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjusting the Import Limit for Certain Wool Apparel Products Exported From the Hungarian People's Republic

ACTION: Increasing the limit established for men's and boys' wool suit-type coats in Category 433 from 7,350 dozen to 7,791 dozen, produced or manufactured in Hungary and exported during the agreement year which began on January 1, 1983, by the application of carryforward.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175) and May 3, 1983 (48 FR 19924).

SUMMARY: The Bilateral Wool Agreement of February 15 and 25, 1983 between the Governments of the United States and the Hungarian People's Republic provides, among other things, for the borrowing of yardage in certain categories from the succeeding year's level with the amount used being deducted from the level in the following year (carry forward). At the request of the Government of the Hungarian People's Republic, carry forward is being applied to the limit for Category 433.

EFFECTIVE DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Gordana Slijepcevic, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. (202/377-4212).

SUPPLEMENTARY INFORMATION: On May 2, 1983, there was published in the **Federal Register** (48 FR 19770) a letter dated April 27, 1983 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs which established limits for certain wool textile products, including Category 433, produced or manufactured in Hungary, which may be entered into the United States for consumption, or withdrawal from warehouse for consumption, during the twelve-month period which began on January 1, 1983.

In the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to permit entry for consumption and withdrawal from warehouse for consumption of wool textile products in Category 433, produced or manufactured in Hungary, at the increased level of

7,791 dozen during the agreement year which began on January 1, 1983.

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textile Agreements.

November 18, 1983.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C.

Dear Mr. Commissioner: On April 27, 1983, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry beginning on January 1, 1983 of wool textile products in certain specific categories, produced or manufactured in Hungary, and exported during 1983 in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

Effective on November 23, 1983, paragraph 1 of the directive of April 27, 1983 is amended to include an adjusted level of restraint of 7,791 dozen for Category 433.[2]

The action taken with respect to the Government of the Hungarian People's Republic and with respect to imports of wool textile products from Hungary has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 533. This letter will be published in the **Federal Register.**

Sincerely,

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 83-31497 Filed 11-22-83; 8:45 am]

BILLING CODE 3510-DR-M

[1] The term "adjustment" refers to those provisions of the Bilateral Wool Textile Agreement of February 15 and 25, 1983, between the Governments of the United States and the Hungarian People's Republic which provide, in part, that: (1) Within the aggregate and applicable group limits of the agreement, specific levels of restraint may be exceeded by designated percentages; (2) these same levels may be increased for carryover and carryforward; and (3) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

[2] The level has not been adjusted to reflect any imports exported after December 31, 1982.

Adjusting the Limit for Certain Wool and Man-Made Fiber Apparel Products Exported From the Polish People's Republic

ACTION: Increasing the limits established for wool suit-type coats in Category 433, and men's and boys' wool suit-type coats and man-made fiber suits in Category 443/643/644, produced or manufactured in Poland exported during the agreement year which began on January 1, 1983, by the application of swing.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175) and May 3, 1983 (48 FR 19924).

SUMMARY: The Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of September 15, 1980 and March 21, 1981 between the Governments of the United States and the Polish People's Republic provides, among other things, for percentage increases in certain categories during an agreement year (swing). At the request of the Government of the Polish People's Republic swing is being applied to Categories 433 and 443/643/644.

EFFECTIVE DATE: November 18, 1983.

FOR FURTHER INFORMATION CONTACT: Carl Ruths, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. (202/377-4212).

SUPPLEMENTARY INFORMATION: On December 23, 1982, a letter dated December 17, 1982 was published in the **Federal Register** from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs which established levels of restraint for certain cotton, wool, and man-made fiber textile products, including Categories 433 and 443/643/644, produced or manufactured in Poland and exported during the twelve-month period which began on January 1, 1983, which may be entered into the United States for consumption, or withdrawn from warehouse for consumption.

In the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to permit entry for consumption and withdrawal from warehouse for consumption of textile products in Categories 433, and 442/643/644, produced or manufactured in Poland, at the designated levels during the agreement year which began on January 1, 1983.

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textile Agreements.

November 18, 1983.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C.

Dear Mr. Commissioner: On December 17, 1982, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry beginning on January 1, 1983 of cotton, wool, and man-made fiber textile products in certain specific categories, produced or manufactured in Poland, and exported during 1983 in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

Effective on November 18, 1983, paragraph 1 of the directive of December 17, 1982 is further amended to include adjusted levels of restraint for the following categories.

Category	Adjusted 12-mo level of restraint [1]
433	8,102 dozen.
443/643/644	16,968 dozen of which not more than 14,065 dozen shall be applied to all T.S.U.S.A. numbers in these categories except 379.8351, 379.8352, 379.8920 and 379.9560.

[1] The levels have not been adjusted to reflect any imports exported after December 31, 1982.

The action taken with respect to the Government of the Polish People's Republic and with respect to imports of wool and man-made fiber textile products from Poland has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 533. This letter will be published in the **Federal Register.**

Sincerely,

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 83-31496 Filed 11-22-83; 8:45 am]

BILLING CODE 3510-DR-M

[1] The term "adjustment" refers to those provisions of the Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement of September 15, 1980 and March 21, 1981, between the Governments of the United States and the Polish People's Republic which provide, in part, that: (1) Within the aggregate and applicable group limits of the agreement, specific levels of restraint may be exceeded by designated percentages; (2) these same levels may be increased for carryover and carryforward; and (3) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

DEPARTMENT OF DEFENSE

Department of the Air Force

USAF Scientific Advisory Board; Meeting

November 10, 1983.

The USAF Scientific Advisory Board Ad Hoc Committee on the Environmental Technical Applications Center will meet at the Pentagon, Washington, D.C. on December 15-16, 1983. The purpose of the meeting will be

to review the scope and mission of the USAF Air Weather Service's Environmental Technical Applications Center. The meeting will convene at 9:00 a.m. and adjourn at 5:00 p.m. each day.

The meeting concerns matters listed in Section 552b(c) of Title 5, United States Code, specifically subparagraph (1) and (4) thereof, and accordingly, will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 697-4648.

Winnibel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 83-31435 Filed 11-22-83; 8:45 am]

BILLING CODE 3910-01-M

Corps of Engineers, Department of the Army

Intent To Prepare a Draft Environmental Impact Statement (DEIS) for a Regulatory Permit Action for a Proposed Oil Shale Project by Southern Pacific Petroleum, N.L. and Central Pacific Minerals, N.L.

AGENCY: Army Corps of Engineers, Louisville District, DOD.

ACTION: Notice of intent to prepare a Draft Environmental Impact Statement (DEIS).

SUMMARY: 1. *Proposed Action.* Southern Pacific Petroleum, N.L. and Central Pacific Minerals, N.L. propose to construct and operate an oil shale facility on a site principally in Montgomery County, Kentucky near the community of Means, Kentucky. The proposed project is currently estimated to produce 13,000 barrels per day of upgraded shale oil from approximately 62,500 tons per day of oil bearing shale. In addition to the primary production of upgraded shale oil, electrical energy will be produced from gases generated during the shale retorting process and elemental sulfur will be recovered as a byproduct. The oil bearing shale will be extracted from mines proximal to the oil shale processing area. The project schedule proposes to complete construction and reach production in mid- to late 1988. Preliminary estimates indicate the cost of the facility will be approximately $1,000,000,000. Manpower requirements are expected to include a construction workforce which will peak at approximately 2,400 persons and a permanent operating workforce of about 790 persons.

2. *Alternatives.* Along with the "no action" alternative and the facility currently proposed by Southern Pacific Petroleum, N.L. and Central Pacific Minerals, N.L., alternatives that will be considered will include, but not necessarily be limited to:

a. A discussion of the need for synthetic fuel options as compared to more conventional energy forms and sources.

b. A discussion of the need for synthetic fuel options as compared to other less conventional (but not synthetic fuels) energy forms and conservation.

c. The various synthetic fuel alternatives available.

d. Alternate process systems available to accomplish the proposed action.

e. Various air pollution control alternatives.

f. Alternate wastewater treatment systems.

g. Alternate methods for disposal of solid wastes and spent shale.

h. Product alternatives available with the proposed project systems

i. Transporation alternatives for raw materials, products, and construction and operation personnel.

j. Alternate sources of water for the proposed project.

k. Alternative sites for the proposed action.

l. Alternative courses of action for permitting agencies.

3. Scoping Process. The public scoping process for this project begins with this Notice of Intent. All affected Federal, state, and local agencies, and all other interested organizations, groups, and individuals are encouraged to participate in this scoping process. Written comments and concerns regarding issues that should be considered in the development of the scope of the EIS will be accepted until a public scoping meeting is held in the proposed project area. A schedule for this meeting has not yet been established, but it is anticipated that it will occur in January 1984. After a date, time, and location are set for the scoping meeting, notification will be made in the region of the project. Those who wish to receive notice of the schedule of this meeting should make a written request to the contact person noted at the end of this Notice of Intent.

The merits of the Southern Pacific Petroleum, N.L. and Central Pacific Minerals, N.L. proposal will not be debated at the public scoping meeting. The purpose of the scoping meeting is to assist in developing the scope of the Draft EIS. Public and agency comments on the merits of the project will be received following the issuance of the Draft and Final EIS and at a Public Hearing, if held, on the permit application and the Draft EIS.

Significant issues that have already been identified include air quality impacts, water quality impacts, impacts on waste disposal, human health effects, loss of wildlife habitat, socioeconomic effects on local population and communities, and energy needs including the development of a synthetic fuel industry.

4. It is anticipated that the Draft EIS for this project will be filed with the U.S. Environmental Protection Agency and released for public review and comment on or about July 1985.

5. *Address.* Questions about the proposed action and the Draft EIS can be answered by and written requests for notification of the public scoping meeting should be made to Mr. Terry Seimsen, Environmental Specialist, Planning Division, U.S. Army Corps of Engineers, Louisville District, P.O. Box 59, Louisville, Kentucky 40201, Telephone: 502-582-5550 or 582-5657 (FTS 352-5550 or 352-5657).

Dated: November 16, 1983.

Dwayne G. Lee,

Colonel, Corps of Engineers, District Engineer.

[FR Doc. 83-31437 Filed 11-22-83; 8:45 am]

BILLING CODE 3710-JB-M

Intent to Prepare a Draft Environmental Impact Statement (DEIS) for a Continuing Authorities Section 205 Flood Control Project at Limestone Creek in the Village of Fayetteville, NY

AGENCY: U.S. Army Corps of Engineers Buffalo District, DOD.

ACTION: Notice of Intent To Prepare a Draft Envrionmental Impact Statement (DEIS).

Proposed Action: The study is being accomplished under the authority of Section 205 of the 1948 Flood Control Act, as amended. The plan formulated for the Fayetteville project vicinty involves utilization of levee structures, where possible, or floodwall structures, in constrictive areas, to prevent floodwaters from inundating the existing floodprone community developments. Some channelization and clearing and snagging measures would also be necessary to facilitate channel design capacity near and just south of the Route 5-Genesee Bridge. The floodwaters would, therefore, be confined to the existing stream channel and remaining undeveloped-unprotected flood plain areas; substantially reducing potential for flood related damages and

hazards. Based on a preliminary assessment of engineering and economic feasibility and environmental and social acceptability, to date, this proposed plan is the most practical and feasible alternative solution.

Alternatives Considered: A number of flood damage reduction measures were initially investigated in developing solutions to flood related problems.

They include: (1) No-Action; (2) Nonstructural; (3) Structural; and (4) Combination Measures.

The No-Action measure implies that the Federal Government, acting through the Corps of Engineers, could take no action to provide flood damage reduction in the village of Fayetteville, NY. The No-Action measure serves as a base condition to which all other plans are compared.

Nonstructural measures include institutional type measures such as flood insurance and flood plain management, and measures aimed at protecting structures on an individual basis through means such as relocation or floodproofing.

Structural measures are measures significantly altering either the nature or extent of flooding. Structural measures considered include: dams and reservoirs; levees, dikes, and floodwalls; diversions; and channelization.

Combination measures incorporate combinations of both nonstructural and structural measures. Measures are incorporated by channel reach where they may be most feasible to provide maximum benefits and minimized adverse effects. The proposed action is representative of this type of measure incorporating levee/floodwall, channelization, and clearing and snagging measures. Nonstructural measures are encouraged in avoiding problems in future utilization of flood plain areas.

Public Involvement: An investigation to determine the applicability of the Section 205 authority was initiated in response to a letter dated 23 October 1980 from James H. Lannon, Mayor of the village of Fayetteville, NY. The letter requested that the Corps of Engineers conduct a study of areas within the village that are periodically subject to flooding from Limestone Creek. The Reconnaissance Report was prepared in May 1981 and approved in June 1981. Subsequently, the detailed planning investigation and preparation of the Detailed Project Report was initiated in August of 1982.

Upon initiation of the detailed study, the Corps conducted a September 1982 field trip to view the project site, meet with key identified local public, discuss problems and preliminary possible solutions, and gather basic local information. In May 1983, a second field trip was conducted by the Corps to discuss study progress and schedule with local officials, and to participate in a cooordinated local public interview and survey to identify and discuss flooding problems, the planning process, considerations, constraints, possible alternative measures, and potential impacts with local residents. Additionally, a news letter, a formal public meeting, and additional coverage via the local newspaper are planned.

Preliminary coordination with several Federal, State, and local agencies and private interest groups has been initiated and will continue throughout the study process to ensure that their views are considered on the proposed action. Close coordination has been maintained with the village of Fayetteville, the town of Manlius, and the New York State Department of Environmental Conservation (NYSDEC—who acts as the local sponsor). Close coordination has also been maintained with the U.S. Fish and Wildlife Service (USFWS) which has conducted a fisheries baseline study and prepared a planning aid letter for the Corps on the Limestone Creek project. Coordination for the required Fish and Wildlife Coordination Act Report is currently being accomplished. A cultural Resources Reconnaissance Level Survey has also been conducted and coordinated with appropriate Federal and State cultural resources review agencies.

Public participation and correspondence is encouraged throughout the study period. Concerns expressed by the public will be addressed in the Draft and Final Detailed Project Report (DPR) and associated Draft and Final Environmental Impact Statement (EIS).

Issues: Significant issues to be analyzed in the Draft EIS include a determination of the extent to which the selected plan and any reasonable alternatives might positively or negatively impact upon the natural and human environments—to include: air quality, water quality, fish and wildlife, noise, aesthetics, community and regional growth and development, health and safety, and cultural resources.

Review Compliance: The study shall be conducted so as to comply with the various Federal and State environmental statutes and Executive Orders and associated review procedures. When the Draft EIS is completed for review, it will be filed with the U.S. Environmental Protection Agency to be reviewed under the National Environmental Policy Act procedures.

Scoping Meeting: Since Federal, State, and local interests have been involved in preliminary stages of the study, and additional public coordination and meetings are planned for the final planning stage of the study, no additional scoping meeting will be held. In New York State, for Corps investigations conducted under the Section 205 study authority, NYSDEC is usually—as in this case—the project local cooperator, and coordinates with the Corps and the local officials to attain necessary local assurances.

Availability: The Draft Detailed Project Report and associated Draft Environmental Impact Statement will be made available to the public on or about 30 June 1984.

Address: Questions concerning preparation of the Draft Environmental Impact Statement can be answered by Mr. Tod Smith, U.S. Army Engineer District, Buffalo, 1776 Niagara Street, Buffalo, NY 14207, (716) 876-5454 or FTS 473-2171.

Dated: November 16, 1983.

Robert R. Hardiman,

Colonel, Corps of Engineers District Commander.

[FR Doc. 83-31542 Filed 11-22-83; 8:45 am]

BILLING CODE 3710-GP-M

DEPARTMENT OF EDUCATION

National Advisory Council on Women's Educational Programs; Meeting

AGENCY: National Advisory Council on Women's Educational Programs, Department of Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a joint meeting of the National Advisory Council on Women's Educational Programs Executive Committee and the Committee on Standing Committees. The agenda will include a discussion of budget, planning Council activities for the coming year, utilization of staff resources and committee projects for 1984. 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: December 7, 1983, 8:00 a.m. to 12:00 p.m., and 8:00 p.m. to 10:00 p.m., and if necessary, continuing on December 8, 1983, 9:00 a.m. to 11:00 a.m.

ADDRESS: The meeting will be held at the Sheraton Meridian Hotel, 2820 N. Meridian, Indianapolis, Indiana 46208.

FOR FURTHER INFORMATION CONTACT: Sharon Petersen, Special Assistant to the Executive Director, National Advisory Council on Women's Educational Programs, 425 13th Street, NW., Suite 416, Washington, D.C. 20004, (202) 376-1038.

SUPPLEMENTARY INFORMATION: The National Advisory Council on Women's Educational Programs is established pursuant to Pub. L. 95-561. The Council is mandated to (a) advise the Secretary on matters relating to equal eduction opportunities for women and policy matters relating to the administration of the Women's Educational Equity Act of 1978; (b) make recommendations to the Secretary with respect to the allocation of any funds pursuant to the Act, including criteria developed to insure an appropriate geographical distribution of approved programs and projects throughout the Nation; (c) recommend criteria for the establishment of program priorities; (d) make such reports as the Council determines appropriate to the President and Congress on the activities of the Council; and (e) disseminate information concerning the activities of the Council.

The joint meeting of the Executive/Committee on Standing Committees will be open to the public. Records will be kept of the proceedings and will be available for public inspection at the office of the National Advisory Council on Women's Educational Programs, 425 13th Street, NW., Suite 416, Washington, D.C. 20004

Signed at Washington, D.C. on November 18, 1983.

Rosemary Thomson,

Executive Director.

[FR Doc. 83-31501 Filed 11-22-83; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

Proposed Remedial Order; Fedco Oil Co.

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of proposed remedial order to Fedco Oil Company.

SUMMARY: Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives Notice of a Proposed Remedial Order which was issued to fedco Oil Company, One Houston Center, Suite 1800, Houston, Texas 77002. This Proposed Remedial Order alleges violations in the pricing of crude oil of 10 CFR 212.186, 210.62 and 205.202. The principal amount of the alleged violation of 10 CFR 212.186, 210.62 and 205.202 for the period March 1978 through July 1979 is $369,896.16. A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from: U.S. Department of Energy Economic Regulatory Administration, ATTN: Sandra K. Webb, Director, One Allen Center, Suite 610, 500 Dallas Street, Houston, Texas 77002.

Within fifteen (15) days of publication of this Notice any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, U.S. Department of Energy, Room 3304, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Houston, Texas on the 1st day of November, 1983.

Sandra K. Webb,

Director, Houston Office, Economic Regulatory Administration.

[FR Doc. 83-31405 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Proposed Remedial Order; Mar-Low Corp. and Ruffin T. Lowry

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of proposed remedial order to Mar-Low Corporation and Ruffin T. Lowry.

SUMMARY: Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives Notice of a Proposed Remedial Order which was issued to Mar-Low Corporation and Ruffin T. Lowry, 1144 Collidge Boulevard, Lafayette, Lousiana 70501. This Proposed Remedial Order alleges violations in the pricing of crude oil of 10 CFR 212.93, 212.10(a), 210.62 and 205.202 for the period April 1974 through February 1976. During this period, Mar-Low and Ruffin T. Lowry sold crude oil at prices in excess of its maximum lawful selling price in violation of 10 CFR 212.93 and 212.10(a). The principal amount of these pricing violations is $276,468.42. In addition, the pricing practices of Mar-Low and Lowry in regard to the sale of this crude oil violated 10 CFR 205.202 and 210.62(c). These violations resulted in Mar-Low and Lowry receiving unlawful revenues in the principal amount of $280,936.71. A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from: U.S. Department of Energy, Economic Regulatory Administration, ATTN: Sandra K. Webb, Director, One Allen Center, Suite 610, 500 Dallas Street, Houston, Texas 77002.

Within fifteen (15) days of publication of this Notice any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, U.S. Department of Energy, Room 3304, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Houston, Texas on the 1st day of November, 1983.

Sandra K. Webb,

Director, Houston Office, Economic Regulatory Administration.

[FR Doc. 83-31404 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Office of Hearings and Appeals

Objection to Proposed Remedial Orders Filed; Week of September 19 Through September 23, 1983

During the week of September 19 through September 23, 1983, the notices of objection to proposed remedial orders listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Any person who wishes to participate in the proceeding the Department of Energy will conduct concerning the proposed remedial orders described in the Appendix to this Notice must file a request to participate pursuant to 10 CFR 205.194 within 20 days after publication of this Notice. The Office of Hearings and Appeals will then determine those persons who may participate on an active basis in the proceeding and will prepare an official service list, which it will mail to all persons who filed requests to participate. Persons may also be placed on the official service list as non-participants for good cause shown.

All requests to participate in these proceedings should be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

George B. Breznay,

Director, Office of Hearings and Appeals.

November 9, 1983.

Intercoastal Operating Company, Houston, Texas, HRO-0192

On September 22, 1983, the following companies and individuals filed Notices of Objection to a Proposed Remedial Order which the DOE Economic Regulatory Administration (ERA) issued to them on August 18, 1983: Intercoastal Operating Company and I.O.C. Production, Inc., both of

2807 Buffalo Speedway, Houston, Texas 77027; John C. O'Leary, 19 River Hollow Lane, Houston, Texas 77027; W. R. Dean, 2 River Hollow Lane, Houston, Texas 77027; Joe N. Pratt, 1706-A North Navarro, Victoria, Texas 77901; and Karen Sue Royce, 2515 Locke Lane, Houston, Texas 77019. On September 26, 1983, J. H. Gilley, Jr., 6012-A Country Club Lane, Victoria, Texas 77904 and L. E. Lewis, 3609 Parader, Dallas, Texas 75228, also filed Notices of Objection.

In the PRO the ERA found that during September 1, 1973 to September 30, 1980, the firm sold crude oil at prices in excess of those permitted by 10 CFR Part 212, Subpart D.

According to the PRO the Intercoastal violation resulted in $1,055,285.76 of overcharges.

MAPCO International, Inc., Tulsa, Oklahoma, HRO-0193

On September 22, 1983, MAPCO International, Inc. of Tulsa, Oklahoma, filed a Notice of Objection to a Proposed Remedial Order which the DOE Economic Regulatory Administration (ERA) issued to the firm on June 30, 1983.

In the PRO the ERA found that between August 1978 and November 1980, MAPCO resold crude oil for which it provided no function traditionally and historically associated with the resale of crude oil at prices in excess of its actual acquisition costs in violation of 10 CFR 210.62(c) and 212.186.

According to the PRO the MAPCO International, Inc. violation resulted in $3,185,873.64 of overcharges.

[FR Doc. 83-31399 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Issuance of Decisions and Orders; Week of October 10 Through October 14, 1983

During the week of October 10 through October 14, 1983, the decision and order summarized below was issued with respect to applications for relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Copies of the full text of these decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

George B. Breznay,

Director, Office of Hearings and Appeals.

November 9, 1983.

Refund Application

OKC Corp./Pester Refining Co., W. E. Allford, Inc., Molo Oil Co., 10/14/83, RF13-26, RF13-14, RF13-30

The DOE issued a Decision and Order concerning Applications for Refund filed by Pester Refining Co., W. E. Allford, Inc., and Molo Oil Co. Each firm requested a portion of the OKC Corporation consent order fund. The DOE found Pester eligible for a refund based upon the monthly purchase threshold level of 50,000 gallons of OKC motor gasolines, notwithstanding the fact that Pester purchased over 160,000 gallons from OKC in a single month. The DOE determined that Pester's refund could not exceed the purchase threshold level since the firm failed to demonstrate that it was injured by OKC's alleged overcharges. W. E. Allford was granted a refund covering its entire purchase volume of OKC motor gasoline. However, Allford's purchases of OKC diesel fuel were found to be ineligible for refund consideration because they occurred after diesel fuel was exempted from the DOE price control program. Molo Oil Co., agreed to accept a refund based upon the purchase threshold level of 50,000 gallons per month rather than submit the documentation necessary to demonstrate that it was injured by OKC's pricing practices. Each refund was determined by the use of a volumetric formula. The refunds granted in this Decision total $5,025 plus accrued interest.

Dismissals

The following submissions were dismissed:

Name and Case No.

B & C Oil Company—RF21-12060
Bibb Oil Company—RF21-3311
Davies Oil Co., Inc.—RF21-7923, RF21-7924, RF21-7925, RF21-7928
Merwin Oil Company—RF21-7092
Monarch Air Service—RF21-3465
Niederauer Oil Company—RF21-1559
Teut's Standard Service—RF21-11076
Van's Standard—RF21-10796
Kenneth M. Voss—RF21-10947
Walsh Oil Company—RF21-11414
Ward Oil Company—RF21-10802, RF21-10803

[FR Doc. 83-31400 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Cases Filed; Week of October 14 Through October 21, 1983

During the Week of October 14 through October 21, 1983, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy. Submissions inadvertently omitted from earlier lists have also been included.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

George B. Breznay,

Director, Office of Hearings and Appeals.

November 8, 1983.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of October 14 through October 21, 1983]

Date	Name and location of applicant	Case No.	Type of submission
Apr. 26, 1983	Economic Regulatory Administration, State of California, Washington, D.C.	HRZ-0174	Interlocutory order. If granted: The State of California would not be permitted to participate in the proceeding involving a January 13, 1983, Proposed Remedial Order issued to Revere Petroleum Corporation (Case No. HRO-0125) by the Economic Regulatory Administration.
Oct. 11, 1983	Charter Company, Washington, D.C.	HCF-0480	Implementation of second stage refund procedures. If granted: The Office of Hearings and Appeals would implement the second stage refund proceeding in the Consent Order entered into with Charter Company (Case No. HEF-0005).
Oct 17, 1983	The Bakersfield California, Bakersfield, California	HFA-0190	Appeal of an information request. If granted: The September 30, 1983, Freedom of Information Request Denial issued by the Director of Naval Petroleum Reserves in California would be rescinded, and the Bakersfield California would receive access to certain documents relating to Grant Supply Company.
Oct. 18, 1983	Kunz Oil Company, Minneapolis, Minnesota	HRH-0171, HRD-0171.	Motion for discovery and request for evidentiary hearing. If granted: Discovery would be granted and an evidentiary hearing would be convened in connection with the Statement of Objections submitted by Kunz Oil Company in response to the May 20, 1983, Proposed Remedial Order (Case No. HRO-0165) issued to Kunz Oil Company.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of October 14 through October 21, 1983]

Date	Name and location of applicant	Case No.	Type of submission
Oct. 19, 1983	Hydrocarbons, Ltd., San Dimas, California	HRH-0022	Request for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with the Statement of Objections submitted by Hydrocarbons, Ltd. in response to the May 10, 1983, Proposed Remedial Order issued to Hydrocarbons, Ltd. (Case No. HRO-0197).
Oct. 14, 1983	Mobil Oil Corporation, Dallas, Texas	HRD-0172	Motion for discovery. If granted: Discovery would be granted to the Economic Regulatory Administration in connection with the Statement of Objections submitted in response to the Proposed Remedial Order (Case No. HRO-0030) issued to Mobil Oil Corporation.
Oct. 19, 1983	Warrior Oil Company, Washington, D.C.	HRD-0182, HRH-0182.	Motion for discovery and request for evidentiary hearing. If granted: Discovery would be granted and an evidentiary hearing would be convened in connection with the Statement of Objections submitted by Warrior Oil Company in response to the Proposed Remedial Order (Case No. HRO-0182) issued to Warrior Oil Company.
Oct. 20 1983	Crown Central Petroleum Corporation, Baltimore, Maryland	HRR-0075	Request for modification/rescission. If granted: The October 17, 1983, Decision and Order (Case Nos. DRO-0111 and HRR-0059) issued to Crown Central Petroleum Corporation would be modified regarding the review of a response filed by Crown Central Petroleum Corporation on August 12, 1983.
Oct. 21, 1983	A.V. Wright, Los Angeles, California	HRS-0039, HRT-0039.	Request for stay and temporary stay. If granted: A.V. Wright would receive a Stay and a Temporary Stay of the proceedings regarding the Proposed Remedial Order (Case No. HRO-0186) issued to Petroex Energy Corporation.

REFUND APPLICATIONS RECEIVED

[Week of October 14 to October 21, 1983]

Date	Name of refund proceeding/name of refund applicant	Case No.
Oct. 17, 1983	Palo Pinto/Virginia	RQ5-24.
Oct. 21, 1983	Palo Pinto/Minnesota	RQ5-25.
Sept. 9, 1983	Amoco/Ward Oil Company	RF21-12217.
July 18, 1983	Amoco/30 Piercelon Truck Plaza	RF21-12218.
July 18, 1983	Amoco/Tekon, Inc	RF21-12219.
Oct. 19, 1983	Amoco/Joe's Standard Service	RF21-12220.

[FR Doc. 83-31401 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Cases Filed; Week of October 21 Through October 28, 1983

During the Week of October 21 through October 28, 1983, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

George B. Breznay,

Director, Office of Hearings and Appeals.

November 8, 1983.

List of Cases Received by the Office of Hearings and Appeals

[Week of October 21 through October 28, 1993]

Date	Name and location of applicant	Case No.	Type of submission
Oct. 21, 1983	Crown Central Petroleum Corporation, Baltimore, Maryland	HRZ-0175	Interlocutory order. If granted: The September 28, 1983, Proposed Remedial Order issued to Crown Central Petroleum Corp. (Case No. HRO-0198) would be dismissed.
Do	Merit Petroleum, Inc., Washington, D.C.	HRD-0174, HRH-0174.	Motion for discovery and request for evidentiary hearing. If granted: Discovery would be granted and an evidentiary hearing would be convened in connection with the Statement of Objections submitted by Merit Petroleum, Inc. in response to the Proposed Remedial Order (HRO-0174) issued to Merit Petroleum, Inc.
Oct. 26 1983	Dr. Jeffrey L. Turek, Blacksburg, Virginia	HFA-0191	Appeal of an information request denial. If granted: The September 30, 1983, Privacy Act request Denial issued by the Savannah River Operations, DOE, would be rescinded and Dr. Jerrey L. Turek would receive access to information, records, and other material relating to his employment.
Do	do	HFA-0192	Appeal of an information request denial. If granted: The September 23, 1983, Freedom of Information Request Denial issued by the Savannah River Operations, DOE would be rescinded, and Dr. Jeffery L. Turek would receive access to information, records, and other material relating to his employment.
Oct. 27, 1983	Liberty Trading Company & Mr. Ray Levrier, Houston, Texas	HRD-0181, HRH-0181.	Motion for discovery and request for evidentiary hearing. If granted: Discovery would be granted and an evidentiary hearing would be convened in connection with the Statement of Objections submitted by Liberty Trading Company and Mr. Ray Levrier in response to the April 29, 1983 Proposed Remedial Order (Case No. HRO-0181) issued to Liberty Trading Company and Mr. Ray Levrier.
Do	Nordstrom Oil Company, Cedar Rapids, Iowa	HQF-0481	Implementation of second stage refund procedures. If granted: The Office of Hearings and Appeals would implement the second stage refund proceeding in the Consent Order entered into with Nordstrom Oil Company (Case No. BEF 0061).

List of Cases Received by the Office of Hearings and Appeals—Continued

[Week of October 21 through October 28, 1993]

Date	Name and location of applicant	Case No.	Type of submission
Oct 28, 1983	Ashland Oil, Inc., Pittsburgh, Pennsylvania	HFA-0193	Appeal of an information request denial. If granted: The September 27, 1983, Freedom of Information Request Denial issued by the Office of Fuels Program would be rescinded, and Ashland Oil, Inc. would receive access to an updated drafting of the January, 1981 Entitlements Notice.
Do	Economic Regulatory Administration/Hideca Petroleum Corp., Washington, D.C.	HRJ-0041	Protective order. If granted: The Economic Regulatory Administration would enter into a Protective Order whith Hideca Petroleum Corporation regarding the release of proprietary information to Hideca Petroleum Corporation concerning Shell Pipe Line Corporation (Case No. HRO-0150).
Do	Thriftway Company, Washington, D.C.	HCX-0096	Supplemental order. If granted: The March 11, 1982, Decision and Order (Case Nos. BEE-1206 & BXE-1490) issued to Thriftway Company by the Office of Hearings and Appeals would be modified in connection with the October 18, 1983, Order Adopting the Proposed Order of September 15, 1983 issued by the Federal Energy Regulatory Commission.

REFUND APPLICATIONS RECEIVED

[Week of October 21 to October 28, 1983]

Date	Name of refund proceeding/name of refund applicant	Case No.
Oct 25, 1983	Sid Richardson/Ravenna Propane, Inc	RF26-12.
Sept. 26, 1983	Amoco/S&H Standard	RF21-12222.
Oct. 26, 1983	Palo Pinto/North Carolina	RQ5-26.
Aug. 4, 1983	Amoco/Sandy Register's Amoco	RF21-12223.
Oct. 25, 1983	Amoco/Mike's Standard Service	RF21-12221.

[FR Doc. 83-31402 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. ER84-74-000]

Canal Electric Co.; Filing

November 17, 1983.

The filing Company submits the following:

Take notice that on November 8, 1983, Canal Electric Company (Canal) tendered for filing, as an initial rate schedule an agreement dated November 1, 1983 (Agreement) by and between itself, Commonwealth Electric Company and Cambridge Electric Light Company (Purchasers). The Agreement governs the sale of unit power from Canal's joint-ownership interest in the two unit Seabrook generating station currently under construction at a site in Seabrook, New Hampshire to Purchasers jointly.

Canal states that it owns a 3.52317% joint-ownership interest in each of the two generating units now under construction at said Seabrook site (or approximately 40.5 megawatts each) under the terms of a joint-ownership agreement dated May 1, 1973 as amended. By the tendered initial rate schedule, Canal proposes to make available to Purchasers jointly 100% of the capacity and related energy secured by Canal over the expected life of said generating units. Purchasers jointly will reimburse Canal for such capacity and related energy pursuant to the terms of a cost of service formula contained in the Agreement. In addition, Purchasers will reimburse Canal for its costs eligible for inclusion in rate base under the Commission's recently promulgated Order No. 298 concerning construction work in progress and will bear any costs incurred by Canal for decommissioning such generating units at the end of their useful life.

Canal requests an effective date of November 1, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing have been served upon Purchasers and upon the Massachusetts Department of Public Utilities.

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, D.C. 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR § 385.211, 385.214). All such motions or protests should be filed on or before December 5, 1983. 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. 83-31409 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-77-000]

Central Maine Power Co.; Filing

November 17, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Central Maine Power Company (CMP) tendered for filing as a rate schedule an executed agreement dated as of September 17, 1983 between CMP and New England Power Company. The proposed rate schedule provides for the sale of interruptible energy by CMP to New England Power Company.

CMP requests an effective date of September 17, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of the filing have been served upon New England Power Company and the Maine Public Utilities Commission.

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, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 5, 1983. 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. 83-31410 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-78-000]

Central Maine Power Co.; Filing

November 17, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Central Maine Power Company (CMP) tendered for filing as a rate schedule an executive agreement dated as of October 1, 1983 between CMP and New England Power Company of Westborough, Massachusetts. The proposed rate schedule provides for the sale of W. F. Wyman United No. 4 capacity and related energy by CMP to New England Power Company.

CMP requests an effective date of October 1, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of the filing have been served upon New England Power Company and the Maine Public Utilities Commission.

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, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 5, 1983. 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 the filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31411 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-69-000]

Central Vermont Public Service Corp.; Filing

November 17, 1983.

The filing Company submits the following:

Take notice that on November 4, 1983, Central Vermont Public Service Corporation (CVPS) tendered for filing as an initial rate schedule a System Power Sales Agreement (the Agreement) between the New England Power Company (NEPCO) and CVPS. CVPS states that the Agreement dated October 1, 1983, provides for CVPS to sell energy from its system and NEPCO expects to purchase such energy.

CVPS further states that the Agreement provides that the parties will determine prior to 11:00 am of the day preceding the commencement of a transaction during the term of the Agreement whether it is economically advantageous to the parties that a sale, pursuant to the Agreement, take place during that day. CVPS and NEPCO will determine whether or not to initiate a transaction based on the expectations of achieving overall economic benefits for both parties.

CVPS further states that during the hours when the agreement is in effect, NEPCO will buy system power from CVPS. NEPCO will pay CVPS for its system power at a rate which shall be an hourly charge on a dollar per megawatt hour basis and an hourly energy reservation charge on a dollar per megawatt hour basis.

CVPS requests an effective date of October 1, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing have been served upon the New England Power Company, and the Vermont Public Service Board.

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, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before November 30, 1983. 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. 83-31412 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ST80-109-002]

Cranberry Pipeline Corp.; Extension Reports

November 17, 1983.

The companies listed below have filed extension reports pursuant to Section 311 of the Natural Gas Policy Act of 1978 (NGPA) and Part 284 of the Commission's regulations giving notice of their intention to continue transportation and sales of natural gas for an additional term of up to 2 years. These transactions commenced on a self-implementing basis without case-by-case Commission authorization. The sales may continue for an additional term if the Commission does not act to disapprove or modify the proposed extension during the 90 days preceding the effective date of the requested extension.

The table below lists the name and addresses of each company selling or transporting pursuant to Part 284; the party receiving the gas; the date that the extension report was filed; and the effective date of the extension. A letter "B" in the Part 284 column indicates a transportation by an interstate pipeline which is extended under § 284.105. A letter "C" indicates transportation by an intrastate pipeline extended under § 284.125. A "D" indicates a sale by an intrastate pipeline extended under § 284.146. A "G" indicates a transportation by an interstate pipeline pursuant to § 284.221 which is extended under § 284.105. A "G(HS)" indicates transportation, sales or assginments by a Hinshaw Pipeline pursuant to a blanket certificate issued under Section 284.222 of the Commission's Regulations.

Any person desiring to be heard or to make any protests with reference to said extension report should on or before December 15, 1983, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214).

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 party to a proceeding.

Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

Docket No.	Transporter/seller	Recipient	Date filed	Part 284 subpart	Effective date
ST80-109-002	Cranberry Pipeline Corporation, P.O. Box 3710, Charleston, WV 25337.	Industrial Gas Corporation	Oct. 20, 1983	C	Jan. 16, 1984.
*ST82-150-001	Transcontinental Gas Pipe Line Corp., P.O. Box 1396, Houston, TX 77251.	Michigan Wisconsin Pipe Line Co	Oct. 19, 1983	G	Jan. 15, 1984.
ST82-169-001	United Gas Pipe Line Co., P.O. Box 1478, Houston, TX 77001	Monterey Gas Pipeline Co	Oct. 27, 1983	B	Jan. 26, 1984.
ST82-183-001	Southern Natural Gas Co., P.O. Box 2563, Birmingham, AL 35202	Tennessee Gas Pipeline Co	Oct. 17, 1983	G	Jan. 19, 1984.
ST82-189-001	Delhi Gas Pipeline Corp., Fidelity Union Tower, Dallas, TX 75201	Northern Natural Gas Co	Oct. 20, 1983	C	Jan. 25, 1984.
ST82-192-001	Natural Gas Pipeline Co. of America, 122 South Michigan Ave., Chicago, IL 60603.	Southwestern Gas Pipeline, Inc	Oct. 25, 1983	B	Jan. 26, 1984.
ST82-199-001	Houston Pipe Line Co., 1200 Travis, Box 1188, Houston, TX 77001	Texas Gas Transmission Corp	Oct. 27, 1983	C	Feb. 1, 1984.
ST82-200-001	Oasis Pipe Line Co., 1200 Travis, Box 1188, Houston, TX 77001	Texas Gas Transmission Corp	Oct. 27, 1983	C	Feb. 1, 1984.

* These extension reports were filed after the date specified by the Commission's Regulations, and shall be the subject of a further Commission order.

NOTE.—The noticing of these filings does not constitute a determination of whether the filings comply with the Commission's Regulations.

[FR Doc. 83-31413 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-4-002]

El Paso Natural Gas Co.; Petition To Amend

November 17, 1983.

Take notice that on October 31, 1983, El Paso Natural Gas Company (Petitioner), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP82-4-002 pursuant to Section 7(c) of the Natural Gas Act a petition to amend the Commission's order issued on July 27, 1982, in Docket No. CP82-4-000, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is stated that by the Commission's order issued July 27, 1982, Petitioner was authorized to transport up to 10,000 Mcf of natural gas per day for the account of Texas Gas Transmission Corporation (Texas Gas). Petitioner receives natural gas for the account of Texas Gas from Northwest Pipeline Corporation at the Ignacio Receipt Point in La Plata County, Colorado and delivers such quantities to Transcontinental gas Pipe Line Corporation (Trnasco) for the account of Texas Gas at three existing points of delivery located in Waller, Fort Bend, and Harris Counties, Texas.

Petitioner states that due to capacity constraints on Transco's system, Transco cannot continue to receive natural gas at the three existing delivery points in Waller, Fort Bend, and Harris Counties, Texas. Petitioner requests amendment of the Commission's July 27, 1982, order so as to delete authorization to deliver gas at the three existing delivery points and add, as a new delivery point, an existing point of interconnection between the facilities of High Island Offshore System and Michigan Wisconsin Pipeline Company (Michigan Wisconsin) in the West Cameron area, offshore Louisiana.

Petitioner explains that Michigan Wisconsin presently trnasports natural gas for Texas Gas through existing pipeline facilities from the proposed new delivery point in the West Cameron Area, offshore Louisiana, to two existing points of interconnection between the facilities of Michigan Wisconsin and Texas Gas in Cameron the Lafayette Parishes, Louisiana.

In addition, Petitioner requests authority to make certain conforming changes in its transportation agreement with Texas Gas that were necessitated by Petitioner's conversion to dekatherm billing and balancing.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 8, 1983, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practices and Procedure (18 CFR 385.214 or 385.211) 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31414 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP66-112-007 and CP71-223-003]

Great Lakes Gas Transmission Co.; Petition To Amend

November 17, 1983.

Take notice that on October 26, 1983, Great Lakes Gas Transmission Company (Petitioner), 2100 Buhl Building, Detroit, Michigan 48226, filed in Docket Nos. CP66-112-007 and CP71-223-003 pursuant to Sections 3 and 7 of the Natural Gas Act a petition to amend orders issued in Docket Nos. CP66-112 and CP71-223 [1] so as to authorize a proposal to continue importing, transporting, and exporting natural gas for the account of TransCanada PipeLines Limited (TransCanada), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Petitioner seeks authorization to extend, through November 1, 2005, a transportation contract between Petitioner and TransCanada dated Septembr 12, 1967, as amended, under which Petitioner transports up to 815,000 Mcf of natural gas per day.

It is further stated Petitioner proposes to import these volumes at an existing interconnection of the facilities of Petitioner and TransCanada near Emerson, Manitoba, and to export same by redelivery to TransCanada at points of interconnection between the facilities of Petitioner and TransCanada near Sault Ste. Marie and St. Clair, Michigan.

Applicant states that current authorizations would expire November 1, 1992.

Any person desiring to be heard or to make any protest with reference to said petition should on or before December 8, 1983, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

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. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31415 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ES84-13-000]

Gulf States Utilities Co.; Application

November 17, 1983.

Take notice that on November 9, 1983, Gulf States Utilities Company (Applicant) filed an application under Section 204(a) of the Federal Power Act authorizing the Applicant to issue not more than 3,000,000 shares of Preferred Stock via negotiated placement.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 8, 1983, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, petitions or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). The application is on file with the Commission and available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31416 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. SA84-1-000]

JM Resources; Petition for Adjustment

November 17, 1983.

On October 24, 1983, JM Resources (JM) P.O. Box 390, Cassadaga, New York, 14718, filed with the Federal Energy Regulatory Commission (Commission) a petition for adjustment under section 502(c) of the Natural Gas Policy Act of 1978 (NGPA), 15 U.S.C. 3301-3432 (Supp. V 1981), and 18 CFR 385.1101-385.1117 of the Commission's Rules of Practice and Procedure. JM seeks relief from § 270.101(e) of the Commission's regulations (18 CFR 270.101(e) (1983)), concerning the obligation to refund, with interest, amounts collected in excess of the applicable NGPA maximum lawful price.

JM's petition involves natural gas produced by JM's Lepp #4 and Knight-Kofoed #5 wells and sold to National Fuel Gas Corporation (National Fuel). Production from the Lepp #4 well began on July 2, 1980 and this production was sold to National Fuel at a price set under NGPA section 103. However, a section 103 well category determination application was not filed with the state jurisdictional agency until October 17, 1980. Likewise, the Knight-Kofoed #5 well began producing on December 3, 1979, and National Fuel paid the section 103 rate, although JM did not file a section 103 well category application until April 25, 1980. Under § 273.202 of the Commission's regulations, a seller may not begin collecting and NGPA rate until the seller has filed a well category application with the appropriate state jurisdictional agency. After National Fuel later discovered the filing dates of the section 103 applications for the subject wells, it demanded refunds with interest of the difference between the section 103 price and the alleged otherwise applicable maximum lawful price set out in NGPA section 109.

JM admits that the section 103 well category determinations were not filed until after production from the subject wells had already commenced. JM asserts, however, that National Fuel caused the late filing by delaying in supplying JM with contract information which JM believed was necessary for filing a complete FERC Form 121. JM states that a contract date and price are necessary to complete the FERC Form 121. JM alleges that the Knight-Kofoed #5 contract was requested from National Fuel by telephone in 1979 and not delivered until April 15, 1980, while production began on December 3, 1979. JM also alleges that the Lepp #4 contract was requested from National Fuel on May 13, 1980, and was not delivered until October 3, 1980, while production began on July 2, 1980. JM concludes that the filing delays were a direct result of National Fuel's lack of diligence. In addition, JM states that National Fuel did not send JM a copy of National Fuel's Interim Payment Guidelines, stating that no payments would be made until National Fuel received a FERC Form 121 from the producer, until 1981. JM states that it may well have delayed the start of production had it received these guidelines at an earlier date. JM concludes that these circumstances show that the imposition of a refund obligation with interest would place a disproportionate burden on JM and the royalty owners.

The procedures applicable to the conduct of this adjustment proceeding are found in Rules 1101-1117 of the Commission's Rules of Practice and Procedure, 18 CFR 385.1101-.1117.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of Rule 214 (18 CFR 385.214). All petitions to intervene must be filed within 15 days after publication of this notice in the **Federal Register.**

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31417 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-43-000]

National Fuel Gas Supply Corp., Request Under Blanket Authorization

November 17, 1983.

Take notice that on November 3, 1983, National Fuel Gas Supply Corporation (Supply), 10 Lafayette Square, Buffalo, New York 14303, filed in Docket No. CP84-43-000, as supplemented, a request pursuant to Sections 157.205 and 157.209 of the Regulations under the Natural Gas Act (18 CFR 157.205 and 18 CFR 157.209) that Supply proposes to transport natural gas for an eligible end user under the authorization issued in Docket No. CP83-4-000 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.

Supply proposes to transport up to 648 Mcf of gas per day and 236,520 Mcf of gas per year, for the account of Occidental Chemical Corporation (Occidental), to National Fuel Gas Distribution Corporation (Distribution) which, in turn, would deliver the gas to Occidental at Occidental's facilities in Niagara Falls, New York, pursuant to the terms of the Gas Transportation Agreement dated as of September 1, 1983 (Transportation Agreement).[1] Supply states that the current transportation rate is 29.14 cents per Mcf plus 2.0 percent retainage for shrinkage which is in accordance with its transportation Rate Schedule T-1. In addition, the current transportation rate charged by Distribution is currently 0.88 cent per Mcf plus the surcharge to reflect the tax rates applicable within the municipality where Occidental is taking service plus 2.5 percent of the gas for loss allowance in accordance with Distribution's New York Tariff (P.S.C. No. 7-Gas), it is asserted.

---

[1] The Transportation Agreement currently provides for a maximum daily volume of 471 Mcf. Supply is presently considering a request to increase this volume to 648 Mcf and is, therefore, requesting authorization to transport the higher volume.

Supply states that currently the Transportation Agreement does not provide for an added incentive charge (AIC); however, during the term of this service an AIC of 5.0 cents per Mcf would be applicable to it. It is indicated that at such time, the transportation charge by Supply for this service would be in accordance with its T-2 transportation rate schedule, which is presently 34.14 cents per Mcf plus 2.0 percent retainage for shrinkage. Occidental would use the gas transported by Supply for any eligible end use as set forth in § 157.209(e)(2) of the Regulations, it is asserted. Supply states that no new facilities are necessary to effectuate the proposed transportation. It is stated that the proposed transportation would commence on December 29, 1983, and terminate at 11:59 p.m. on June 30, 1985, or upon termination of the contract which term is for 3 months, effective September 1, 1983, and month to month thereafter, whichever occurs first.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31418 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GP84-3-000]

Nortex Gas and Oil Co.; Protest of Denial of Application for Section 102(c)(1)(C) Well Category Determination

November 17, 1983.

On October 21, 1983, the Nortex Gas and Oil Company (Nortex) filed a protest with the Federal Energy Regulatory Commission (Commission) pursuant to § 275.204 of the Commission's regulations. Nortex protests the denial by the Bureau of Land Management (BLM) of Nortex's application for a section 102(c)(1)(C) well category determination under the Natural Gas Policy Act of 1978, 15 U.S.C. 3301-3432 (Supp. V 1981) (NGPA). The well in question is the Nortex-Hart Federal No. 1-25X Well, located in Converse County, Wyoming.

On July 9, 1982, Nortex filed with BLM an application requesting a section 102(c)(1)(C) well category determination for the Nortex-Hart Federal No. 1-25X Well. Nortex states that it heard nothing from BLM until receiving notification on September 9, 1983, of a denial of the section 102(c)(1)(C) application.[1] The notice from BLM referred to a preliminary determination of August 12, 1983, but Nortex states that it never received notice of the preliminary determination. The notice also indicated that BLM denied the section 102(c)(1)(C) application because gas from two other wells, located in the same reservoir as the subject well, had produced and sold gas prior to April 15, 1977. Section 102(c)(1)(C) states that "new gas" qualifying for the section 102 incentive price includes, subject to certain listed exceptions, natural gas produced from a reservior from which natural gas was not produced in commercial quantities before April 20, 1977.

Nortex alleges that, had it received notification of BLM's preliminary negative determination, Nortex would have submitted supplemental information showing that while the two other wells produced from the same formation as the Nortex-Hart Federal No. 1.25X Well, they did not produce from the same reservior as defined in NGPA section 2(b). Section 2(b) defines "reservoir" to include:

> * * * any producible natural accumulation of natural gas, crude oil, or both, confined—
>
> (A) by impermeable rock or water barriers and characterized by a single natural pressure system; or
>
> (B) by lithologic or structural barriers which prevent pressure communication.

Nortex included the above-mentioned supplemental information in its protest petition.

Finally, Nortex indicates that the impact of the negative determination is significant. Nortex claims it will suffer a loss of revenues equal to the difference between the section 102 price and the section 103 price for all gas produced from the date of initial delivery until such time as a section 102 category determination can be obtained. Nortex therefore requests that the Commission reverse BLM's negative determination and find that the Nortex-Hart Federal No. 1-25X Well qualified under NGPA section 102(c)(1)(C) or, alternatively, remand the proceeding to BLM for reconsideration in light of the additional information submitted by Nortex with its petition. Nortex also requests that any determination in this proceeding be effective from the date of the filing of the original application with BLM.

Any person desiring to be heard or to make protest to this petition should file within 30 days after notice is published in the **Federal Register**, with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of Rules 211 or 214 of the Commission's Rules of Practice and Procedure. All protests filed will be considered but will not make the protestants to the proceeding.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31419 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[1] Notice of BLM's determination was received by the Commission on September 15, 1983, and was noticed in the **Federal Register** on October 6, 1983 (48 FR 45,698).

[Docket No. ER84-75-000]

Southern California Edison Co.; Filing

November 17, 1983.

The filing Company submits the following:

Take notice that on November 8, 1983, Southern California Edison Company (SCE) tendered for filing proposed changes in its FERC Electric Service Tariffs, time-of-use resale (TOU-R) schedule, hereafter called R-3, effective January 7, 1984, or 60 days after filing. Such tariff changes would increase jurisdictional sales and service by an estimated $42.6 million if applicable during the test year (the 12-month period ending December 31, 1984). The increase is proposed to be made effective in two steps. The Step 1 rate increase would be effective January 7, 1984, or 60 days after filing, and if applicable during the 12-month period ending December 31, 1984, the increase would amount to $280.9 million in revenues for the test year. The Step 2 rate increase would be effective January 8, 1984, or 61 days after filing, and would amount to an additional $9.9 million in revenues for the test year.

SCE states that the initial increase in charges in Step 1 rates averages an estimated 13.1 percent over current resale revenues. Step 2 would represent an additional 4.0 percent increase in resale revenues.

SCE further states that the reason for the proposed increases is the inadequacy of existing rates to cover

present and projected levels of operating costs, including a return component commensurate with the present and projected cost of capital.

Copies of the filing were served upon the utility's jurisdictional customers, the California Public Utilities Commission, and upon the Arizona Corporation Commission.

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, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before November 30, 1983. 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. 83-31420 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. EF84-4051-000]

Southwestern Power Administration; Filing

November 17, 1983.

Take notice that on November 14, 1983, the Assistant Secretary for Conservation and Renewable Energy submitted for filing Propopsed Rate Schedule TDC-82 for FERC confirmation and approval.

The Assistant Secretary states that this proposed rate schedule supercedes existing Rate Schedule TDC-2, which was confirmed and approved by the FERC for the period January 1, 1981, through September 30, 1983, in the Order issued July 31, 1981 under Docket No. EF81-4051-000. On August 31, 1983, the Assistant Secretary confirmed and approved Rate Schedule TDC-2 on an interim basis through March 31, 1984, to allow the FERC time to act on Proposed Schedule TDC-82.

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, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of practice and Procedure (18 CFR 385. 211, 385.214). All such motions or protests should be filed on or before December 2, 1983. 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. 83-31421 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CI84-49-000 and CI84-51-000]

Tenneco Oil and Conoco Inc.; Applications for Conditional Certificates of Public Convenience and Necessity

November 17, 1983.

Take notice that on November 2, 1983, Tenneco Oil Company (Tenneco) of 1100 Milam, Room 805, Houston, Texas 77002 and on November 3, 1983, Conoco Inc. (Conoco) of P.O. Box 2197, Houston, Texas 77252 filed conditional applications for permanent certificates of public convenience and necessity covering the sale of gas to El Paso Natural Gas Company (El Paso) from certain wells in the San Juan Basin of New Mexico. These filings were made because El Paso has asserted a right to reassign these certain wells and has instituted litigation with respect to the right to reassign these properties to applicants, *inter alia*, in *El Paso Natural Gas Co.* v. *Tenneco Oil Co., et al.*, No. 83-50539 (D.Ct., Harris County, Texas, 11th Judicial District).

Applicants state that the pendency of such litigation requires them to protect themselves and to ensure that all applicable laws are fully complied with. In the event El Paso's claims are rejected in that litigation, as applicants believe they must be, these petitions, and any certificates issued pursuant thereto, would be rendered *void ab initio* since applicants will have never become a first seller of natural gas.

Any person desiring to be heard or to make any protest with reference to said applications should on or before December 7, 1983, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determing the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the 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 on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates or the authorization for the proposed abandonment is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where 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 Applicants to appear or to be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31422 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CI84-54-000]

Zenith Exploration Co. et al.; Applications for Certificates, Abandonment of Service and Petitions To Amend Certificates [1]

November 17, 1983.

Take notice that each of the Applicants listed herein has filed an application or petition pursuant to Section 7 of the Natural Gas Act for authorization to sell natural gas in interstate commerce or to abandon service as described herein, all as more fully described in the respective applications and amendments which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before December 7, 1983, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All protests filed with the Commission will be considered

[1] This notice does not provide for consolidation for hearing of the several matters covered herein.

by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the 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 on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates or the authorization for the proposed abandonment is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where 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 Applicants to appear or to be represented at the hearing.

Kenneth F. Plumb,

Secretary.

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft.[a]	Pressure base
CI84-54-000, B, Oct. 31, 1983	Zenith Exploration Company	Consolidated Gas Supply, Steele District Field, Wood County, West Virginia.	[1]	
CI84-55-000 (CI81-144-000), B, Nov. 7, 1983.	Getty Oil Company, P.O. Box 1404, Houston, Texas 77001.	Consolidated Gas Supply Corporation, South Glenville Field, Gilmer County, West Virginia.	[2]	
CI84-56-000 (CI81-469-000), B, Nov. 7, 1983.	do	Cities Service Gas Company, Ames Field, Major County, Oklahoma.	[2]	
CI84-57-000 (CI81-149-000), B, Nov. 7, 1983.	do	Northern Natural Gas Company Bernstein Field, Hansford County, Texas.	[2]	
CI84-58-000 (CI81-368-000) B, Nov. 7, 1983.	do	Northern Natural Gas Company, Hansford Area, Ochiltree County, Texas.	[2]	
CI84-59-000 (CI81-156-000), B, Nov. 7, 1983.	do	Columbia Gas Transmission Corporation, Otter Field, Braxton and Gilmer Counties, West Virginia.	[2]	
CI84-60-000 (CI81-465-000), B, Nov. 7, 1983.	do	Transcontinental Gas Pipeline Company, Mosquito Bay Field, Terrebonne Parish, Louisiana.	[2]	
CI84-61-000 (CI81-319-000), B, Nov. 7, 1983.	do	El Paso Natural Gas Company, Epley A-1 and 2; Meeks 1 & 2; Frazier #1; Tunnell 11 & 1; Hill #1; Spraberry Trend Field, Glasscock County, Texas.	[2]	
CI84-62-000 (CI81-246-000), B, Nov. 7, 1983.	do	Cities Service Gas Company, Beaver and Texas Counties, Oklahoma.	[2]	
CI84-63-000 (CI80-183), B, Nov. 7, 1983.	do	Texas Eastern Transmission Corporation, Willow Springs Field, Gregg County, Texas.	[2]	
CI84-64-000 (CI61-835), B, Nov. 7, 1983.	do	Transwestern Pipeline Company, Mocane Field, Cimarron Field, Oklahoma.	[2]	
CI84-65-000 (CI81-132-000), B, Nov. 7, 1983.	do	Michigan Wisconsin Pipeline Company, El Reno Field, Canadian County, Oklahoma.	[2]	
CI84-66-000 (CI81-135-000), B, Nov. 7, 1983.	do	Northern Natural Gas Company, Mocane Field, Beaver County, Oklahoma.	[2]	
CI84-67-000 (CI81-134-000), B, Nov. 7, 1983.	do	Northern Natural Gas Company, Hansford Field, Ochiltree County, Texas.	[2]	
CI84-68-000 (CI81-143-000), B, Nov. 7, 1983.	do	Equitable Gas Company, South Glenville Field, Gilmer County, West Virginia.	[2]	
CI84-69-000 (CI81-157-000), B, Nov. 7, 1983.	do	Northern Natural Gas Company, N.E. Cedeardale Field, Woodward County, Oklahoma.	[2]	
CI84-70-000 (CI81-151-000), B, Nov. 7, 1983.	do	Consolidated Gas Supply Corporation, South Glenville Field, Gilmer Country, West Virginia.	[2]	
CI84-71-000 (CI81-145-000), B, Nov. 7, 1983.	do	Carnegie Natural Gas Company, Glenville Field, Gilmer County, West Virginia.	[2]	
CI84-72-000 (CI81-131-000), B, Nov. 7, 1983.	do	Southern Natural Gas Company, Bayou Sale Field, St. Mary Parish, Louisiana.	[2]	
CI84-73-000 (CI81-137-000), B, Nov. 7, 1983.	do	Equitable Gas Company, South Glenville Field, Gilmer County, West Virginia.	[2]	
CI84-74-000, B, Nov. 9, 1983	Carl W. Summerville	Consolidatd Gas, R.D.I. Albion Field, Erie County, Pennsylvania.	[4]	
CI84-75-000 (G-19214), B, Nov. 9, 1983.	Shell Oil Company, One Shell Plaza, P.O. Box 2463, Houston, Texas 77001.	United Gas Pipe Line Company, North Turtle Bayou, Terrebonne Parish, Louisiana.	[1]	
CI84-76-000 (CI81-141-000), B, Nov 7, 1983.	Getty Oil Company, P.O. Box 1404, Houston, Texas 77001.	Equitable Gas Company, South Glenville Field, Gilmer County, West Virginia.	[2]	
CI84-77-000 (CI81-148-000), B, Nov. 7, 1983.	do	Northern Natural Gas Company, Mocane Field, Beaver County, Oklahoma.	[2]	
CI84-78-000, A, Nov. 7, 1983	Pogo Producing Company, Post Office Box 61289, Houston, Texas 77208.	Texas Eastern Transmission Corporation, South Pass Blocks 33 and 49 and Mississippi Canyon Block 63, Offshore Louisiana.	[3]	15.025
CI84-79-000, B, Nov. 7, 1983	Warrent R. Haught, Agent, Route #3, Box 14, Smithville, West Virginia 26178.	Consolidated Gas Supply Corp., Murphy District, Ritchie County, West Virginia.	[2]	
CI84-80-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp., Murphy District, Richie County, West Virginia.	[2]	
CI84-81-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	
CI84-82-000, B, Nov. 7, 1983	Haught, Inc., Route #3 Boc 14, Smithville, West Virginia 26178.	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	
CI84-83-000, B, Nov. 7, 1983	Warren R. Haught, Agent, Route #3, Box 14, Smithville, West Virginia 26178.	Consolidated Gas Supply Corp. Murphy District, Ritchia County, West Virginia.	[2]	
CI84-84-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	
CI84-85-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	
CI84-86-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	
CI84-87-000, B, Nov. 7, 1983	do	Consolidated Gas Supply Corp. Murphy District, Ritchie County, West Virginia.	[2]	

[1] Depletion.

[2] On January 1, 1983, certain properties were assigned from Getty Oil Company to Getty Reserve Oil Inc. On August 16, 1983, Collete Oil Ventures, Inc. purchased all of the capital stock of Getty Reserve Oil, Inc.

[3] The only well under this contract—the Davis GU-E was plugged and abandoned in June of 1980. There are no plans for future drillings.

*The Wesley Hawkins No. 1 well was plugged and abandoned on May 8, 1981. This was the only well on the lease dedicated to this contract. The lease was then released on October 21, 1981.
*The Petree No. 7-1 was plugged and abandoned on February 24, 1982 and the oil and gas lease was released. This was the only well dedicated to the contract under this rate schedule.
*Do not choose to pay service fee.
*The 1120-acre Continental Land & Fur Company "E" Lease is beyond its primary term. The lease was maintained by CL&F "E" No. 3. Said well was abandoned in November 1978. Our geological interpretation indicates there are no propects for futher development on the lease.
*Applicant is willing to accept a certificate of public convenience and necessity conditioned in price to the applicable ceiling rates as established by the Natural Gas Policy Act of 1978.
*Low gas production.

Filing Code: A—Initial Service. B—Abandonment. C—Amendment to add acreage. D—Amendment to delete acreage. E—Total Succession. F—Partial Succession.

[FR Doc. 83-31427 Filed 11-22-83; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. QF83-440-000]

Small Power Production and Cogeneration Facilities; Abbott Energy, Inc.; Application for Commission Certification, of Qualifying Status

November 17, 1983.

On September 23, 1983, Abbott Energy, Inc., (Appliant) of P.O. Box 278, Barceloneta, Puerto Rico 00617, filed with the Federal Energy Regulatory Commission (Commission) an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's rules. On November 2, 1983, supplemental information was filed to complete the application.

The topping-cycle cogeneration facility will be located in Barceloneta, Puerto Rico. The facility will consist of a diesel generator set with waste heat recovery equipment. The useful thermal output will be hot water, which is used for refrigeration, and process steam. The primary energy source will be fuel oil No. 6. The electric power production capacity of the facility will be 20,230 kilowatts.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of publication of this notice and must be served on the applicant. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 83-31408 Filed 11-22-83; 8:45 am]
BILLING CODE 6712-01-M

[Docket No. CP83-203-001]

Transcontinental Gas Pipe Line Corp.; Notice of Amendment

November 17, 1983.

Take notice that on October 27, 1983, Transcontinental Gas Pipeline Corporation (Applicant), P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP83-203-001 an amendment to its pending application filed in Docket No. CP83-203-000 requesting authorization to acquire lease rights to certain compression facilities, all as more fully set forth in the amendment and application on file with the Commission and open to public inspection.

Applicant states that in Docket No. CP83-203-000 Applicant requested authorization to acquire lease rights to certain compressors located at South Marsh Island Block 66, offshore Louisiana. It is stated that such compressors had been previously installed and placed into operation by Aminoil USA (Aminoil), Amerada Hess Corporation (Amerada Hess), The Louisiana Land & Exploration Co. (LL&E), and Union Texas Petroleum Corporation (Union Texas) pursuant to preliminary discussions and eventual consummation of a letter agreement providing for installment and reimbursement of such compressors.

Applicant has amended its application by including assignment of lease rights between Aminoil as operator of the production facilities at South Marsh Island Block 66 and Applicant. It is stated that the lessors of the compressors have further provided Applicant with a consent to the referenced assignment.

Applicant states that since it would no longer attempt to recover historical costs associated with the compressors, estimated costs for lease and removal of the facilities has been adjusted downward from $3,359,017 to $664,030.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before December 8, 1983, filed with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,
Secretary.

[FR Doc. 83-31423 Filed 11-22-83; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. CI77-18-002, et al.]

TXP Operating Co. (Successor in Interest to Transco Exploration Co) et al.; Application of Succession in Interest From Transco Exploration Company to TXP Operating Company

November 17, 1983.

Take notice that on July 22, 1983, and November 2, 1983, TXP Operating Company (TXP), of P.O. Box 1396 Houston, Texas 77251, as successor in interest to Transco Exploration Company (Transco), filed an application to amend certain certificates currently held by Transco to show TXP as certificate holder and to redesignate the related rate schedule listed in the attached appendix.

Effective as of July 20, 1983, Transco assigned its interest in certain properties to TXP. As a result of such assignments, TXP acquired all of the interest of Tranco in the properties which are subject to the certificates of public convenience and necessity issued to Transco in the dockets listed in the attached appendix.

Any person desiring to be heard or to make any protest with reference to said applications should on or before December 6, 1983 file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to

intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). 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. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rule.

Take further notice that, pursuant to authority contained in and subject to the 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 on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates or the authorization for the proposed abandonment is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where 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 Applicants to appear or to be represented at the hearing.

Kenneth F. Plumb,

Secretary.

APPENDIX

Rate Schedule No.	Certificate Docket No.	Purchaser
7	C177-16-000	Transcontinental Gas Pipe Line Corporation
24	C178-431-000	Do.
27	C178-1060-000	Do.
32	C178-561-000	Do.
33	C178-586-000	Do.
34	C178-773-000	Do.
36	C178-818-000	Do.
37	C179-169-000	Do.
41	C179-335-000	Do.
51	C180-216-000	Do.
54	C180-346-000	Do.
56	C180-348-000	Do.
58	C181-75-000	Do.
59	C181-89-000	Do.
61	C181-508-000	Do.
62	C182-196-000	Do.
64	C183-3-000	Do.
65	C183-121-000	Do.
66	C183-155-000	Do.
4	C175-667-001	Do.
5	C176-210-001	Do.
28	C178-550-001	Columbia Gas Transmission Corporation
40	C179-296-001	Trunkline Gas Company
45	C179-504-001	Transcontinental Gas Pipe Line Corporation
46	C180-58-001	Do.
47	C180-57-001	United Gas Pipe Line Company

APPENDIX—Continued

Rate Schedule No.	Certificate Docket No.	Purchaser
48	C180-32-001	Transcontinental Gas Pipe Line Corporation
49	C180-71-001	Michigan Wisconsin Pipe Line Company
50	C180-169-001	United Gas Pipe Line Company
52	C180-244-001	Michigan Wisconsin Pipe Line Company
53	C180-293-001	Transcontinental Gas Pipe Line Corporation
55	C180-347-001	Do.
57	C180-376-001	Trunkline Gas Company
60	C181-225-001	Transcontinental Gas Pipe Line Corporation
63	C182-410-002	Texas Eastern Transmission Corporation

[FR Doc. 83-31424 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP84-39-000]

United Gas Pipe Line Co.; Request Under Blanket Authorization

November 17, 1983.

Take notice that on October 28, 1983, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP84-39-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) that United proposes to transport gas on behalf of American Cyanamid Company (American Cyanamid) under the authorization issued in Docket No. CP82-430-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file and open to public inspection.

United proposes to receive from American Cyanamid up to 8,500 million Btu per day on a firm basis from various points in Jackson, Cameron, Caddo and Calcasieu Parishes, Louisiana, and redeliver thermally equivalent volumes to American Cyanamid at an existing metering and regulating station near Pensacola, Florida.

United estimates peak day and average day transportation volumes of 8,500 million Btu and annual volumes of 3,102,500 million Btu. United proposes to charge the transportation rate for its Northern Rate Zone (currently 49.05¢ including a component for gas consumed in the operation of United's pipeline system) as reflected on Sheet 4-C of its FERC Gas Tariff, First Revised Volume No. 1. United indicates that no new facilities would be required and that no intermediate transporter is involved. Also, United asserts that it has been advised by American Cyanamid that the gas would be used at American Cyanamid's acrylic-fiber plant at Milton, Florida, for boiler fuel.

United also asserts that American Cyanamid has purchased its gas supplies from Gulf South Pipeline Company (Gulf South), an intrastate pipeline, from Gulf South's system supply.

It is stated that the gas supply contract provides that American Cyanamid would take or pay for a minimum daily volume of 75 percent of the 8,500 million Btu maximum daily delivery obligation with no makeup. It is asserted that the contract does provide that if the price of gas plus transportation exceeds the delivered price of 2.5 percent sulfur, No. 6 fuel oil, Gulf South either would reduce its price to the delivered fuel oil price or would waive the minimum bill provision.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31425 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GP84-4-000]

United Gas Pipe Line Co.; Complaint and Petition for Declaratory Order

November 17, 1983.

On October 25, 1983, the United Gas Pipe Line Company (United) filed a complaint with the Federal Energy Regulatory Commission (Commission) against Robert E. Strief, Herry J. Strief, Jr., the Estate of John R. Scott, Pickens Energy Corportion, The Pickens Company, W. H. Oberthier, R. C. Oberthier, M. H. Marr, James Denny Barkell, Charles Frederick Bartell and the Estate of Patricia Pickens Barrett (hereafter referred to jointly as "Respondents"), alleging the Respondents have collected a price in exces of maximum lawful prices set by the Natural Gas Policy Act of 1978 (NGPA), 15 U.S.C. 3301-3422 (Supp. V

1981), for gas sold to United from the Emma Eddy No. 3 Well located in the Carthage Field, Panola County, Texas. United requests that the Commission order refunds under § 270.101(e) (18 CFR 270.101(e) (1983)) of the Commission's regulations and that the Commission declare that the applicable maximum lawful price for gas produced from the Emma Eddy No. 3 well is that price set under NGPA section 103.

In its complaint, United states that it purchases natural gas produced from the Emma Eddy No. 3 well from Respondents pursuant to a gas purchase contract dated March 1, 1976. Getty Oil Company (Getty) is the operator of the well. Respondents own a non-operating, minority working interest. Getty drilled and completed the subject well during 1981 in a tight sands formation designated pursuant to § 271.703 of the Commission's regulations. United purchases the production from Getty's interest in the Emma Eddy No. 3 well under a separate gas purchase contract. United notes that United and Getty renegotiated their contract before Getty drilled the Emma Eddy No. 3 well to include language satisfing the "negotiated contract price" requirement set out in § 271.703 and defined in § 271.702 of the Commission's regulations. United alleges that the contract with respondents was not renegotiated to include "negotiated contract price" language and therefore, under § 271.703, respondents may not lawfully charge the section 107(c)(5) tight sands incentive price for their portion of production from the Emma Eddy No. 3 well. United contends that Respondents may charge only the otherwise applicable maximum lawful price, which is the price established under NGPA section 103.[1]

United states, however, that it mistakenly paid to Respondents the section 107(c)(5) incentive price for gas purchases from November 9, 1981 through July 1982. United later discovered the mistake and notified Respondents by letter dated September 8, 1982. In that letter, United informed Respondents that United would recover the overpayment, alleged to be $461,647.80 from Respondents' future sales to United. United states that as of September 25, 1983, $120,623.82 exclusive of interest, remained to be recovered from Respondents. By letter on that date, United demanded refund of the balance with interest. Meanwhile, United notes, Respondents have filed suit in state court to recover the amount withheld by United after September, 1982, and receive prospectively from September, 1982, the section 107(c)(5) incentive price for gas produced from the Emma Eddy No. 3 well.

In its complaint, United requests that the Commission order Respondents to refund the remaining balance of payments made by United to Respondents in excess of the section 103 price, and declare that the section 103 price is the maximum lawful price applicable to Respondents' interest in gas produced from the Emma Eddy No. 3 well. In support of its complaint, United argues that the Commission has exclusive jurisdiction to enforce NGPA maximum lawful prices and also to police the section 107(c)(5) eligibility requirements. United contends that it is clear from the face of the gas purchase contract with Respondents that the contract contains no "negotiated contract price," and therefore does not confer eligibility on Respondents to collect the section 107(c)(5) incentive price for gas sold under the contract. United contends that the otherwise applicable maximum lawful price is the NGPA section 103 price, and because Respondents have collected a price in excess of the section 103 rate, these over collections must be refunded with interest to United.

Any person desiring to be heard or to make any protest or answer to this complaint should file, with in 30 days after notice is published in the **Federal Register**, with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, a motion to intervene or a protest or answer in accordance with requirements of Rules 211, 213, or 214 of the Commission's Rules of Practice and Procedure. All protests filed will be considered but will not make the protestants parties to the proceeding.

Kenneth F. Plumb,

Secretary.

[FR Doc. 83-31426 Filed 11-22-83; 8:45 am]

BILLING CODE 6717-01-M

[1] The section 103 well category application for the Emma Eddy No. 3 Well was filed with the Texas Railroad Commission on November 9, 1981. The affirmative determination was received by the Commission on June 4, 1982, and became final on July 9, 1982.

Office of Conservation and Renewable Energy

[F-011]

Energy Conservation Program for Consumer Products; Petition for Waiver of Furnace Test Procedures From The Coleman Company, Inc.

AGENCY: Conservation and Renewable Energy Office, DOE.

ACTION: Notice.

SUMMARY: Today's notice publishes a "Petition for Waiver" from The Coleman Company (Coleman) of Wichita, Kansas, requesting a waiver from the existing Department of Energy (DOE) test procedures for furnaces. Coleman manufactures residential and commercial heating appliances. The firm has developed a line of high efficiency, gas-fired warm air furnaces that will recover latent heat by condensing water vapor in the products of combustion before they exit the furnace. The petition requests DOE to grant relief from the test procedure requirements relating to the efficiency attributable to the condensing of flue gases. Coleman seeks to use a National Bureau of Standards (NBS) condensate test method for determining AFUE and steady-state efficiency instead of the present DOE test procedures which base condensation calculations on the average flue gas temperature. Also, the firm seeks to eliminate the one and one-half minute delay DOE requires between burner on and blower on during heat-up tests. DOE is soliciting comments, data, and information respection the petition.

DATE: DOE will accept comments, data and information not later than December 23, 1983.

ADDRESSES: Written comments and statements shall be sent to: Department of Energy, Office of Conservation and Renewable Energy, Case No. F-011, Mail Stop CE-112.1, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585.

FOR FURTHER INFORMATION CONTACT:

Michael J. McCabe, U.S. Department of Energy, Office of Conservation and Renewable Energy, Mail Station CE-112.1, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585, (202) 252-9127.

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Cousel, Mail Station GC-33, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585, (202) 252-9513.

SUPPLEMENTARY INFORMATION:

Background

The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act (EPCA), Pub. L. 94-163, 89 Stat. 917, as amended by the National Energy Conservation Policy Act (NECPA), Pub. L. 95-619, 92 Stat. 3266, which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer

products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at 10 CFR Part 430, Subpart B.

DOE has amended the prescribed test procedures by adding 10 CFR 430.27, Petitions for Waiver, to allow the Assistant Secretary for Conservation and Renewable Energy temporarily to waive test procedures for a particular basic model. 45 FR 64108 (September 26, 1980). Waivers may be granted when one or more design characteristics of a basic model either prevent testing of the basic model according to the prescribed test procedures or lead to results so unrepresentative of the model's true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of the waiver.

Coleman's petition seeks a waiver from the DOE test method basing condensation calculations on the average flue gas temperature. Instead, Coleman requests the use of the condensate measuring method as set forth in Appendix C of National Bureau of Standards' Interagency Report 80-2210, "Recommended Testing and Calculation Procedures for Estimating the Seasonal Performance of Residential Condensing Furnaces and Boilers," dated April 1980, to determine the AFUE of its condensing furnace. The firm also is requesting the use of the condensate measurement method for determining the steady-state efficiency improvement of its condensing furnace instead of using the flue loss method in the existing test procedures. Finally, the firm is requesting to be waived from DOE's test requirements regarding time delays between burner on and blower on during heat-up tests.

Pursuant to paragraph (b) of 10 CFR 430.27, DOE is hereby publishing the "Petition for Waiver" in its entirety. The petition contains no confidential information. DOE solicits comments, data, and information respecting the petition.

Issued in Washington, D.C., November 15, 1983.

Pat Collins,

Acting Assistant Secretary, Conservation and Renewable Energy.

The Coleman Company, Inc.

Heating & Air Conditioning Group, P.O. box 1762, Wichita, Kansas 67201. Telephone 316-261-3211; (316) 832-6548

September 9, 1983.

Assistant Secretary for Conservation and Solar Energy,

United States Department of Energy, Washington, D.C. 20549

Re: Petition for Waiver

Gentlemen: This is a petition for waiver from the test procedures of 10 CFR Part 430, Subpart B, Appendix N, dated August 12, 1980, made pursuant to 10 CFR 430.27 by The Coleman Company Inc., 250 N. St. Francis Street, Wichita, Ks 67202.

The Coleman Company, Inc., is a manufacturer of gas fired heating equipment intended for installation in conventional residential housing, manufactured housing and light commercial applications. It is preparing to offer a gas fired, forced air, condensing line of furnaces (designated 90 series) for these applications. The procedures specified in 10 CFR 430 subpart B, Appendix N yield results which fail to provide credit for an efficiency improvement of between 1% and 3% yielded by the condensing mode of operation. Reporting of the results pursuant to the standard measurement procedures could materially mislead members of the consuming public, would encourage installation of less efficient equipment and would cause economic harm to Coleman.

In order to more accurately report the characteristics of its equipment, Coleman requests a waiver authorizing optional use in its laboratory of the procedures specified in the April 1981 National Bureau of Standards Interagency Report 81-2110 "Recommended Testing and Calculation Procedures for Estimating the Seasonal Performance of Residential Condensing Furnaces and Boilers" at Appendix C. In addition, Coleman requests a waiver authorizing the use of the condensate measurement test method to determine steady-state efficiency which is used in calculating furnace heating capacity. The use of these procedures is described in a proposed amendment to "Appendix N to Subpart B of Part 430—"Uniform Test Method for Measuring the Energy Consumption of Furnaces" at section 3.6 published in the June 17, 1983 **Federal Register** (48 FR 28028)

The Coleman Company, Inc. Further petitions for a waiver from Section 3.3.1 "Flue Gas Temperature Measurements-Heat-up Test" of Appendix N to Subpart B of Part 430. Section 3.3.1 requires a delay of 1.5 minutes between burner start up and blower start up. The equipment to be offered by petitioner utilizes a time delay relay which activates the blower approximately 20 seconds after burner start up regardless of ambient air temperature and for other factors. A delay of 1.5 minutes causes stack temperature overshoot which reduces the recovered latent heat of condensation by approximately 1%. The method specified in the Regulation, therefore improperly yields lower efficiency results materially misrepresentative of what would actually be achieved by one of these furnaces when installed as intended.

Amana Refrigeration, Inc., Hyrotherm, Inc., Duo-Matic/Olsen, Inc., Lennox Industries, Heil Quaker Corporation and Arkla Industries offer equipment sharing certain of the Characteristics of the subject Coleman base model.

I respectfully request prompt and favorable action on this petition by the Assistant Secretary. You may contact me if additional information is required.

Very truly your,

William Harrigill,

Design Engineer.

[FR Doc. 83-31452 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

Western Area Power Administration

Fort Peck-Havre Transmission Lines Project; Record of Decision To Construct

AGENCY: Western Area Power Administration, DOE.

ACTION: Record of Decision to Construct the Fort Peck-Havre Transmission Line Project, Montana.

SUMMARY:

Decision: The Western Area Power Administration (Western) has made the decision to construct the Fort Peck-Havre, Montana, transmission line following the environmentally preferred alternative identified in the draft and final environmental impact statement (EIS). The transmission line will be constructed on wood pole H-frame structures to 230-kV design standards and initially operated at 161-kV. Western will proceed with land and right-of-way (ROW) acquisition, construction, and subsequent operation and maintenance of the proposed facilities. The availability of the final EIS for the project was announced in the **Federal Register** by the Environmental Protection Agency on July 29, 1983.

Western has adopted the mitigation measures listed in the EIS. A specific mitigation plan for cultural resource impacts will be developed in consultation with the Montana State Historic Preservation Officer (SHPO) and this plan will be implemented before construction. In addition, any site specific mitigation requirements identified during subsequent construction will be addressed by Western and coordinated with appropriate Federal, State, or local agencies. General mitigation measures are discussed below.

Background

The existing Fort Peck-Havre 161-kV transmission line was constructed in 1935 to provide electrical energy for the construction of Fort Peck Dam. The line remains an essential element in Western's system and the interconnected electric transmission system in Montana. Because of its age and outdated design, the wood pole H-frame structure, grounding system, crossarms, and hardware have begun to deteriorate, making maintenance of the line costly and operations unreliable.

In 1979, Western began a planning process to determine alternative courses of action to insure adequate and reliable electrical service to the area between Fort Peck and Havre in northern Montana. In November 1979, Western conducted a series of scoping meetings with Federal, State and local agencies; the Fort Belknap Indian Reservation; and the public in Glasgow, Malta, Chinook, and Havre, Montana, to identify the key issues and concerns related to the project. Primary concerns identified during the scoping meetings included floodplains and wetlands, wildlife refuges and other habitat, threatened or endangered species, esthetics, the economic implications of alternatives, planned and existing residential areas, irrigated or potentially irrigable agricultural lands, the Fort Belknap Indian Reservation, and cultural resources on or eligible for the National Register of Historic Places (National Register).

Following the scoping meetings, Western evaluated the resources within a study area to identify potential transmission line corridors.

Areas were identified of opportunity, least impact, avoidance, and exclusion for transmission line construction.

In December 1980, in order to present the environmentally preferred corridor and solicit comments, Western conducted a total of 11 planning workshops with Federal, State, and local agencies and the general public at Glasgow, Malta, Harlem, and Havre Montana. Western defined the environmentally preferred corridor and conducted a second series of five public planning workshops during March 1981. Additional refinements were followed by a public planning workshop in Glasgow, Montana, in August 1981.

In June 1982, the draft EIS was published. Western's proposed action, all of the reasonable alternatives considered, and the environmental impacts of the proposal and the alternatives were evaluated in the draft. The alternatives are discussed below. Public hearings on the draft EIS were conducted in Glasgow, Malta, Harlem, and Havre, Montana, in July 1982, and written and oral comments were received. A group of residents in a subdivision near Havre, Montana, objected to the proposed line being routed on or near their property and suggested that a study be made of routing across nearby State-owned land. The State land is the Northern Montana Agricultural Research Center (NMARC) which is part of the Fort Assinniboine site, a former U.S. Army outpost which Western and the SHPO agree is eligible for inclusion on the National Register. A special public workshop was conducted in Havre, Montana, in August 1982, and the draft EIS comment period was extended to October 1982, to provide more opportunity for affected parties to be heard. In order to adequately respond, Western conducted a detailed local siting study of the Fort Assinniboine area. The siting study considered potential impacts on historical and archeological resources, Native American interests, visual resources, floodplains and wetlands, existing and future economic and experimental agricultural land use, and residential and recreational land use. In November 1982, the results of the study were presented to administrators of the NMARC, the SHPO, and the public. A revised environmentally preferred corridor was identified that would span a future range experiment plot, cross a NMARC economic agriculture plot, and cross a portion of the Fort Assinniboine historic site. The significant features of the historic site would be avoided.

Description of Alternatives: The alternatives considered by Western were:

1. No Action—Western would construct no new transmission facilities between Fort Peck and Havre. The existing line would be kept in service and maintained by treating wood-pole structures with preservative and replacing structures as they give indication of failure and hardware as it deteriorates.

2. Energy conservation—Western encourages energy conservation which eliminates wasteful or unnecessary uses of energy resulting in the reduction of energy consumption and documented adverse environmental impacts. However, in this instance, Western's need is not to reduce energy consumption but to replace an existing deteriorating transmission line that provides the only means of transferring hydroelectric power out of the Fort Peck powerplant to the west and bulk power to substations between Fort Peck and Havre for distribution to ultimate consumers.

3. Alternative Technologies—Construct a direct current (dc) transmission system as an alternative to an alternating current (ac) system or construct an underground system.

4. Design Alternatives—The existing Fort Peck-Havre line is operated at 161-kV, the minimum voltage considered feasible to provide adequate outlet transmission for Fort Peck generation and capacity for loads served by the line. Western considered 161-kV, 230-kV, and 345-kV construction. Also considered was elimination of one or more of the existing or planned intermediate interconnections at Harlem, Richardson Coulee, and Malta. Two types of structures were considered for the line, steel lattice and wood pole H-frame.

5. Routing Alternatives—A total of more than 600 miles of alternative corridors, each 2,000 feet wide, were studied. These corridors were subdivided into sets between each substation between Fort Peck and Havre. Each set consisted of a number of paths made up of continuous links. Set I, between Fort Peck and Richardson Coulee, consisted of 10 paths made up of 13 links. Set II, between Richardson Coulee and Malta, consisted of 19 paths made up of 21 links. Set III, from Malta to Harlem, consisted of 13 paths made up of 12 links. Set IV, from Harlem to Havre, consisted of 11 paths made up of 15 links. The Fort Assinniboine local siting study southwest of Havre consisted of one set made up of 13 links.

Basis of Decision—Western's no action alternative was eliminated because its implementation would constitute virtually rebuilding the line in a piecemeal fashion on the existing right-of-way without adding overhead grounding, improving system reliability, or taking advantage of opportunities to improve the location of the line and reduce impacts on cultivated land.

Since energy conservation can only affect energy demand but not provide the means of transmitting electric power or eliminate the need for the transmission of power, it was determined not to be an alternative action for meeting the stated need.

Alternative technologies were eliminated. A dc system with the power-transfer capability of a 230-kV ac line would cost approximately two to three times as much as a 230-kV ac line with, on balance, no apparent environmental benefits. Underground systems were eliminated because of uncertain reliability due to present technological limitations, the risk of prolonged outages, significantly higher costs (8 to 10 times higher), and greater

environmental impacts due to trenching and above-ground ancillary facilities.

The 345-kV alternative was eliminated because of increased costs and no foreseeable need for a transmission line of such capacity. Line performance analysis of 161-kV and 230-kV systems for this project indicated that line losses of a 230-kV system would be lower than 161-kV; the 230-kV alternative affords better voltage performance and regulation, has greater transfer capability because of lower impedance, and is less vulnerable to instability. Therefore, Western decided to construct the line to 230-kV standards with initial operation at 161-kV.

Elimination of one or more of the existing or planned intermediate interconnections was rejected because each of the interconnections is essential to the 69-kV distribution system serving local loads of Western, the Montana Power Company, and the Basin Electric Power Cooperative between Fort Peck and Havre, Montana.

Because of economic factors and environmental considerations including primarily esthetic and agricultural impacts, wood pole H-frame structures were selected rather than steel lattice.

A resource inventory of the environmental study area identified exclusion and avoidance areas, and areas of least potential impact and opportunity for transmission line routing. The alternative paths within each set were compared and ranked by an interdisciplinary environmental study team. The environmentally preferred paths from the four sets were then combined to form the environmentally preferred corridor for the project. Based on further studies of the environmentally preferred corridor and input from public planning workshops, it was identified as Western's preferred corridor in the draft and final EIS.

Mitigation

All practicable means to avoid or minimize environmental harm from Western's preferred alternative were identified in the draft and final EIS. Western will incorporate these measures in the proposed project and special environmental requirements for sensitive or fragile areas will be included in the project construction specifications including requirements for right-of-way clearing and site preparation, tower erection, conductor stringing, timing of construction, and for the protection of archeological and historical resources. Western's project specifications will incorporate additional specific mitigation measures developed during consultation with other Federal and State agencies.

Western project inspectors will be fully familiarized with the project mitigation measures and will insure their implementation during construction. In crossing Federal and State lands, Western will work with the appropriate agencies to insure that representatives from the agencies are able to perform their monitoring functions as agreed during the consultation process.

A cultural resource mitigation plan will be developed in consultation with the SHPO and the specifications will incorporate the plan. The specifications will provide that in the event previously undiscovered cultural resources are encountered during the construction of the line, activities which could jeopardize those resources will cease until a qualified archeologist or historian can evaluate their significance and recommend appropriate steps for their disposition.

Western will monitor project construction and reclamation activities to insure that construction standards and site specific mitigation requirements are met. The mitigation measures which have been adopted are generally self-executing through Western's standard construction procedures and the construction contract specifications.

Integration With Other Requirements

Under requirements of the Intergovernmental Coordination Act, Western notified the Montana State Clearinghouse of the project by sending it copies of the draft and final EIS. Western coordinated project planning with other Federal and State agencies. Closely involved in the project were the Bureau of Land Management, designated as a cooperating agency, and the Montana DNRC, which served in an advisory and review capacity. Also involved were the SHPO, the Advisory Council on Historic Preservation, and the U.S. Fish and Wildlife Service.

Western will obtain any necessary permits in accordance with the Federal Clean Air and Clean Water Acts. Copies of this ROD will be sent to the Montana State Clearinghouse, appropriate Federal and State agencies, and to other agencies, organizations, and individuals commenting on the draft or final EIS.

FOR FURTHER INFORMATION CONTACT: Mr. James Davies, Area Manager, Billings Area Office, Western Area Power Administration, P.O. Box EGY, Billings, MT 59101. Telephone: (406) 657-6532.

Issued at Golden, Colorado, September 21, 1983.

Robert L. McPhail,

Administrator.

[FR Doc. 83-31403 Filed 11-22-83; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[PF-351; PH-FRL 2475-S]

Certain Companies; Pesticide, Food, and Feed Additive Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received pesticide, food, and feed additive petitions relating to the establishment, amendment, and/or withdrawal of tolerances for residues of certain pesticide chemicals in or on certain commodities.

ADDRESS: Written comments identified by the document control number [PF-351], should be submitted by mail to:

Program Management and Support Division (TS-757C), Attn: Product Manager (PM) 21, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, deliver comments to: Rm. 236, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington VA 22202.

Written comments may be submitted while the petitions are pending before the Agency. All written comments filed in response to the notice will be available for public inspection in the PM's office from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Henry Jacoby, PM-21, (703-557-1900).

SUPPLEMENTARY INFORMATION: EPA gives notice that the Agency has received the following pesticide, food, and feed additive petitions relating to the establishment, amendment, and/or withdrawl of certain pesticide chemicals in or on certain commodities in accordance with the Federal Food, Drug, and Cosmestic Act. The analytical method for determining residues, where required, is given in each petition.

I. Initial Filings

1. *PP 3F2964.* Rhone-Poulenc Inc., Agrochemical Division, P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852. Proposes amendment 40 CFR 180.399 by establishing tolerances for the combined residues of the fungicide

iprodione in or on the following commodities as follows:

a. Iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboximide], its isomer (3-(1-methylethyl)-*N*-3, 5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboximide], and its metabolite [3-(3,5-dichlorophenyl)-2, 4-dioxo-1-imidazolidine-carboximide] in or on the commodity grapes at 60 parts per million (ppm).

b. Iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2, 4-dioxo-1-imidazolidinecarboxamide] and its non-hydroxylated metabolites (expressed as iprodione equivalents) in or on the commodities eggs at 0.8 ppm, fat, meat and meat byproducts (except kidney and liver) of cattle, goats, hogs, horses, and sheep at 0.4 ppm; and kidney and liver of cattle, goats, hogs, horses, and sheep at 3.0 ppm.

c. Iprodione [3(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2, 4-dioxo-1-imidazolidinecarboxamide] and its non-hydroxylated and hydroxylated metabolites (expressed as iprodione equivalents in or on the commodity milk at 0.3 ppm. The analytical method for determining residues is thin-layer chromatography.

2. *FAP 4H5415.* Rhone-Poulenc Inc. Proposes amending 21 CFR Part 193 by establishing a regulation permitting residues of the fungicide iprodione [3-(3, 5-dichlorophenyl)-*N*-(1-methylethyl)-*N*-3, 5-dichlorophenyl)-2, 4-dioxo-1-imidazolidinecarboximide], its isomer [3-(1-methylethyl)-*N*-3, 5-dichlorophenyl)-2, 4-dioxo-1-imidazolidinecarboximide], and its metabolite [3-(3, 5-dichlorophenyl)-2, 4-dioxo-1-imidazolidinecarboximide] in or on the commodity raisins at 300 ppm.

3. *FAP 4H5415.* Rhone-Poulenc Inc. Proposes amending 21 CFR Part 561 by establishing a regulation permitting residues of the fungicide iprodione as expressed in I.2. above, in or on the commodities raisin waste at 1,000 ppm and dried grape pomace at 225 ppm.

4. *PP 4F2975.* Merck & Co., Inc., 126 E. Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065. Proposes amending 40 CFR 180.242 by establishing tolerances for residues of the fungicide thiabendazole (2-(4-thiazolyl) benzimidazole in or on the commodity beans, dry at 0.1 ppm. The analytical method for determining residues is spectrophotofluorometric analysis.

II. Amended Petitions

1. *PP 2E2736.* Merck & Co. EPA issued a notice published in the **Federal Register** of September 29, 1982 (47 FR 42805) which announced that Merck & Co. had submitted pesticide petition 2E2736 to the Agency proposing to amend 40 CFR 180.242 by establishing tolerances for the residues of the fungicide thiabendazole in or on the raw agricultural commodities cantaloupes at 12.0 ppm, strawberries at 5.0 ppm., and tomatoes at 0.5 ppm.

Merck & Co. has amended the petition by deleting the commodity tomatoes and increasing the tolerance on cantaloupes from 12.0 ppm to 15.0 ppm. The proposed analytical method for determining residues is spectrophotofluorometrical analysis.

2. *PP 3F2840.* Rhone-Poulenc Inc. EPA issued a notice published in the **Federal Register** of April 6, 1983 (48 FR 15002) proposing to amend 40 CFR 180.399 by establishing tolerance for the combined residues of the fungicide iprodione [3-(3, 5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidine-carboxamide], its isomer [3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in or on the commodity lettuce at 7.0 ppm and garlic at 0.1 ppm.

Rhone-Poulenc Inc. has amended the petition by redesignating the commodity from "lettuce" to "lettuce (head)" and increasing the tolerance level to 15.0 ppm. The analytical method for determining residues is gas-liquid chromatography with electron capture detector.

3. *PP 2F2590.* EM Industries Inc., Plant Protection Division, 5 Skyline Drive, Hawthorne, NY 10532. EPA issued a notice published in the **Federal Register** of December 16, 1981 (46 FR 61331) which announced that EM Industries Inc. had submitted pesticide petition 2F2590 to the Agency proposing to amend 40 CFR 180.382 by establishing tolerances for residues of the fungicide triforine [*N,N'*-(1,4-piperazinediyl-bis(2,2,2-trichloroethylidene)]-bis-[formamide]] in or on the raw agricultural commodities almonds at 0.01 ppm and almond hulls at 0.1 ppm.

EM Industries Inc. has amended the petition by increasing the tolerance level on almond hulls from 0.1 ppm to 0.2 ppm. The proposed analytical method for determining residues is gas chromatographic technique.

4. *PP 2F2729.* Pennwalt Corp., Agrochemicals Division, Three Parkway, Philadelphia, PA 19102. EPA issued a notice published in the **Federal Register** of August 25, 1982 (47 FR 37287) which announced that Pennwalt Corp. has submitted pesticide petition 2F2729 to the Agency proposing to amend 40 CFR 180.371 by establishing tolerances for the combined residues of the fungicide thiophanate-methyl (diemthyl [(1,2-phenylene) bis (iminocarbonothioyl)] bis[carbamate]), its oxygen analogue dimethyl-4,4'-*O*-phenylenebis (allophanate), and its benzimidazole-containing methabolites (calculated as thiophanate-methyl) in or on the raw commodities cucumbers, melons, pumpkins, and squash at 1.0 ppm; grapes (fresh) at 10.0 ppm; rice at 5.0 ppm; and rice straw at 15.0 ppm.

Pennwalt Corp. has amended the petition by deleting fresh grapes, rice, and rice straw.

III. Withdrawal of Petitions

EPA issued a notice published in the **Federal Register** of August 25, 1982 (47 FR 37287) which announced that Pennwalt Corp. had submitted food/feed additive petition 2H5364 to the Agency proposing tolerances for the combined residues of the fungicide thiophanate-methyl in or on raisins at 50.0 ppm and pineapples at 35.0 ppm (21 CFR Part 193) and dried grape pomace at 125.0 ppm and rice hulls at 20.0 ppm (21 CFR 561.387).

Pennwalt Corp. has withdraw the petitions without prejudice to future filling.

(Sec. 408(d)(2) 68 Stat. 512, (21 U.S.C. 346a(d)(2); 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348)))

Dated: November 8, 1983.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 83-31484 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

[OPP-00170; PH-FRL2476-8]

State FIFRA Issues Research and Evaluation Group (SFIREG); Open Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a two-day meeting of the State FIFRA Issues Research and Evaluation Group (SFIREG). The meeting will be open to the public.

DATES: Wednesday, December 14 and Thursday, December 15, 1983, beginning at 8:30 a.m. on December 14 and ending prior to 12 noon on December 15.

ADDRESS: The meeting will be held at: Hyatt Regency—Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202, (703-486-1234).

FOR FURTHER INFORMATION CONTACT: By mail: Philip H. Gray, Jr., Office of Pesticide Programs (TS-766C),

Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460
Office location and telephone number: Rm. 1115B, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-7096).

SUPPLEMENTARY INFORMATION: This will be the sixteenth meeting of the full Group. The tentative agenda thus far includes the following topics:

1. Action items from the July 1983 meeting of the SFIREG.
2. Regional reports.
3. Working Committee reports.
4. Other topics which may arise.

Dated: November 17, 1983.

Edwin L. Johnson,

Director, Office of Pesticide Programs.

[FR Doc. 83-31491 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

[OPP-240039; PH-FRL 2475-4]

State Registration of Pesticides; California et al.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received notices of registration of pesticides to meet special local needs under section 24(c) of the Federal Insecticide, Fungicide, an Rodenticide Act (FIFRA) from 20 States. A registration issued under this section of FIFRA shall not be effective for more than 90 days if the Administrator disapproves the registration or finds it to be invalid within that period. If the Administrator disapproves a registration or finds it to be invalid after 90 days, a notice giving that information will be published in the **Federal Register.**

DATE: The last entry for each item is the date of the State registration of the product became effective.

FOR FURTHER INFORMATION CONTACT:

By mail: Sandra English, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C.
Office location and telephone number: Rm. 718, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-2126).

SUPPLEMENTARY INFORMATION: Most of the registration listed below were received by EPA in September 1983. Receipts of State registrations will be published periodically. Except as indicated by (CUP) in four registrations listed below, there is no change in use pattern in any of these registrations.

California

EPA SLN No. CA 83 0044. Santa Cruz County Agriculture Dept. Registration is for Ronilan Fungicide 50W to be used on kiwifruit to control botrytis rot. (CUP) August 15, 1983.

EPA SLN No. CA 83 0049. Siskiyou County Health Dept. Registration is for Clorox to be used in potable water to control bacteria. September 12, 1983.

EPA SLN No. CA 83 0050. Shasta County Agriculture Dept. Registration is for Ortho Paraquat CL to be used on strawberry nursery plant beds to control broadleaf and grassy weeds. September 12, 1983.

EPA SLN No. CA 83 0053. California Dept. of Food and Agriculture. Registration is for Methyl Bromide 100, Namco Methyl Bromide, Dow Methyl Bromide, and Meth-O-Gas to be used on pomegranate fruits (post harvest) to control comstock mealybug (*pseudococcus comstocki*). September 6, 1983.

EPA SLN No. CA 83 0054. San Diego County Department of Agriculture. Registration is for Ortho Paraquat Plus to be used on cucurbits to control broadleaf weeds and grasses. September 19, 1983.

EPA SLN No. CA 83 0064. Mobay Chemical Corp. Registration is for Monitor 4 to be used on seed alfalfa and seed clover to control aphids, lygus, thrips, armyworms, and spider mites. September 1, 1983.

EPA SLN No. CA 83 0065. Rohm and Haas Co. Registration is for Goal 1.6E Herbicide to be used for noncrop use to control weeds. July 30, 1983.

Florida

EPA SLN No. FL 83 0022. Estech, Inc. Registration is for Par EX Fertilizer Plus Ronstar to be use on golf course fairways, parks, and lawns to control crabgrass, annual bluegrass goosegrass, Florida pusley, oxalis, stinging nettle, carpetgrass, and pigweed. September 7, 1983

EPA SLN No. FL 83 0023. Union Carbide Agricultural Products Co., Inc. Registration is for Amiben DS Chloramben Herbicide to be used between mulched tomato and pepper row middles to control weeds. September 9, 1983.

Idaho

EPA SLN No. ID 83 0033. Ciba-Geigy Corp. Registration is for Apron 70SD to be used on pea seeds to control downy mildew and seedling damping off. September 15, 1983.

Illinois

EPA SLN No. IL 83 0024. Rohm and Haas Co. Registration is for Dithane FZ to be used on corn (field, hybrid seed, and popcorn) to control *Helminthosporium* leaf blight. (CUP) September 1, 1983.

EPA SLN No. IL 83 0025. Rohm and Haas Co. Registration is for Dithane M-45 Agricultural Fungicide to be used on corn (hybrid seed production) to control *Helminthosporium* leaf blight. (CUP) September 1, 1983.

Indiana

EPA SLN No. IN 83 0006. Mobay Chemical Corp. Registration is for Di-Syston 8 Insecticide to be used on soybeans to control mites. September 2, 1983.

Louisiana

EPA SLN No. LA 83 0028. Mobay Chemical Corp. Registration is for Oftanol 2 Insecticide to be used on turf grasses to control white grub larvae (such as Japanese beetles, black turf grasses ataenius, chafers, green June beetles, and oriental beetles). September 22, 1983.

EPA SLN No. LA 83 0029. Mobay Chemical Corp. Registration is for Oftanol 5% to be used on turf grasses to control white grub larvae (such as Japanese beetles, black turf grasses ataenius, chafers, green June beetles, and oriental beetles). June 22, 1983.

Maryland

EPA SLN No. MD 83 0010. FMC Corp. Registration is for Pounce 3.2 EC to be used on soybeans to control cabbage loopers, corn earworms, green cloverworms, Mexican bean beetles, soybean loopers, and velvetbean caterpillars. September 19, 1983.

Michigan

EPA SLN No. MI 83 0018. Mobay Chemical Corp. Registration is for Mesurol 50% Hopper-Box Treater to be used on corn to control slugs and snails. September 19, 1983.

EPA SLN No. MI 83 0019. FMC Corp. Registration is for Furadan 4F Insecticide/Nematicide to be used on commercially grown ornamentals to control root weevils (black vine weevil). September 20, 1983.

Minnesota

EPA SLN No. MN 83 0012. Platte Chemical Co. Registration is for Clean Crop Paraquat Plus to be used on Kentucky bluegrass seed fields for postharvest desiccation to facilitate burning. (CUP) August 26, 1983.

Missouri

EPA SLN No. MO 83 0010. PBI Gordon Corp. Registration is for Acme Ultra-

Sulv Amine to be used on noncrop pastures and rangeland to control weeds. September 9, 1983.

Montana

EPA SLN No. MT 83 0006. The Charles H. Lilly Co. Registration is for Lilly/Miller Chlorban Insect Granules to be used on broccoli, brussels sprouts, cabbage, cauliflower, Chinese cabbage, rutabagas, and turnips to control root maggots. September 2, 1983.

New Hampshire

EPA SLN No. NH 83 0009. Shell Chemical Co. Registration is for Pydrin Insecticide 2.4 EC to be used on peppers and eggplants to control corn earworms, flea beetles, fall armyworms, beet armyworms, European corn borers, and Colorado potato beetles. September 9, 1983.

New Jersey

EPA SLN No. NJ 83 0013. Agway, Inc. Registration is for Agway Greenlawn Plus Fertilizer with Oftanol Insect Killer to be used on turf grasses to control white grub larvae (such as Japanese beetles, black turf grasses ataenius, chafers, *phyllophaga* spp., green June beetles, oriental beetles, and Asiatic garden beetles). September 13, 1983.

EPA SLN No. NJ 83 0014. Agway, Inc. Registration is for Agway Professional Fairway and Athletic Turf 19-4-9 Fertilizer with Oftanol Insect Killer to be used on turf grasses to control grub larvae (such as Japanese beetles, black turf grasses ataenius, chafers, *phyllophaga* spp., green June beetles, oriental beetles, and Asiatic garden beetles). September 18, 1983.

Ohio

EPA SLN No. OH 83 0009. FMC Corp. Registration is for Furadan 4F Insecticide/Nematicide to be used on commercially grown ornamentals to control root weevils (black vine weevil). September 21, 1983.

Oklahoma

EPA SLN No. OK 83 0024. NL Treating Chemicals. Registration is for Surflo-B315 to be used on oil fields to control bacteria. September 7, 1983.

EPA SLN No. OK 83 0025. NL Treating Chemicals. Registration is for Surflo-B315W to be used on oil fields to control bacteria. September 7, 1983.

EPA SLN No. OK 83 0026. Drexel Chemical Co. Registration is for Drexel Atrazine 4L Herbicide to be used on Bermuda grass highway rights-of-way to control annual weeds. September 28, 1983.

Oregon

EPA SLN No. OR 83 0057. Mobay Chemical Corp. Registration is for Di-Syston 15% Granular to be used on potatoes to control aphids. September 8, 1983.

EPA SLN No. OR 83 0058. Mobay Chemical Corp. Registration is for Di-Syston 8 to be used on potatoes to control aphids. September 8, 1983.

EPA SLN No. OR 83 0059. J. R. Simplot Co. Registration is for Dimethoate 2.67 to be used on cherries to control cherry fruit flies. September 19, 1983.

EPA SLN No. OR 83 0060. J. R. Simplot Co. Registration is for Dimethoate 25W to be used on cherries to control cherry fruit flies. September 19, 1983.

Pennsylvania

EPA SLN No. PA 83 0015. Hess and Clark, Inc. Registration is for DC&R Spray Fumigant Concentrate to be used on mushroom-rearing facilities and equipment to control disease germs. September 19, 1983.

EPA SLN No. PA 83 0016. The ArChem Corp. Registration is for Parapel Paraffinized Pellets to be used on orchards to control meadow voles. September 19, 1983.

Tennessee

EPA SLN No. TN 83 0014. FMC Corp. Registration is for Furadan 4F to be used on field corn to control southwestern corn borers and European corn borers. August 31, 1983.

EPA SLN No. TN 83 0015. Great Lakes Chemical Corp. Registration is for Brom-O-Gas to be used on cured ham, bacon, and sausage to control cheese skippers, larder beetles, red-legged ham beetles, and mites. September 16, 1983.

EPA SLN No. TN 83 0016. Diamond Sharmrock Corp. Registration is for DSMA Liquid to be used on cotton to control weeds. September 20, 1983.

EPA SLN No. TN 83 0017. Diamond Shamrock Corp. Registration is for Bueno 6 to be used on cotton to control weeds. September 20, 1983.

EPA SLN No. TN 83 0018. BFC Chemicals, Inc. Registration is for Attac 6 (60% toxaphene) to be used on soybeans to control sicklepod. September 20, 1983.

EPA SLN No. TN 83 0019. BFC Chemicals, Inc. Registration is for Attac 8 (72% toxaphene) to be used on soybeans to control sicklepod. September 20, 1983.

Texas

EPA SLN No. TX 83 0035. E. I. du Pont de Nemours & Co. Registration is for Du Pont Glean Weed to be used on winter wheat to suppress annual ryegrass. September 20, 1983.

Washington

EPA SLN No. WA 83 0034. Pennwalt Corp. Registration is for Ziram F-4 to be used on pears to control fruit rots August 25, 1983.

EPA SLN No. WA 83 0035. Ciba-Geigy Corp. Registration is for Apron 70SD to be used on pea seeds to control downy mildew. September 6, 1983.

EPA SLN No. WA 83 0038. Van Waters & Rogers. Registration is for Formaldehyde Solution to be used on bulbs of daffodils and bulbous irises to control mites, nematodes, and bulb flies September 9, 1983.

Dated: November 9, 1983.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 83-31485 Filed 11-22-83; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL RESERVE SYSTEM

BankAmerica Corp.; Proposal To Engage in the Issuance and Sale of Variably Denominated Instruments and To Provide Data Processing and Marketing Services

BankAmerica Corporation, San Francisco, California, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to engage *de novo* in the issuance and sale of general purpose variably denominated instruments with a maximum face value of up to $10,000 and for approval for its subsidiary, BA Cheque Corporation, to provide data processing and marketing services related to payment instruments issued to non-affiliated depository institutions.

These activities would be performed from offices of Applicant's subsidiary in Rapid City, South Dakota and San Francisco, California and the geographic areas to be served are the United States and abroad. Such activities have not been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies.

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any

request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco.

Any views or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C., not later than December 16, 1983.

Board of Governors of the Federal Reserve System, November 17, 1983.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 83-31430 Filed 11-22-83; 8:45 am]

BILLING CODE 6210-01-M

Farmers Bancshares, Inc., et al.; Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become bank holding companies by acquiring voting shares or assets of a bank. The factors that are considered in acting on the applications are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Band indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. 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 specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President), 400 South Akard Street, Dallas, Texas 75222:

1. *Farmers Bancshares, Inc.*, Center, Texas; to become a bank holding company by acquiring at least 80 percent of the voting shares of Farmers State Bank, Center, Texas. Comments on this application must be received not later than December 16, 1983.

B. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President), 101 Market Street, San Francisco, California 94105:

1. *Valley Community Bancorp*, McMinnville, Oregon; to become a bank holding company by acquiring 100 percent of the voting shares of Valley Community Bank, McMinnville, Oregon. Comments on this application must be received not Later than December 14, 1983.

Board of Governors of the Federal Reserve System, November 17, 1983.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 83-31431 Filed 11-22-83; 8:45 am]

BILLING CODE 6210-01-M

Bank Holding Companies; Norwest Corp., et al.; Proposed de Novo Nonbank Activities

The organizations identified in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to these applications, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any comment that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

The applications may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated. Comments and requests for hearing should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than the date indicated.

A. **Federal Reserve Bank of Minneapolis** (Bruce J. Hedblom, Vice President), 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Norwest Corporation*, Minneapolis, Minnesota (financing, insurance and travelers checks activities; North Dakota): To engage through its subsidiary, Norwest Financial North Dakota, Inc., in the activities of consumer finance, sales finance and commercial finance, the sale of credit life, credit accident and health and property and credit-related casualty insurance related to extensions of credit by that company (such sale of credit-related insurance being a permissible activity under Subparagraph D of Title VI of the Garn-St Germain Depository Institutions Act of 1982) and the offering for sale and selling of travelers checks. These activities will be conducted from an office in Grand Forks, North Dakota. This notification is for the relocation of an existing office in Grand Forks, North Dakota, to engage *de novo* in the activities of commercial finance from said office, as relocated. Upon relocation, said office will serve Grand Forks, North Dakota, and nearby communities. Comments on this application must be received not later than December 14, 1983.

B. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President), 101 Market Street, San Francisco, California 94105:

1. *Security Pacific Corporation*, Los Angeles, California (trust company activities; United States): To engage through its subsidiary, Pacific Century Group, a trust company organized pursuant to the California Financial Code, in certain trust company activities, including acting as trustee, executor, conservator, administrator, guardian, managing agent, custodian or in other similar capacities and providing investment or financial advice to institutions and individuals. These activities would be conducted from offices of Pacific Century Group, located in Los Angeles, Newport Beach, San Diego and San Francisco, California, serving the United States. Comments on this application must be received not later than December 16, 1983.

Board of Governors of the Federal Reserve System, November 17, 1983.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 83-31432 Filed 11-22-83; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

December Meetings

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix I), announcement is made of the following national advisory bodies scheduled to assemble during the month of December.

Board of Scientific Counselors, NIAAA, December 2; 9:00 a.m., Flow Building Conference Room, 12501 Washington, Avenue, Rockville, Maryland 20852

Open—December 2; 9:15 a.m.

Closed—Otherwise

Contact: Laura S. Rosenthal, Deputy Director, Division of Intramural Research, NIAAA, Room 2, Flow Building 12501 Washington Avenue Rockville, Maryland 20851, (301) 443-1073

Purpose: The Board of Scientific Counselors provides expert advice to the Director, NIAAA, on the alcohol intramural research program through periodic visits to the laboratories for assessment of the research in progress and evaluation of productivity and performance of staff scientists.

Agenda: The Board will meet in the Flow Building for approximately 15 minutes for a report on recent administrative developments. The remainder of the session will be devoted to a review of the intramural research projects of the Division of Intramural Research including an evaluation of individual scientific programs, and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 5552b(c)(6), and Section 10(d) of Pub. L. 92-463 (5 U.S.C. Appendix I).

* * * * *

National Advisory Mental Health Council, December 5-6; 9:00 a.m., National Institutes of Health, Building 31C, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20205

Open—December 5-6; 9:00 a.m.-5:00 p.m.

Contact: Ms. Helen W. Garrett, Committee Management Officer, Parklawn Building, Room 17C-26, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4333

Purpose: The National Advisory Mental Health Council advises the Secretary of Health and Human Services, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute of Mental Health, regarding policies and programs of the Department in the field of mental health. The Council reviews applications for grants-in-aid relating to research and training in the field of mental health and makes recommendations to the Secretary with respect to approval of applications for, and amount of, these grants.

Agenda: The meeting scheduled for December 5 and 6 will be open for discussion of NIMH policy issues and will include current administrative legislative, and program developments. Attendance at this two-day open meeting will be limited to space available.

* * * * *

Substantive information may be obtained from the contact persons listed above. Summaries of the meetings and rosters of Committee members may be obtained as follows: NIAAA: Mrs. Diana Widner, Committee Management Officer, Room 16C-20 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4375. NIMH: Ms. Helen W. Garrett, Committee Management Officer, Room 17C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4333.

Dated: November 17, 1983.

Sue Simmons,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 83-31518 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-20-M

Public Health Service

National Committee on Vital and Health Statistics; Meeting

Pursuant to the Federal Advisory Act (Pub. L. 92-463), notice is hereby given that the National Committee on Vital and Health Statistics (NCVHS) established pursuant to 42 U.S.C. 242k, section 306(k)(2) of the Public Health Service Act, as amended, will convene on Thursday, December 8, at 9:00 a.m., in the Snow Room, Room 5051, of the Department of Health and Human Services Building, 330 Independence Avenue, SW., Washington, D.C. 20201; and on Friday, December 9, at 9:00 a.m. in the Auditorium of the Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201. Attendees on Thursday will be required to use the C Street entrance to the DHHS buliding and to sign in at the guard desk.

Agenda items will include an overview of the National Health and Nutrition Examination Survey, the National Death Index, and Environmental Health Statistics; review of Subcommittee interim reports; and a proposed plan for the Committee deliberations.

Further information regarding the Committee may be obtained by contacting Gail F. Fisher, Ph.D., Executive Secretary, National Committee on Vital and Health Statistics, Room 2-28 Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, telephone (301) 436-7051.

Dated: November 15, 1983.

Robert A. Israel,

Acting Director.

[FR Doc. 83-31473 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-17-M

National Committee on Vital and Health Statistics; Meeting

Pursuant to the Federal Advisory Act (Pub.L. 92-643), notice is hereby given that the Subcommittee on Uniform Minimum Health Data Sets of the National Committee on Vital and Health Statistics, pursuant to functions established by Section 306(k)(2) of the Public Health Service Act, as amended, (42 U.S.C. 242k), will convene on Tuesday, December 6 and Wednesday, December 7, at 9:00 a.m. in the Snow Room, Room 5051, of the Department of Health and Human Services Building, 330 Independence Avenue, SW., Washington, D.C. 20201. Attendees will be required to use the C Street entrance to the building and to sign in at the guard desk.

The Subcommittee will review the experience of various users with the Uniform Hospital Discharge Data Set, explore any problems reported by users, and make recommendations regarding the items and their definitions.

Further information regarding this meeting of the Subcommittee or other matters pertaining to the National Committee on Vital and Health Statistics may be obtained by contacting William F. Stewart, National Committee on Vital and Health Statistics, Room 2-28 Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, telephone (303) 436-7122.

Dated: November 15, 1983.

Robert A. Israel,

Acting Director.

[FR Doc. 83-31474 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-17-M

Office of the Assistant Secretary for Health

Privacy Act of 1974; System of Records

AGENCY: Public Health Service, HHS.

ACTION: Notification of establishment of a new Privacy Act system of records 09-25-0154, "Biomedical Research: Records of Subjects in Cancer Studies of the Division of Resources, Centers and Community Activities," HHS/NIH/NCI.

SUMMARY: In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) is publishing notice of a proposal to establish a new Privacy Act system of records 09-25-0154, "Biomedical Research: Records of Subjects in Cancer Studies of the Division of Resources, Centers and Community Activities," HHS/NIH/NCI. We are also proposing routine uses for this system.

The Division of Resources, Centers and Community Activities (DRCCA) in the National Cancer Institute (NCI) will use this system of records to support research on the causes and prevention of cancer.

PHS invites interested persons to submit comments on the proposed routine uses on or before December 23, 1980.

DATE: PHS has sent a Report of New System to the Congress and to the Office of Management and Budget (OMB) on November 16, 1983. The system of records will be effective 60 days from the date submitted to OMB unless PHS receives comments on the routine uses which would result in a contrary determination.

ADDRESS: Comments should be addressed to the National Institutes of Health (NIH) Privacy Act Coordinator at the address listed below. Comments received will be available for inspection from 9 a.m. to 3 p.m., Monday through Friday, in Room 3B03, Building 31, at that address.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth Thibodeau, NIH Privacy Act Coordinator, Building 31, Room 3B07, 9000 Rockville Pike, Bethesda, MD 20205, or call 301-496-4606.

This is not a toll free number.

SUPPLEMENTARY INFORMATION: NIH proposes to establish a new system of records: 09-25-0154, "Biomedical Research: Records of Subjects in Cancer Studies of the Division of Resources, Centers and Community Activities," HHS/NIH/NCI. This proposed system of records will comprise records generated in research projects supported by DRCCA in fulfilling its responsibility for research on prevention, intervention and control of cancer, including screening, detection, and diagnosis studies and evaluation of cancer control strategies.

Such research will involve scientists on the staff of NCI and other scientists working under contracts awarded competitively by NCI. NCI may award research contracts to hospitals, medical schools, universities, research institutions, commercial organizations, and to State and Federal Government agencies.

NCI will not create any comprehensive index identifying individuals on whom records are maintained in the different projects covered by this system. However, NCI will treat the records as a single system under the Privacy Act (1) because all of the records will serve the same research purposes and contain similar types of data; (2) in order to apply consistent policies and practices in the maintenance and use of such records; (3) for efficient management of the system; and (4) to facilitate subject individuals' exercise of their rights of notification, access, and amendment.

The records in this system will be maintained in a secure manner compatible with their content and purpose. Only physicians, scientists, and support staff who need such information in order to contribute to the research or administrative purposes of this system will have regular access to the records. The system manager will specifically authorize one-time and special access by others on a need-to-know basis consistent with the purposes and routine uses of the system. Records will be kept in limited access areas which are locked during off-duty hours. Where possible, information on individual identities will be kept separate from data used for analysis.

Access to computer files will be controlled through security codes known only to authorized users. Names and other details necessary to identify individuals will not be included in data files used for analysis. These files will be indexed by code numbers. Code numbers and complete identifiers will be linked only if there is a specific need, such as for data verification.

Contractors, grantees, or collaborators who maintain records in this system will be instructed to make no further disclosure except as authorized by the system manager. Contracts and agreements with grantees or collaborators participating in research activities supported by this system will include explicit Privacy Act requirements. HHS project directors, contract officers, and project officers will oversee compliance with these requirements.

The particular safeguards implemented in each project will be developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS hf: 45-13, and part 6, "ADP Systems Security," of the HHS ADP Systems Manual and the National Bureau of Standards Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

The routine uses proposed for this system are compatible with the stated purposes of the system in planning for, conducting, managing, and evaluating biomedical research. The first two of the proposed routine uses are essential to the achievement of the basic research purpose of the system. The first proposed routine use will allow for disclosure to contractors, grantees, and collaborators working on the research projects. The second proposed routine use, which provides for audits of the research activities, will allow the Department to ensure that these research activities are properly conducted.

A routine use allowing disclosure to contractors for the purpose of processing or refining the records will permit NCI to administer research projects efficiently when contracting for such services is advisable because the agency lacks necessary internal resources or because processing or refining the records under contract would be cost-effective. Contracted services may include transcription, collation, computer input, or other records processing.

A routine use for research is included because occasionally the progress, quality or fruitfulness of a research program may be enhanced, and the public interest served, by disclosing the data to additional researchers who may contribute special insight or expertise or who may use the data to generate additional knowledge. Disclosure to researchers outside of the Department is compatible with the research purposes of this system.

A routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire.

The possibility of lawsuits in which individuals may claim to have been harmed mentally, physically, or financially as a result of the research activities supported by this system motivates the proposal of a routine use to allow the Department of Justice to

defend the Federal Government, the Department, or employees of the Department in case of such lawsuits.

The proposed system of records will not become effective until 60 days after the date it was reported to OMB, as discussed above. However, the following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: November 17, 1983.

Wilford J. Forbush,

Deputy Assistant Secretary for Health Operations, and Director, Office of Management.

09-25-0154

SYSTEM NAME:

Biomedical Research: Records of Subjects in Cancer Studies of the Division of Resources, Centers and Community Activities, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Blair Building, Room 6A01; NIH, 9000 Rockville Pike, Bethesda, MD 20205.
Building 12, NIH, 9000 Rockville Pike, Bethesda, MD 20205.
And at hospitals, medical schools, universities, research institutions, commercial organizations, collaborating State and Federal Government agencies, and Federal Records Centers. Write to system manager at the address below for the address of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and children in the following categories: Patients with cancer; persons for whom cancer risk can potentially be lowered; and persons without signs or symptoms who may be identified through screening and detection methods as having cancer or being at increased risk of developing cancer. For certain types of epidemiologic studies, e.g., case-control studies, NCI may also collect, for purposes of comparison, records on other persons. These comparison groups could include normal individuals (e.g., family members or neighborhood controls), or other patient groups (e.g., hospital controls) who do not have cancer or are not at a particularly high risk of developing cancer.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information identifying participants (such as name, address, Social Security Number), medical records, progress reports correspondence, epidemiological data, and records on biological specimens (e.g., blood, tumors, urine, etc.).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301, Research and Investigation, and Title IV, Part A, National Cancer Institute, of the Public Health Service Act (42 U.S.C. 241, and 281-286).

PURPOSES:

Records in this system will be used:

1. To evaluate cancer control programs, including prevention, screening, detection, diagnosis, treatment, rehabilitation, and continuing care;

2. To identify characteristics of persons who may be particularly susceptible to environmental or occupational factors or substances which cause or prevent cancer, and/or to cancer;

3. To determine risk factors or substances which cause or prevent cancer, and the ways in which they do so;

4. To evaluate statistical and epidemiological methodologies for risk factor assessment, clinical trials, cancer control studies, and the study of the natural history of cancers;

5. To plan for, administer, and review research activities as described in the above purposes;

6. Information from this system may be reported to the Food and Drug Administration (FDA) as a condition for approval of clinical investigations of new drugs, or to report adverse effects of drugs so that FDA can make informed decisions on authorizing use of such drugs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purposes for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. A record may be disclosed for a research purpose, when the Department:

(A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(B) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(C) Has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety or any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;

(D) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending a claim against the Public Health Service based upon an

individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, microfilm, charts, graphs, computer tapes, disks, and punch cards.

RETRIEVABILITY:

By name, Social Security Number when supplied voluntarily or contained in existing records used in projects under this system, or other identifying number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

(1) Authorized users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists, and support staff of the National Cancer Institute (NCI), or its contractors, grantees or collaborators who need such information in order to contribute to the research or administrative purpose of the system. The system manager specifically authorizes one-time and special access by others on a need-to-know basis consistent with the purposes and routine uses of the system.

(2) Physical safeguards: Records are kept in limited access areas. Offices and records storage locations are locked during off-duty hours. Input data for computer files is coded to avoid individual identification. Where possible, information on individual identities is kept separate from data used for analysis.

(3) Procedural safeguards: Access to manual files is granted only to authorized personnel, as described above. Access to computer files is controlled through security codes known only to authorized users. Names and other details necessary to identify individuals are not included in data files used for analysis. These files are indexed by code numbers. Code numbers and complete identifiers are linked only if there is a specific need, such as for data verification.

Contractors, grantees or collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act. Privacy Act requirements are specifically included in contracts and in agreements with grantees or collaborators participating in research activities supported by this system. HHS project director, contract officers and project officers oversee compliance with these requirements.

The particular safeguards implemented at each site are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45–13, and part 6, ADP Systems Security, of the HHS ADP Systems Manual.

RETENTION AND DISPOSAL:

NCI retains research records in accordance with the NIH Records Control Schedule, item 3000–G–3, which allows the system manager to keep the records as long as they are useful in scientific research. Contractors, grantees and collaborators who receive disclosures of records from this system retain the records only as long as necessary to accomplish the purpose for which the disclosures are made. Inactive records may be transfered to a Federal Records Center. Disposal methods included burning hard copy and erasing computer tapes and disks.

SYSTEM MANAGER AND ADDRESS:

Chief, Biometrics and Operations Research Branch, DRCCA, National Cancer Institute, Blair Building, Room 6A01, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

NOTIFICATION PROCEDURE:

To determine if a file exists, write to the system manager and provide the following information:

a. System name: "Biomedical Research: Records of Subjects in Cancer Studies of the Division of Resources, Centers and Community Activities";

b. Complete name at time of participation;

c. Facility and home address at the time of participation;

d. In some cases, where records are retrieved by an identifying number, such as the Social Security Number or Hospital Identification Number, it may be necessary to provide that number. In some cases, to ensure proper identification it may be necessary to provide date(s) of participation (if known), birthdate, or disease type (if known).

The requester must also verify his or her identity by providing either a notorization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a maximum fine of five thousand dollars.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Write to the system manager and provide the same information as requested under the notification procedure above. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures which have been made of your record.

CONTESTING RECORD PROCEDURES:

Write to the system manager, identify the record, and specify the information contested. State the corrective action sought and your reasons for requesting the correction, and provide supporting information to show that the record is inaccurate, incomplete, irrelevant, untimely, or unnecessary.

RECORD SOURCE CATEGORIES:

HHS agencies, institutions under contract to the U.S. Government, such as universities, medical schools, hospitals, research institutions, commercial institutions, state agencies, other U.S. Government agencies, patients and normal volunteers, physicians, research investigators and other collaborating personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 83-31517 Filed 11-22-83; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-83-1307]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comments regarding these proposals. Comments should refer to the proposal by name and should be sent to: Robert Neal, OMB Desk Officer, Office of Management and Budget, New Eexcutive Office Building, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Acting Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C. 20410, telephone (202) 755-5310. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals described below for the collection of information to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the agency form number, if applicable; (4) how frequently information submissions will be required; (5) what members of the public will be affected by the proposal; (6) an estimate of the total number of hours needed to prepare the information submission; (7) whether the proposal is new or an extension or reinstatement of an information collection requirement; and (8) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Copies of the proposed forms and other available documents submitted to OMB may be obtained from David S. Cristy, Acting Reports Management Officer for the Department. His address and telephone number are listed above. Comments regarding the proposals should be sent to the OMB Desk Officer at the address listed above.

The proposed information collection requirements are described as follows:

Notice of Submission of Proposed Information Collection to OMB

Proposal: Weekly Payroll
Office: Labor Relations
Form No. WH-347
Frequency of submission: Weekly
Affected public: Businesses or Other For-Profit and Small Businesses or Organizations
Estimated burden hours: 900,000
Status: Extension
Contact: Richard S. Allen, HUD, (202) 755-7373; Robert Neal, OMB, (202) 395-7316.

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: November 15, 1983.

Lea Hamilton,

Director, Office of Information Policies and Systems.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Request for Determination and Response to Request
Office: Labor Relations
Form No: SF-308
Frequency of submission: On Occasion
Affected public: State or Local Govrnments and Federal Agencies or Employees
Estimated burden hours: 667
Status: Extension
Contact: Richard S. Allen, HUD, (202) 755-7373; Robert Neal, OMB, (202) 395-7316.

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: November 15, 1983.

Lea Hamilton,

Director, Office of Information Policies and Systems.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Dealer-Contractor Application
Office: Housing
Form No: FH-13
Frequency of submission: On Occasion
Affected public: Individuals or Households and Small businesses or Organizations
Estimated burden hours: 5,000
Status: New
Contact: James L. Anderson, HUD, (202) 755-6880; Robert Neal, OMB, (202) 395-7416.

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: November 15, 1983.

Lea Hamilton,

Director, Office of Information Policies and Systems.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Letter of Transmittal Package
Office: Government National Mortgage Association
Form No. HUD-11700, HUD-11702, HUD-11707, HUD-11749, and HUD-11771
Frequency of submission: On Occasion
Affected public: Businesses or Other For-Profit
Estimated burden hours: 3,145
Status: New
Contact: Patricia Gifford, HUD, (202) 755-5550; Robert Neal, OMB, (202) 395-7316.

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: November 15, 1983.

Lea Hamilton,

Director, Office of Information Policies and Systems.

[FR Doc. 83-31492 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-01-M

[Docket No. D-83-711]

Delegation of Authority; Office of the Manager, Pittsburgh Office; Designation

AGENCY: Department of Housing and Urban Development.

ACTION: Designation of Order of Succession.

SUMMARY: The Manager is designating officials who may serve as Acting Manager during the absence, disability or vacancy in the position of the Manager.

EFFECTIVE DATE: This designation is effective September 6, 1983.

FOR FURTHER INFORMATION CONTACT: Michael R. Zysman, Director, Management and Budget Division, Office of Administration, Philadelphia Regional Office, Department of Housing and Urban Development, Curtis Building, 6th & Walnut Streets, Philadelphia, PA 19106. Phone Number: (215) 597-2495. (This is not a toll-free number).

Designation: Each of the officials appointed to the following positions are designated to serve as Acting Manager during the absence, disability, or vacancy in the position of the Manager, with all the powers, functions and duties redelegated or assigned to the Manager: Provided, that no official is authorized to serve as Acting Manager unless all preceding listed officials in this designation are unavailable to act by reason of absence, disability, or vacancy in the position:

1. Deputy Manager
2. Director, Housing Management Division
3. Director, Community Planning and Development Division
4. Chief Counsel
5. Director, Housing Development Division

This designation supersedes the designation effective May 1, 1981.

Authority: Delegation of Authority by the Secretary effective October 1, 1970; 36 FR 3389, February 23, 1971.

Dated: November 16, 1983.

Kenneth J. Finlayson,

Regional Administrator—Regional Housing Commissioner, Region III.

John E. Pisano,

Manager, Pittsburgh Office.

October 7, 1983.

[FR Doc. 83-31394 Filed 11-22-83; 8:45 am]

BILLING CODE 4210-32-M

DEPARTMENT OF THE INTERIOR

Presidential Commission on Indian Reservation Economies; Meeting

The Presidential Commission on Indian Reservation Economies; established pursuant to Executive Order 12401, as amended by Executive Order 12442, will conduct a site visit at the Mississippi Choctaw Reservation at Philadelphia, Mississippi, on December 7, from 9:00 a.m. until 5:00 p.m. 1983, and its second meeting on December 8, from 9:00 a.m. until 3:00 p.m. in the Holiday Inn South at Highway 45 South and Interstate 20, Meridian, Mississippi.

The agenda of the site visit and the meeting is summarized as follows:

The Commissioners will inspect the Tribe's physical plants of the greeting card, construction and electrical wiring industries and tour the surrounding Indian community. Informal discussions will be held with tribal leaders, plant managers and workers, and community members. These discussions will center around factors of success in the development of the industries inspected, and the impact of the industries on the community.

The meeting on December 8, 1983 will be devoted to receiving testimony from the Tribal Chairman and representatives from the public and private sectors concerning the development and sustainment of economic enterprises within Indian reservation environments, and other items of business the members of the Commission wish to discuss, with emphasis on the future work of the Commission.

For further information, please contact Mr. Roy H. Sampsel at (202) 653-2436.

Robert Robertson,

Co-chairman.

[FR Doc. 83-31505 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-02-M

Fish and Wildlife Service

Endangered Species Permit; National Zodogical Park et al; Receipt of Applications

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*):

Applicant: National Zoological Park, Washington, D.C.—PRT 2-11321

The applicant requests a permit to import and export samples of blood, body fluids or other tissues of Asian elephant (*Elephas maximus*) for scientific research (genetics, reproductive and other biomedical evaluation).

Applicant: Steven E. Martin, Acton, CA—PRT 2-11256

The Applicant request a permit to import one captive-born male orangutan (*Pongo pygmaeus*) from Duisburg Zoo, West Germany for enhancement of propagation and survival.

Applicant: Cheyenne Mountain Zoological Park, Colorado Springs, CO—PRT2-11302

The applicant requests a permit to export one female Siberian tiger (*Panthera tigris altaica*) for breeding loan, to the Calgray Zoo, Alberta, Canada, for enhancement of propagation or survival.

Documents and other informaton submitted with these applications are available to the public during normal business hours in Room 601, 1000 N. Glebe Rd., Arlington, Virginia, or by writing to the U.S. Fish & Wildlife Service, WPO, P.O. Box 3654, Arlington, VA 22203.

Interested persons may comment on these applications within 30 days of the date of this publication by submitting written data, views, or arguments to the above address. Please refer to the file number when submitting comments.

Dated: November 18, 1983.

R. K. Robinson,

Chief, Branch of Permits, Federal Wildlife Permit Office, U.S. Fish & Wildlife Service.

[FR Doc. 83-31502 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-55-M

Bureau of Land Management

[AA-16670]

Alaska Native Claims Selection; Cook Inlet Region, Inc.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 12(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (43 U.S.C. 1601, 1611 (1976)) (ANCSA), will be issued to Cook Inlet Region, Inc., for approximately 8,243 acres. The lands involved are within the Seward Meridian Alaska.

T. 9 N., R. 9 W.
T. 6 N., R. 9 W.
T. 3 N., R. 10 W.

The decision to issue conveyance will be published once a week, for four (4) consecutive weeks, in the ANCHORAGE TIMES upon issuance of the decision. For informtion on how to obtain copies, contact Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest in lands affected by this decision, an agency of the Federal Government, or regional corporation may appeal the decision to the Interior Board of Land Appeals, Office of Hearings and Appeals, in accordance with the regulations in 43 Code of Federal Regulation (CFR), Part 4, Subpart E, as revised.

If an appeal is taken, the notice of appeal must be filed in the Bureau of Land Management, Alaska State Office, Division of Conveyance Management (960), 701 C Street, Box 13, Anchorage, Alaska 99513. Do not send the appeal directly to the Interior Board of Land Appeals. The appeal and copies of pertinent case files will be sent to the Board from this office. A copy of the appeal must be served upon the Regional Solicitor, 701 C Street, Box 34, Anchorage, Alaska 99513.

The time limits for filing an appeal are:

1. Parties receiving service of the decision by personal service or certified mail, return receipt requested, shall have thirty day from the receipt of the decesion to file an appeal.

2. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who failed or refused to sign their return receipt, and parties who received a copy of the decision by regular mail which is not certified, return receipt requested, shall have until December 23, 1983 to file an appeal.

Any party known or unknown who is adversely affected by the decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Bureau of Land Management, Alaska State Office, Division of Conveyance Management.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeal. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the party to be served with a copy of the notice of appeal is: Cook Inlet Region, Inc., P.O. Box Drawer 4–N, Anchorage, Alaska 99509.

Kamilah F. Rasheed,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 83–31446 Filed 11–22–83; 8:45 am]

BILLING CODE 4310–84–M

[AA–16670]

Alaska Native Claims Selection; Cook Inlet Region, Inc.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 12(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (43 U.S.C. 1601, 1611 (1976)) (ANCSA), will be issued to Cook Inlet Region, Inc., for approximately 59,484 acres. The lands involved are within the Seward Meridian, Alaska:

T.9 N., R. 7 W.
T.8 N., R. 8 W.
T.9 N., R. 8 W.
T.4 N., R. 9 W.
T.3 N., R. 10 W.
T.3 N., R. 11 W.
T.6 N., R. 11 W.
T.7 N., R. 11 W.

The decision to issue conveyance will be published once a week, for four (4) consecutive weeks, in the ANCHORAGE DAILY NEWS upon issuance of the decision. For information on how to obtain copies, contact Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest in lands affected by this decision, an agency of the Federal Government, or regional corporation may appeal the decision to the Interior Board of Land Appeals, Office of Hearings and Appeals, in accordance with the regulations in 43 CFR, Part 4, Subpart E, as revised.

If an appeal is taken, the notice of appeal must be filed in the Bureau of Land Management, Alaska State Office, Division of Conveyance Management (960), 701 C Street, Box 13, Anchorage, Alaska 99513. Do not send the appeal directly to the Interior Board of Land Appeals. The appeal and copies of pertinent case files will be sent to the Board from this office. A copy of the appeal must be served upon the Regional Solicitor, 701 C Street, Box 34, Anchorage, Alaska 99513.

The time limits for filing an appeal are:

1. Parties receiving service of the decision by personal service or certified mail, return receipt requested, shall have thirty days from the receipt of the decision to file an appeal.

2. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who failed or refused to sign their return receipt, and parties who received a copy of the decision by regular mail which is not certified, return receipt requested, shall have until December 23, 1983 to file an appeal.

Any party known or unknown who is adversely affected by the decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Bureau of Land Management, Alaska State Office, Division of Conveyance Management.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeal. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the party to be served with a copy of the notice of apeal is: Cook Inlet Region, Inc., P.O. Drawer 4–N, Anchorage, Alaska 99509.

Kamilah Rasheed,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 83–31447 Filed 11–22–83; 8:45 am]

BILLING CODE 4310–84–M

[AA–20298]

Alaska Native Claims Selection; Cook Inlet Region, Inc.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 12(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (43 U.S.C. 1601, 1611 (1976) (ANCSA), will be issued to Cook Inlet Region, Inc., for approximately 1,165.81 acres. The lands involved are within the Seward Meridian, Alaska:

T. 5 N., R. 10 W.
T. 4 N., R. 11 W.
T. 5 N., R. 11 W.
T. 2 N., R. 12 W.

The decision to issue conveyance will be published once a week, for four (4) consecutive weeks, in the Anchorage Times upon issuance of the decision. For information on how to obtain copies, contact Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest in lands affected by this decision, an agency of the Federal Government, or regional corporation may appeal the decision to the Interior Board of Land Appeals, Office of Hearings and Appeals, in accordance with the regulations in 43 Code of Federal Regulation (CFR), Part 4, Subpart E, as revised.

If an appeal is taken, the notice of appeal must be filed in the Bureau of Land Management, Alaska State Office, Division of Conveyance Management (960), 701 C Street, Box 13, Anchorage, Alaska 99513. Do not send the appeal directly to the Interior Board of Land Appeals. The appeal and copies of pertinent case files will be sent to the Board from this office. A copy of the appeal must be served upon the Regional Solicitor, 701 C Street, Box 34, Anchorage, Alaska 99513.

The time limit for filing an appeal are:

1. Parties receiving service of the decision by personal service or certified mail, return receipt requested, shall have thirty days from the receipt of the decision to file an appeal.

2. Unknown parties, parties unaole to be located after reasonable efforts have been expended to locate, parties who failed or refused to sign their return receipt, and parties who received a copy of the decision by regular mail which is not certified, return receipt requested, shall have until December 23, 1983 to file an appeal.

Any party known or unknown who is adversely affected by the decision shall

be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Bureau of Land Management, Alaska State Office, Division of Conveyance Management.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeal. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the party to be served with a copy of the notice of appeal is: Cook Inlet Region, Inc., P. O. Drawer 4–N, Anchorage, Alaska 99509.

Kamilah F. Rasheed,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 83-31448 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

Availability of Planning Criteria for Amendments to Scattered Blocks and East Mendocino Management Framework Plans, California.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to 43 CFR 1610.4–2 notice is hereby given that draft planning criteria for on amendment to the Scattered Blocks and East Mendocino management framework plans in th Arcata Resource Area is available for public review and comment.

DATES: Comments will be accepted from the public for 30 days after publication of this notice.

FOR FURTHER INFORMATION CONTACT: William Dabbs, Realty Specialist, P.O. Box 940, 555 Leslie Street, Ukiah, California 95482, Telephone (707) 462–3873.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management is considering an exchange proposal by Louisiana-Pacific Corporation, and three tracts of public land indentified for disposal require planning amendment. These parcels would be exchanged for privately owned land north of the King Range National Conservation Area to consolidate BLM administered land in that area. Additional information is available in the notice of intent (48 FR 48719) dated October 20, 1983.

Dated: November 14, 1983.

Joel Verner,

Acting District Manager.

[FR Doc. 83-31453 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

[W-80910]

Conveyance; Sale of Public Land in Johnson County, Wyoming

November 15, 1983.

Notice is hereby given that pursuant to Section 203 of the Federal Land Policy and Management Act of 1976; 43 U.S.C. 1713 (1976), John D. Hall, Phyllis J. Hall, David W. Hall, and Joyce E. Hall, doing business under the firm name of John D. Hall and Son Partnership, have purchased and received a patent for the following described public land in Johnson County, Wyoming:

Sixth Principal Meridian

T. 51 N., R. 82 W.,
Sec. 30, lots 8 and 9.
Containing 48.66 acres.

James L. Edlefsen;

Chief, Branch of Land Resources.

[FR Doc. 83-31441 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

[W-81604]

Wyoming; Realty Action Non-Competitive Sale of Public Land in Park County

The following described land has been examined and identified for disposal by a proposed sale under Section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C 1713) at no less than the appraised fair market value ($160,000.00):

Sixth Principal Meridian, Wyoming

T. 52 N., R. 101 W.,
Sec. 7: lot 1.
Sec. 8: lots 3 and 4, N½NW¼SW¼, N½SE¼SW¼, N½SE¼NW¼SW¼.
Containing 156.87 acres.

This land is being offered by direct sale to the City of Cody, Wyoming at the appraised fair market value.

The sale of this land to the City of Cody will allow for orderly growth. The land has potential for development as a light industrial park.

This sale is consistent with Department of the Interior programs, and with the Bureau of Land Management's planning system. The public interest would be served by offering these lands for direct sale to the City. The land will not be offered for sale until 60 days after the date of this Notice.

Patent for these lands, when issued, will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by authority of the United States, Act of August 30, 1890, 26 Stat. 391; 43 U.S.C. 945.

2. All minerals with the right to explore, prospect for, mine and remove under applicable law and such regulations as the Secretary may prescribe. "All minerals" is defined as, but not limited to, metaliferous and non-metaliferous, locatable minerals, leasable minerals, such as oil, gas, coal, sodium, potassium, and geothermal resources; and salable minerals such as sand and gravel.

3. Pipeline right-of-way W–0136202.

4. Powerline right-of-way W–0157228.

5. Pipeline right-of-way C–073432.

6. Wyoming State Highway right-of-way C–060054 (Highway 120).

7. Canal right-of-way reserved for Bureau of Reclamation in PLO 6401 (43 CFR 3816.4).

For a period of 45 days from the date of this Notice, interested parties may submit comments to the District Manager, Bureau of Land Management, P.O. Box 119, Worland, Wyoming 82401. Any adverse comments will be evaluated by the District Manager who may vacate or modify this realty action. In the absence of any action by the District Manager, this realty action will become the final determination of the Department of the Interior.

Dated: November 14, 1983.

Chester E. Conard,

District Manger.

[FR Doc. 83-31436 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

New Mexico: Chaco Management Framework Plan Amendment: Exchange of Coal Resources

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting: Santa Fe Pacific Railroad Company's Proposed McKinley County Coal Exchange.

SUMMARY: In August of 1982, the Santa Fe Pacific Railroad Company proposed to exchange some of their checkerboard private coal for checkerboard federal coal. The private coal occurs in alternate sections with the federal coal in a checkerboard pattern in McKinley County, New Mexico.

This coal lease exchange proposal also involves the transfer of 160 acres of federal surface into private ownership. In addition to analyzing the coal exchange and surface transfer, the MFP Amendment/Environmental Assessment also applies the coal unsuitability criteria to the Santa Fe Pacific coal that the BLM could acquire.

DATE: Public meetings on this coal exchange proposal will be held on

December 20, 1983, at 10:00 a.m. and 7:00 p.m.

Location: Western Bank Building, 505 Marquette Avenue NW, Room 712, Albuquerque, New Mexico.

FOR FURTHER INFORMATION CONTACT: Betty Sladek, Bureau of Land Management, Albuquerque District Office; Commercial (505) 766-2455, FTS 474-2455.

Monte Jordan,

Acting State Director.

[FR Doc. 83-31493 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

Albuquerque District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: District Advisory Council Meeting.

SUMMARY: The BLM Albuquerque District Advisory Council will hold its next meeting Tuesday, January 10, 1983, in the seventh floor conference room at the District Office's headquarters in the Western Bank Building in Albuquerque, 505 Marquette Street, NW. Meeting begins at 10 a.m.

The public is welcome to attend all portions of the Council meeting. Time is scheduled at 3:00 p.m. for members of the public to address the Council.

Agenda items include: update on the MMS-BLM merger; update on State BLM issues; a resolution on maintenance of the BLM's Rio Puerco Water Pipeline Systems; review and discussion of the Second Draft San Juan River Regional Coal Environmental Impact Statement; and discussion of the Advisory Council's role in the federal coal leasing program during the Round One Lease Schedule and Round Two Lease Schedule.

This council is managed in accordance with the Federal Advisory Committee Act of 1972, the Federal Land Policy and Management Act of 1976, and the Rangeland Improvement Act of 1976. Minutes of the meeting will be prepared and made available for review within 30 days following the meeting.

L. Paul Applegate,

District Manager.

[FR Doc. 83-31494 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

Wyoming; Casper District Advisory Council; Meeting

AGENCY: Casper District, Bureau of Land Management, Interior.

ACTION: Casper District Advisory Council Meeting.

SUMMARY: The Casper District Advisory Council will meet on January 11, 1984 at 9 a.m. at the BLM office at 951 Rancho Road, Casper, WY 82601. The agenda will include: the Story Application for Permit to Drill, Onshore Oil and Gas Order 1, Cooperative Management Agreements, revisions to the coal and grazing portions of the Buffalo Resource Management Plan, and other topics suggested by council members and the public. The meeting is open to the public. Proceedings will be available within 30 days after the meeting.

DATE: January 11, 1984 at 9 a.m.

ADDRESS: 951 Rancho Road, Casper, WY 82601.

FOR FURTHER INFORMATION CONTACT: Laura Cockerham, (307) 261-5593.

Dated: November 15, 1983.

James W. Monroe,

District Manager.

[FR Doc. 83-31440 Filed 11-22-83; 8:45 am]

BILLING CODE 4310-84-M

AGENCY FOR INTERNATIONAL DEVELOPMENT

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given of the A.I.D. Research Advisory Committee meeting on December 19-20, 1983 at the Pan American Health Organization Building, 525-23rd Street, NW., Washington, D.C., Conference Room C. The Committee will discuss recent developments in A.I.D. research policy.

The meeting will begin at 9:00 a.m. and adjourn at 5:30 p.m. each day. The meeting is open to the public. Any interested persons may attend, may file written statements with the Committee before or after the meeting, or may present oral statements in accordance with procedures established by the Committee and to the extent the time available for the meeting permits. Mr. Curtis H. Barker, Acting Coordinator, Research and University Relations, Bureau for Science and Technology, is designated as the A.I.D. representative at the meeting. It is suggested that those desiring more specific information contact Mr. Floyd O'Quinn, 1601 N. Kent Street, Arlington, Virginia 22209 or call area code (703) 235-8929.

Dated: November 10, 1983.

Curtis H. Barker,

A.I.D. Representative, Research Advisory Committee.

[FR Doc. 83-31541 Filed 11-22-83; 8:45 am]

BILLING CODE 6116-01-M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB-39 (Sub-No. 6X)]

Railroad Services Abandonment; St. Louis Southwestern Railway Co.; Ford County, KS; Exemption

St. Louis Southwestern Railway Company (SSW) has filed a notice of exemption for an abandonment under 49 CFR Part 1152, Subpart F—*Exempt Abandonments*. The line to be abandoned is SSW's Dodge City Branch between milepost 351.00 and milepost 374.59 in Ford County, KS, a distance of 23.59 miles.

SSW has certified (1) that no local traffic has moved over the line for at least 2 years and there is no overhead traffic on the line, and (2) that no formal complaint filed by a user of rail service on the line regarding cessation of service over the line either is pending with the Commission or has been decided in favor of the complainant within the 2-year period. The Public Service Commission (or equivalent agency) in Kansas has been notified in writing at least 10 days prior to the filing of this notice. *See Exemption Out of Service Rail Lines*, 366 I.C.C. 885 (1983).

As a condition to use of this exemption, any employees affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

The exemption will be effective on December 23, 1983 (unless stayed pending reconsideration). Petitions to stay the effective date of the exemption must be filed by December 5, 1983, and petitions for reconsideration, including environmental, energy and public use concerns, must be filed by December 13, 1983, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to SSW's representative: G. A. Laakso, One Market Plaza, Southern Pacific Building, San Francisco, CA 94105.

If the notice of exemption contains false or misleading information, the use of the exemption is void *ab initio*.

A notice to the parties will be issued if use of the exemption is conditioned

upon environmental or public use conditions.

Decided: November 15, 1983.

By the Commission, Richard Lewis, Acting Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 83-31577 Filed 11-22-83; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30324]

Rail Carriers; Seaboard System Railroad, Inc., and Southern Railway Co.; Trackage Rights Exemption

November 16, 1983.

Seaboard System Railroad, Inc., and its affiliate Columbia, Newberry & Laurens Railroad Company (together referred to as SBD) and Southern Railway Company (Southern) have jointly filed a notice of temporary exemption for reciprocal trackage rights over their parallel lines in Columbia, SC. The proposed trackage rights will allow (a) SBD to operate over 1.4 miles of Southern's rail line between Calhoun Street and Blossom Street in Columbia, and (b) Southern to operate over 1.35 miles of SBD's parallel line.

The trackage rights are necessary in view of the line relocation and grade crossing elimination project by the City of Columbia. Service to rail customers will not be adversely affected by the relocation of lines.

Because SBD's line will be the first to be removed and relocated, SBD's trackage rights will commence before Southern's and extend over the estimated 2-year construction period. Upon completion of SBD's line, its trackage rights will cease and Southern's rights over the new line of SBD will begin and continue through the scheduled 1-year construction period for Southern's line.

This joint project involves the relocation of a line or lines of railroad which does not disrupt service to shippers and falls within the class of transactions identified at 49 CFR 1180.2(d) which the Commission has found to be exempt under 49 U.S.C. 10505. See *Railroad Consolidation Procedures*, 366 I.C.C. 75, 94 (1982).

As a condition to the use of this exemption, any employees affected by the trackage rights agreement shall be protected pursuant to *Norfolk and Western Ry., Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified by *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980). This will satisfy the statutory requirements of 49 U.S.C. 10505(g)(2).

The underlying agreement between SBD and Southern provides that their respective trackage rights will terminate upon completion of the line relocation phase of the project. ccordingly, the parties' request for a notice of exemption limited in duration will have the effect of terminating their respective trackage rights upon the end of line construction without the need for further administrative action by this Commission.

By the Commission, Richard Lewis, Acting Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 83-31466 Filed 11-22-83; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30298]

Rail Carriers; Seaboard System Railroad, Inc; Abandonment Exemption; Putnam County, FL

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Exemption.

SUMMARY: The Interstate Commerce Commission exempts from the requirement of prior approval under 49 U.S.C. 10903 *et seq.*, the abandonment by the Seaboard System Railroad, Inc. of a 2.0-mile line segment in Putnam County, FL subject to standard labor protection provisions.

DATES: This decision shall be effective on December 23, 1983. Petitions for reconsideration must be filed by December 13, 1983. Petitions to stay this decision must be filed by December 5, 1983.

ADDRESSES: Send pleadings referring to Finance Docket No. 30298 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

(2) Petitioner's representative: Neill W. McArthur, Jr., 500 Water Street, Jacksonville, FL 32202

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer (202) 275-7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision write to T.S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, DC 20423, or call 289-4357 (DC Metropolitan area) or toll free (800) 424-5403.

Decided: November 16, 1983.

By the Commission, Chairman Taylor, Vice Chairman Sterrett, Commissioners Andre and Gradison.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 83-31469 Filed 11-22-83; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Western Fher Laboratories, Inc.; Application

Pursuant to Section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 19, 1983, Western Fher Laboratories, Inc., Carretera 132, KM. 25.3, P.O. Box 7468, Ponce, Puerto Rico, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the Schedule II controlled substance Phenmetrazine (1630).

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than December 23, 1983.

Dated: November 15, 1983.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 83-31471 Filed 11-22-83; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Wyeth Laboratories; Application

Pursuant to §1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 12, 1983, Wyeth Laboratories, Inc., 611 East Nield Street, West Chester, Pennsylvania 19380, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

	Schedule
Drug:	
Pethidine (Meperidine) (9230)	II.
Pethidine-Intermediate-A (9232)	II.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative (Room 1203), and must be filed no later than December 23, 1983.

Dated: November 15, 1983.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 83-31472 Filed 11-22-83; 8:45 am]

BILLING CODE 4410-09-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 83-92]

National Environmental Policy Act; Finding of No Significant Impact

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of finding of no significant impact.

SUMMARY: The ninth Space Shuttle flight (STS-9) with a crew of six astronauts, including the first non-US astronaut from the Federal Republic of Germany, is currently scheduled for November 1983 from Kennedy Space Center, Florida. This 9-day mission will be the first launch of the reusable Spacelab which will carry about 70 to 75 experiments to a 250 km orbit at an inclination of 57 degrees.

The Shuttle Orbiter Columbia is being reconfigured to acommodate the Spacelab as its primary payload. The Spacelab, a system of human-occupied work volumes and pallets exposed to space, has been developed by the European Space Agency (ESA) as part of the US Space Transportation System. Ten European counties and approximately 50 firms are participating in the development and production of Spacelab through ESA's prime contractor, ERNO, at Bremen, Germany. ESA is performing all development work and providing the first flight units without charge to NASA. NASA is purchasing the second set of flight units as part of the agreement with ESA.

The experiments cover investigations in life sciences, atmospheric and space plasma physics, astronomy, solar physics, Earth observations, and material science and technology. The experiments all require some property of the space environment for proper operation. These properties include: weightlessness, the ability to view the sky without looking through the atmosphhere, access to the space enviroment near the Earth, and synoptic views of the Earth. Most of the life science experiments also require the presence of astronauts as test subjects.

Some student experiments will be selected from among those ready to go at flight time. These are carried aboard in suitcase-type containers and stowed in lockers. Because of the late selection, information on these experiments is not available at this time.

There are two major alternatives to the proposed action: (1) No action, and (2) use of expendable launch vehicles (ELV's) or sounding rockets to accomplsih the experiments.

Since the experiments for STS-9 require access to space or some property of the space environment, such as prolonged weightlessness, which can only be obtained in space, there are no terrestrial equivalents. The no action alternative thus implies abandoning the research experiments, their information goals, and the benefits of the anticipated applications.

While the experiments have been designed for use on the Shuttle, many of them could be reconfigured to fly as automated experiments on ELV's. Use of unmanned ELV's, however, would require abandoning most of the life science experiments which use astronauts as test subjects. Conceptually, the other expermiments and reentry system (to permit recovery of the instruments, data, and specimens) could be launched on one Titan vehicle. For economic and technical reasons, it might be desirable to divide the experiments into smaller groups and launched on smaller vehicles, such as NASA's Delta or Scout vehicles. Some of the experiments have been developed or tested with use of sounding rockets, and the Spacelab experiments could be approxmiated by their cintinued use. Sounding rockets do not achieve orbit and therefore provide only a few minutes in the space environment. They are considered to be of questionable usefulness for those applications because most the experiments require operating times in space far beyond those achievable with sounding rockets.

Many of the experiments are being performed to gather information which will lead to further applications in space. They have been developed under the assumption that the Space Shuttle, with its relatively benign launch and recovery environment, will be available to support those later applications. If the Shuttle were not to be used for the current experiments, funding constraints both in Europe and the US are such that it is unlikely that many of the experiments could be funded now or in the foreseeable future. For the proposed action and the alternative of using expendable launch vehicles, there are no measurable, long-term, adverse environmental consequences from normal operations. The Spacelab will be taken from a controlled environment, launched to a low Earth orbit and returned after a short time. Small items of debris which may be released from the Orbiter at a 250 km altitude will experience residual drag from the atmosphere and reenter and burn up in less than a year.

The Shuttle launch, however, can cause some local, temporary adverse impacts to the enviroment. These are chiefly noise and potential localized spotting of vegetation from hydrogen chloride (HCl) in the exhaust of the Shuttle's Solid Rocket Boosters. The HCl can combine with the water vapor in the exhaust and atmosphere to form an acid mist which can be precipitate downwind from the launch pad.

Low probability accidents to the Shuttle on the pad or in flight might result in a locally catastophic fire or explosion. If the astronauts were aboard the Shuttle, it is likely they would lose their lives. There also would be locally severe damage to the environment, including the potential for additional human exposure to acid mist or rain. Additional information on the environmental consequences of Shuttle launches and accidents is given in the Final Environmental Impact Statement for the Space Shuttle Program.

The Spacelab and its experiments have undergone extensive safety reviews in accordance with NASA's safety policies and requirements. These policies are directed at reducing the probability and extent of accidents. The Spacelab and its experiments do not contain substances which would be likely to intensify an accident to the Shuttle.

Use of ELV's would result in the same type of temporary and local environmental impacts, but they would

have lower magnitude because the ELV's are smaller than the Shuttle. Use of ELV's also would remove risks to the astronauts, but at the expense of not having their services.

The impacts of the no action alternative would be predominately socioeconomic. There would be a loss of the employment associated with Spacelab as well as its cost and benefits. The potential future benefits of the applications of the experimental information would be foregone.

SUPPLEMENTARY INFORMATION: The environment assessment for this proposed project was completed by the National Aeronautics and Space Administration in September 1983.

Conclusion: The Shuttle launch of the STS-9 payloads will not result in any significant adverse environmental impacts. No environmental impact statement is required for this launch.

EFFECTIVE DATE: November 23, 1983.

ADDRESS: National Aeronautics and Space Administration, Code MC, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Don Turner, 202-755-3036.

Dated: November 16, 1983.

John W. Boyd,

Associate Administrator for Management.

[FR Doc. 83-31456 Filed 11-22-83; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum Services; General Operating Support Program

AGENCY: Institute of Museum Services, NFAH.

ACTION: Grant Application Notice for Fiscal Year 1984.

This grant application announcement applies only to the General Operating Support Program (GOS).

Applications are invited by the Institute of Museum Services (IMS) for General Operating Support (GOS) awards under 45 CFR Part 1180 for Fiscal Year 1984.

Nature of Program: IMS makes awards under the GOS Program to museums to maintain, increase, or improve museum services. The purpose of these awards is to ease the financial burden borne by museums as a result of their increased use by the public and to help them carry out their educational role, as well as other functions. Section 206 of the Museum Services Act, Title II of Pub. L. 94-462, as amended, contains authority for this program. (20 U.S.C. 965)

Deadline Date for Transmittal of Applications: An application for a new grant must be mailed or hand-delivered by February 15, 1984.

Applications Delivered by Mail: An application sent by mail must be addressed to the Institute of Museum Services, 1100 Pennsylvania Avenue, N.W., Room 609, Washington, D.C. 20506.

An applicant must be prepared to show one of the following as proof of timely mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other dated proof of mailing acceptable to the Director of IMS.

If an application is mailed through the U.S. Postal Service, the Director does not accept either of the following as proof of mailing: (1) A private metered postmark; or (2) a mail receipt that is not date-cancelled by the U.S.Postal Service.

Applications Delivered by Hand: An application that is hand-delivered must be taken to the Institute of Museum Services, Old Post Office Building, 1100 Pennsylvania Avenue, NW., Room 609, Washington, D.C. 20506.

IMS will accept a hand-delivered application between 9:00 a.m. and 4:30 P.M. (Washington, D.C. time) daily, except Saturdays, Sundays, and Federal holidays.

An application that is hand-delivered will not be accepted after 4:30 p.m. on the deadline date.

Program Information: Program information is contained in the final regulations published on June 17, 1983 in FR Vol. 48, No. 118, pages 27727-27734 and in the application forms and accompanying instructions in the Application Package. See paragraph on *Application Form.*

Available Funds: An appropriation for the Institute of Museum Services for Fiscal Year 1984 is contained in the Department of the Interior and Related Agencies Appropriation Act, 1984 Pub. L. 98-146 (November 4, 1983). This Act appropriates $20,150,000 for the IMS for Fiscal Year 1984, $15,460,000 of which is expected to be available for GOS grants.

It is anticipated that no museum will receive more than $50,000 under the Act for Fiscal Year 1984 and that most museums which are funded will receive a smaller amount. (45 CFR 1180.9). In addition, IMS normally does not make grants for more than 10 percent of a museum's most recently completed fiscal year's actual non-federal operating income. (See 45 CFR 1180.16(b)).

Application Forms: IMS is mailing application forms and program information in an Application Packet to museums and other institutions on its mailing list. Applicants may obtain Application Packets by writing to the Institute of Museum Services, 1100 Pennsylvania Avenue, N.W., Room 609, Washington, D.C. 20506.

Applicable Regulations: Final regulations for the General Operating Support grant program were published in the **Federal Register** on June 17, 1983 FR Vol. 48, No. 118., pages 27727-27734. The National Museum Services Board has approved the issuance of a limited number of technical amendments to these regulations to reflect legislative changes or requests for clarification. These amendments will be set forth in a future publication in the **Federal Register.** These amendments are expected to apply to the Fiscal Year 1984 GOS competition.

In particular amendments will be made to implement language in the Fiscal Year 1984 Appropriation Act regarding the applicability of Section 1180.5(g) of the regulations (relating to receipt of challenge grant funds). Clarification will also be made regarding the submission of financial information by museums using a cash basis system of accounting. Other technical and clarifying amendments are expected to be made. As revised, the regulations published on June 17, 1983 will apply to the award of grants for Fiscal Year 1984.

FOR FURTHER INFORMATION CONTACT: Ruth Weant, Program Director, Institute of Museum Services, 1100 Pennsylvania Avenue, NW., Room 609, Washington, D.C. 20506. Telephone: (202) 786-0539.

(Catalog of Federal Domestic Assistance No. 45.301 Institute of Museum Services)

Dated: November 17, 1983.

Susan Phillips,

Director, Institute of Museum Services.

[FR Doc. 83-31477 Filed 11-22-83; 8:45 am]

BILLING CODE 7036-01-M

Institute of Museum Services; Museum Assessment Program

AGENCY: Institute of Museum Services; NFAH.

ACTION: 1Grant application Announcement for Fiscal Year 1984.

This grant application announcement applies only to the Museum Assessment Program (MAP).

Following the date of publication of this announcement of Institute of Museum Services ((IMS) will be

receiving applications for grants under the Museum Assessment Program (MAP) for Fiscal Year 1984.

Nature of Program: The Director of IMS makes grants under the Museum Assessment Program to assist museums in carring out institutional assessments. The program is designed to help museums—paricularly those with small budgets—to provide better services and broaden their bases of private and other non-Federal financial support through an independent professional assessment of their programs and operations. A museum as defined in 45 CFR 1180.3 may apply for a MAP grant. A museum which receives a MAP grant for a fiscal year may not receive another MAP grant in the name or any subsequent fiscal year. Accordingly, a museum which received a grant under the MAP program in Fiscal Year 1981 or Fiscal Year 1983 (the only prior fiscal years in which grants were made) is ineligible for such assistance in Fiscal Year 1984 or any subsequent fiscal year. A museum which applies for a MAP grant for Fiscal Year 1984 is not barred from applying for or receiving a General Operating Support or Special Project grant for Fiscal Year 1984.

A museum must use the grant for assessment assistance to pay for: expenses of institutional assessment such as registration fees; surveyor honoraria; travel and other expenses of a surveyor; and technical assistance materials. The amount of a MAP grant to a museum may not exeed $600.

Grant Application Procedures: The Director considers an application (on a form supplied by IMS) *by a museum* for a grant for assessment assistance only if: (1) The museum first applies for assessment to an appropriate professional organization as defined in the regulations and (2) that professional organization notifies IMS that the application (to the professional organization) for assessment is complete and that the museum applying for assessment is eligible to participate as a museum as defined in 45 CFR 1180.3 of the regulations. The American Association of Museums (AAM) is an organization which has been designated as an appropriate professional organization. To participate in the assessment program, a museum MUST APPLY to AAM and complete the self-study questionnaire provided by AAM.

In order to avoid needless paperwork by museums, IMS supplies an application form and instructions to a museum *only after* the professional organization has notified IMS that the museum qualifies under the above-described procedures. Applications are supplied by IMS to such museums until available funds are exhausted or until July 13, 1984, whichever first occurs. Accordingly, a museum interested in the program should first apply to the professional organization (AAM). Interested museums should contact AAM for further information: The American Association of Museums, 1055 Thomas Jefferson Street, N.W., Washington, D.C. 20007. Telephone: (202) 338-5300.

The Director approves applications meeting the MAP grant requirements on a first-come, first-served basis, (i.e., in the order in which an application is received and has been determined to have met applicable requirements). Applications are approved for awards, subject to the availability of funds, until a given date in the fiscal year established by publication in the **Federal Register**. For Fiscal Year 1984, IMS establishes three such dates, December 30, 1983, March 30, 1984, and July 13, 1984. If a museum's MAP application is received on or before the indicated date, it will be processed together with other MAP applications received during that period. Applications received after the indicated date will be processed during the subsequent period. In no event will applications received after July 13, 1984 be processed for Fisal Year 1984 awards. There are no selection criteria. Matching requirements do not apply.

Applicable Regulations: Applicable regulations may currently be found in 34 CFR Part 64, Subpart B, §§ 64.20–64.26 (46 FR 33247, June 29, 1981). These regulations and procedures set forth therein were the regulations and procedures used in conducting the program in Fiscal Years 1981 and 1983. Because these regulations were issued and published prior to the transfer of IMS to the National Foundation on the Arts and the Humanities, IMS anticipates reissuing and publishing these regulations, with technical amendments, as a new subpart of part 1180 of Title 45 CFR (part 1180 now contains other final regulations of IMS).

The reissued MAP regulations will contain technical amendments to conform the regulations to the transfer of IMS to the National Foundation, including provisions for administrative functions to be carried out by the Director of IMS rather that the Secretary of Education and cross-references to the appropriate provisions of the IMS grant regulation, Subparts A, B, and C of Part 1180, rather than the Education Department General Administrative Regulations. Part 1180 was most recently published on June 17, 1983, 48 FR 27727. No substantive changes will be made in the operation of the MAP program. The National Museum Services Board has, at its meeting of October 14, 1983, approved the reissuance of these MAP regulations and a draft of them is in final clearance process. It is anticipated that the reissued MAP regulations will govern the award of grants under MAP in Fiscal Year 1984.

FOR FURTHER INFORMATION CONTACT: Ruth Weant, Program Director, Institute of Museum Services, 1100 Pennsylvania Avenue, NW., Room 609, Washington, D.C. 20506. Telephone: (202) 786-0539.

(Catalog of Federal Domestic Assistance No. 45.301 Institute of Museum Services)

Dated: November 16, 1983.

Susan Phillips,

Director, Institute of Museum Services.

[FR Doc. 83-31478 Filed 11-22-83; 8:45 am]

BILLING CODE 7036-01-M

NATIONAL SCIENCE FOUNDATION

Forms Submitted for OMB Review

In accordance with the Paperwork Reduction Act and OMB Guidelines, NSF is posting this notice of information collection that will affect the public.

Agency Clearance Officer: Herman G. Fleming, (202) 357-9421

OMB Officer: Andrew Velez-Rivera, (202) 395-7313

Title: Survey of Scientific and Engineering Expenditures at Universities and Colleges: FY 1984, 85, 86.

Affected Public: Universities and Colleges

Number of Responses: 422; total of 8,100 hours

Abstract: This unique data system which is unavailable from any other source provides the basis for National planning and policy formation regarding academic science and technology. These data are used by Congress, other Federal agencies, Industry, Pofessional societies and Foundations, States, Universities, the Press, International groups, and NSF. The affected public include universities and colleges and their associated Federally Funded Research and development Centers.

Dated: November 18, 1983.

Herman G. Fleming,

OMB Clearance Officer.

[FR Doc. 83-31429 Filed 11-22-83; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Applications for Licenses To Export and Import Nuclear Facilities or Materials

Pursuant to 10 CFR 110.70(b) "Public notice of receipt of an application", please take notice that the Nuclear Regulatory Commission has received the following applications for export and import licenses. Copies of the applications are on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H Street, NW., Washington, D.C.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the Secretary, U.S. Nuclear Regulatory Commission, and the Executive Secretary, Department of State, Washington, D.C. 20520.

In its review of applications for licenses to export production or utilization facilities, special nuclear materials or source material, noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the facility or material to be exported. The table below lists all new major applications.

Dated this 17th day of November 1983, at Bethesda, Maryland.

For the Nuclear Regulatory Commission.

James V. Zimmerman,

Assistant Director, Export/Import and International Safeguards, Office of International Programs.

FEDERAL REGISTER EXPORTS AND IMPORTS

Name of applicant, date of application, date received, application number	Material type	Material in kilograms		End-use	Country of destination
		Total element	Total isotope		
Westinghouse Electric Corp., Oct. 26, 1983, Oct. 31, 1983, XSNM0740 (02).	4.15 percent enriched uranium.	[1] 97,200	[1] 4,034	Four reloads of fuel for Kori 1	Korea.
Braunkohle Transport USA, Dec. 11, 1983, Dec. 15, 1983, XUO8586.		(*)	(*)	For use in light water reactors located in EURATOM only	EURATOM.
Braunkohle Transport USA, Dec. 11, 1983, Dec. 15, 1983, XUO8587.		(*)	(*)	For use in light water reactors located in EURATOM only	EURATOM (thru USSR).
Braunkohle Transport USA, Dec. 10, 1983, Dec. 14, 1983, ISNM83011 (02).	Natural and low enriched uranium.	[1] 4,500,000	[1] 160,000	Amend to authorize increased quantity for import. Use as fuel in light water reactor.	Various countries.

[1] Additional.
[2] 1,500,000 kilograms uranium as natural hexafluoride.
[3] 500,000 kilograms uranium as natural hexafluoride.

[FR Doc. 83-31509 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-440A]

Cleveland Electric Illuminating Co., Ohio Edison Co., Toledo Edison Company and Duquesne Light Co.; Finding of No Significant Antitrust Changes and Time for Filing Requests for Reevaluation

The Director of Nuclear Reactor Regulation has made an initial finding in accordance with Section 105c(2) of the Atomic Energy Act of 1954, as amended, that no significant (antitrust) changes in the licensees' activities or proposed activities have occurred subsequent to the previous construction permit review of Unit 1 of the Perry Nuclear Power Plant by the Attorney General and the Commission. The finding is as follows:

Section 105c(2) of the Atomic Energy Act of 1954, as amended, provides for an antitrust review of an application for an operating license if the Commission determines that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous construction permit review. The Commission has delegated the authority to make the "significant change" to the Director, Office of Nuclear Reactor Regulation. Based upon an examination of the events since issuance of the Perry 1 construction permit to the Cleveland Electric Illuminating Co., Ohio Edison Co., Toledo Edison Co. and the Duquesne Light Co., the staffs of the Antitrust and Economic Analysis Section of the Site Analysis Branch, Office of Nuclear Reactor Regulation and the Antitrust Section of the Office of the Executive Legal Director, hereafter referred to as "staff," have jointly concluded, after consultation with the Department of Justice, that the changes that have occurred since the antitrust construction permit (CP) review are not of the nature to require a second antitrust review at the operating license (OL) stage of the application.

In reaching this conclusion, the staff considered the structure of the electric utility industry in northern Ohio and western Pennsylvania, the events relevant to the Perry construction permit review and the events that have occurred subsequent to the construction permit review.

The conclusion of the staff's analysis is as follows:

The Perry/Davis-Besse construction permit antitrust review represented one of the three NRC cases to date which have come to trial. As a result of extensive testimony and documentation regarding anticompetitive conduct by the applicants in the CP antitrust review, Licensing Board issued and the Appeal Board affirmed, a set of the license conditions that addressed the applicants planning and operating procedures in effect within the CCCT.

Even though the applicants, jointly and individually, maintain substantial market power in the CCCT, the relative significance of their market power has been lessened and to the extent previously abused, mitigated by the institution of the Perry/Davis-Besse license conditions. Applicants have begun to work with and provide smaller systems in the area the means to search out alternative sources of power and energy. At the same time applicants have helped enhance the reliability of these same smaller systems by offering them power and services previously denied, but now mandated by the Perry/Davis-Besse license conditions.

The changes in the applicants' activities since the construction permit review have been largely procompetitive. The smaller power systems in the area, notably the Cities of Cleveland and Painesville and the wholesale customers of Ohio Edison, have taken advantage of, 1) newly constructed interconnections, 2) the ability to wheel power over applicants' transmission facilities, and 3) partial requirements wholesale power purchases—all types of service denied by the applicants prior to the CP antitrust review and remedied by the license conditions that resulted from that review process.

One significant change with anticompetitive implications was noted in the

analysis since the CP review, i.e., the problems associated with the transmission scheduled initially filed by CEI before the FERC and ultimately litigated at the agency. As discussed *supra*, this change did not lend itself to review and remedy through the mechanism provided for operating license antitrust reviews. The anticompetitive posture taken by CEI in its dealings with the City of Cleveland during the time period between the conclusion of the CP review but prior to the OL review process was satisfactorily remedied through the Commission's rules governing compliance procedures.

At present, there is an on-going process pursuant to a recommendation by the Department of Justice that the NRC issue a civil penalty against CEI for its role in delaying implementation of effective wheeling rates before the FERC. It is the staff's opinion that such a civil penalty is not warranted. Should the Commission disagree with staff's recommendation and pursue the civil penalty issue further, the procedural steps associated with the civil penalty issue would be divorced from and conducted independently of the OL antitrust review. Consequently, in terms of the OL antitrust review, no Commission remedy would be warranted and no negative significant change determination would result from the civil penalty proceeding.

Staff has identified a number of changes that, 1) have occurred since the construction permit review, and 2) are reasonably attributable to the licensees. However, many of these changes are in conformance with the construction permit antitrust license conditions and have had positive performance effects on the availability of bulk power supply and on competition in the area generally. The other changes which have been documented herein have not had significant negative antitrust implications that would likely warrant remedial action by the Commission in an OL forum and therefore do not warrant a significant change finding.

Based upon, 1) the successful implementation of the construction permit antitrust license conditions, 2) the satisfactory resolution of a compliance problem which occurred after the CP review yet prior to the OL review, and 3) the expected resolution of the civil penalty issue in a separate and distinct format from the OL review process, staff recommends that no affirmative significant change determination be made pursuant to he application for an operating license for Unit 1 of the Perry Nuclear Power Plant.

Based on the staff's analysis, it is my finding that a formal operating license antitrust review of the Perry Nuclear Power Plant, Unit 1 is not required.

Signed on November 7, 1983 by Harold R. Denton, Director of Office of Nuclear Reactor Regulation.

Any person whose interest may be affected by this finding may file with full particulars a request for reevaluation with the Director of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 by (30 days). Requests for a reevaluation of the no significant changes determination shall be accepted after the date when the Director's finding becomes final but before the issuance of the OL only if they contain new information, such as information about facts or events of antitrust significance that have occurred since that date, or information that could not reasonably have been submitted prior to that date.

For the Nuclear Regulatory Commission.

Wm. H. Regan, Jr.,

Chief, Site Analysis Branch, Division of Engineering, Office of Nuclear Reactor Regulation.

[FR Doc. 83-31510 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-440, 50-441]

Cleveland Electric Illuminating Co., et al.; Perry Nuclear Power Plant, Units 1 & 2

Notice is hereby given that the Director, Office of Inspection and Enforcement, has denied a petition under 10 CFR 2.206 filed by Ms. Susan L. Hiatt on behalf of Ohio Citizens for Responsible Energy (OCRE), of Mentor, Ohio. This petition related to the Perry Nuclear Power Plant, Units 1 & 2. In its petition, OCRE alleged that Cleveland Electric Illuminating Co. had made false statements in its application concerning the use of herbicides to control vegetation along transmission lines.

The reasons for the denial of OCRE's petition are fully described in the "Director's Decision Under 10 CFR 2.206" issued on this date, which is available for public inspection in the Commission's Public Document Room located at 1717 H Street, NW., Washington, D.C. 20555, and in the local public document room for the Perry Nuclear Power Plant located at Perry Public Library, 3753 Main Street, Perry, Ohio 44081. A copy of the decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR 2.206(c).

Dated at Bethesda, Maryland this 15th day of November 1983.

For the Nuclear Regulatory Commission.

Richard C. DeYoung,

Director Office of Inspection and Enforcement.

During the course of the ongoing operating license proceeding for Cleveland Electric Illuminating Company's (CEI) Perry Nuclear Power Plant (PNPP), Ms. Susan L. Hiatt, on behalf of the Ohio Citizens for Responsible Energy (OCRE), filed a motion before the Atomic Safety and Licensing Board (ASLB) for summary disposition and dismissal of the license application on the basis that CEI had made material false statements in its application concerning the use of herbicides to control vegetation along transmission lines. On May 9, 1983, the ASLB ruled that the motion was directed at an issue not permitted before the Board and consequently denied the motion. The Board, however, asked the NRC Staff to provide OCRE's documentation to the appropriate persons for consideration as a petition for enforcement action under 10 CFR 2.206. Notice of receipt of the petition for handling as a 2.206 request was published in the **Federal Register** on June 14, 1983 (48 FR 27327). OCRE supplemented its petition by letter dated July 5, 1983.

OCRE contends that information given in response to a staff question on use of herbicides along transmission line right-of-ways, and used by the staff in preparing the Draft and Final Environmental Statements, was subsequently contradicted in a submission by the licensee to the Ohio Power Siting Board. The licensee did not change the information previously provided to the NRC. Thus, OCRE contends, the licensee made a material false statement either in its original statement to the Commission or by its failure to correct it. Consequently, OCRE request that the licensee's operating license application be dismissed, its construction permit be revoked or a civil penalty be assessed. For the reasons set forth below, OCRE's request for action is denied.

Background

Prior to granting a construction permit to CEI[1] for the Perry facilities, the Commission prepared a Final Environmental Statement (issued April 1974). In that statement, the Commission discussed the proposed methods for initial clearing and maintenance of transmission line right-of-ways for the licensee's two proposed lines—the Macedonia-Inland line and the Perry-Hanna line. CEI indicated in Section 3.9 and Appendix B3.9 of its Environmental Report for its construction permit that, when permitted and where feasible, it would use herbicides on selected plants as a basal spray before cutting. Where such use was not feasible, mechanical clearing would be used. The

[1] CEI is the applicant, acting as agent for the other co-owners Duquesne Light Company, Ohio Edison Company and Toledo Edison Company. CEI is responsible for all submittals to the NRC and for construction and operation of the PNPP facility. Other co-owners have responsibilities for those portions of the distribution system offsite within their respective service areas.

Environmental Report indicated that, in service areas of Ohio Edison, herbicides would be used for clearing, with extra care taken in certain areas and in compliance with all regulations. (FES–CP, Section 2.2.1.2, p. 5–22 and 5–23). The Commission found no significant effects from such proposed practices and imposed no specific limitations on use of the herbicides when the construction permit was issued.

The applicant submitted its PNPP Environmental Report—Operating License Stage (ER–OL) on June 20, 1980. It was docketed on June 19, 1981. The staff then initiated it operating license environmental review.

The applicant indicated in Section 5.5 of the ER–OL that, "The operation and maintenance methods for the transmission system are unchanged from those described in the ER–CP. The estimated effects of the operation and maintenance of the transmission system are also unchanged." ER–OL, p. 5.5–1. In section 2.2 of the ER–OL, the applicant also reported the results of its construction monitoring program and of terrestrial ecology studies conducted onsite between March and October 1972. In Section 2.2.2.2.3, the applicant indicated that the spotted turtle (*clemmys guttata*), a species listed as "endangered" by the State of Ohio, had been found onsite in several locations, including the transmission corridor in the southeastern part of the site.

As part of its environmental analysis for the operating license review, the NRC staff posed a number of questions to the applicant. On July 31, 1981, the staff asked the applicant to "Provide an assessment of the effects of transmission line maintenance procedures on the spotted turtle *(clemmys guttata)*. Indicate whether herbicides will be used along any portions of the Perry Transmission lines." Question 290.08. The applicant's response on November 20, 1981 was "It is not the policy of CEI to use herbicides for vegetation control along the Perry transmission lines. CEI cuts the vegetation with a bush hog. To date, there have not been any apparent effects on the spotted turtle."

In January 1982, the Ohio Power Siting Board denied joint applicants, CEI and Ohio Edison, a certificate of environmental compatibility and public need for the Perry-Hanna transmission line.

In its Draft Environmental Statement, issued in March 1982, and its Final Environmental Statement, NUREG–0884, issued in August 1982, the staff described the facility and related environment for areas where additional or changed information existed and any changes in the staff's evaluation of the environmental effects of operting the PNPP facility in light of information gained since the FES-CP was issued in April 1974. The staff noted in the FES that the Perry-Macedonia-Inland line was under construction but that the originally proposed Perry-Hanna line had been denied approval by the Ohio Power Siting Board. The staff stated that, when final alignments for the Perry-Hanna line are approved by the State, the applicant will be required to provide a description and analyses of any changes pursuant to conditions of the construction permit.[2] NUREG–0884, section 4.2.7, p. 4–10. The staff also discussed the presence of the spotted turtle onsite and noted that it was the staff's understanding that the applicant was currently discussing with the Division of Wildlife of the Ohio Department of Natural Resources habitat requirements and methods of protection. NUREG–0884, 4.3.7.2, p. 4–25.

In its discussion of environmental consequences, the staff summarized as follows:

> Maintenance procedures for vegetative control along the PNPP transmission lines will consist of periodical mechanical cutting employing a bush hog. The applicant indicates that is is not his policy to use herbicides for vegetation control along the PNPP transmission lines. Thus, it is the staff's evaluation that adverse impacts from the maintenance activities will be minimal. NUREG–0884 at 5–8.

The consturction permits state:

With respect to any impacts of PNPP operation on the spotted turtle, the staff found that to date, the spotted turtle's habitat has not been affected by activities at PNPP and that the applicant was discussing the possible effects of future construction and operating activities on the turtle with the State of Ohio.

In October 1982, CEI and Ohio Edison filed an amended application before the Ohio Power Siting Board for the Perry-Hanna transmission line. In the amended application, as in their orginal 1978 application, the applicants stated they would use a number of herbicides and described the methods of application and chemical components of those to be used.

Analysis

The issue is whether the applicant's statement in its response to Question 290.08 concerning the use of herbicides or its failure to correct the staff's conclusions in the FES on maintenance procedures is a "material false statement," and, if so, what enforcement action, if any, is appropriate.

The Commission's authority to take enforcement action for material false statements derives from section 186 of the Atomic Energy Act of 1954, as amended:

> Any license may be revoked for any material false statement in the application or any statement of fact required under section 182, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Commission to refuse to grant a license on an original application. . . . 42 U.S.C. 2236(a).

The Commission addressed the meaning of the term "material false statement" in its decision in *Virginia Electric & Power Co.*, (North Anna Power Station, Units 1 & 2), CLI–76–22, 4 NRC 480 (1976), *aff'd*, 571 F.2d 1289 (4th Cir. 1978) (hereinafter *VEPCO*). In *VEPCO*, the Commission determined that material false statements encompass material omisions. 4 NRC at 489–91. Knowledge of falsity is not necessary for liability for a material false statement. 4 NRC at 486. With respect to the materiality of an omission, the Commission stated:

> By reading material false statements to encompass omissions of material data, we do not suggest that unless all information, however trivial, is forwarded to the agency the applicant will be subject to civil penalties. An omission must be material to the licensing process to bring Section 186 into play . . . [D]eterminations of materiality require careful, common-sense judgments of the context in which information appears and the stage of the licensing process involved. Materiality depends upon whether information has a natural tendency or capability to influence a reasonable agency expert. 4 NRC at 491.

The first question to be addressed is whether the applicant's response to Question 290.08 was false or whether pertinent information was omitted. The staff asked the applicant to assess the effects of transmission line maintenance procedures on the spotted turtle and to state whether herbicides would be used along any portion of the Perry transmission lines. CEI, the entity responsible for submittals to the NRC and for construction and operation of the PNPP, replied with regard to its own

---

2 Before engaging in a construction activity that may result in a significant adverse environmental impact that was not evaluated or that is significantly greater than evaluated in the Final Environmental Statement, Applicants shall provide written notification to the Director, Division of Site Safety and Environmental Analysis; and

If unexpected harmful effects or evidence of irreversible damage are detected during facility construction, Applicants shall provide to the Commission an accepteble analysis of the problem and a plan of action to eliminate or significantly reduce the harmful effects of damage. (See License Conditions F.6 & F.7 construction permit numbers of CPPR–148 & CPPR–149).

practices but did not address the practices of its co-applicants. CEI's response that CEI's policy was not to use herbicides along the Perry Transmission lines was true as far as it went. However, CEI omitted the fact that the other owners of the plant planned to use herbicides to maintain portions of the transmission line corridors passing through their service areas. Under the criteria established by the Commission, both the applicant's initial incomplete statement in response to the staff's question and the failure to correct the staff's use of the statement in the FES are "false statements" by omission.

The second question is whether these omissions are "material," in the sense of having the capability to influence a reasonable agency expert or cause him or her to inquire further. With respect to the general issue of the use of herbicides for transmission line maintenance, the staff had previously evaluated the practice in its FES–CP and concluded that the environmental impact would not be significant. This conclusion was based upon information supplied by the applicant in the ER–OL. The applicant had correctly stated in the ER–OL that transmission line maintenance would be as stated in the ER–CP, *i.e.*, by use of herbicides. This statement was correct because some co-owners intended to use herbicides. The staff apparently did not notice the discrepancy between the ER–OL and the response to Question 290.08. It relied on the response to Question 290.08 and included that information in its discussion in the FES.

If the applicant had told the staff reviewer in response to Question 290.08 that it intended to use herbicides along some transmission line right-of-ways, the reviewer would then have tried to determine whether the use of specific herbicides to be applied would be detrimental to the spotted turtle or its habitat. If no specific information was available, or the information indicated a detrimental impact, the staff would have consulted with the State specialist on the spotted turtle for specific recommendations. Thus, the omissions were material because, had accurate information been provided, the staff would have taken additional actions.

After determining that the licensee made a material false statement, the Director examined what enforcement action would be appropriate under the Commission's Enforcement Policy, 10 CFR Part 2, Appendix C. The Enforcement Policy provides for categorization of violations under one of five Severity Levels depending upon the safety and regulatory significance of the violation.

The applicant's initial incomplete statement and its failure to correct the staff's use of the statement in the FES have not had any significant regulatory impact. The staff's review of the transmission lines for the PNPP is not yet complete. The Perry-Hanna line (the only line where herbicides may be used) has not yet been approved and, therefore, any impact of the use of herbicides on the spotted turtle or its habitat offsite is speculative. Moreover, the State reviewers who have the expertise in this area (since it is a State-listed endangered species) have had accurate information on the use of herbicides. When a utility applies for a permit from th Ohio Power Siting Board, the Department of Natural Resources, Division of Wildlife, reviews the request to determine its environmental consequences. Once the Ohio Power Siting Board approves a transmission line route, the NRC will rely on its conclusions regarding the environmental consequences of the route for the State's endangered species such as the spotted turtle. Thus, the environmental consequences of herbicide usage at Perry are being adequately considered and the applicant's false statement has not impeded that consideration.

There is no indication that this was other than an isolated occurrence or that there was any intent on the part of the applicant to mislead the Commission or gain any economic advantage. Counsel for the applicant had indicated that apparently when CEI reviewed the DES, it did not notice that the staff had broadened CEI's response to include all the transmission lines rather than just CEI's portion alone.[3] Thus, the Director has concluded that this violation should be categorized as a Severity Level IV violation.

A Notice of Violation will be issued to the applicant following the Commission's review in accordance with 10 CFR 2.206(c). The Notice of Violation will require the applicant to respond and describe its corrective actions to prevent similar occurrences in the future. OCRE's request for other enforcement actions is *denied*.

[3] Cleveland Electric Illuminating Company (Perry Nuclear Power Plant, Units 1 & 2), Dockets No. 50–440 and 50–441, transcript of Telephone Conference, May 9, 1983, Tr. 845–847.

Dated at Bethesda, Maryland this 15 day of November 1983.

For the Nuclear Regulatory Commission.

Richard C. DeYoung,

Director, Office of Inspection and Enforcement.

[FR Doc. 83–31511 Filed 11–22–83; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–289/320]

General Public Utilities Nuclear, Corp.; Three Mile Island Nuclear Station, Units 1 and 2

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has issued an interim decision concerning a petition dated March 23, 1983, submitted by Randy King on behalf of the Three Mile Island Public Interest Resource Center and others. The petition has requested that the Commission halt all work at Three Mile Island (TMI) Units 1 and 2 immediately, except for maintenance necessary for safety. The petitioners based their request on the allegations of Richard D. Parks, a senior startup engineer at TMI Unit 2, concerning implementation of the quality assurance program and related areas at TMI. The Director, Office of Nuclear Reactor Regulation, has determined to deny the petitioners' request to the extent that it seeks to have the NRC prohibit the licensee from conducting a load test of the TMI Unit 2 polar crane.

The reasons for this decision are explained in an "Interim Director's Decision under 10 CFR 2.206" (DD–83–18) which is available for public inspection in the Commission's Public Document Room 1717 H Street, NW., Washington, D.C., and in the local Public Document Room for the TMI facility, located in the Government Publications Section of the State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pa., 17126. A copy of this decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR 2.206(c).

Dated at Bethesda, Maryland, this 18th day of November, 1983.

For The Nuclear Regulatory Commission.

Horold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 83–31512 Filed 11–22–83; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 030-09049, 030-19445, 030-01795; License Nos. 08-00216-22, 08-00216-23, SNM-1499; EA No. 83-73]

The George Washington University Medical Center; Order Imposing Civil Monetary Penalties

I

The George Washington University Medical Center, 2300, Eye Street, NW., Washington, D.C. 20037 (the "licensee") is the holder of License Nos. 08-00216-22, 08-00216-23, and SNM-1499 (the "licenses") issued by the Nuclear Regulatory Commission (the "Commission" or "NRC") which authorize the licensee to possess and use radioactive materials for medical research, diagnosis, therapy, and teaching and training in accordance with conditions specified therein. License No. 08-00216-22 was issued on October 26, 1973, License No. 08-00216-23 was issued on October 26, 1981, and License No. SNM-1499 was issued on February 13, 1973.

II

A routine NRC safety inspection of the licensee's activities under the licenses was conducted on June 1-2, 1983. As a result of the inspection, the NRC staff determined that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalities was serve upon the licensee by letter dated Septembr 1, 1983. The Notice states the nature of the violations, the provisions of the Nuclear Regulatory Commission's requirement that the licensee had violated, and the amount of civil penalty for each violation. A response dated September 26, 1983 to the Notice of Violation and Proposed Imposition of Civil Penalties was received from the licensee.

III

Upon consideration of the answers received, the statements of fact, explanations, and arguments for remission or mitigation of the proposed civil penalites contained therein, and as set forth in the Appendix to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalties should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended 42(U.S.C. 2282, Pub. L. 96-295), and 10 CFR 2.205, it is herby ordered that:

The licensee pay civil penalties in the amount of Two Thousand Five Hundred Dollars ($2,500) within thirty 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 of the Office of Inspection and Enforcement, USNRC, Washington, D.C. 20555.

V

The licensee may, within thirty days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection and Enforcement. A copy of the hearing request shall also be sent to the Executive Legal Director, USNRC, Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. Upon failure of the licensee to request a hearing within thirty days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection. In the event the license requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the licensee violated NRC requirements as set forth in the Notice of Violation and Proposed Imposition of Civil Penalties; and

(b) Whether, on the basis of such violations, this Order should be sustained.

Dated at Bethesda, Maryland this 15th day of November 1983.

For the Nuclear Regulatory Commission.

Richard C. DeYoung,

Director, Office of Inspection and Enforcement.

Appendix—Evaluations and Conclusions

Although the licensee essentially admits the twelve violations, the licensee's September 26, 1983 response to the Notice of Violation and Proposed Imposition of Civil Penalties dated September 1, 1983 requests that the Severity Level of the aggregate problem be reduced from Level III to Level V, and that the proposed fine be waived. The response provides the reasons why the licensee believes reduction of the Severity Level and waiving of the penalties are appropriate. Provided below are (1) restatement of each violation, (2) the licensee's assertions in support of their requests, and (3) the NRC response to each of the licensee's assertions.

Restatement of Violations:

A. 10 CFR 20.106(a) requires that no licensee release radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR 20, Appendix B, Table II, when averaged over one year. 10 CFR 20, Appendix B, Table II, specifies the effluent release limit for airborne xenon-133 to be 3.0 x 10-7 microcuries per milliliter.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20 and that each licensee make or cause to be made such surveys that are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of June 2, 1983, an adequate survey had not been performed to assure compliance with 10 CFR 20.106(a) in that no evaluation of the concentrations of xenon-133 was made at the boundary of the restricted area to determine the concentration of xenon-133 resulting from releases made during the one-year period ending March 31, 1982, even though surveys at the release point within the restricted area showed xenon-133 in concentrations of 7.5 x 10-7 microcurie per milliliter when averaged over one year.

B. 10 CFR 20.301 requires that no licensee dispose of licensed material except in accordance with certain authorized methods which are specified in 10 CFR 20.301(a), (b) and (c).

Condition 22 of License No. 08-00216-22 requires a survey to be made of material placed in normal trash.

Contrary to the above, on January 25, 1983, a bag of waste consisting of disposable protective clothing and plastic-backed absorbent pads, containing approximately 70 microcuries of iodine-125, was removed from a restricted laboratory and placed in the normal trash without a survey. As a result, this waste was subsequently removed and transported to a public landfill near Lorton, Virginia, a method of disposal not authorized by 10 CFR 20.301(a), (b), or (c).

C. 10 CFR 35.43 requires diagnostic misadminstrations be reported to the NRC Regional Office within 10 days after the end of the calendar quarter in which the misadministration occurred.

Contrary to the above, misadministrations which occurred on October 13, 1982, and November 16, 1982, were not reported to the NRC Regional Office within 10 days after the end of the 4th quarter 1982 (December 31, 1982), and had not been reported as of June 2, 1983.

D. Condition 13 of License No. 08-00216-22 requires that sealed sources containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, sealed sources containing millicurie quantities of cesium-137 for brachytherapy use were not leak tested during the first six months of 1981, or during the entire twelve months of 1982.

E. Condition 21 of License No. 08-00216-22 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in applications dated March 21, 1978, and January 31, 1979; letters with attachments dated March 27, 1979, and April 18, 1979; Items A (ALARA Program), D, and E of letter dated May 15, 1981; and letters dated January 28, 1982, July 1, 1982, and July 13, 1982.

1. Item No. 10 of an attachment to the letter dated March 27, 1979, requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8 (January 1979).

Procedure E of Appendix D, Section 2, requires dose calibrators to be tested quarterly for linearity.

Contrary to the above, as of June 1, 1983, although records of linearity tests were maintained, no records were available to demonstrate that linearity tests were performed on a dose calibrator for the 3rd and 4th quarters of 1980, the 1st quarter of 1981, and the 2nd quarter of 1982.

2. Item No. 10 of the attachment to the letter dated March 27, 1979, requires that survey meters be calibrated every six months.

Contrary to the above, on June 1 1983, an NRC inspector identified that several survey meters located in the research laboratories had not been calibrated since March 1982, an interval in excess of six months.

3. Item No. 15 of the attachment to the letter dated March 27, 1979, requires adherence to the "General Rule for Safe Use of Radioactive Materials" contained in Appendix G of Regulatory Guide 10.8.

a. Rule 2 of Appendix G requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, on June 1, 1982, an NRC inspector observed personnel in the Nuclear Medicine Department who were not wearing disposable gloves while handling and injecting radiopharmaceuticals.

b. Rule 5 of Appendix G requires that there be no eating, drinking, smoking, or application of cosmetics in any area where radioactive materials are stored or used.

Contrary to the above, on June 2, 1982, an NRC inspector observed an individual smoking in Room 407AB, Ross Hall, where radioactive materials are stored, and found evidence of eating and drinking, namely eating utensils and cups, in several other of the research laboratories where radioactive materials are stored.

c. Rule 8 of Appendix G requires that TLD finger badges be worn during elution of generators, and during preparation, assay, and injection of radiopharmaceuticals.

Contrary to the above, on June 1, 1983, an NRC inspector observed a student technologist who was not wearing a TLD ring badge while preparing radiopharmaceuticals.

d. Rule 9 of Appendix G requires that radioactive waste be disposed of only in specifically designated receptacles.

Contrary to the above, on June 2, 1983, a receptacle designated as non-radioactive "cold trash" contained radioactive materials in that a radiation level of seven milliroentgens per hour was identified by the NRC inspector at the surface of the receptacle.

e. Rule 10 of Appendix G requires that there be no pipetting by mouth.

Contrary to the above, on June 2, 1983, an NRC inspector observed evidence (hose) of mouth pipetting in Room 234, Ross Hall, and an individual admitted pipetting quantities of phosphorous-32 by mouth.

f. Rule 11 of Appendix G requires surveys of generator, kit preparation, and injection areas after each procedure or at the end of the day.

Contrary to the above, as of June 1, 1983, documentation reviewed by an NRC inspector demonstrated that surveys were not performed on May 9 and 10, 1983 in the Nuclear Medicine areas and between June 18 to August 2, 1982, October 10 to November 8, 1982 and December 18, 1982 to January 31, 1983 in the Nuclear Cardiology areas.

Collectively, the above twelve violations have been evaluated as a Severity Level III problem (Supplements IV and VI).

(Cumulative Civil Penalty—$2,500—assessed equally among the violations.)

Evaluation of Licensee's Response

Licensee's Assertion: The NRC conclusion that there has been a significant breakdown in management oversight and control of the Radiation Safety Program (RSP) is unwarranted. Rather, a meritorious RSP exists, as demonstrated by the following:

(1) Although the size of the program increased in the past three years, the number of personnel with radiation exposures exceeding low ALARA trigger levels decreased during that time. Also, of 800 thyroid bioassays performed during the same three-year period, only once was the ALARA trigger level exceeded.

(2) An active radiation safety program exists for both students and workers, including on the job radiation safety training, three radiation safety courses for credit, and exams for research personnel who work with radioactive materials.

(3) The Radiation Safety Office (RSO) has developed a calibration technique to provide more accurate indications of exposure levels when working with various isotopes. Further the RSO has developed a method of converting oil-soluble radioactive waste to stable oil-in-water emulsions so they may be disposed in a similar manner as is water-soluble radioactive waste.

(4) An NRC licensing representative commended the security and precautions taken for the cesium irradiator.

NRC Response:

The NRC expects that individuals who work with radioactive materials will be appropriately educated and trained. Further, the NRC expects that licensees will take appropriate measures to ensure adherence to ALARA principles. Such actions on the part of a licensee are not considered extraordinary.

While the NRC recognizes the stated development of calibration techniques and waste-disposal methods as positive factors, the violations described in the Notice of Violation and Proposed Imposition of Civil Penalties cannot be considered reflective of a meritorious RSP.

The NRC staff maintains that the twelve violations do represent a significant breakdown in the control and oversight of the RSP. The staff's conclusions are based on the facts that:

(1) Of the twelve violations described in the Notice, eight were identified by the NRC (Violations C, E2, E3a-E3f), demonstrating that management's monitoring of the RSP was not adequate to identify existing deficiencies.

(2) Six of the violations involved program personnel disregarding program requirements (Violations E3a-E3f), demonstrating that adequate supervision to ensure acceptable

personnel performance was not provided.

(3) One of the violations (Violation A), involving failure to perform an adequate survey to determine the xenon-133 release in March 1982, at the boundary of a restricted area, was identified by the licensee in March, 1982, but was not adequately corrected until after the NRC inspection and enforcement conference, when an adequate survey was then performed, demonstrating that prompt and appropriate corrective action was not taken.

(4) Three of the violations (Violations B, E3c, E3d) were similar to violations identified during an NRC inspection conducted in May 1980, demonstrating that actions to prevent recurrence were not effective.

Management is responsible for proper development of the RSP, including procedures and training, proper supervision of program implementation, and proper actions to correct improper program implementation, including actions to correct identified deficiencies, and actions to prevent recurrence including disciplinary actions.

Licensee's Assertion: The NRC's characterization of the violations in the aggregate as Severity Level III is inappropriate. The NRC Enforcement Policy defines Severity Level III as violations which have an actual or potential impact on the public. The NRC's characterization of the violations as a breakdown in management oversight and control appears to be analogous to the definition of a Severity Level IV violation, namely, degradation of management control systems. The NRC Enforcement Policy further states that Severity Level IV problems are the sort of violations that, if left uncorrected, could lead to matters of significant concern.

NRC Response: Contrary to the licensee's assertions, the NRC Enforcement Policy (10 CFR 2, Appendix C) does not define a Severity Level III violation as one having a high actual or potential impact on the public. Rather, that is the definition of a Severity Level I or II violation, as defined in Section III of the NRC Enforcement Policy. In Section III, Severity Level III violations are defined as cause for significant concern. The twelve violations, representing a significant breakdown in management control of the RSP, are cause for significant concern since personnel failures to adhere to procedures were not identified, identified deficiencies were not promptly and effectively corrected, and previously identified deficiencies recurred. The problem is appropriately classified as Severity Level III and civil penalties are appropriate.

The NRC staff further notes that Violation B, involving improper disposal of radioactive waste, could itself be classified as Severity Level III in accordacne with Section C.6 of Supplement IV of the NRC Enforcement Policy. However, the staff has decided to consider all twelve violations in the aggregate as Severity Level III, so that the emphasis of the civil penalty is placed on the underlying cause of the violations.

Licensee's Assertion: The NRC's allegations that corrective actions were not promptly taken when previous violations were noted by the NRC are incorrect. All violations identified during the NRC inspection conducted in May 1980, were promptly corrected.

NRC Response: Although the specific violations identified in May 1980 were corrected, the actions taken at that time to prevent recurrence were not effective since three of the violations (B, E3c, E3d) recurred. The staff's concerns are increased because one of the violations identified in 1980, involving placement of radioactive trash in the wrong containers, recurred not once, but twice, in January 1983 and again in June 1983.

Licensee Assertion: Many of the violations had been identified and corrected prior to the NRC inspection. Most of the remaining items had been identified and were being worked on by the Radiation Safety Committee.

NRC Response: Only four of the twelve violations were identified by the licensee (Violations A, B, D, E1). The remaining eight violations were identified by the NRC. Additionally, Violation A, which occured in March 1981, was not adequately corrected at the time of the inspection in June 1983. Further, three violations (B, E3c, E3d) were recurrences of previous violations, indicating that actions to prevent recurrence were not effective.

NRC Conclusion:

The violations did occur as originally stated and are appropriately classified in the aggregate as Severity Level III. Assessment of a $2,500 civil penalty for these violations is appropriate. The information provided in the licensee's response does not provide a basis for modifying the enforcement action.

[FR Doc. 83-31515 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-482-OL; ASLBP No. 81-453-03OL]

Kansas Gas & Electric Co., et al., Wolf Creek Generating Station, Unit 1; Reconstitution of Board

Pursuant to the authority contained in 10 CFR 2.721, the Atomic Safety and Licensing Board for *Kansas Gas & Electric Company, et al.* (Wolf Creek Generating Station, Unit 1), Docket No. 50-482-OL, is hereby reconstituted by appointing Administrative Judge Sheldon J. Wolfe in place of Administrative Judge James A. Laurenson, who, because of a schedule conflict, is unable to serve.

As reconstituted, the Board is comprised of the following Administrative Judges:

Sheldon J. Wolfe, Chairman
Dr. George C. Anderson
Dr. Hugh C. Paxton

All correspondence, documents and other material shall be filed with the Board in accordance with 10 CFR 2.701 (1980). The address of the new Board member is:

Administrative Judge Sheldon J. Wolfe, Atomic Safety and Licensing Board, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Dated at Bethesda, Maryland, this 15th day of November, 1983.

B. Paul Cotter, Jr.,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 83-31513 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

Power Authority of the State of New York; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Prior Hearing

The United States Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-59, issued to Power Authority of the State of New York (the licensee), for operation of the James A. FitzPatrick Nuclear Power Plant located in Oswego County, New York.

The amendment proposed by the licensee would revise the operating license and the provisions in the Technical Specifications relating to changes to permit reactor operation at power levels not to exceed 50% of rated power with one recirculation loop out of service. Presently, the FitzPatrick operating license requires plant shutdown if an idle recirculation loop cannot be returned to service within 24

hours. The change proposed by the licenses would modify the Technical Specifications (TSs) as necessary to provide for appropriate Average Power Range Monitor (APRM) flux scram trip and rod block settings, an increase in the safety limit Minimum Critical Power Ratio (MCPR) value and revisions to the allowable Average Planar Linear Heat Generation Rate (APLHGR) values suitable for use with an idle recirculation loop.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By December 23, 1983, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Domenic B. Vassallo: (petitioner's name and telephone number); (date petition was mailed); (plant name); and (publication date and page number of this **Federal Register** notice). A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Mr. Charles M. Pratt, Assistant General Counsel, Power Authority of the State of New York 10019, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated December 29, 1982, as supplemented January 27, 1983 and July 25, 1983 which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Penfield Library, State University College of Oswego, Oswego, New York.

Dated at Bethesda, Maryland this 16th day of November, 1983.

For the Nuclear Regulatory Commission.

Domenic B. Vassallo,

Chief, Operating Reactors Branch No. 3, Division of Licensing.

[FR Doc. 83-31514 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards Subcommittee on Extreme External Phenomena; Meeting

The ACRS Subcommittee on Extreme External Phenomena will hold a meeting on December 8 and 9, 1983, in the Presidential Room at the Airport Executive Inn, 275 South Airport Blvd., San Francisco, CA, (telephone: 415/873-3550).

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows:

Thursday, December 8, 1983-8:30 a.m. until the conclusion of business

Friday, December 9, 1983-8:30 a.m. until the conclusion of business

The Subcommittee will be conducting a workshop on the quantification of seismic design margins. The main topics of discussion will be the adequacy of the available methodology and the ongoing NRC and Industry programs in this area. The agenda will include a discussion

period with interested persons attending the meeting in the audience.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by an hold discussions with representatives of the NRC Staff, Industry, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Dr. Richard Savio (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m., EST.

Dated: November 16, 1983.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 83-31516 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

Advisory Panel for the Decontamination of Three Mile Island, Unit 2; Meeting

Notice is hereby given pursuant to the Federal Advisory Committee Act that the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 will be meeting on December 8, 1983, from 7:00 p.m. to 10:00 p.m. at the Holiday Inn, 23 South Second Street, Harrisburg, Pennsylvania 17101. The meeting will be open to the public.

At this meeting, the Panel will discuss Three Mile Unit 2 cleanup activities. Specifically addressed will be the plans for reactor pressure vessel headlift.

Further information on the meeting may be obtained from Dr. Michael T. Masnik, Three Mile Island Program Office, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301/492-7466.

Dated: November 21, 1983.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 83-31611 Filed 11-22-83; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

SES Performance Review Board

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: Notice is hereby given of the name of a new ad hoc member of the OPM Performance Review Board.

DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Marybeth Sisson, Policy Development Branch, Office of Personnel and EEO, Office of Personnel Management, 1900 "E" Street, NW., Washington, D.C. 20415 (202-632-5462).

SUPPLEMENTARY INFORMATION: Sec. 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 appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive.

Office of Personnel Management.

Donald J. Devine,

Director.

The following Senior Executive Service member has been selected to serve as an ad hoc member of the Performance Review of the Office of Personnel Management:

James W. Morrison, Jr., Associate Director for Compensation.

[FR Doc. 83-31438 Filed 11-22-83; 8:45 am]

BILLING CODE 6325-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 23116; (70-6910)]

Eastern Edision Co., et al.; Proposed Sale of Short Term Notes to Banks

In the matter of Eastern Edison Co., 110 Mulberry Street, Brockton, Massachusetts 02403; Blackstone Valley Electric Co., Washington Highway, P.O. Box 1111, Lincoln, R.I. 02865; Montaup Electric Co., P.O. Box 2333, Boston, Massachusetts 02107.

November 16, 1983.

Eastern Edison Company ("Eastern Edison"), Montaup Electric Company ("Montaup"), and Blackstone Valley Electric Company ("Blackstone") (collectively, the "Companies"), electric utility subsidiaries of Eastern Utilities Associates, a registered holding company, have filed a declaration with this Commission pursuant to Sections 6(a), 7, and 12(c) of the Public Utility Holding Company Act of 1935 ("Act") and Rules 42(b)(2) and 50(a)(2) under the Act.

The Companies propose to issue short-term notes to banks, from time to time during the period December 30, 1983 to December 28, 1984, in aggregate outstanding amounts not to exceed $10 million for Eastern Edison, $30 million for Montaup, and $5 million for Blackstone.

Each note will be dated as of the date of issuance and mature no later than September 30, 1985. Some notes will bear interest at a floating prime rate, have maximum maturities of nine months and be prepayable at any time without premium. Other notes will bear interest at available money, market rates, in all cases less than the prime rate at time of issuance, have maximum maturities of sixty days, and will not be prepayable. Credit lines with banks are subject in some cases to commitment fees (3/8% on the line of credit), or compensating cash balances (no greater than 10% on the line of credit), or both. With such fees or balances, no line of credit would result in an effective cost of borrowing greater than 11.64% based on a prime rate of 11%.

The companies will use the proceeds of the proposed short-term borrowings for general corporate purposes including the renewal of outstanding notes and the financing of cash construction expenditures.

The declaration and any amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by December 12, 1983, to Secretary, Securities and Exhange Commission, Washington, D.C. 20549, and serve a copy on the declarants at the addresses specified above. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for a hearing shall identify specifially the issues of fact or law that are disputed. A person who so requests will be notified of any hearing and will receive a copy of any notice or order issued. After said date, the declaration as then amended, may be permitted to become effective.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 83-31449 Filed 11-22-83; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 20327; (SR-MSRB-83-14)]

Self-Regulatory Organizations; Filing and Immediate Effectivenes of Proposed Rule Change; Municipal Securities Rulemaking Board

October 25, 1983.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that the Muncipal Securities Rulemaking Board ("MSRB" or "Board"), 1120 Connecticut Avenue, NW., Washington, D.C. 20006, filed with the Securities and Exchange Commission a proposed rule change on September 29, 1983, and an amendment thereto on October 21, 1983. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The proposed rule change amends MSRB Rule A-3 to permit individuals who are not associated with any broker, dealer, or muncipal securities dealer, other than by reason of being under common control with or indirectly controlling any broker or dealer which is not a municipal sucurities broker or municipal securities dealer, to serve on the Board as a public representative. The Board has adopted this rule change to conform MSRB Rule A-3 to the new language of Section 15B(b)(2)(B) of the Act which was amended on June 6, 1983, by Public Law No. 98-38 and which redefines the category of individuals who can serve on the Board as public representatives.

The Board has adopted the proposed rule change pursuant to Section 15B(b)(2)(I) of the Act which establishes the Board's general authority to adopt rules relating to the operation and administration of the Board and pursuant to Section 15B(b)(2)(B) of the Act as amended.

The foregoing change has become effective, pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b-4 under the Act. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change within 21 days after the date of publication in the **Federal Register**. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. Reference should be made to File No. SR-MSRB-83-14.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the MSRB.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

George A. Fitzsimmons,

Secretary.

[FR Doc. 83-31450 Filed 11-22-83; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms, and Recordkeeping Requirements; Submittals to OMB October 21-November 4, 1983

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements, transmitted by the Department of Transportation, during the period Oct. 21-Nov. 4, 1983, to the Office of Management and Budget (OMB) for its approval. This notice is published in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35).

FOR FURTHER IMFORMATION CONTACT: John Windsor, John Chandler, or Annette Wilson, Information Requirements Division, M-34, Office of the Secretary of Transportation, 400 7th Street, SW., Washington, D. C. 20590, (202) 426-1887 or Gary Waxman or Wayne Leiss, Office of Management and Budget, New Executive Office Building, Room 3001, Washington, D.C. 20503, (202) 395-7313.

SUPPLEMENTARY INFORMATION:

Background

Section 3507 of Title 44 of the United States Code, as adopted by the Paperwork Reduction Act of 1980, requires that agencies prepare a notice for publication in the **Federal Register**, listing those information collection requests submitted to the Office of Management and Budget (OMB) for approval under that Act. OMB reviews and approves agency submittals in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms, reporting and recordkeeping requirements.

On Mondays and Thursdays, as needed, the Department of Transportation will publish in the **Federal Register** a list of those forms, reporting and recordkeeping requirements that it has submitted to OMB for review and approval under the Paperwork Reduction Act. The list will include new items imposing paperwork burdens on the public as well as revisions, renewals and reinstatements of already existing requirements. OMB approval of an information collection requirement must be renewed at least one every three years. The published list also will include the following information for each item submitted to OMB:

(1) A DOT control number.

(2) An OMB approval number if the submittal involves the renewal, reinstatement or revision of a previously approved item.

(3) The name of the DOT Operating Administration or Secretarial Office involved.

(4) The title of the information collection request.

(5) The form numbers used, if any.

(6) The frequesncy of required responses.

(7) The persons required to respond.

(8) A brief statement of the need for, and uses to be made of, the information collection.

Information Availability and Comments

Copies of the DOT information collection requests submitted to OMB may be obtained from the DOT officials listed in the "For Further Information Contact" paragraph set forth above. Comments on the requests should be forwarded, as quickly as possible, directly to the OMB officials listed in the "For Further Information Contact" paragraph set forth above. If you anticipate submitting substantive comments, but find that more than 5 days from the date of publication is needed to prepare them, please notify the OMB officials of your intent immediately.

Items Submitted for Review by OMB

The following information collection requests were submitted to OMB from Oct. 21–Nov. 4, 1983:

DOT No: 2251
OMB No: 2115–0092
By: U.S. Coast Guard
Title: Fleeting Facility Records
Forms: N/A
Frequency: On occasion
Respondents: Owners of barge fleeting facilities located in vicinity of New Orleans, LA.

Need/Use: This is purely a recordkeeping requirement which requires the persons in charge of barge fleeting facilities to keep records of barge mooring activities and hazardous cargo movements. The records are used to assure regulatory compliance and to provide documentary evidence should enforcement action be necessary. The twice daily mooring inspection is a safety requirement to prevent barges from drifting into navigable waters unattended.

DOT No: 2252
OMB No: 2115–0100
By: U.S. Coast Guard
Title: Shipment of Hazardous Bulk Solids (by water)
Forms: N/A
Frequency: On occasion
Respondents: Solid Bulk Cargo Vessel Owners/Operators

Need/Use: This reporting requirement is needed to ensure that the laws and regulations for safe transportation and stowage of hazardous solid bulk cargoes are complied with. The information is used in three ways: (1) To determine the physical and chemical properties of material to be shipped for proper classification of the new cargo, (2) to study the experience of the manufacturer in handling the material, and (3) to determine the recommended safety precautions to use in preparing the Special Permit. The Coast Guard requires Shipping Papers for barges and vessels and Dangerous Cargo Manifests for vessels for the following reasons: (1) To inform the shipper, handlers and persons in charge of the shipment of the nature and quantity of the hazardous materials being transported; (2) to provide the Coast Guard inspectors the information they need to ascertain whether the proper safety precautions and safe stowage requirements are being observed and; (3) to allow for proper emergency responses if problems of a hazardous nature should develop.

DOT No: 2253
OMB No: 2115–0095
By: U.S. Coast Guard
Title: Plan Approval and Records for Small Passenger Vessels
Forms: N/A
Frequency: On occasion
Respondents: Shipbuilders, owners and operators

Need/Use: This information collection requirement is needed to enforce the laws and regulations promoting the safety of life and property in marine transportation. 46 U.S.C. 3301 and 3305, both of Subchapter T, require every small passenger vessel to be inspected before it is put into service to determine its structural adequacy, and to make sure it has suitable accommodations and equipment to meet regulations. The plans submitted to the Coast Guard are those normally developed by a shipyard designer or manufacturer for the construction of the vessel.

DOT No: 2254
OMB No: 2115–0105
By: U.S. Coast Guard
Title: Evidence of Competency; Person-in-Charge
Forms: N/A
Frequency: On occasion
Respondents: Operators of Waterfront Facilities

Need/Use: This information collection requires waterfront facilities handling hazardous liquids in bulk to provide documentary proof of the competency of persons in charge. This is needed to control accidents due to inexperience or lack of knowledge. The Captain of the Port uses this information to evaluate the qualifications of those persons.

DOT No: 2255
OMB No: 2137–0035
By: Research and Special Programs Administration
Title: Blasting Agent Approvals
Forms: None
Frequency: On occasion
Respondents: Businesses producing blasting agents

Need/Use: Needed to ascertain that materials represented by the manufacturer as being blasting agents do in fact react like a blasting agent and not as an unstable explosive which presents high risks to heat, shock or fire during transporting.

DOT No: 2256
OMB No: New
By: Research and Special Programs Administration
Title: Reports Required from Master of Vessels (To Captain of Port)
Forms: None
Frequency: On occasion
Respondents: Masters of Cargo Vessels

Need/Use: To enable masters of vessels transporting hazardous materials to obtain intructions from the Captain of the Port in the event of emergencies involving hazardous materials prior to entering a port.

DOT No: 2257
OMB No: 2120–0067
By: Federal Aviation Administration
Title: Airport Activity Survey (By Selected Air Carriers)
Forms: FAA Form 1800–31
Frequency: Annually
Respondents: Businesses (Air Taxi and Commercial Operators)

Need/Use: Enplanement data collected from air taxi and commercial operators are required for calculation of air carrier airport sponsor apportionments based on volume of travellers using the facilities as specified by the Airport and Airway Improvement Act of 1982.

DOT No: 2258
OMB No: 2120–0034
By: Federal Aviation Asministration
Title: Application for Airman Medica' Certificate and Student Pilot Certificate
Forms: FAA Form 8500–8
Frequency: Annually
Respondents: Individual applicants

Need/Use: To determine if applicant is medically fit to perform aviation duties and use the airways of the USA.

DOT No: 2259
OMB No: New
By: National Highway Traffic Safety Administration
Title: 49 CFR, New Pneumatic Tires—Passenger Cars Standard 109 Labeling
Forms: None
Frequency: On occasion
Respondents: Manufacturers of tires

Need/Use: This standard requires all new tires for use on motor vehicles other than passengers cars to be labeled with certain information.

DOT No: 2260
OBM No: 2125–0030
By: Federal Highway Administration
Title: Outdoor Advertising and Junkyard Report
Forms: FHWA–1424
Frequency: Annually
Respondents: State Highway Agencies

Need/Use: For the FHWA to administer and monitor the control of outdoor advertising and junkyards as implemented by the States and mandated by the U.S. Congress.

DOT No: 2261
OBM No: New
By: Research and Special Programs Administration
Title: Cigarette Lighter Approvals
Forms: None

Frequency: One time for each type of lighter and packing
Respondents: Manufacturers of cigarette lighter

Need/Use: To ascertain that cigarette lighters being shipped charged with fuel and having an ignition element are so packaged that there will be no ignition during the course of their transportation.

DOT No: 2262
OBM No: 2115-0101
By: United States Coast Guard
Title: Designs for New Marine Portable Tanks
Forms: None
Frequency: On occasion
Respondents: Marine Portable Tank Manufacturers

Need/Use: This information collection is needed in order for the Coast Guard to administer and enforce the laws and regulations promoting the safety of life and property in marine transportation. The plan for the marine portable tank includes detailed engineering specifications which are reviewed by the local Coast Guard technical office to be sure that the tanks can be safely used aboard vessels without danger of fires, chemical spills or similar casualty losses.

DOT No: 2263
OBM No: 2115-0119
By: U.S. Coast Guard
Title: Cargo Container and Road Vehicle Certification for Transport Under Customs Seal
Forms: None
Frequency: On occasion, quarterly
Respondents: Intermodal container owners, operations and manufacturers

Need/Use: This information collection contains both recordkeeping and reporting requirements. The Coast Guard and other delegated certifying authorities need and use this information to (1) transmit specific design information for plan review and approval; (2) ensure that approved designs are not changed when additional containers are manufactured; (3) allow sufficient time for scheduling any needed inspections; and (4) ensure that adequate documentation is available to verify the approval of any design type or individual container or road vehicle.

Issued in Washington, D.C. on November 10, 1983.

Jon H. Seymour,

Acting Deputy Assistant Secretary for Administration.

[FR Doc. 83-31524 Filed 11-22-83; 8:45 am]

BILLING CODE 4910-62-M

Federal Highway Administration

Environmental Impact Statement; Carteret County, North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Carteret County, North Carolina.

FOR FURTHER INFORMATION CONTACT: Gary D. Holly, Environmental Engineer, Federal Highway Administration, 310 New Bern Avenue, P.O. Box 26806, Raleigh, North Carolina 27611, Telephone (919) 755-4270.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the North Carolina Department of Transportation (NCDOT), has retained a private engineering firm to prepare an environmental impact statement (EIS) on a proposed crossing of Bogue Sound in Carteret County. The proposed action would be construction of a new bridge from near Morehead City on the mainland to Bogue Banks, a barrier island. The proposed project is needed to serve the existing and anticipated traffic demand between the mainland and Atlantic Beach, Pine Knoll Shores and other developed and developing areas on Bogue Banks. It will provide an additional crossing of Bogue Sound between the two existing bridge crossings, which are approximately twenty (20) miles apart, and help relieve existing and future congestion, delay and inconvenience.

Alternatives under consideration include (1) The "no-build", and (2) study of up to four corridors for construction of a new high level bridge.

Letters describing the proposed action and soliciting comments are being sent to appropriate Federal, State and local agencies. A public meeting and a meeting with local officials will be held in the study area. A public hearing will also be held. Information on the time and place of the public hearing will be provided in the local news media. The draft EIS will be available for public and agency review and comment at the time of the hearing. No formal scoping meeting is planned at this time.

To ensure that the full range of issues related to the proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments and questions concerning the proposed action should be directed to the FHWA at the address provided above.

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning, and Construction. The provisions of OMB Circular No. A-95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects apply to this program.

Issued on: November 15, 1983.

Roger D. Lewis,

Assistant Division Administrator.

[FR Doc. 83-31445 Filed 11-22-83; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF THE TREASURY

Office of the Secretary

Boycott Provisions (Section 999) of the Internal Revenue Code; Additional Boycott Guidelines

AGENCY: Office of the Secretary, Treasury.

ACTION: Notice of additional guidelines.

SUMMARY: This document contains proposed additional guidelines relating to those provisions of the Tax Reform Act of 1976, found in section 999 of the Internal Revenue Code, which deny certain tax benefits for participation in or cooperation with international boycotts. These proposed guidelines consist of corrections or clarifications of earlier guidelines and new guidelines which will elaborate on the Department of the Treasury's enforcement of section 999, primarily in the areas of compliance with local laws and the use of vessel eligible clauses.

DATE: Comments must be received on or before Jan 23, 1984.

ADDRESS: Send comments to: Office of the General Counsel, Department of the Treasury, 15th & Pennsylvania Avenue, NW., Washingtion, DC 20220. Attention: David D. Joy.

FOR FURTHER INFORMATION CONTACT: David D. Joy, Office of the General Counsel, Department of the Treasury, 15th & Pennsylvania Avenue, NW., Washington, DC 20220, (202-566-5569—not a toll-free call).

SUPPLEMENTARY INFORMATION: This document contains proposed additional guidelines relating to the Department of the Treasury's enforcement of section 999 of the Internal Revenue Code. Section 999 incorporates provisions of the Tax Reform Act of 1976 (90 Stat. 1649-54), specifically sections 1061-1064 (known as the "Ribicoff Amendent"), which deny certain tax benefits for participation or cooperation with international boycotts. Published

guidelines which are still in effect today are found at 44 FR 66272 (November 19, 1979) and 43 FR 3454 (January 25, 1978).

Executive Order 12291

The Department of the Treasury has determined that these guidelines are not a major rule as defined in Executive Order 12291, and that a Regulatory Impact Analysis is therefore not required.

Comments

Before these proposed guidelines are adopted, consideration will be given to any written comments that are timely submitted to the Office of the General Counsel. All written comments will be available for public inspection and copying at the Department of the Treasury Library, 5th Floor, Department of the Treaury, 15th and Pennsylvania Avenue NW., Washington, D.C.

Drafting Information

The principal author of these proposed guidelines is Leonard Santos, formerly of the Office of the General Counsel, Department of the Treasury. David Joy from the Office of the General Counsel also participated in developing the proposed guidelines.

It Is Proposed To Amend the Guidelines as Follows:

* * * * *

A-9 (correction). Q: Section 999(b)(4) permits a person to agree to comply with certain laws without being treated as having agreed to participate in or cooperate with an international boycott. In the course of its operations in or related to a boycotting country, a person agrees to comply with a prohibition on importation and exportation that is described in section 999 (b)(4)(B) and section 999(b)(4)(C). Is that person required to report the operations on Form 5713?

A: Yes. Although agreements described in section 999(b)(4) (B) and (C) do not constitute participation in or cooperation with an international boycott, the operations in or related to a boycotting country must be reported on Form 5713. However, requests to enter into agreements described in section 999(b)(4) (B) and (C) are not reportable on Form 5713.

* * * * *

J-3 (correction). Q: Company C competes for an industrial plant construction contract for which Company P of Country W is inviting international tenders. The contract is to be financed by Country X which maintains a blacklist of companies. Country X requires contracts for projects which it finances to state that the contractor is required to refrain from making any purchase for project from any blacklisted company. Country W does not boycott those companies. Company C wins the tender and signs the contract with Company P with the blacklist provision. Does Company C's action constitute participation in or cooperation with an international boycott under section 999 (b)(3)(A)(ii)?

A: Generally, yes (see Guideline H-1A). Although the boycott is not implemented by Country W, but by Country X, and the project is being carried out in Country W, Company C has agreed not to do business with blacklisted U.S. companies as a condition of doing business indirectly with Country X. Similarly, if the contract financed by Country X in Country W precluded the use of Country Y goods in connection with the project in Country W, the exception reflected in section 999(b)(4)(B) would apply to Company C's agreement and that agreement would not constitute participation in or cooperation with an international boycott.

* * * * *

M-5 (correction). Q: Company C enters into a contract to export goods to or from Country X. The contract requires Company C not to ship the goods on a Country Y flag vessel or on a vessel owned, controlled, operated or chartered by Country Y or by companies or nationals of Country Y, or on a ship which during the voyage calls at Country Y enroute to or from Country X. Does Company C's action constitute participation in or cooperation with an international boycott under section 999 (b)(3)?

A: No. The requirement in the contract is not a restrictive boycott practice. Rather, the contract provision is presume to arise from the need to protect goods from damage or loss. However, this answer would not cover a restriction on the choice or route of a vessel when it carries no goods destined for or originating in Country X. The presumption described in this answer arises in every case where such clauses are used in connection with countries which are hostile to each other.

* * * * *

M-7 (correction). Q: Company C signs a contract to export goods to Country X. The contract provides that the goods may not be shipped on a vessel that has been blacklisted by Country X because it has called at Country Y in the past. Does Company C's action constitute participation in or cooperation with an international boycott under section 999 (b)(3)(B)?

A: Yes.

* * * * *

It is proposed to add the following Guidlines

* * * * *

C-2. Q: Company C is engaged in the sale of machinery to Country W. Company C has no knowledge or reason to know that Country W requires participation in or cooperation with an international boycott as a condition of doing business within Country W or with its government, companies or nationals, except that Company C is asked to sign a contract with Country W of the type described in Guideline M-5. Does Company C have knowledge that Country W is a boycotting country such that its operations with Country W are reportable?

A: No. Where the only Country W requirements of which Company C knows or has reason to know involve requests which, if agreed to, are not defined to constitute participation in or cooperation with an international boycott, Company C has no reason to treat Country W as a boycotting country.

* * * * *

H-37. Q: Company C signs a contract which provides that in connection with its performance Company C acknowledges that the import and customs laws and regulations of Country X shall apply to the furnishing and shipment of any products or components thereof to Country X, and that Company C acknowledges that such import and customs laws and regulations prohibit, among other things, the importation into Country X of products or components: (1) originating in Country Y; (2) manufactured, produced or furnished by companies organized under the laws of Country Y; and (3) manufactured, produced or furnished by nationals or residents of Country Y. Does Company C's contract constitute an agreement under section 999(b)(3)?

A: No. (see Guideline H-3). Company C has merely acknowledged that such import and customs laws shall apply to the furnishing of goods under the contract. However, an agreement by Company C to comply with Country X's restriction on the importation of goods furnished either by companies organized under Country Y's laws or by nationals of Country Y would constitute an agreement under section 999(b)(3).

H-38. Q: Company C signs a contract in which it agrees to comply with the laws, rules and regulations of Country X, except to the extent such compliance is penalized under laws of the United States. Does Company C's contract

constitute an agreement under section 999(b)(3)?

A: No. An agreement to comply with the laws, rules and regulations of Country X does not constitute an agreement under section 999(b)(3) when such a commitment is qualified by excepting out compliance penalized by U.S. law, including section 999. Any phrase which effectively excludes the agreements described in section 999 from the requirements of a contract with Country X would support the same result. For example, a compliance clause qualified by "except to the extent inconsistent with U.S. law" would also suffice to take the contract out of the coverage of section 999. However, a compliance clause qualified by the phrase "except to the extent *prohibited* by U.S. law" would not defeat the presumption that the contractual provision requires agreements penalized under section 999, since section 999 does not prohibit anything, but merely penalizes certain agreements.

H-39. Q: Company C signs a contract to constuct an industrial plant in Country X. The contract states that the laws, regulations, requirements or administrative practices of Country X shall govern Company C's performance of the contract in Country X. The laws, regulations, requirements or administrative practices of Country X prohibit the importation into Country X of goods manufactured by any company engaged in trade in Country Y or with the government, companies or nationals of Country Y. Does Company C's action constitute an agreement under section 999(b)(3)?

A: No. (see Guideline H-3). The answer would be the same if the contract had instead stated that Company C would be "subject to" the laws, regulations, requirements or administrative practices of Country X.

H-40. Q: Company A signs a contract to export goods to Country X. The contract provides that payment will be made by means of a letter of credit confirmed by Bank C. The letter of credit requires Company A to provide Bank C a certificate stating that the ship on which the goods are to be shipped is eligible to enter the ports of Country X in conformity with its laws and regulations, and that the insurer of the goods has a duly qualified and appointed agent or representative in Country X. Country X's laws and regulations prohibit, *inter alia*, black listed vessels from calling at its ports and blacklisted insurance companies from qualifying or appointing an agent in Country X. Bank C confirms the letter of credit requiring the shipping and insurance certificates. Does Bank C's action constitute an agreement under section 999(b)(3)?

A: Yes. Unless Country X has offered the kind of explanation described in Guidelines M-12 and M-13, Bank C's confirmation of the letter of credit constitutes an agreement to refrain from doing business with a U.S. person under section 999(b)(3)(A)(ii). The answer would be the same under section 999(b)(3)(A)(i), if the beneficiary of the letter of credit were organized under the laws of Country Y, and under section 999(b)(3)(A)(iii), if Bank C had reason to know that it would not be able to obtain the required certificate because of the nationality, race, or religion of the beneficiary's ownership, management, or directors. See Guideline H-29 A.

* * * * *

L-6. Q: Company C signs a construction contract that provides that Company C is not to employ individuals or nationals of any country not diplomatically recognized by Country X. Does Company C's action constitute participation in or cooperation with an international boycott under section 999(b)(3)(A)(iv)?

A: To the extent that Country Y is only one of several countries not recognized by Country X, the exclusion of nationals from unrecognized countries under the contract is not, on its face, boycott related. In those circumstances, agreement to the clause in question would not constitute an agreement to participate in or cooperate with an international boycott under section 999(b)(3). However, where Country Y is the only country not recognized by Country X, agreement to such a clause will constitute an agreement to participate in or cooperate with an international boycott under section 999(b)(3).

* * * * *

M-15. Q: Company C signs a contract to export goods to Country X. The contract provides that payment will be made by means of a letter of credit confirmed by Bank C. The letter of credit requires Company C to provide to Bank C a certificate stating that the goods are being shipped on a U.S. or Country X flag carrier *or*, alternatively, that the ship on which the goods are being shipped is eligible to enter the ports of Country X. Company C provides a certificate stating that the goods have been shipped on a U.S. or Country X flag carrier. Does Company C's acceptance of the letter of credit constitute an agreement under section 999(b)(3)?

A: No. Where the letter of credit requires alternative certifications, one of which is acceptable within the terms of section 999(b)(3), and Company C performs in accordance with that acceptable alternative (i.e., shipping on a U.S. or Country X flag carrier), it is presumed that Company C's agreement included only the acceptable alternative. If Company C were to utilize a ship "eligible to enter the ports of Country X," Guideline M-10 would apply.

Dated: November 16, 1983.

John E. Chapoton,

Assistant Secretary (Tax Policy).

[FR Doc. 83-31463 Filed 11-22-83; 8:45 am]

BILLING CODE 4810-25-M

Public Information Collection Requirements Submitted to OMB for Review

On November 17, 1983 the Department of Treasury submitted the following public information collection requirement(s) to OMB (listed by submitting bureaus), for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of these submissions may be obtained from the Treasury Department Clearance Officer, by calling (202) 535-6020. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of each bureau's listing and to the Treasury Department Clearance Officer, Room 7227, 1201 Constitution Avenue, NW., Washington, D.C. 20220.

Internal Revenue Service

OMB Number: 1545-0117
Form Number: 1099-OID
Type of Review: Revision
Title: Statement for Participants of Original Issue Discount
OMB Reviewer: Norman Frumkin (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Cathy Thomas,

Departmental Reports, Management Office.

[FR Doc. 83-31464 Filed 11-22-83; 8:45 am]

BILLING CODE 4810-25-M

Public Information Collection Requirements Submitted to OMB for Review

On November 16, 1983 the Department of Treasury submitted the following public information collection requirement(s) to OMB (listed by submitting bureaus), for review and clearance under the Paperword Reduction Act of 1980, Pub. L. 96-511. Copies of these submissions may be obtained from the Treasury Department Clearance Officer, by calling (202) 535-

6020. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of each bureau's listing and to the Treasury Department Clearance Officer, Room 7227, 1201 Constitution Avenue, N.W., Washington, D.C. 20220.

Internal Revenue Service

OMB Number: 1545-0165
Form Number: 4224
Type of Review: Revision
Title: Exemption From Withholding of Tax on Income Effectively Connected With Conduct of Trade or Business Existing Regulations

OMB Number: 1545
Form Number: 5473
Type of Review: New
Title: Return Required Under Section 6046A

OMB Number: 1545
Form Number: None
Type of Review: Existing Collection
Title: Notice or Regulations Requiring Records, Statements and Special Returns

Alochol, Tobacco and Firearms

OMB Number: 1512-0247
Form Number: ATF Rec 5000/2
Type of Review: Reinstatement
Title: Manufacturers or Ammunition, Records and Supporting Data of Ammunition Manufactured and Disposed of

OMB Number: 1512-0049
Form Number: ATF F 96 (5100.6)
Type of Review: Revision
Title: Importer's Report of Red Strip Stamps

OMB Number: 1512-0265
Form Number: ATF 5110/19
Type of Review: Reinstatement
Title: DSP Storage—Record of Mingling and Blending of Spirits

OMB Number: 1512-0262
Form Number: ATF 5110/15
Type of Review: Extension
Title: DSP—Inventories of All Phases of Operations

OMB Number: 1512-0260
Form Number: ATF Rec 5110/13
Type of Review: Reinstatement
Title: DSP Storage—Summary of Activity; Inventory, Losses and Gains

OMB Number: 1512-0265
Form Number: ATF Rec 5110/18
Type of Review: Reinstatement
Title: DSP—Storage Receipts of Spirits, Wines and Alcholic Ingredients

OMB Number: 1512-0256
Form Number: ATF 5110/9
Type of Review: Reinstatement
Title: DSP Storage Record—Voluntary Destructions

OMB Number: 1512-0264
Form Number: ATF 5110/17
Type of Review: Reinstatement
Title: DSP Storage—Returns, Transfers and Final Disposition of Spirits and Wines

OMB Number: 1512-0267
Form Number: ATF 5110/20
Type of Review: Reinstatement
Title: DSP Storage—Packages Filled, Change of Packages, Retained in Storage

OMB Number: 1512-0388
Form Number: ATF Rec 7570/1
Type of Review: Reinstatement
Title: Registered Importers of Arms, Ammunition and Implements of War on US Munitions List; Records of Acquisition and Disposition

OMB Number: 1512-0372
Form Number: ATF Rec 5400/2
Type of Review: Reinstatement
Title: Licensed Explosives Manufacturers and Manufacturers-(Limited), Daily Summaries, Records of Production, Storage, and Disposition and Supporting Records

OMB Number: 1512-0371
Form Number: ATF Rec 5400/1
Type of Review: Reinstatement
Title: Inventory, Licensed Explosives, Importers, Dealers, and Permittees

OMB Number: 1512-0370
Form Number: ATF Rec 5300/2
Type of Review: Reinstatement
Title: Transferees of NFA Weapons Retain Approval Application Requesting Transfer and Transfer Tax Stamp (NFA—National Firearms Act)
OMB Reviewer: Norman Frumkin (202) 395-6880, Office of Management and Budget Room 3208, New Executive Office Building, Washington, D.C 20503

Comptroller of the Currency

OMB Number: 1557
Form Number: None
Type of Review: New
Title: Fair Housing Home Loan Data System Regulation (12 CFR 27) Home Loan Data Submissions Statement for Recipients of Certain Government Payments

OMB Number: 1557
Form Number: None
Type of Review: New
Title: Community Reinvestment Act Statement, Notice and Public Comment File
OMB Reviewer: Judy McIntosh (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Cathy Thomas,
Departmental Reports, Management Office.
[FR Doc. 83-31465 Filed 11-22-83; 8:45 am]
BILLING CODE 4810-25-M

Treasury Announces a Public Hearing of the Worldwide Unitary Tax Working Group Task Force

The Treasury Department announced today that it will hold a public hearing of the Task Force of the Worldwide Unitary Tax Working Group for the purpose of receiving testimony from interested parties on the subject of the worldwide unitary method of taxation and related issues. The Working Group, chaired by Secretary Regan, was established at the request of President Reagan in order to find a solution to the problems that may be caused by the worldwide unitary method of taxation. The hearing will be held Wednesday, November 30, 1983 from 9:00 a.m. to 5:00 p.m., in Room 4125 of the Main Treasury Building, 15th and Pennsylvania Avenue, NW.

Participants wishing to reserve a ten minute time slot for their presentation may do so by sending a written request, along with 30 copies of their prepared statement, to Dr. Charles E. McLure, Deputy Assistant Secretary (Tax Analysis), Room 3108, Main Treasury Building, 15th and Pennsylvania Avenue, NW., Washington, D.C. 20220; requests must be received before noon, Monday, November 28, 1983. Participants are requested to keep their presentations brief and concise, and should expect to answer follow-up questions of a technical nature.

Dated: November 18, 1983.

John E. Chapoton,
Assistant Secretary (Tax Policy).
[FR Doc. 83-31476 Filed 11-22-83; 8:45 am]
BILLING CODE 4810-25-M

Office of Foreign Assets Control

Ban on Imports of Cuban Nickel-Bearing Materials from the U.S.S.R.

The Office of Foreign Assets Control has reason to believe that certain nickel-bearing materials imported into the United States from the U.S.S.R. contain Cuban nickel. Except as licensed by the Secretary of the Treasury, importation into the United States of materials derived from nickel of Cuban origin is prohibited under Section 5(b) of the Trading With the Enemy Act, 50 U.S.C. App. 5, and by §§ 515.201 and 515.204 of the Cuban Assets Control Regulations, 31 CFR Part 515.

Notice is hereby given that, effective 30 days from the date of this notice, unfabricated nickel-bearing materials imported directly or indirectly from the U.S.S.R. will be detained by the United States Customs Service until such time

as their release from Customs custody or other disposition is authorized by the Office of Foreign Assets Control. As used herein, "unfabricated nickel-bearing materials" includes: (1) Nickel ore in any stage of refinement, including nickel matte and nickel oxide; (2) primary nickel in any form, including nickel cathode, powder and flakes; (3) wrought nickel in its basic shapes and forms, including ingots, slabs, bars, plates and rods; (4) nickel waste and scrap; (5) nickel alloys in their basic shapes and forms, including ferronickel; and (6) stainless steel in its basic shapes and forms containing more than 2.5% nickel. Fabricated items such as flatware, pots and pans are not covered by the ban.

This detention order shall not apply to nickel alloys and stainless steel that are manufactured from Soviet nickel in any country other than the U.S.S.R. Nickel alloys and stainless steel that are manufactured in the U.S.S.R., however, may not be imported into the United States merely because they have been transshipped through a third country or cut, pressed, milled, drawn or otherwise wrought in another country. For example, stainless steel bars from the Soviet Union that are cut, rolled or otherwise processed short of fabrication in a third country may not be imported into the United States.

Beginning 30 days from the date of this notice, unfabricated nickel-bearing materials (not including nickel alloys and stainless steel) made from Soviet nickel may not be imported into the United States. For example, nickel rods, plates, bars or sheets wrought in a third country from nickel cathode or another form of primary nickel from the U.S.S.R. may not be imported. Importers of such materials that have questions regarding their admissibility through U.S. Customs should contact the Office of Foreign Assets Control. Inquiries may be addressed to either Raymond W. Konan, Chief Counsel, 202/376-0236, or Marilyn L. Muench, Chief of Licensing, 202/376-0408.

The Office of Foreign Assets Control is considering whether to require that imports into the United States of certain unfabricated nickel-bearing materials from countries that import nickel from the U.S.S.R. be accompanied by documentation showing that they were not manufactured in the U.S.S.R. or from Soviet nickel. If imposed, the requirement will become effective within 30 days following the date of its publication in the **Federal Register.**

The Office of Foreign Assets Control will generally issue specific licenses authorizing the release from Customs custody of unfabricated nickel-bearing materials, except nickel granules and nickel sulphate, where, prior to the date of this notice, the materials were paid for by a person in the United States or covered by an irrevocable letter of credit established in a domestic bank. Specific licenses may be issued authorizing the release from Customs of materials that depart the U.S.S.R. in transit to the United States before the date of this notice, and are presented to U.S. Customs within 60 days following that date.

This notice supersedes the earlier notices of February 4, 1969, dealing with importation of nickel granules from the U.S.S.R., and of October 3, 1969, dealing with importation of nickel sulphate from the U.S.S.R.

(Sec. 5, 40 Stat. 415, as amended, 50 U.S.C. App. 5; Sec. 620(a), 75 Stat. 445, 22 U.S.C. 2370(a); Proc. 3447, 27 FR 1085, 3 CFR 1959-1963 Comp.; E.O. 9193, 7 FR 5205, 3 CFR Comp. Supp., p. 1174; E.O. 9989, 13 FR 4891, 3 CFR, 1943-1948 Comp., p. 748)

Dated: November 21, 1983.

Dennis M. O'Connell,

Director, Foreign Assets Control.

John M. Walker, Jr.,

Assistant Secretary.

[FR Doc. 83-31567 Filed 11-21-83; 11:27 am]

BILLING CODE 4810-25-M

Sunshine Act Meetings

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

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).

CONTENTS

	Items
Commodity Futures Trading Commission	1–11
Federal Energy Regulatory Commission	12
Federal Reserve System	13
International Trade Commission	14
Synthetic Fuels Corporation	15

1

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, November 25, 1983.

PLACE: 2033 K Street NW., Washington, D.C. Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1637-83 Filed 11-21-83; 12:05 pm]

BILLING CODE 6351-01-M

2

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 2, 1983

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1633-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

3

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday, December 6, 1983.

PLACE: 2033 K Street NW., Washington, D.C., fifth Floor Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Proposed contract market designation for the Commodity Exchange, Inc. in Aluminum

Proposed contract market designation for Chicago Mercantile Exchange in S&P Energy Subindex

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1630-83 Filed 11-21-83; 11:58 am]

BILLING CODE 6351-01-M

4

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 9, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1631-83 Filed 11-21-83; 11:59 am]

BILLING CODE 6351-01-M

5

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday December 13, 1983.

PLACE: 2033 K Street NW., Washington, D.C. Fifth Floor Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Proposed contract market designation for Chicago Merchantile Exchange on options of Deutshe Mark Futures.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1629-83 Filed 11-21-83; 11:58 am]

BILLING CODE 6351-01-M

6

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Tuesday, December 13, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Rule enforcement review

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1635-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

7

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Thursday, December 15, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Briefing on Mandated Studies

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1632-83 Filed 11-21-83; 12:00 pm]

BILLING CODE 6351-01-M

8

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 16, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[FR Doc. 83-1630 Filed 11-21-83; 12:06 pm]

BILLING CODE 6351-01-M

9

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday, December 20, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Fifth Floor Hearing Room.

STATUS: Open.

MATTER TO BE CONSIDERED:

Proposed contract market designation for the Chicago Mercantile Exchange in S&P High Technology Subindex

Proposed contract market designation for Chicago Mercantile Exchange in Gold Coins

Proposed contract market designation for Commodity Exchange in Gold Coins

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1634-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

10

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 23, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1638-83 Filed 11-21-83; 12:06 pm]

BILLING CODE 6351-01-M

11

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 30, 1983.

PLACE: 2033 K Street NW., Washington, D.C., eighth Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1636-83 Filed 11-21-83; 12:05 pm]

BILLING CODE 6351-01-M

12

FEDERAL ENERGY REGULATORY COMMISSION

November 21, 1983.

TIME AND DATE: Approximately 12 noon, November 22, 1983 (following open meeting).

PLACE: Room 9306, 825 North Capitol Street NE., Washington, D.C. 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED: IN83–2–000, Various Producer-Owned Natural Gas Processing Plants.

CONTACT PERSON FOR MORE INFORMATION: Kenneth F. Plumb, Secretary, telephone (202) 357–8400.

Kenneth F. Plumb,

Secretary.

[S-1641-83 Filed 11-21-83; 1:59 pm]

BILLING CODE 6717-02-M

13

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Monday, November 28, 1983.

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed alternatives for future space requirements of the Federal Reserve Bank of Dallas.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. 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.

Dated: November 18, 1982.

James McAfee,

Associate Secretary of the Board.

[S-1628-83 Filed 11-18-83; 4:11 pm]

BILLING CODE 6210-01-M

14

INTERNATIONAL TRADE COMMISSION

[USITC SE-83-49]

TIME AND DATE: 2 p.m., Friday, December 2, 1983.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints, if necessary.
5. Investigations 731–TA–149 and –150 (Preliminary) (Barium Chloride and Barium Carbonate from the People's Republic of China)—briefing and vote.
6. Any Items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

[S-1640-83 Filed 11-21-83; 1:44 pm]

BILLING CODE 7020-02-M

15

SYNTHETIC FUELS CORPORATION

Meeting of the Board of Directors

TIMES AND DATES:

9 a.m., November 30, 1983; and 8:30 a.m., December 1, 1983

PLACES:

Embassy Room, Dupont Plaza Hotel, Washington, D.C. (November 30, 1983); and

Room 503, 2121 K Street NW., Washington, D.C. (December 1, 1983)

SUMMARY: Interested members of the public are invited to attend and observe a meeting of the Board of Directors of the United States Synthetic Fuels Corporation to be held at the time, date and place specified below. This public announcement is made pursuant to the open meeting requirements of Section 116(f)(1) of the Energy Security Act (9 Stat. 611, 637; 42 U.S.C. 8701, 8712(f)(1) and Section 4 of the Corporation's Statement of Policy on Public Access to Board meetings. During the meeting, the Board of Directors will consider a resolution to close a portion of the meeting pursuant to Article II, Section 4 of the Corporation's By-laws, Section 116(f) of the said Act and Sections 4 and 5 of the said policy.

MATTERS TO BE CONSIDERED: *November 30, 1983.*

Open Session

1. Chairman's Opening Remarks.
2. Meeting with Advisory Committee.

Closed Session

3. Staff Briefing on Project Negotiations.
4. Consideration of Third Solicitation Oil Shale Projects.
5. Consideration of Great Plains Cool Gasification Project.
6. Consideration of Gulf Coast Lignite Project Proposal.

December 1, 1983:

Open Session

7. Approval of Minutes.
8. Report of Acting Executive Vice President.
9. Report of Audit Committee on the Management Audit.
10. Report of the Compensation Committee on Officer Reviews.
11. Election of Officers/Officer Positions.
12. Consideration of Third Solicitation Oil Shale Projects: Letters on Intent.
13. Consideration of Coal-Water Mixture Solicitation.
14. Consideration of Section 127(c) Requests.
15. Consideration of Bituminous Coal Solicitation Proposals.
16. Approval of Directors' Travel Policy.

Closed Session

17. Consideration of Gulf Coast Lignite Technical Proposal and Bid.
18. Consideration of Projects Removed from Solicitations.

19. Staff Report on Coal and Tar Sands Project Negotiations.

20. Consideration of General Coal Gasification Solicitation.

In addition, the Board of Directors will consider such other matters as may be properly brought before the meeting.

PERSON TO CONTACT FOR MORE INFORMATION: If you have any questions regarding this meeting, please contact Mr. Owen J. Malone, Assistant Secretary, at (202) 822-6336.

November 21, 1983.

United States Synthetic Fuels Corporation.

Leonard C. Axelrod,

Acting Vice President.

[S-1642-83 Filed 11-21-83; 3:51 pm]

BILLING CODE 0000-00-M

federal register

Wednesday
November 23, 1983

Part II

Department of Health and Human Services

Food and Drug Administration

Gastroenterology-Urology Devices; General Provisions and Classification of 56 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 78N-1945]

Gastroenterology-Urology Devices; General Provisions and Classification of 56 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 56 gastroenterology-urology devices. The preamble to this rule responds to comments received on the proposals regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: Norman T. Welford, National Center for Devices and Radiological Health (HFK-420), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, Md 20910; 301-427-7750.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 23, 1981 (46 FR 7562-7641), FDA published proposed regulations containing general provisions applicable to the classification of gastroenterology-urology devices. FDA also published individual proposed regulations to classify 57 gastroenterology-urology devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). FDA published a correction of several proposals in the **Federal Register** of April 7, 1981 (46 FR 20687).

Of the 57 gastroenterology-urology devices subject to the proposals, FDA is classifying 9 devices into class I, 32 devices into class II, and 9 devices into class III. Four devices are classified into either class I or class II, two depending upon how the device is powered and two for other reasons. In addition, two devices are classified into either class II or class III, depending upon other criteria. FDA is withdrawing the proposed regulation for one device.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392).

The effect of classifying a device into class I is to require that the device 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 the safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments and that either was in commercial distribution before May 28, 1976, or 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 June 30, 1986, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(l) of the act (21 U.S.C. 360j(1)).

The preamble to the general provisions described the development of the general provisions and the proposed regulations classifying gastroenterology-urology devices and the activities of the Gastroenterology-Urology Device Section of the General Medical Devices Panel (formerly the Gastroenterology-Urology Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of gastroenterology-urology devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publising as one document the general provisions and classifications of 56 gastroenterology-urology devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed to exempt manufacturers of three generic types of gastroenterology-urology devices from certain requirements of the current good manufacturing practice (GMP) regulations in Part 820 (21 CFR Part 820): Enema kit (Docket No. 78N-2060), protective garment for incontinence (Docket No. 78N-2062), and hernia support (Docket No. 78N-1967). The final rule exempts manufacturers of the three devices from certain GMP requirements. additionally, in response to comments, the agency has granted partial exemptions to manufacturers of one other device: the urine collector not connected to an indwelling catheter (Docket No. 78N-2010). If the devices are not labeled or represented as sterile, the final rule exempts the manufacturers of these four devices from all of the GMP requirements with the exception of §§ 820.180 and 820.198 relating to records and complaint files. The agency has determined that exemption of any manufacturer of a device from §§ 820.180 and 820.198 of the current GMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the current GMP regulations, if one has been granted, is still appropriate. Also, for the reasons given in the proposal, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

Changes in Classification in Final Regulations

Based on the comments received or upon consideration of additional information, FDA has changed the classification in the final regulation of each of 10 devices or accessories to these devices from that originally proposed: Gastroenterology-urology evacuator (Docket No. 78N-1994), ribdam (Docket No. 78N-2067), urological table and accessories (Docket No. 78N-2070), continent ileostomy catheter (Docket No. 78N-1972), urological clamp for males (Docket No. 78N-2009), urine collector and accessories (Docket No. 78N-2010), blood access device and accessories (Docket No. 78N-2044), nonimplanted electrical continence device (Docket No. 78N-2069), ostomy pouch and accessories (Docket No. 78N-1974), and hernia support (Docket No. 78N-1967).

The nonimplanted electrical continence device was proposed to be in class III, but is classified into class II in the final rule. The implanted blood access device and its accessories was proposed to be in class III; although the final rule places the device itself in class III, the accessories to the device are classified into class II. The eight remaining devices were proposed to be in class II, but are either completely or partially classified into class I in the final rule. The reasons for these changes are identified in the discussion below for each of these 10 devices. FDA does not believe that it is necessary to issue a new proposal concerning these changes. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device is correct. After reviewing the comments submitted on a proposal or upon reconsideration, the agency may determine that its proposed classification is incorrect. Therefore, persons interested in the classification process should 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 general provisions for gastroenterology-urology devices (see 46 FR 7562; January 23, 1981). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

Minor Changes or Clarifications

Occasionally the agency has made minor changes in a device name or identification to clarify the final regulation. Additionally, the agency is adding an explanation in § 876.1 that references in Part 876 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

Proposed Regulation to be Withdrawn

The proposed regulation for one gastroenterology-urology device, the circumcision instrument (Docket No. 78N-1990), was withdrawn in a separate document (47 FR 41139; Sept. 17, 1982). FDA has determined that the circumcision instrument is included in or is the same as the circumcision clamp identified in § 884.4530 *Obstetric-gynecologic specialized manual instrument*, which already has been classified into class II (February 26, 1980; 45 FR 12705).

Changes in Device Advisory Committee Names

On April 28, 1978, the agency terminated all of the device classification panels, then reestablished them under new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Gastroenterology-Urology Device Classification Panel was terminated, and its functions are now conducted by the Gastroenterology-Urology Device Section of the General Medical Devices Panel.

Further, in the **Federal Register** of September 3, 1982 (47 FR 38883), FDA announced the establishment on August 5, 1982, of the Obstetrics-Gynecology Devices Panel and the Radiologic Devices Panel and the termination of the Obstetrics-Gynecology and Radiologic Devices Panel.

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, Section, and Name	Publication date in **Federal Register**
Circulatory Systems Devices Panel	Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel	
Clinical Chemistry Device Section	Feb. 2, 1982, 47 FR 4802 (proposals).
Clinical Toxicology Device Section	Do.
Hematology and Pathology Device Section	Sept. 11, 1979, 44 FR 53063 (proposals); Sept. 12, 1980, 45 FR 60576-60651 (final regulations).
General Medical Devices Panel	
General Hospital and Personal Use Device Section	Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980, 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Device Section	Jan. 23, 1981, 46 FR 7562-7641 (proposals); Nov. 23, 1983 (final regulations).
Immunology and Microbiology Devices Panel	
Immunology Device Section	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Microbiology Device Section	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel	Apr. 3, 1979, 44 FR 19894-19971 (proposals); Feb. 26, 1980, 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel	
Ophthalmic Device Section	Jan. 26, 1982, 47 FR 3694-3749 (proposals).
Ear, Nose, and Throat Device Section	Jan. 22, 1982, 47 FR 3280-3325 (proposals).
Dental Device Section	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Respiratory and Nervous System Devices Panel	
Anesthesiology Device Section	Nov. 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Device Section	Nov. 23, 1978, 43 FR 54840-56732 (proposals); Sept. 4, 1979, 44 FR 51726-51778 (final regulations).
Surgical and Rehabilitation Devices Panel	
Physical Medicine Device Section	Aug. 28, 1979, 44 FR 50458-50537 (proposals).
Orthopedic Device Section	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Device Section	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

List of Gastroenterology-Urology Devices and an Identification of Those Proposed Classification Regulations That Received Public Comments

The following is a list of gastroenterology-urology devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the proposed classification regulation, the classification of each device, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, the classification of the device is being adopted as proposed. Comments were received on the proposals on 33 of the 57 gastroenterology-urology devices.

Because the proposal to classify the circumcision instrument (Docket No. 78N-1990) was withdrawn by means of a separate document (47 FR 41139; Sept. 17, 1982), the comment on that proposal, and FDA's response to it, were included in the withdrawal.

SUBPART B—DIAGNOSTIC DEVICES

Section and device	Docket No.	Class	Comments
876.1075 Gastroenterology-urology biopsy instrument.	78N-1946	II	Yes.
876.1400 Stomach pH electrode.	78N-1952	II	No.
876.1500 Endoscope and accessories.	78N-1953	II	Yes.
876.1620 Urodynamics measurement system.	78N-1950	II	Yes.
876.1725 Gastrointestinal motility monitoring system.	78N-1955	II	No.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
876.1800 Urine flow or volume measuring system.	78N-1964	II	Yes.

SUBPART C—MONITORING DEVICES

876.2040 Enuresis alarm.	78N-1958	II	No.

SUBPART D—PROSTHETIC DEVICES

876.3350 Penile inflatable implant.	78N-1968	III	No.
876.3630 Penile rigidity implant.	78N-1979	III	Yes.
876.3750 Testicular prosthesis.	78N-1981	III	Yes.

SUBPART E—SURGICAL DEVICES

876.4020 Fiberoptic light ureteral catheter.	78N-1947	II	Yes.
876.4270 Colostomy rod.	78N-1971	II	No.
876.4300 Endoscopic electrosurgical unit and accessories.	78N-1993	II	No.
876.4370 Gastroenterol-ogyurology evacuator.	78N-1994	I & II	Yes.
876.4400 Hemorrhoidal ligator.	78N-1995	II	No.
876.4480 Electrohy-draulic lithotriptor.	78N-1998	III	No.
876.4500 Mechanical lithotriptor.	78N-2001	II	Yes.
876.4530 Gastroenterol-ogyurology fiberoptic retractor.	78N-1999	I	No.
876.4560 Ribdam	78N-2067	I	Yes.
876.4590 Interlocking urethral sound.	78N-2068	II	Yes.
876.4620 Ureteral stent	78N-1984	II	Yes.
876.4650 Water jet renal stone dislodger system.	78N-1988	II	Yes.
876.4680 Ureteral stone dislodger.	78N-2002	II	No.
876.4730 Manual gastroenterology-urology surgical instrument and accessories.	78N-1996	I	Yes.
876.4770 Urethrotome	78N-2004	II	Yes.
876.4890 Urological table and accessories.	78N-2070	I & II	Yes.

SUBPART F—THERAPEUTIC DEVICES

876.5010 Biliary cathether and accessories.	78N-2005	II	No.
876.5030 Continent ileostomy catheter.	78N-1972	I	Yes.
876.5090 Suprapubic urological catheter and accessories.	78N-1989	II	Yes.
876.5130 Urological catheter and accessories.	78N-2006	II	Yes.
876.5160 Urological clamp for males.	78N-2009	I	Yes.
876.5210 Enema kit	78N-2060	I	No.
876.5220 Colonic irrigation system.	78N-2011	II & III	Yes.
876.5250 Urine collector and accessories.	78N-2010	I & II	Yes.
876.5270 Implanted electrical urinary continence device.	78N-1978	III	No.
876.5280 Implanted mechanical/hydraulic urinary continence device.	78N-1969	III	No.

SUBPART F—THERAPEUTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
876.5230 Nonimplanted electrical continence device.	78N-2069	II	Yes.
876.5365 Esophageal dilator.	78N-2058	II	No.
876.5450 Rectal dilator	78N-1992	II	No.
876.5470 Ureteral dilator.	78N-2057	II	No.
876.5520 Urethral dilator.	78N-2059	II	Yes.
876.5540 Blood access device and accessories.	78N-2044	II & III	Yes.
876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.	78N-2019	II	No.
876.5630 Peritoneal dialysis system and accessories.	78N-2051	II	No.
876.5665 Water purification system for hemodialysis.	78N-2047	II	Yes.
876.5820 Hemodialysis system and accessories.	78N-2014	I & II	Yes.
876.5830 Hemodialyzer with disposable insert (Kill type).	78N-2038	II	No.
876.5860 High permeability hemodialysis system.	78N-2039	III	No.
876.5870 Sorbent hemoperfusion system.	78N-2061	III	No.
876.5880 Isolated kidney perfusion and transport system and accessories.	78N-2063	II	No.
876.5895 Ostomy irrigator.	78N-1975	II	Yes.
876.5900 Ostomy pouch and accessories.	78N-1974	I	Yes.
876.5920 Protective garment for incontinence.	78N-2062	I	Yes.
876.5955 Peritoneo-venous shunt.	78N-1980	III	Yes.
876.5970 Hernia support.	78N-1967	I	Yes.
876.5980 Gastroin-testinal tube and accessories.	78N-2072	II	No.

Summaries of Comments and FDA's Responses to Comments

FDA is responding to specific comments received on the proposed regulations for 32 gastroenterology-urology devices and to three general comments as follows:

1. One comment stated that the majority of the device classifications appeared correct; however, some changes seem desirable. The comment suggested that before the agency publishes the final regulations to classify the gastroenterology-urology devices, select committees representing the medical specialties that use these devices be asked to assist FDA in determining the final classifications of the devices. The comment believed that such a supplemental review would allow the practitioners in the medical specialties to continue to use the devices without impedance and also would allow the development of additional scientific data regarding the devices.

FDA disagrees with the comment. The agency has established the Gastroenterology-Urology Device Section of the General Medical Devices Panel, an FDA advisory committee of experts representing the medical specialties that use Gastroenterology-urology devices. The advisory committee was established as specified in section 513 (b) and (c) of the act, as amended by the 1976 amendments, and the Federal Advisory Committee Act. The classifications of gastroenterology-urology devices proposed by FDA and published in the **Federal Register** were based on recommendations of the agency's advisory committees established in accordance with these statutes. FDA solicited public nominations for members of these advisory committees and held meetings that were open to the public. The agency believes that further consultation with other scientific or medical committees is unnecessary and would be subject to the statutory provisions cited above. Additionally, final classification of a device, in itself, has a limited impact, as described at the conclusion of this preamble. FDA believes that the classification of a device will not cause hardship to the medical community or hinder innovation.

2. A comment requested an extension of the comment period because of the length of the proposed regulations.

The agency disagrees with the comment. Sixty days for public comment is reasonable. See section 520(d)(2) of the act (21 U.S.C. 360j(d)(2)) and § 10.40(b)(2) of the regulations (21 CFR 10.40(b)(2)). Moreover, FDA's proposed device classifications were based on FDA advisory committees' recommendations that have been available to the public for several years. Therefore, the agency believes that an extension of the comment period is not necessary. (Comment 8.a. below describes a limited reopening of the comment period.)

3. A comment approved of the agency's policy of merging for classification purposes similar devices into a broad generic type of device.

FDA agrees with the comment.

4. Section 876.1075; 78N-1946; Gastroenterology-urology biopsy instrument. FDA published in the **Federal Register** (46 FR 7569) a proposed regulation to classify the gastroenterology-urology biopsy instrument into class II. The one comment received on the proposal suggested that the gastroenterology-urology biopsy instyrument be classified

into class I rather than class II as was proposed. The comment stated that the device has been used for over 30 years and that it would be impossible to write safe, practical standards of use for a nonsurgeon.

FDA disagrees with the comment. The comment erroneously believes that a performance standard for the device applies to the skill ("performance") of the user of the device. Rather, a standard for the gastroenterology-urology biopsy instrument is needed because the design, mechanical properties, and tissue removal mechanisms of the device—all performance properties of the device, not the user—must be controlled by a performance standard to assure that unnecessary cutting or tissue removal does not occur. The design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, or perforation and to enable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

5. Section 876.1500; 78N-1953; Endoscope and accessories. FDA published in the **Federal Register** (46 FR 7571) a proposed regulation to classify the endoscope and accessories into class II. The one comment received on the proposal suggested that the endoscope and its accessories be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. The agency agrees that the principal hazard associated with the use of the device may be due to unskilled users. The agency believes that the endoscope and accessories should be classified into class II because the electrical, optical, mechanical, biocompatibility, and lighting characteristics of the device must be controlled by a performance standard to prevent injury to the patient resulting from devices of improper design or construction. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

6. Section 876.1620; 78N-1950; Urodynamics measurement system. FDA published in the **Federal Register** (46 FR 7573) a proposed regulation to classify the urodynamics measurement system into class II. The one comment received on the proposal suggested that the urodynamics measurement system be classified into class I rather than class II as was proposed. The comment believed that the establishment of a performance standard for the device may stop the development of new or improved devices.

FDA disagrees with the comment. FDA believes that issuance of a final regulation to classify the urodynamics measurement system into class II will not prevent the development of new or improved devices. Classifying a device, in itself, has a limited impact, which is described at the conclusion of this preamble. Moreover, the agency believes that the urodynamics measurement system should be classified into class II because the design and construction of the device must be controlled by a performance standard to ensure that air or other insoluble gas does not enter the system, that the amount and pressure of the delivered carbon dioxide or water do not overdistend the bladder, that the device can be properly cleaned and sterilized to prevent infrection, that electrical properties are controlled to prevent electrical injury to the patient or the operator, and that measurement results are accurate to prevent development of inaccurate diagnostic information. Any performance standard that might be developed must be periodically evaluated to determine if it should be changed to reflect new medical, scientific, or other technological data (21 U.S.C. 360d(a)(4)). Expedited procedures are available to amend standards (21 U.S.C. 360(g)(4)(B)). Accordingly, the proposed regulation is being adopted with a minor clarifying change.

7. Section 876.1800; 78N-1964; Urine flow or volume measuring system. FDA published in the **Federal Register** (46 FR 7575) a proposed regulation to classify the urine flow or volume measuring system into class II. The one comment received on the proposal suggested that the urine flow or volume measuring system be classified into class I rather than class II as was proposed. The comment stated that the device is noninvasive and that it is unnecessary for the device to provide precise measurements.

FDA disagrees with the comments. Many users of the device may not routinely require a high degree of measurement accuracy of urine flow or volume. However, FDA believes that on those occasions when measurement accuracy is required, the user should be able to determine readily the measurement accuracy. Additionally, FDA believes that a performance standard is necessary to control the electrical properties of the device to prevent electrical injury to the patient or the operator and to enable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

Section 876.3630; 78N-1979; Penile rigidity implant. FDA published in the **Federal Register** (46 FR 7578) a proposed regulation to classify the penile rigidity implant into class III. Two comments were received on the proposal.

a. One comment stated that FDA was incorrect in its description of the Section's classification recommendations for the penile rigidity implant, because the Section recommended that the device be classified into class II, not class III as stated in the proposed regulation.

FDA agrees with the comment. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology Device Section of the General Medical Devices Panel to discuss the classification of the penile rigidity implant and other devices. During the Section meeting, the Section again recommended that the penile rigidity implant be classified into class II. FDA continues to believe, nevertheless, that the penile rigidity implant should be classified into class III. Since the Section meeting, FDA has searched the medical literature and has documented further the risks to health resulting from silicone implants (Refs. 1 through 8), as noted below.

b. A comment suggested that the penile rigidity implant be classified into class II rather than class III as was proposed. The comment stated that clinical experience with the device and available data fully support classification of the device into class II and that standards can be established that would assure its safety and effectiveness. The comment stated that the problems which occur with use of the implant are most likely the result of improper implantation, rather than inadequate performance of the device.

FDA disagrees with the comment. FDA recognizes the long history of use of this device, as well as other prostheses made of similar materials and having similar construction. FDA has examined recent scientific data available concerning silicone implants and the migration of silicone in the body. The fate and importance of the

migrated silicone in the human body are currently incompletely understood and controversial. There are many reports (Refs. 1 through 8) which contain data concerning the harmful effects of silicone with respect to biological catabolism. Some of these reports reveal occurrence of allergic reaction (Ref. 1), silicone lymphadenoma (Refs. 2, 3, and 4), morbidity due to silicone (Refs. 5 and 6), and silicone migration (Refs. 7 and 8). FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of the device. In addition, the device is purported or represented to be for use (treatment of sexual dysfunction) that is of substantial importance in preventing impairment of human health, even though implantation of the device in the treatment of erectile impotence is discretionary. Furthermore, the device is an implant, which the act (21 U.S.C. 360c(d)) requires to be classified into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Because use of the device is discretionary, FDA believes that its use must be balanced against the risks presented by unknown long-term effects of silicone migration in the body—of which a physician should fully inform the patient before the patient decides whether to have the device implanted. Accordingly, the proposed regulation is being adopted without change.

9. Section 876.3750; 78N-1981; Testicular prosthesis. FDA published in the **Federal Register** (46 FR 7580) a proposed regulation to classify the testicular prosthesis into class III. Five comments were received on the proposal.

a. One comment stated that FDA was incorrect in its description of the Section's classification recommendations for the testicular prosthesis, because the Section recommended that the device be classified into class II, not class III as stated in the proposed regulation.

FDA agrees with the comment. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology Device Section of the General Medical Devices Panel to discuss the classification of the testicular prosthesis and other devices. During the Section meeting, the Section again recommended that the testicular prosthesis be classified into class II. FDA continues to believe, nevertheless, that the testicular prosthesis should be classified into class III. Since the Section meeting, FDA has searched the medical literature and has documented further the risks to health resulting from silicone implants (Refs. 1 through 8), as noted below.

b. Three comments suggested that the testicular prosthesis should be classified into class II rather than class III as was proposed. Additionally, one comment stated that no ill effects had been observed following implantation of the device during the 20 years of clinical experience with it. Further, the comment stated that standards can be established that would assure its safety and effectiveness. The comment said that there are no reports of the release of extremely minute quantities of silicone from an intact prosthesis, but if there were such reports, there would not be any basis for clinical concern about them. The comment stated that classifying the device into class III would not resolve any of the agency's concerns about the unknown long-term effects of implanting the device.

FDA disagrees with the comments. FDA recognizes the long history of use of this device, as well as other prostheses made of similar materials and having similar construction. FDA has examined recent scientific data available concerning silicone implants and the migration of silicone in the body following the bleeding of the silicone gel through the silicone shell of a device. The fate and importance of the migrated silicone in the human body are currently incompletely understood and controversial. There are many reports (Refs. 1 through 8) which contain data concerning the harmful effects of silicone with respect to biological catabolism. Some of these reports reveal occurrence of allergic reactions (Ref. 1), silicone lymphadenoma (Refs. 2, 3, and 4), morbidity due to silicone (Refs. 5 and 6), and silicone migration (Refs. 7 and 8). The device presents a potential unreasonable risk of illness or injury to the patient. The silicone within the prosthesis may migrate in the body of the patient, as described above, with unknown long-term effects. Furthermore, the device is an implant which the act (21 U.S.C. 360c(d)) requires to be classified into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of a device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary for the device because FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of the device. In addition, the device is purported or represented to be for a use (reconstructive surgery) that is of substantial importance in preventing impairment of human health, even though implantion of the testicular prosthesis is discretionary cosmetic surgery. The agency has determined that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because use of the device is discretionary, use of the device must be balanced against the long-term unknown effects of silicone migration in the body—of which a physician should fully inform the patient before the patient decides whether to have the device implanted.

c. One comment stated that the occasional migration of silicone from a silicone gel-filled prosthesis should not cause the agency to classify the solid silicone testicular prosthesis into class III. Therefore, the comment suggested that the solid silicone testicular prosthesis be classified into class II instead of class III.

FDA disagrees with the comment. Recent reports in the medical literature (Refs. 3 and 4) reveal instances of silicone migration in the body from solid implants. Therefore, FDA believes that both the solid and the gel filled types of the device should be classified into class III. Accordingly, the proposed regulation is being adopted without change.

10. Section 876.4020; 78N-1947; Fiberoptic light ureteral catheter. FDA published in the **Federal Register** (46 FR 7581) a proposed regulation to classify the fiberoptic light ureteral catheter into class II. The one comment received on the proposal suggested that the fiberoptic light ureteral catheter be classified into class I rather than class II as was proposed. The comment stated that this device is no more complex than

the ureteral catheter without a fiberoptic light.

FDA disagrees with the comment's suggestion about classifying the device into class I. FDA believes that characteristics of the fiberoptic light ureteral catheter, such as the shape, size, rigidity, flexibility, surface finish, and the light intensity produced, must be controlled by a performance standard to prevent trauma, hemorrhage, or perforation, and to enable the device to be properly cleaned and sterilized to prevent infection. Elsewhere in this final rule (§ 876.5130), FDA is also classifying the ureteral catheter without a fiberoptic light into class II. Accordingly, the proposed regulation is being adopted without change.

11. Section 876.4370; 78N-1994; Gastroenterology-urology evacuator. FDA published in the **Federal Register** (46 FR 7585) a proposed regulation to classify the gastroenterology-urology evacuator into class II. The one comment received on the proposal suggested that the gastroenterology-urology evacuator be classified into class I rather than class II as was proposed. The comment stated that this is a simple device and that establishment of a performance standard will not prevent its misuse.

FDA partially agrees with the comment. FDA now believes that the gastroenterology-urology evacuator when manually powered, should be classified into class I rather than class II as was proposed. FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manually powered device. FDA disagrees with the comment's suggestion that all gastroenterology-urology evacuators, even those that are other than manually powered, be classified into class I. FDA believes that a performance standard is necessary for the device when it is other than manually powered. The performance standard is necessary to control the design and construction of the device to prevent excessive irrigant pressure in the bladder of the patient during irrigant instillation. The electrical properties of the device must be controlled by a standard to prevent electrical injury to the patient or the operator. In this final rule, the agency is classifying into class I the gastroenterology-urology evacuator, a simple device when manually powered, and classifying the device into class II, when other than manually powered. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the changes in identification and classification described above.

12. Section 876.4500; 78N-2001; Mechanical lithotriptor. FDA published in the **Federal Register** (46 FR 7588) a proposed regulation to classify the mechanical lithotriptor into class II. The one comment received on the proposal suggested that the mechanical lithotriptor be classified into class I rather than class II as was proposed. The comment stated the device may be extremely dangerous and that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with this device may be due to unskilled users, the agency believes that the mechanical lithotriptor should be classified into class II because the mechanical design and performance of the device, especially the jaws, must be controlled by a performance standard to prevent injury to the patient. Also, the design and construction of the device must be controlled by standards to ensure that it can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

13. Section 876.4560; 78N-2067; Ribdam. FDA published in the **Federal Register** (46 FR 7590) a proposed regulation to classify the ribdam into class II. The one comment received on the proposal suggested that the ribdam be classified into class I rather than class II as was proposed. The comment stated that these devices are only large surgical rubber drains which can be cut to any size when copious drainage is expected.

FDA agrees with the comment. FDA now believes that ribdams should be classified into class I, because general controls, particularly GMP requirements, are sufficient to assure proper construction, continued use of known biocompatible materials, and uniform bulk, and thus will provide reasonable assurance of the safety and effectiveness of this simple device. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change.

14. Section 876.4590; 78N-2068; Interlocking urethral sound. FDA published in the **Federal Register** (46 FR 7591) a proposed regulation to classify the interlocking urethral sound into class II. The one comment received on the proposal suggested that the interlocking urethral sound be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the interlocking urethral sound should be classified into class II because the design of the device must be controlled by a performance standard to prevent further injury to the urethra of the patient and to ensure that the device may be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

15. Section 876.4620; 78N-1984; Ureteral stent. FDA published in the **Federal Register** (46 FR 7592) a proposed regulation to classify the ureteral stent into class II. The one comment received on the proposal suggested that the ureteral stent be classified into class I rather than class II as was proposed. The comment stated that performance standards for the device would be extremely difficult to develop because there are so many diverse designs of the device.

FDA disagrees with the comment. Although FDA recognizes the wide diversity of designs of this generic device, the agency believes that present among the various designs are enough common features to allow the establishment of a performance standard. FDA believes that the design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, perforation, or migration of the device, and to anable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

16. Section 876.4650; 78N-1988; Water jet renal stone dislodger system. FDA published in the **Federal Register** (46 FR 7593) a proposed regulation to classify the water jet renal stone dislodger system into class II. The one comment received on the proposal suggested that the water jet renal stone dislodger system be classified into class I rather than class II as was proposed. The comment asserted that the data needed to establish a performance standard for the device are not currently available.

FDA disagrees with the comment. The agency believes that a performance standard for the device is necessary to prevent kidney damage that may result from excessive water pressure delivered by the device and to enable it to be properly cleaned and sterilized to prevent infection. FDA also believes that there is sufficient information available to develop a performance standard for the device. Accordingly, the proposed regulation is being adopted without change.

17. Section 876.4730; 78N-1996; Manual gastroenterology-urology surgical instrument and accessories. FDA published in the **Federal Register** (46 FR 7595) a proposed regulation to classify the manual gastroenterology-urology surgical instrument and accessories into class I without exemptions. The one comment received on the proposal agreed with the proposed classification. Accordingly, the proposed regulation is being adopted without change.

18. Section 876.4770; 78N-2004; Urethrotome. FDA published in the **Federal Register** (46 FR 7597) a proposed regulation to classify the urethrotome into class II. The one comment received on the proposal suggested that the urethrotome be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the urethrotome should be classified into class II because the design of the cutting blade, together with its associated complex mechanical linkages and lighting system, must be controlled by a performance standard to prevent injury to the patient or the operator. Also, the design and construction must be controlled by standards to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

19. Section 876.4890; 78N-2070; Urological table and accessories. FDA published in the **Federal Register** (46 FR 7598) a proposed regulation to classify the urological table and accessories into class II. The one comment received on the proposal suggested that the urological table and accessories be classified into class I rather than class II as was proposed. The comment stated that performance standards would not improve the safety and effectiveness of manually powered urological tables and their accessories.

FDA partially agrees with the comment. FDA now believes that manually powered urological tables and accessories should be classified into class I, because any defects in the relatively simple manually powered urological table and accessories are readily apparent to the user, and the agency is therefore classifying the manually powered device to class I. FDA has determined that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manually powered device. FDA disagrees with comment's suggestion that the electrically powered urological table and its accessories be classified into class I. FDA believes that the electrical properties of the device must be controlled by a performance standard to prevent electrical injury to the patient or operator.

In sum, the final rule classifies the urological table and accessories into class I when manually powered and into class II when electrically powered. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the changes in identification and classification described above.

20. Section 876.5030; 78N-1972; Continent ileostomy catheter. FDA published in the **Federal Register** (46 FR 7600) a proposed regulation to classify the continent ileostomy catheter into class II. The one comment received on the proposal suggested that the continent ileostomy catheter be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA agrees with the comment. The agency now believes that the continent ileostomy catheter should be classified into class I. FDA has determined that general controls, particularly requirements of current GMP regulations, are sufficient to control the risk of infection and otherwise will provide reasonable assurance of the safety and effectiveness of the device. The agency also agrees that the principal hazard associated with the use of the device may be due to unskilled users. In the final rule, the agency is classifying the continent ileostomy catheter into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification.

21. Section 876.5090; 78N-1989; Suprapubic urological catheter and accessories. FDA published in the **Federal Register** (46 FR 7601) a proposed regulation to classify the suprapubic urological catheter and accessories into class II. The one comment received on the proposal suggested that the suprapubic urological catheter and accessories be classified into class I rather than class II as was proposed. The comment stated that use of the device may be extremely hazardous to patients; however, the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the suprapubic urological catheter and accessories should be classified into class II because the shape, size, rigidity, surface finish, and strength of the device must be controlled by performance standard to prevent injury to the patient resulting from a device of improper design or construction and to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

22. Section 876.5130; 78N-2006; Urological catheter and accessories. FDA published in the **Federal Register** (46 FR 7602) a proposed regulation to classify the urological catheters and accessories into class II. The one comment received on the proposal suggested that the urological catheter and accessories be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the urological catheter and accessories should be classified into class II because the shape, size, rigidity, surface finish, and strength of the device must be controlled by a performance standard to prevent injury to the patient resulting from devices of improper design or construction and to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

23. Section 876.5160; 78N-2009; Urological clamp for males. FDA published in the **Federal Register** (46 FR 7603) a proposed regulation to classify the urological clamp for males into class II. The one comment received on the proposal suggested that the urological clamp for males be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA agrees with the comment. FDA now believes that the urological clamp for males should be classified into class I. The agency believes that general controls, particularly requirements of current GMP regulations, are sufficient to ensure consistency of clamping pressure and the continued use of known biocompatible materials for this simple device and thus will provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that the principal hazards associated with the use of the device may be due to unskilled users. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification.

24. Section 876.5220; 78N-2011; Colonic irrigation system. FDA published in the **Federal Register** (46 FR 7606) a proposed regulation to classify the colonic irrigation system into class II when intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations, and into class III when intended for all other uses, including use routinely for general well being. The one comment received on the proposal agreed with the classification set forth in the proposed regulation. The comment also was presented at the meeting on April 13, 1981 of the Gastroenterology-Urology Device Section. The comment described several risks and hazards concerning the use of the colonic irrigation system. The comment emphasized the need for appropriate labeling for the device.

FDA agrees with the comment. FDA believes that the risks to health presented by the colonic irrigation system will be controlled through the establishment of a performance standard for the device when it is intended for colon cleansing when medically indicated and premarket approval of the device when intended for other uses, including colon cleansing for general well being. Accordingly, the proposed regulation is being adopted without change.

25. Section 876.5250; 78N-2010; Urine collector and accessories. FDA published in the **Federal Register** (46 FR 7607) a proposed regulation to classify the urine collector and accessories into class II. Four comments were received on the proposal.

a. One comment suggested that the urine collector and accessories be divided into two categories, depending upon whether it is intended for external or internal use. The comment suggested that the urine collector and accessories intended for external use be classified into class I rather than into class II as was proposed and that the urine collector and accessories intended for connection to an indwelling catheter be classified into class II. The comment stated that when the device is not intended for connection to an indwelling catheter, general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A second comment stated that the development of a performance standard for a urine collector intended for external use is unlikely to improve the safety and effectiveness of the device; therefore, the device should be classified into class I when not intended for connection to an indwelling catheter.

FDA agrees with both comments. FDA now believes that general controls, particularly requirements of the current GMP regulations, are sufficient to control the risks to health, such as infection, presented by the urine collector and accessories when it is not intended for connection to an indwelling catheter. Therefore, FDA is changing the identification of the urine collector and accessories to divide the generic device into two categories, depending upon whether or not it is intended for connection to an indwelling catheter. In the final rule, when the device is not intended for connection to an indwelling catheter, it is classified into class I; and when the device is intended for connection to an indwelling catheter, it is classified into class II. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal regarding this decision.

b. A comment suggested that some urinary drainage bags (defined as sterile, disposable, single use, urine collectors) be classified into class I and that others, such as incontinence devices and leg bags, should remain in class II. The comment stated that some urinary drainage bags have no physical contact with the patient until they are attached to an indwelling catheter. The comment also objected to including the urinary drainage bag in the generic type of device, urine collector and accessories, because the urinary drainage bag alone does not cause the risk to health of infection that is associated with the device, as stated in the proposed regulation.

FDA disagrees with the comment. FDA believes that the design, construction, and performance of the urinary drainage bag in the urine collector system has an influence on both the microbial count of the urine in the urinary drainage bag and the rate of infection in patients using the urine collector and accessories when connected to an indwelling catheter. FDA has searched the medical literature and documented the risks of infection to patients that are presented by a urine collector and accessories when connected to an indwelling catheter (Refs. 9 through 13). The literature review shows that patients using a urine collector attached to an indwelling catheter frequently develop infections of the urinary tract with possible serious health risks. The literature states that certain design and construction characteristics, such use of anti-reflex valves, special venting systems, closed irrigation sites, ports to add disinfectants, drainage tubes designed to prevent access of bacteria to the bag, and sample collection ports, all may aid in the reduction of the potential of infection presented by the device (Refs. 9, 11, and 13). Therefore, FDA has determined that the urinary drainage bag should be included in the generic device, the urine collector and accessories. FDA believes that a performance standard is necessary to control the risks to health presented by the urine collector and accessories intended for connection to an indwelling catheter.

c. A comment requested that the urine collector and accessories for external use be exempt from the current GMP regulations. The comment stated that, based on current manufacturing practices and user experience with the device, application of the current GMP regulations is unlikely to improve the safety or effectiveness of the urine collector and accessories not intended for connection to an indwelling catheter.

FDA agees with the comment. FDA believes that the quality and any defects of the urine collector and accessories not intended for connection to an indwelling catheter are readily apparent to the user and that general controls alone are sufficient to provide reasonable assurance of the safety and

effectiveness of the device. Therefore, the agency has determined that a manufacturer of a urine collector and accessories that is not intended for connection to an indwelling catheter and that is not labeled or otherwise represented as sterile be exempt, in the manufacture of the device, from all requirements in the current GMP regulations except § 820.180 with respect to general requirements concerning records, and § 820.198 with respect to complaint files. The agency believes that such a manufacturer must still be required to comply with complaint file requirements, to insure that the manufacturer has an adequate system for complaint investigation and followup, and with the general requirements concerning records, to insure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, and can determine whether the exemption from other sections of the current GMP regulations is still appropriate. A manufacturer of a urine collector and accessories that is labeled or otherwise represented as sterile, whether or not intended for connection to an indwelling catheter, is, in the manufacture of this device, subject to the current GMP regulations in their entirety. Accordingly, the proposed regulation is being adopted with the changes in identification, classification, and exemptions described above.

26. Section 876.5320; 78N-2069; Nonimplanted electrical continence devise. FDA published in the **Federal Register** (46 FR 7611) a proposed regulation to classify the nonimplanted electrical continence device into class III. The one comment received on the proposal suggested that the nonimplanted electrical continence device be classified into class II rather than class III as was proposed. The comment stated that the low-level current and voltage used in the device are harmless and the effects are local. It is mainly used to increase patient awareness of incontinence by conditioning or biofeedback. Further, the comment stated the device is safe and essentially used externally.

FDA agrees with the comment. Therefore, FDA now believes that the concerns of the Obstetrical and Gynecological Device Classification Panel about the safety and effectiveness of the device apply to AC-powered devices. FDA is unaware of any nonimplanted electrical continence device that is AC-powered. Accordingly, the Panel's concerns do not apply to battery-operated electrical continence devices, which produce a safe, low level of electrical current and have been shown to be effective in properly selected patients (Ref. 14) and thus do not provide a potential unreasonable risk of illness or injury to the patient. FDA believes that establishment of performance standards for the device will control the electrical currents produced by the battery-powered device and will provide reasonable assurance of the safety and effectiveness of the device. FDA believes that sufficient information exists to establish performance standards for the battery-powered nonimplanted electrical continence device. The agency also believes that general controls are insufficient to assure the safety and effectiveness of the battery-powered device.

In the final rule, the agency is classifying the device into class II instead of class III as was proposed. For the reasons stated above in this preamble, FDA does not believe it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the change in classification described above and a clarifying change in identification.

27. Section 876.5520; 78N-2059; Urethral dilator. FDA published in the **Federal Register** (46 FR 7615) a proposed regulation to classify the urethral dilator into class II. The one comment received on the proposal suggested that the urethral dilator be classified into class I rather than class II as was proposed, because class I is more appropriate due to the long history of use of the device.

FDA disagrees with the comment. FDA believes that the design and construction of the device and the materials used in the device must be controlled by a performance standard to ensure that the size, shape, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, or perforation. The calibration must be controlled to prevent overdilation of the urethra. The design and construction must be controlled to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

28. Section 876.5540; 78N-2044; Blood access device and accessories. FDA published in the **Federal Register** (46 FR 7616) a proposed regulation to classify the implanted blood access device and accessories into class III and the nonimplanted blood access device and accessories into class II. The one comment received on the proposal stated that the final regulation classifying blood access devices and accessories should not be published, because it will prevent the development of improved devices and hamper technological advances in the field of nephrology.

FDA disagrees with the comment. FDA believes that issuance of a final regulation to classify the blood access device and accessories will not prevent the development of new or improved devices. Classifying a device, in itself, has a limited impact, which is described at the conclusion of this preamble. However, on its own initiative, FDA classified into class II the accessories to the implanted blood access device, because the agency now believes that performance standards are sufficient to control the risks to health presented by the accessories to both the implanted and the nonimplanted device. For the reasons stated above in this preamble, FDA does not believe it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the noted change in classification and clarifying changes in the identification of the device.

29. Section 876.5665; 78N-2047; Water purification system for hemodialysis. FDA published in the **Federal Register** (46 FR 7622) a proposed regulation to classify the water purification system for hemodialysis into class II. The one comment received on the proposal suggested that the water purification system for hemodialysis be classified into class I rather than class II as was proposed. The comment asserted that the device has been used in hemodialysis for over 15 years, during which time there have been no major problems associated with its use. The comment also stated that the general controls of class I are sufficient to assure the safety and effectiveness of the water purification system for hemodialysis.

FDA disagrees with the comment. In the proposed regulation to classify into class II the water purification system for hemodialysis, FDA cited the risks to health of both toxic and pyrogenic reactions. Several other hazards associated with the device are described in the contract report cited in the proposed regulation. FDA believes that the design and construction of the device and the materials used in the device must be controlled by a performance standard to ensure that the device delivers properly purified water to prevent toxic or pyrogenic reactions in the patient and to enable the device to be properly cleaned and sterilized to

prevent infection. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

30. Section 876.5820; 78N-2014; Hemodialysis system and accessories. FDA published in the **Federal Register** (46 FR 7623) a proposed regulation to classify the hemodialysis system and accessories into class II. The regulation proposed to classify certain accessories into class II and other accessories into class I. Two comments were received on the proposal.

a. One comment agreed with the classification of the hemodialysis system and certain accessories into class II. The comment also requested that FDA clarify a statement in paragraph 3 of the preamble to the proposed regulation. The statement was in the summary of the reasons that the Section recommended that the extraluminal blood pump and its accessories be classified into class II.

FDA agrees with the comment. Clarification is needed, and the sentence identified should read as follows: "The design and construction of the extraluminal blood pump and its accessories must be controlled by a performance standard to prevent damage to blood cells or inadequate blood flow due to improper design, and to prevent blood loss due to poor fitting connections or laceration of the tubing."

b. One comment noted that dialysate or dialysate concentrate for hemodialysis was excluded from the proposed classification regulations. The comment further stated that dialysate concentrate should be classified in class II and included in the hemodialysis system and accessories.

FDA agrees with the comment. Dialysate concentrate for hemodialysis is considered to be part of the hemodialysis system and was not specifically identified in the proposed classification regulations. However, in the interest of clarity, FDA is revising the regulation to include dialysate concentrate for hemodialysis by name. FDA is unaware of the commercial marketing of dialysate. Dialysate concentrate for hemodialysis is used (following its dilution with suitable water to make dialysate) in all of the hemodialysis delivery systems classified in this final rule, e.g., § 876.5600 *Sorbent regenerated dialysate delivery system for hemodialysis.* Additionally, as a further point of clarification, it is pointed out that prepackaged dialysis solutions and concentrates that are intended to be introduced directly into the body (e.g., for peritoneal dialysis) are subject to regulation as drugs. The agency has changed the identification of the hemodialysis system and accessories to include dialysate concentrate as part of the dialysate delivery system in the hemodialysis system and accessories. Accordingly, the proposed regulation is being adopted with clarifying changes in the identification of the device.

31. Section 876.5895; 78N-1975; Ostomy irrigator. FDA published in the **Federal Register** (46 FR 7632) a proposed regulation to classify the ostomy irrigator into class II. The one comment received on the proposal suggested that the ostomy irrigator be classified into class I rather than class II as was proposed. The comment stated that the device is simple, made of proven materials, and that no complaints of tissue irritation, trauma, hemorrhage, or perforation had been received due to the device between 1967 and 1980. The comment said that any adverse effects are essentially caused by misuse or abuse of the device by users. The comment stated that the size or shape of the irrigating cone had little relationship to the prevention of leakage of stool or irrigant solutions.

FDA disagrees with the comment. FDA believes that the ostomy irrigator should be classified into class II because the design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device will not cause trauma, hemorrhage, or perforation, or allow leakage of stool or irrigant solution that may cause skin irritation. Although adverse effects may occur due to misuse or abuse of the device by users, FDA believes that general controls are insufficient to control the risks to health presented by the device and the establishment of a performance standard would minimize the risks. Accordingly, the proposed regulation is being adopted without change.

32. Section 876.5900; 78N-1974; Ostomy pouch and accessories. FDA published in the **Federal Register** (46 FR 7633) a proposed regulation to classify the ostomy pouch and accessories into class II. The one comment received on the proposal suggested that the ostomy pouch and accessories be classified into class I rather than class II as was proposed. The comment further stated that the only possible cause of adverse tissue reaction can be the adhesive, and that a review of the company's complaint files for 5 years indicated that the incidence of skin irritation is about 0.00002 percent, with no systemic toxic effects reported. The comment also stated that the design and construction of the ostomy pouch had little to do with the prevention of leakage, slippage, or damage to the stoma.

FDA agrees with the comment. FDA now believes that the ostomy pouch and accessories should be classified into class I. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. As stated in the proposed regulation to classify the ostomy pouch and accessories, the General Hospital and Personal Use Device Section of the General Medical Devices Panel recommended that the ostomy pouch and accessories be exempt from the current GMP regulations (21 CFR Part 820) under section 520(f) of the act. The agency disagrees with this recommendation and believes that compliance with the current GMP regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the current GMP regulations will help prevent production of ostomy pouches and accessories having defects, such as containers that leak, and will ensure the continued use of known biocompatible materials in this relatively simple device. Accordingly, the proposed regulation is being adopted with the change in classification described above and a minor clarifying change.

33. Section 876.5920; 78N-2062; Protective garment for incontinence. FDA published in the **Federal Register** (46 FR 7635) a proposed regulation to classify the protective garment for incontinence into class I. Five comments were received on the proposal.

a. One comment agreed with the proposed classification of the protective garment for incontinence into class I.

b. One comment stated that FDA was incorrect in its description of the Section's classification recommendation for the protective garment for incontinence, because the Section recommended that the device be classified into class II, not class I as stated in the proposed regulation.

FDA agrees with the comment stating that FDA was incorrect in its description of the Section's classification recommendation. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology

Device Section of the General Medical Devices Panel to discuss the classification of the protective garment for incontinence and other devices. During the Section meeting, the Section recommended that the protective garment for incontinence be classified into class I, thus agreeing with the position taken by FDA in the proposed, and now in the final, rule.

c. Two comments believed that a protective garment for incontinence is not a medical device, as device is defined in section 201(h) of the act (21 U.S.C. 321(h)).

FDA disagrees with the comments. Although incontinence is a normal physiological state in infants, so that a diaper intended for use by infants is not a device, incontinence in persons other than infants is frequently the result of a disease process. Thus, protective garments for incontinence are intended to mitigate the consequences of the disease. Thus, FDA believes that a protective garment for incontinence that is intended for use of persons other than infants is a medical device, as defined in section 201(h) of the act.

d. One comment suggested that the identification of the protective garment for incontinence device be limited to those products that make medical claims in their labeling. The comment was concerned that the protective garment for incontinence may be included as a medical device because of its intended use, rather than because of its labeling claims.

FDA disagrees with the comment. As stated in the preamble to the proposed general provisions (46 FR 7563), FDA will regulate a product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." Section 201(h) of the act (21 U.S.C. 321(h)). FDA will determine the intended use of a multipurpose product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, are regulated as medical whether or not medical claims are made for them. Thus, the agency believes that a protective garment for incontinence that is intended for use of persons other than infants is intended only for medical uses and FDA will regulate the product as a medical device whether or not medical claims are made in its labeling. This determination is consistent with a letter of February 15, 1978 (Ref. 15) sent by FDA's Bureau of Medical Devices to the person who submitted the comment. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

34. Section 876.5955; 78N-1980; Peritoneo-venous shunt. FDA published in the **Federal Register** (46 FR 7636) a proposed regulation to classify the peritoneo-venous shunt into class III. The one comment received on the proposal was orally presented at the meeting on April 13, 1981 of the Gastroenterology-Urology Device Section of the General Medical Devices Panel. The comment agreed that the peritoneo-venous shunt should be classified into class III and stated several risks and hazards associated with the peritoneo-venous shunt. The comment also indicated that classification into class III would permit FDA to attach to its premarket approval orders any restrictions necessary on the sale, distribution, or use of the device to assure its safety and effectiveness. Further, the comment emphasized the need for complete labeling for the device.

FDA agrees with the comment. Accordingly, the proposed regulation is being adopted without change.

35. Section 876.5970; 78N-1967; Hernia support. FDA published in the **Federal Register** (46 FR 7638) a proposed regulation to classify the hernia support into class II with a partial exemption from the current GMP regulations. Two comments received on the proposal suggested that the hernia support be classified into class I rather than class II as was proposed. One comment further stated that there are no proven risks to health associated with this device and that the real risk to health comes from not wearing a hernia support.

FDA agrees with the suggestion that the hernia support be classified into class I. FDA now believes that the quality and any defects of the device are readily apparent to the user and that general controls alone are sufficient to ensure the continued use of known biocompatible materials and otherwise provide reasonable assurance of the safety and effectiveness of the device. In the final rule, the agency is classifying the device into class I with a partial exemption from the current GMP regulations. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification and exemptions described above.

References

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 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. Pearl, R. M., et al., "Complications following Silicone Injections for Augmentation of the Contours of the Face," *Plastic and Reconstructive Surgery*, 61:888-891, 1978.

2. Kircher, T., "Silicone Lymphadenopathy. A Complication of Silicone Elastomer Finger Joint Prostheses, "*Human Pathology*, 11:240-244, 1980.

3. Christie, A. J., et al., "Silicone Lymphadenopathy and Synovitis. Complications of Silicone Elastomer Finger Joint Prostheses," *Journal of the American Medical Association*, 237:1463-1464, 1977.

4. Christie, A. J., et al., "Recurrence of Silicone Lymphadenopathy," *Journal of the American Medical Association*, 245:1316, 1981.

5. Ellenbogen, R., et al., "Injectable Fluid Silicone Therapy. Human Morbidity and Mortality," *Journal of the American Medical Association*, 234:308-309, 1975.

6. Rudolph, R., et al., "Myofibroblasts and Free Silicone Around Breast Implants," *Plastic and Reconstructive Surgery*, 62:185-196, 1978.

7. Gibbons, D. F., et al., "Wear and Degradation of Retrieved Ultrahigh Molecular Weight Polyethylene and other Polymeric Implants," *In* "Corrosion and Degradation of Implant Materials," B. C. Syrett and A. Acharya (Eds.), pp. 20-40, ASTM STP 684, 1979.

8. Leong, A. S. Y., et al., "Refractile Particles in Liver of Hemodialysis Patients," *Lancet*, 889-890, 1981.

9. Ansell, J. "Some Observations on Catheter Care," *Journal of Chronic Diseases*, 15:675-682, 1962.

10. Maizels, M. and A. J. Schaeffer, "Decreased Incidence of Bacteriuria Associated with Periodic Instillations of Hydrogen Peroxide into the Urethral Catheter Drainage Bag," *Journal of Urology*, 123:841-845, 1981.

11. Stamm, W. E., "Guidelines for Prevention of Catheter Associated Urinary Tract Infections," *Annals of Internal Medicine*, 82:386-390, 1975.

12. Fincke, B. B. and G. Friedland, "Prevention and Management of Infection in the Catheterized Patient," *Urology Clinic of North America*, 3(2)313-321, 1976.

13. Garibaldi, R. A., J. P. Burke, et al., "Factors Predisposing to Bacteriuria During Indwelling Urethral Catheterization," *New England Journal of Medicine*, 291:215-219, 1974.

14. Godec, C. and A. Cass, "Acute Electrical Stimulation for Urinary Incontinence," *Urology*, 12:340-342, 1978.

15. Letter from the Division of Compliance Operations, Bureau of Medical Devices, to a medical device manufacturer, February 15, 1978.

List of Subjects in 21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 876, to read as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

Subpart A—General Provisions

Sec.
876.1 Scope.

Subpart B—Diagnostic Devices

876.1075 Gastroenterology-urology biopsy instrument.
876.1400 Stomach pH electrode.
876.1500 Endoscope and accessories.
876.1620 Urodynamics measurement system.
876.1725 Gastrointestinal motility monitoring system.
876.1800 Urine flow or volume measuring system.

Subpart C—Monitoring Devices

876.2040 Enuresis alarm.

Subpart D—Prosthetic Devices

876.3350 Penile inflatable implant.
876.3630 Penile rigidity implant.
876.3750 Testicular prosthesis.

Subpart E—Surgical Devices

876.4020 Fiberoptic light ureteral catheter.
876.4270 Colostomy rod.
876.4300 Endoscopic electrosurgical unit and accessories.
876.4370 Gastroenterology-urology evacuator.
876.4400 Hemorrhoidal ligator.
876.4480 Electrohydraulic lithotriptor.
876.4500 Mechanical lithotriptor.
876.4530 Gastroenterology-urology fiberoptic retractor.
876.4560 Ribdam.
876.4590 Interlocking urethral sound.
876.4620 Ureteral stent.
876.4650 Water jet renal stone dislodger system.
876.4680 Ureteral stone dislodger.
876.4730 Manual gastroenterology-urology surgical intsrument and accessories.
876.4770 Urethrotome.
876.4890 Urological table and accessories.

Subpart F—Therapeutic Devices

876.5010 Biliary catherter and accessories.
876.5030 Continent ileostomy catheter.
876.5090 Suprapubic urological catheter and accessories.
876.5130 Urological catheter and accessories.
876.5160 Urological clamp for males.

Sec.
876.5210 Enema kit.
876.5220 Colonic irrigation system.
876.5250 Urine collector and accessories.
876.5270 Implanted electrical urinary continence device.
876.5280 Implanted mechanical/hydraulic urinary continence device.
876.5320 Nonimplanted electrical continence device.
876.5365 Esophageal dilator.
876.5450 Rectal dilator.
876.5470 Ureteral dilator.
876.5520 Urethral dilator.
876.5540 Blood access device and accessories.
876.5600 Sorbent regenarated dialysate delivery system for hemodialysis.
876.5630 Peritoneal dialysis system and accessories.
876.5665 Water purification system for hemodialysis.
876.5820 Hemodialysis system and accessories.
876.5830 Hemodialyzer with disposable insert (Kiil type).
876.5860 High permeability hemodialysis system.
876.5870 Sorbent hemoperfusion system.
876.5880 Isolated kidney perfusion and transport system and accessories.
876.5895 Ostomy irrigator.
876.5900 Ostomy pouch and accessories.
876.5920 Protective garment for incontinence.
876.5955 Peritoneo-venous shunt.
876.5970 Hernia support.
876.5980 Gastrointestinal tube and accessories.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 876.1 Scope.

(a) This part sets forth the classification of gastroenterology-urology 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 provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Diagnostic Devices

§ 876.1075 Gastroenterology-urology biopsy instrument.

(a) *Identification.* A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* Class II (performance standards).

§ 876.1400 Stomach pH electrode.

(a) *Identification.* A stomach pH electrode is a device used to measure intragastric and intraesophageal pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

(b) *Classification.* Class II (performance standards).

§ 876.1500 Endoscope and accessories.

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification

regulations in other parts of the device classification regulations.

(b) *Classification.* Class II (performance standards).

§ 876.1620 Urodynamics measurement system.

(a) *Identification.* A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydrualic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.

(b) *Classification.* Class II (performance standards).

§ 876.1725 Gastrointestinal motility monitoring system.

(a) *Identification.* A gastrointestinal motility monitoring system is a device used to measure peristalic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

(b) *Identification.* Class II (performance standards).

§ 876.1800 Urine flow or volume measuring system.

(a) *Identification.* A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduct the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.

(b) *Classification.* Class II (performance standards).

Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.

(a) *Identification.* An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.

(b) *Classification.* Class II (performance standards).

Subpart D—Prosthetic Devices

§ 876.3350 Penile inflatable implant.

(a) *Identification.* A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.

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

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a single semi-rigid rod or a pair of semi-rigid rods implanted in the penis to provide rigidity. It is used in the treatment of erectile impotence.

(b) *Classification.* Class III (permarket approval).

§ 876.3750 Testicular prosthesis.

(a) *Identification.* A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.

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

Subpart E—Surgical Devices

§ 876.4020 Fiberoptic light ureteral catheter.

(a) *Identification.* A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.

(b) *Classification.* Class II (performance standards).

§ 876.4270 Colostomy rod.

(a) *Identification.* A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.

(b) *Classification.* Class II (performance standards).

§ 876.4300 Endoscopic electrosurgical unit and accessories.

(a) *Identification.* An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

(b) *Classification.* Class II (performance standards).

§ 876.4370 Gastroenterology-urology evacuator.

(a) *Identification.* A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump.

(b) *Classification.* (1) Class II (performance standards) for the gastroenterology-urology evacuator when other than manually powered.

(2) Class I (general controls) for the gastroenterology-urology evacuator when manually powered.

§ 876.4400 Hemorrhoidal ligator.

(a) *Identification.* A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.

(b) *Classification.* Class II (performance standards).

§ 876.4480 Electrohydraulic lithotriptor.

(a) *Identification.* An electrohydraulic lithotriptor is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the

urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.

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

§ 876.4500 Mechanical lithotriptor.

(a) *Identification.* A mechanical lithotriptor is a device with steel jaws that is inserted into the urinary bladder through the urethra to grasp and crush bladder stones.

(b) *Classification.* Class II (performance standards).

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

(a) *Identification.* A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.

(b) *Classification.* Class I (general controls).

§ 876.4560 Ribdam.

(a) *Identification.* A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.

(b) *Classification.* Class I (general controls).

§ 876.4590 Interlocking urethal sound.

(a) *Identification.* An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.

(b) *Classification.* Class II (performance standards).

§ 876.4620 Ureteral stent.

(a) *Identification.* A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

(b) *Classification.* Class II (performance standards).

§ 876.4650 Water jet renal stone dislodger system.

(a) *Identification.* A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.

(b) *Classification.* Class II (performance standards).

§ 876.4680 Ureteral stone dislodger.

(a) *Identification.* A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.

(b) *Classification.* Class II (performance standards).

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification.* A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop.

(b) *Classification.* Class I (general controls).

§ 876.4770 Urethrotome.

(a) *Identification.* A urethrofome is a device that is inserted into the urethra and used to cut urethral strictures and enlarge the urethra. It is a metal instrument equipped with a dorsal-fin cutting blade which can be elevated from its sheath. Some urethrotomes incorporate an optical channel for visual control.

(b) *Classification.* Class II (performance standards).

§ 876.4890 Urological table and accessories.

(a) *Identification.* A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually or electrically.

(b) *Classification.* (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I (general controls) for the manually powered urological table and accessories.

Subpart F—Therapeutic Devices

§ 876.5010 Biliary catheter and accessories.

(a) *Identification.* A biliary catheter and accessories is a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap.

(b) *Classification.* Class II (performance standards).

§ 876.5030 Continent ileostomy catheter.

(a) *Identification.* A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.

(b) *Classification.* Class I (general controls).

§ 876.5090 Suprapubic urological catheter and accessories.

(a) *Identification.* A suprapubic urological catheter and accessories is a flexible tubular device that is inserted through the abdominal wall into the urinary bladder with the aid of a trocar and cannula. The device is used to pass fluids to and from the urinary tract. This generic type of device includes the suprapubic catheter and tube, Malecot catheter, catheter punch instrument, suprapubic drainage tube, and the suprapubic cannula and trocar.

(b) *Classification.* Class II (performance standards).

§ 876.5130 Urological catheter and accessories.

(a) *Identification.* A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudé catheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic

catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-urological irrigation tray (for urological use).

(b) *Classification.* Class II (performance standards).

§ 876.5160 Urological clamp for males.

(a) *Identification.* A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

(b) *Classification.* Class I (general controls).

§ 876.5210 Enema kit.

(a) *Identification.* An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (§ 876.5220).

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of §820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 876.5220 Colonic irrigation system.

(a) *Identification.* A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (§ 876.5210).

(b) *Classification.* (1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

(2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

§ 876.5250 Urine collector and accessories.

(a) *Identification.* A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) a urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

(b) *Classification.* (1) Class II (performance standards) for a urine collector and accessories intended to be connected to an indwelling catheter.

(2) Class I (general controls) for a urine collector and accessories not intended to be connected to an indwelling catheter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 876.5270 Implanted electrical urinary continence device.

(a) *Identification.* An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

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

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

(a) *Identification.* An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra. The totally implanted device may consist of a static pressure pad, or a system with a container of radiopaque fluid in the abdomen and a manual pump and valve under the skin surface that is connected by tubing to an adjustable pressure pad or to a cuff around the urethra. The fluid is pumped as needed from the container to inflate the pad or cuff to pass on the urethra.

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

§ 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§ 884.5940).

(b) *Classification.* Class II (performance standards).

§ 876.5365 Esophageal dilator.

(a) *Identification.* An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).

(b) *Classification.* Class II (performance standards).

§ 876.5450 Rectal dilator.

(a) *Identification.* A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.

(b) *Classification.* Class II (performance standards).

§ 876.5470 Ureteral dilator.

(a) *Identification.* A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.

(b) *Classification.* Class II (performance standards).

§ 876.5520 Urethral dilator.

(a) *Identification.* A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower.

(b) *Classification.* Class II (performance standards).

§ 876.5540 Blood access device and accessories.

(a) *Identification.* A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.

(1) The implanted blood access device consists of various flexible or rigid tubes, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various shunts and connectors specifically designed to provide access to blood, such as the arteriovenous (A–V) shunt cannula and vessel tip.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).

(3) Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).

(b) *Classification.* (1) Class III (premarket approval) for the implanted blood access device.

(2) Class II (performance standards) for the nonimplanted blood access device.

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access device.

§ 876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.

(a) *Identification.* A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (§ 876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials.

(b) *Classification.* Class II (performance standards).

§ 876.5630 Peritoneal dialysis system and accessories.

(a) *Identification.* (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system.

(2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.

(3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.

(4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or "cycler systems") or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or "reverse osmosis" systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.

(b) *Classification.* Class II (performance standards).

§ 876.5665 Water purification system for hemodialysis.

(a) *Identification.* A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

(b) *Classification.* Class II (performance standards).

§ 876.5820 Hemodialysis system and accessories.

(a) *Identification.* A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable

membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860).

(4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

(b) *Classification.* (1) Class II (performance standards) for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.

(2) Class I (general controls) for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties.

§ 876.5830 Hemodialyzer with disposable insert (kiil type).

(a) *Identification.* A hemodialyzer with disposable inserts (Kiil type) is a device that is used as a part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that includes disposable inserts consisting of layers of semipermeable membranes which are sandwiched between support plates. The device is used with the extracorporeal blood system and the dialysate delivery system of the hemodialysis system and accessories (§ 897.5820).

(b) *Classification.* Class II (performance standards).

§ 876.5860 High permeability hemodialysis system.

(a) *Identification.* A high permeability hemodialysis system is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that has a dialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional dialyzer. The device system consists of an extracorporeal blood system, a high permeability dialyzer, and a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood. This highly permeable, semipermeable membrane may also permit greater loss of higher molecular weight substances from the blood, compared with the conventional dialyzer of the hemodialysis system and accessories (§ 876.5820). The extracorporeal blood system is the same generic type of extracorporeal blood system that is used in the hemodialysis system and accessories (§ 876.5820). The controlled dialysate delivery system also is similar to the conventional disalysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller to regulate the rate of the removal of water from the patient's blood and ensure that the pressure on the dialysate side of the membrane is always lower than on the blood side. This generic type of device includes the sealed dialysate delivery system.

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

§ 876.5870 Sorbent hemoperfusion system.

(a) *Identification.* A sorbent hemoperfusion system is a device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (§ 876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.

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

§ 876.5880 Isolated kidney perfusion and transport system and accessories.

(a) *Identification.* An isolated kidney perfusion and transport system and accesssories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

(b) *Classification.* Class II (performance standards).

§ 876.5895 Ostomy irrigator.

(a) *Identification.* An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.

(b) *Classification.* Class II (performance standards).

§ 876.5900 Ostomy pouch and accessories.

(a) *Identification.* An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag,

ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

(b) *Classification.* Class I (general controls).

§ 876.5920 Protective garment for incontinence.

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(b) *Classification.* Class I (general controls). 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.

§ 876.5955 Peritoneo-venous shunt.

(a) *Identification.* A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure activated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

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

§ 876.5970 Hernia support

(a) *Identification.* A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

(b) *Classification.* Class I (general controls). The device is exempt from the currrent good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 876.5980 Gastrointestinal tube and accessories

(a) *Identification.* A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).

(b) *Classification.* Class II (performance standards).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule and has determined that, if promulgated, 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 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were 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 510(f)(2)(B) of the act (21 U.S.C. 360(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approval 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.

Effective date. This regulation is effective December 23, 1983.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: November 14, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31320 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-01-M

federal register

Wednesday
November 23, 1983

Part III

Department of Health and Human Services

Food and Drug Administration

Physical Medicine Devices; General Provisions and Classification of 82 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 890

[Docket No. 78N-1182]

Physical Medicine Devices; General Provisions and Classification of 82 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 82 physical medicine devices. The preamble to this rule responds to comments received on the proposals regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: James G. Dillon, National Center for Devices and Radiological Health (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1979 (44 FR 50458-50537), FDA published proposed general provisions applicable to the classification of physical medicine devices and individual proposed regulations to classify 82 physical medicine devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). Of the 82 physical medicine devices subject to proposals, FDA is classifying 32 devices into class I, 42 devices into class II, 2 devices into class III, 5 devices into either class II or class III, depending upon the intended use of the device and has withdrawn the proposed regulation to classify one device. Additionally, FDA is codifying the reclassification of one device.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392). 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 and that either was in commercial distribution before May 28, 1976, or 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 June 30, 1986, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the general provisions described the development of the general provisions and the proposed regulations classifying physical medicine devices and the activities of the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Physical Medicine Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of physical medicine devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received and FDA's responses to these comments are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publishing as one final regulation the general provisions and classifications of 82 physical medicine devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed and is publishing final regulations to exempt six class I physical medicine devices from the premarket notification procedures in Subpart E of Part 807 (21 CFR Part 807) and from the current good manufacturing practice (CGMP) regulations in Part 820 (21 CFR Part 820), with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The six devices are the plinth (Docket No. 78N-1206), the arm sling (Docket No. 78N-1208), the wheelchair accessories (Docket No. 78N-1225), the daily activity assist devices (Docket No. 78N-1229), the exercise components (Docket No. 78N-1243), and the nonmeasuring exercise equipment (Docket No. 78N-1245).

In response to comments, the agency is also exempting 13 additional class I devices from premarket notification procedures and the CGMP regulations (other than §§ 820.180 and 820.198). The 13 devices are the prosthetic and orthotic accessories (Docket No. 78N-1194), cane (Docket No. 78N-1195), crutch (Docket No. 78N-1198), the external limb orthotic component (Docket No. 78N-1200), the external limb prosthetic component (Docket No. 78N-1201), the limb orthosis (Docket No. 78N-1203), the truncal orthosis (Docket No. 78N-1204), the congenital hip dislocation abduction splint (Docket No. 78N-1209), the Denis Brown splint (Docket No. 78N-1210), the cane, crutch, and walker tips or pads (Docket No. 78N-1217), the mechanical walker (Docket No. 78N-1219), the cold pack (Docket No. 78N-1253), and the moist heat pack (Docket No. 78N-1256).

In response to comments, one device is being exempted only from the CGMP regulations (other than §§ 820.180 and 820.198): traction accessories (Docket No. 78N-1263).

Also, on its own initiative, FDA is providing an exemption from most requirements of the CGMP regulations for four physical medicine devices: electrode cable (Docket No. 78N-1184), nonpowered communication system (Docket No. 78N-1212), wheelchair platform scale (Docket No. 78N-1228), and the nonpowered sitz bath (Docket No. 78N-1232).

The final regulation for each of the above 24 generic types of devices exempts the manufacturers of the devices from all of the CGMP requirements with the exception of §§ 820.180 and 820.198. The agency has determined that exemption of devices from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The general requirements concerning records ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate. The complaint file requirements ensure that device manufacturers have

adequate systems for complaint investigation and followup. Also for the reasons given in the proposals, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

Three manufacturers' petitions (79P-0277, 79P-0279 through 79P-0287, 79P-0289, 79P-0291, 79P-0293, 79P-0295 through 79P-0298, 80P-0323, 80P-0324, 80P-0336, and 81P-0388) requested exemptions from the CGMP regulations for certain physical medicine devices. As described under the heading "Summaries of Comments and FDA's Responses to Comments," FDA granted exemptions from the CGMP regulations to the petitioners and any other manufacturer of some of these generic types of devices. However, for each of the two devices listed below, the agency granted only the petitioner an exemption from the CGMP regulations and other manufacturers of these two generic types of devices are not exempt from the CGMP regulations.

Device name	Docket No.
Flotation cushion	78N-1199
Wheelchair components	78N-1226

FDA is now reviewing all CGMP exemption petitions previously granted to determine whether additional supporting data are necessary as a condition to the continuation of these exemptions.

The exemptions from the CGMP regulations in response to the petitions do not extend to § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files and do not apply to devices that are labeled or otherwise represented as sterile.

FDA has prepared guideline on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device CGMP regulations. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** on Friday, January 18, 1980 (45 FR 3671).

Classification of Biofeedback Devices

The Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel recommended, and FDA proposed, that powered myoelectric biofeedback devices be classified into class II. FDA provided a period of 60 days for interested persons to submit written comments to FDA. No comments were received that objected to classifying powered myoelectric biofeedback devices into class II. However, a comment pointed out that the device identification would apply only to those devices that monitor EMG muscle contraction and relaxation.

FDA agrees with this comment. However, the regulation to classify biofeedback devices (21 CFR 882.5050) published in the September 4, 1979 **Federal Register** (44 FR 51762) with the rules classifying neurological devices applies to physical medicine biofeedback devices. Therefore, FDA has determined that physical medicine biofeedback devices already have been classified into class II in that regulation. The agency published in the **Federal Register** of November 14, 1980 (45 FR 75230) a separate withdrawal of the proposed rule for powered myoelectric biofeedback devices (Docket No. 78N-1183).

Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

Classification of Powered Finger Exercisers

FDA is codifying its 1978 order reclassifying powered finger exercisers (§ 890.5410, Docket No. 77P-0328) from class III to class II. This codification provides details about the reclassification of these devices.

Minor Changes or Clarifications

Occasionally the agency has made minor changes in device names or identifications to clarify the final regulations. Additionally, the agency is adding an explanation in § 890.1 that references in Part 890 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Changes in Device Advisory Committee Names

On April 28, 1978, the agency terminated all of the device classification panels, then reestablished them with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Physical Medicine Device Classification Panel was terminated, and its functions are now conducted by the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel.

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/section name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical Chemistry Device Section.	Feb. 2, 1982; 47 FR 4802-4929 (proposals).
Clinical Toxicology Device Section.	Feb. 2, 1982; 47 FR 4802-4929 (proposals).
Hematology and Pathology Device Section.	Sept. 11, 1979, 44 FR 52950-53063 (proposals); Sept. 12, 1980, 45 FR 60576-60651 (final regulations).
General Medical Devices Panel:	
General Hospital and Personal Use Device Section.	Aug. 24, 1979, 44 FR 49644-49954 (proposals); Oct. 21, 1980, 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Device Section.	Jan. 23, 1981, 46 FR 7562-7641 (proposals).
Immunology and Microbiology Devices Panel:	
Immunology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Microbiology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel.	Apr. 3, 1979, 44 FR 19694-19971 (proposals); Feb. 26, 1980, 45 FR 12662-12720 (final regulations).
Radiologic Devices Panel.	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel:	
Ophthalmic Device Section.	Jan. 26, 1982, 47 FR 3694-3749 (proposals).
Ear, Nose, and Throat Device Section.	Jan. 22, 1982, 47 FR 3280-3325 (proposals).
Dental Device Section.	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Respiratory and Nervous System Devices Panel:	
Anesthesiology Device Section.	Nov. 2, 1979, 44 FR 63292-63342 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Device Section.	Nov. 28, 1978, 43 FR 54640-55732 (proposals); Sept. 4, 1979, 44 FR 51726-51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
Physical Medicine Device Section	Aug. 28, 1979, 44 FR 50458-50537 (proposals); Nov. 23, 1983 (final regulations).
Orthopedic Device Section.	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Device Section.	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

List of Physical Medicine Devices and an Identification of Those Proposed Classification Regulations That Received Public Comment

The following is a list of physical medicine devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the classification regulation, the classification of each device, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, the classification of the device is being adopted as proposed.

SUBPART B—PHYSICAL MEDICINE DIAGNOSTIC DEVICES

Section and device	Docket No.	Class	Comments
890.1175 Electrode cable.	78N-1184	I	No.
890.1225 Chronaximeter.	78N-1185	II	No.
890.1375 Diagnostic electromyograph.	78N-1186	II	Yes.
890.1385 Diagnostic electromyograph needle electrode.	78N-1187	II	No.
890.1450 Powered reflex hammer.	78N-1188	II	No.
890.1575 Force-measuring platform.	78N-1189	II	No.
890.1600 Intermittent pressure measurement system.	78N-1190	II	No.
890.1615 Miniature pressure transducer.	78N-1191	II	No.
890.1850 Diagnostic muscle stimulator.	78N-1192	II	No.
890.1925 Isokinetic testing and evaluation system.	78N-1193	II	No.

SUBPART C [RESERVED]

SUBPART D—PHYSICAL MEDICINE PROSTHETIC DEVICES

Section and device	Docket No.	Class	Comments
890.3025 Prosthetic and orthotic accessory.	78N-1194	I	Yes.
890.3075 Cane.	78N-1195	I	Yes.
890.3100 Mechanical chair.	78N-1196	I	Yes.
890.3110 Electric positioning chair.	78N-1197	II	No.
890.3150 Crutch.	78N-1198	I	Yes.
890.3175 Flotation cushion.	78N-1199	I	Yes.
890.3410 External limb orthotic component.	78N-1200	I	Yes.
890.3420 External limb prosthetic component.	78N-1201	I	Yes.
890.3450 Mechanical automobile hand and foot driving control.	78N-1202	II	No.
890.3475 Limb orthosis.	78N-1203	I	Yes.
890.3490 Truncal orthosis.	78N-1204	I	Yes.
890.3500 External assembled lower limb prosthesis.	78N-1205	II	Yes.
890.3520 Plinth.	78N-1206	I	No.
890.3610 Rigid pneumatic structure orthosis.	78N-1207	III	No.
890.3640 Arm sling.	78N-1208	I	Yes.

SUBPART C [RESERVED]—Continued

Section and device	Docket No.	Class	Comments
890.3665 Congential hip dislocation abduction splint.	78N-1209	I	Yes.
890.3675 Denis Brown splint.	78N-1210	I	Yes.
890.3690 Powered wheeled stretcher.	78N-1211	II	No.
890.3700 Nonpowered communication system.	78N-1212	I	No.
890.3710 Powered communication system.	78N-1213	II	No.
890.3725 Powered environmental control system.	78N-1214	II	No.
890.3750 Mechanical table.	78N-1215	I	No.
890.3760 Powered table.	78N-1216	II	No.
890.3790 Cane, crutch, and walker tips and pads.	78N-1217	I	Yes.
890.3800 Motorized three-wheeled vehicle.	78N-1218	II	No.
890.3825 Mechanical walker.	78N-1219	I	Yes.
890.3850 Mechanical wheelchair.	78N-1220	I	Yes.
890.3860 Powered wheelchair.	78N-1221	II	No.
890.3880 Special grade wheelchair.	78N-1222	II	No.
890.3890 Stair-climbing wheelchair.	78N-1223	III	No.
890.3900 Standup wheelchair.	78N-1224	II	No.
890.3910 Wheelchair accessory.	78N-1225	I	Yes.
890.3920 Wheelchair component.	78N-1226	I	Yes.
890.3930 Wheelchair elevator.	78N-1227	II	No.
890.3940 Wheelchair platform scale.	78N-1228	I	No.

SUBPART E [RESERVED]

SUBPART F—PHYSICAL MEDICINE THERAPEUTIC DEVICES

Section and device	Docket No.	Class	Comments
890.5050 Daily activity assist device.	78N-1229	I	No.
890.5100 Immersion hydrobath.	78N-1230	II	No.
890.5110 Paraffin bath.	78N-1231	II	No.
890.5125 Nonpowered sitz bath.	78N-1232	I	No.
890.5150 Powered patient transport.	78N-1233	II	No.
890.5160 Air-fluidized bed.	78N-1234	II	No.
890.5170 Powered flotation therapy bed.	78N-1235	II	No.
890.5180 Manual patient rotation bed.	78N-1236	I	No.
890.5225 Powered patient rotation bed.	78N-1237	II	No.
890.5250 Moist steam cabinet.	78N-1238	II	No.
890.5275 Microwave diathermy.	78N-1239	II & III	No.
890.5290 Shortwave diathermy.	78N-1241	II & III	Yes.
890.5300 Ultrasonic diathermy.	78N-1242	II & III	No.
890.5350 Exercise component.	78N-1243	I	Yes.
890.5360 Measuring exercise equipment.	78N-1244	II	Yes.
890.5370 Nonmeasuring exercise equipment.	78N-1245	I	Yes.
890.5380 Powered exercise equipment.	78N-1246	II	Yes.
890.5410 Powered finger exerciser.	77P-0328	II	No.

SUBPART F—PHYSICAL MEDICINE THERAPEUTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
890.5500 Infrared lamp.	78N-1248	II	Yes.
890.5525 Iontophoresis device.	78N-1249	II & III	Yes.
890.5575 Powered external limb overload warning device.	78N-1250	II	No.
890.5650 Powered inflatable tube massager.	78N-1251	II	No.
890.5660 Therapeutic massager.	78N-1252	II	No.
890.5700 Cold pack.	78N-1253	I	Yes.
890.5710 Hot or cold disposable pack.	78N-1254	I	No.
890.5720 Water circulating hot or cold pack.	78N-1255	II	No.
890.5730 Moist heat pack.	78N-1256	I	Yes.
890.5740 Powered heating pad.	78N-1257	II	No.
890.5765 Pressure-applying device.	78N-1258	I	No.
890.5850 Powered muscle stimulator.	78N-1259	II	No.
890.5860 Ultrasound and muscle stimulator.	78N-1260	II & III	No.
890.5880 Multi-function physical therapy table.	78N-1261	II	No.
890.5900 Powered traction equipment.	78N-1262	II	No.
890.5925 Traction accessory.	78N-1263	I	Yes.
890.5940 Chilling unit.	78N-1264	II	No.
890.5950 Powered heating unit.	78N-1265	II	No.
890.5975 Therapeutic vibrator.	78N-1266	II	No.

Summaries of Comments and FDA's Responses to Comments

FDA is responding to specific comments received on the proposed regulations for 29 physical medicine devices and to several general comments as follows:

1. A comment was received objecting to the language of § 890.1. The comment suggested that the language be changed to limit the scope of the rule to products intended for therapeutic or diagnostic use in a medical or other professional setting by a health care professional.

The agency disagrees with this comment. The act requires FDA to classify all medical devices, whether intended for use by licensed practitioners or by the consumer in the home. The agency does not believe that it is necessary to change proposed § 890.1 for clarification. FDA will regulate a product that has both medical and nonmedical uses as a medical device if it is intended for a medical purpose, that is, for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the

circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them. Examples of claims relevant to physical medicine devices that would cause a product to be considered a device include, but are not limited to, claims relating to the following: Re-education, correction, improvement, or maintenance of bodily functions impaired by abnormal bodily states or physiologic functions. Examples of abnormal bodily states or physiologic functions include, but are not limited to, the following: (1) Neuromuscular disorders (such as stroke, muscular dystrophy, multiple sclerosis, and cerebral palsy); (2) limb amputations; and (3) musculoskeletal disorders (such as arthritis, tendonitis, fractures, and low back pain). FDA has changed the regulations classifying many physical medicine devices to clarify that the regulations apply only to those products intended for medical purposes.

2. A comment objected to the general classification process and to the process for classifying physical medicine devices. The comment stated that the American Orthotic and Prosthetic Association's (AOPA) February 7, 1979 presentation to the Section for exemption of 40 orthotic/prosthetic devices from requirements under sections 510, 519, and 520(f) of the act (21 U.S.C. 360, 360i, and 360j(f)), and the Section recommendation to accept AOPA's request for these exemptions, should have been stated under each regulation involved, rather than in the proposed General Provisions (44 FR 50461) portion. The comment suggested that, for each device, FDA provide a separate description of the agency's response to the Section's recommended exemption and also provide a second comment period.

FDA disagrees with the comment. The preamble to the proposed General Provisions for this part included a description of AOPA's request and the Section's recommendation. This description provided adequate notice and opportunity to comment and met the statutory requirement that, for a class I device, FDA publish a panel recommendation that includes a recommendation on whether the device should be exempted from the requirements of section 510, 519, or 520(f) of the act. Although FDA could have repeated this information in the individual documents, the act does not require that this be done. FDA has reviewed the Section's recommendations on these exemptions, AOPA's request, and other comments and is presenting the agency's decisions in this classification regulation under the heading "Summaries of Comments and FDA's Responses to Comments" and the docket number involved. Additional information on exemptions is found above under the heading "Exemptions for Class I Devices." Accordingly, the agency believes that it would be an unnecessary procedural step to publish a reproposal to classify each of the 40 orthotic/prosthetic devices as suggested by the comment.

3. One comment suggested that the device registration and listing classification name and product code issued by FDA for use by industry to accomplish device listing should be used or cross-referenced by FDA as part of the identification of the device in its classification regulation.

The agency disagrees with this comment. Some manufacturers have become accustomed to identifying a device by its registration and listing name and code used for purposes of device listing under section 510 of the act. However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register.** The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register.** FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

4. Section 890.1375; Docket No. 78N-1186; Diagnostic electromyograph.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50467), a proposed regulation to classify diagnostic electromyographs into class II.

a. One comment suggested that the word "diagnostic" should be deleted from the device's name. The comment suggested that the device is not diagnostic until correlated with clinical and other laboratory data by the physician.

The agency believes that inclusion of "diagnostic" in the device's name is appropriate. The intended use of the electromyograph is to gather data to enable a physician to make a diagnosis or prognosis of a patient's condition. Although these data may need to be correlated with other information, they will be used in diagnosis. Also, this regulation applies only to the electromyograph's diagnostic use.

b. A comment suggested that this device not be classified into class II, because this classification may cause the use of the device to be restricted.

The agency disagrees with this comment because classification of a device, and restrictions on its use under section 520(e) of the act, are not interdependent, as the comment implies. This device presents risks to health that can, and should, be controlled by performance standards. Establishment of performance standards may, but need not, restrict the use of diagnostic electromyographs. The application of these standards will provide reasonable assurance of the safety and effectiveness of the device. Therefore, the agency rejects the comment not to classify diagnostic electromyographs into class II.

c. Forty-one comments objected to a recommendation made by the Section to restrict the use of the device to a physician trained in electromyography. In particular, the comments were concerned that physical therapists would be excluded from using the devices.

Because these comments do not relate to classification but rather to restrictions that may be imposed on the device in the future in separate proceedings, FDA has determined it is not necessary to revise § 890.1375 at this time. FDA advises, however, its present position is

that the restriction to physicians should apply only to the use of the device with needle electrodes, and that its use with surface electrodes not be so restricted. FDA agrees with the comments that there are competent health professionals, other than physicians, who are capable of performing diagnostic electromyography; however, FDA believes the interpretation of the data and the final diagnostic determination should be made by a qualified physician. On December 28, 1979, FDA referred these comments to the Section which essentially agreed with FDA's position stated above. Also, the Section revised their recommended restriction of use to read: "The Section recommends that the device be restricted to use, when used with needle electrodes, by or under the direct supervision of a physician trained in diagnostic electromyography."

Accordingly, the proposed regulation is being adopted with a minor clarifying change.

5. Section 890.3025; Docket No. 78N-1194; Prosthetic and orthotic accessories.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50472), a proposed regulation to classify prosthetic and orthotic accessories into class I.

a. Three comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

The Section shares the views expressed in the comments. The Section held a meeting on December 12, 1979, at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic prosthetic devices, including prosthetic and orthotic accessories, be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA argued that the prosthetic and orthotic accessories are simple and noncritical, and that the additional burden and expense of complying with these requirements is not justified. The Section agreed with AOPA and recommended that manufacturers of these devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The Section believes that this generic type of device is safe and has a demonstrated quality and safety record over a period of time and that application of the above requirements is not justified. For the reasons given in the proposals, FDA disagrees in part with the comment's request and the recommendations of the Section that manufacturers of the device be exempt from records and reports requirements. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. FDA believes that manufacturers of prosthetic and orthotic accessories should be exempt from premarket notification procedures and from most requirements of the CGMP regulations. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the CGMP regulations is unlikely to improve the safety and effectiveness of the device. FDA has determined that the exemption of devices from the CGMP regulations (21 CFR Part 820) should not extend to § 820.180 relating to general requirements concerning records, or § 820.198 relating to complaint files. See the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

b. The agency on its own initiative has made minor changes in the identification of the device to clarify that the rule also applies to casting bandages. Casting bandages were inadvertently omitted from the list of examples in the proposal.

Accordingly, the proposed rule is being adopted with these changes.

6. Section 890.3075; Docket No. 78N-1195; Cane.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50475), a proposed regulation to classify canes into class I.

Two comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the CGMP regulations under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA did not provide the rationale to exempt canes as it did for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for canes. The Section agreed with the comments and recommended that manufacturers of this device be exempt from the requirements of premarket notification, records and reports, and CGMP's.

FDA disagrees in part with the comments and the recommendations of the Section. For the reasons given in the proposals, FDA believes that any manufacturer of a device should be subject to the records and reports requirements of section 519 of the act.

In response to the comments received and the Section's recommendation that manufacturers of canes be exempt from the premarket notification procedures and the CGMP's, FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures under section 510(k) of the act and Subpart E of Part 807 of the regulations. For the reasons given in the proposals, FDA believes that any manufacturer of a device not exempted under § 807.65 (21 CFR 807.65) must be subject to registration and device listing, under section 510 (a) through (j) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning canes. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice concerning new products within this generic type of device.

Additionally, FDA is changing the final regulation to provide that manufacturers of canes be exempt, in the manufacture of the device, from all requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the CGMP regulations, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that

manufacturers of canes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of canes must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the CGMP regulations is still appropriate.

There are two procedures by which FDA may exempt a manufacturer of a device from complying with any or all of the requirements of the CGMP regulations. First, a manufacturer of a device subject to any requirement under the CGMP regulations may petition the agency pursuant to section 520(f)(2)(A) of the act for a variance or an exemption from the requirement. A variance or an exemption granted in response to such a petition applies only to the manufacturer who submitted the petition. However, FDA may conclude that an exemption granted in response to a petition may be applied to all manufacturers of the device; in this case, if the device has been classified in a final regulation, FDA will publish in the **Federal Register** a notice of its decision and its intention to change the codified classification of the device to grant the exemption to all manufacturers of the device. Second, in classifying a medical device into class I under section 513 of the act (21 U.S.C. 360c), the agency may determine that certain of the requirements of the CGMP regulations shall not apply to the device. In that instance, the exemption applies to all manufacturers of the generic type of device that is the subject of the classification regulation. The agency may grant an exemption under either procedure only if it determines that compliance with the requirement is not necessary to assure that the device will be safe and effective and otherwise in compliance with the act. The agency previously granted two manufacturers' petitions (79P-0285, 79P-0286, and 80P-0336) for exemption of their "aluminum canes," "telescoping aluminum canes," "wood canes," and "canes" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. As explained above, those exemptions applied only to the two petitioners. The agency's policies and criteria for granting exemptions were discussed in the preamble to the proposed general provisions for this part, published in the **Federal Register** of August 28, 1979 (44 FR 50458). Additional information regarding the procedures for petitioning for exemptions or variances from the CGMP regulations is available, as described in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671). See the discussion in this preamble under the heading "Exemptions for Class I Devices" for more information regarding the agency's policies regarding exemptions.

Accordingly, the proposed rule is being adopted with the noted changes.

7. Section 890.3100; Docket No. 78N-119; Mechanical chair.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50476), a proposed regulation to classify mechanical chairs into class I.

The one comment received on the proposal stated that this device should be exempt from premarket notification under section 510(k) and the CGMP requirements under section 520(f) of the act.

FDA disagrees with the comment because the agency cannot make the required finding under section 510(g)(4) of the act that compliance is not necessary for the protection of the public health. Premarket notification by these manufacturers assures that FDA learns of new products and of significant modifications of existing products for which premarket approval may be required. FDA disagrees with the comment that manufacturers of mechanical chairs be exempt from the CGMP regulations. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of mechanical chairs having defects that could harm users. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly the proposed rule is being adopted with a minor clarifying change.

8. Section 890.3150; Docket No. 78N-1198; Crutch.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50477), a proposed regulation to classify crutches into class I.

Two comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices, including crutches, be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA argued that a crutch is a simple and noncritical device, and that the additional burden and expense of complying with these requirements is not justified. The Section agreed with AOPA and recommended that manufacturers of the device be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The Section believes that this generic type of device is safe and has a demonstrated quality and safety record over a period of time and that application of the above requirements is not justified for this generic type of device. For the reasons given in the proposals, FDA disagrees with the Section's recommendation that manufacturers of the device be exempt from records and reports requirements. In response to the comments received and the Section's recommendation that manufacturers of crutches be exempt from the premarket notification procedures and the CGMP's, FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures and section 510(k) of the act and Subpart E of Part 807 of the regulations. Additionally, FDA is changing the final regulation to provide that manufacturers of crutches be exempt, in the manufacture of the device, from all requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted two manufacturers' petitions (80P-0324 and 81P-0388) for exemption of their "crutch" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with the noted changes.

9. Section 890.3175; Docket No. 78N-1199; Flotation cushion.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50478), a

proposed regulation to classify flotation cushions into class I.

a. Two comments requested a change in the identification to expand the regulation to include various materials as outer coverings of the device. The comments suggested that the outer covering include material such as elastomeric foam, plastic, rubber, and any other nonflammable material.

FDA agrees with this comment in part and is making minor changes to the identification of the device to clarify that the regulation permits various outer coverings and that it only applies to flotation cushions intended for medical purposes.

b. One comment suggested that the inner fillings include materials such as foam, metal, and plastic springs.

FDA rejects this comment because these materials would not necessarily provide a flotation media, and would be covered in § 890.3920 in this document, classifying wheelchair components (Docket No. 78N-1226), in which the wheelchair cushion is included. However, the agency recognizes that there may be materials other than those listed in the proposal that would provide a flotation media, and is making minor changes to the identification to make it clear that the rule also applies to those materials.

c. Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and the CGMP requirements under section 520 of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP's. The representative stated that AOPA had also submitted a comment to the proposal requesting the above exemptions for flotation cushions. AOPA did not provide the rationale to exempt this device, as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all of the requirements are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of flotation cushions should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA also believes that manufacturers of flotation cushions should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that all manufacturers of flotation cushions be exempt from the CGMP regulations. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of flotation cushions having defects that could harm users. The agency has, however, previously granted an individual manufacturer's petition (79P-0287) for exemption of its "invalid ring" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* and the discussion under the heading "Exemptions for Class I Devices" for further discussion of exemptions.

Accordingly, the proposed regulation is being adopted with a minor clarifying change.

10. Section 890.3410; Docket No. 78N-1200; External limb orthotic component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50478), a proposed regulation to classify external limb orthotic components into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes, however, that this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes this device should be exempt from CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion regarding exemptions.

Accordingly, the proposed rule is being adopted with these changes.

11. Section 890.3420; Docket No. 78N-1201; External limb prosthetic component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50479), a proposed regulation to classify external limb prosthetic components into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of this device should be exempt from CGMP's in Part 820, with the exception of § 820.180, with respect to general

requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion regarding exemptions.

Accordingly, the proposed rule is being adopted with these and minor editorial changes.

12. Section 890.3475; Docket No. 78N-1203; Limb orthosis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50481), a proposed regulation to classify limb orthoses into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section heard a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time, and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations. FDA believes that this device should not be exempt from records and reports regulations established under section 519 of the act. The agency has determined that compliance with the CGMP regulations, except for § 820.180, general requirements concerning records, and § 820.198, complaint files, is not required to assure that limb orthoses will be safe and effective and otherwise in compliance with the act. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further information on exemptions. The agency previously granted a manufacturer's petitions (79P-0279, 79P-0282, 79P-0293, 79P-0296, 79P-0297 and 79P-0298) for exemption of its "knee joint brace," "knee joint brace (x-back)," "ankle joint brace," "elbow brace," "wrist brace," and "wrist brace splint" from the requirements of the CGMP regulations, except § 820.180, concerning records, and § 820.198, complaint files.

Accordingly, the proposed rule is being adopted with these changes.

13. Section 890.3490; Docket No. 78N-1204; Truncal orthosis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50481), a proposed regulation to classify truncal orthoses into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. The agency agrees that compliance with the CGMP regulations, except for § 820.180, general requirements concerning records, and § 820.198, complaint files, is not required to assure that truncal orthoses will be safe and effective and otherwise in compliance with the act. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. The agency previously granted a manufacturer's petitions (79P-0277, 79P-0280, 79P-0289, and 79P-0295) for exemption of its "cervical orthosis," "sacroiliac orthosis," "rib fracture orthosis," "posture aid brace," and "abdominal belt" from the requirement of the CGMP regulations, except § 820.180, requirements concerning records, and § 820.198, complaint files.

Accordingly, the proposed regulation is being adopted with these changes.

14. Section 890.3500; Docket No. 78N-1205; External assembled lower limb prosthesis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50482), a proposed regulation to classify external assembled lower limb prostheses into class II.

a. A comment stated that this device should be exempt from premarket notification under section 510 and the CGMP requirements under section 520(f) of the act.

FDA disagrees with the comment that this device should be exempt from premarket notification requirements under section 510 because the agency cannot make the required finding under section 510(g)(4) of the act that compliance is not necessary for the protection of public health. FDA also disagrees with the comment that this device should be exempt from the CGMP's under section 520(f) of the act. Compliance with the CGMP's will help prevent production of devices having defects that could cause harm to users.

b. A comment questioned why the proposed rule did not include an upper limb device.

On December 12, 1979, FDA referred this comment to the Section which stated that it was unaware of any preassembled upper limb prostheses being manufactured or offered for sale. FDA also is not aware of any of these devices being marketed.

Accordingly, the regulation is being adopted as proposed.

15. § 890.3640; Docket No. 78N-1208; Arm sling.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50485), a proposed regulation to classify arm slings into class I.

Three comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

FDA proposed that this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations, and in this respect, the comments suggest no change in the final rule. FDA disagrees with the comments that this device be exempt from records and reports regulations under section 519 of the act. FDA also proposed that this device be exempt from the CGMP's in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Thus, the comments suggest no change

regarding CGMP exemption. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. The agency previously granted a manufacturer's petition (79P-0284) for exemption of its "arm sling" from the requirement of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files.

Accordingly, the regulation is being adopted as proposed with only a minor clarifying change.

16. Section § 890.3665; Docket No. 78N-1209; Congenital hip dislocation abduction splint.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50487), a proposed regulation to classify congenital hip dislocation abduction splints into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the comment that manufacturers of this device should be exempt from records and reports regulations established under section 519 of the act. FDA agrees with the comment that manufacturers of this device should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes.

17. Section 890.3675; Docket No. 78N-1210; Denis Brown splint.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50487), a proposed regulation to classify Denis Brown splints into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of this device should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes and minor clarifying changes.

18. Section 890.3790; Docket No. 78N-1217; Cane, crutch, and walker tips and pads.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50493), a proposed regulation to classify cane, crutch, and walker tips into class I.

a. One comment suggested that crutch pads and hand grips should also be included in this regulation.

The agency agrees with this comment and has made minor changes in the name and identification of the device to incorporate other rubber (and rubber substitute) accessories in this regulation.

b. Three comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for cane, crutch, and walker tips or pads. AOPA did not provide the rationale to exempt these devices, as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for these devices. The Section recommends that manufacturers of these devices not be required to comply with premarket notification, records and reports, or CGMP's because they are simple devices that present no undue risks to health when used in a normal manner for the purpose recommended. FDA believes that manufacturers of these devices should comply with section 501 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA also believes that manufacturers of these devices should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of these devices should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted two manufacturers' petitions (79P-0291 and 81P-0388) for exemption of their "crutch handgrips" and "crutch tips, grips, and pads" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes and minor clarifying changes.

19. Section 890.3825; Docket No. 78N-1219; Mechanical walker.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50494), a proposed regulation to classify mechanical walkers into class I.

Two comments stated that this device should be exempt from premarket notification under section 510(k), records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA did not provide the rationale to exempt this device as it had for other devices, and the representative stated the AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. However, FDA, in part, disagrees with the recommendation of the Section. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures under section 510(k) of the act and Subpart E of Part 807 of the regulations. Additionally, FDA is changing the final regulation to provide that manufacturers of a mechanical walker be exempt, in the manufacture of the device, from requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted a manufacturer's petition (80P-0323) for exemption of its "mechanical walker" from the requirement of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See the response to comments in paragraph number 6 for §890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes.

20. Section 890.3850; Docket No. 78N-1220; Mechanical wheelchair.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50495), a proposed regulation to classify mechanical wheelchairs into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA has also submitted a comment on the proposal requesting the above exemptions for mechanical wheelchairs. AOPA did not provide the rationale to exempt mechanical wheelchairs as it had for other devices and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for mechanical wheelchairs. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of this device should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that manufacturers of mechanical wheelchairs be exempt from the CGMP regulations under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of a mechanical wheelchair having defects that could harm users.

Accordingly, the proposed rule is being adopted with a minor clarifying change.

21. Section 890.3910; Docket No. 78N-1225; Wheelchair accessory.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50499), a proposed regulation to classify wheelchair accessories into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the exemptions above for wheelchair accessories. AOPA did not provide the rationale to exempt wheelchair accessories as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of these devices if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section agreed with the comment and recommended that manufacturers of this device be exempt from the requirements of premarket notification, records and reports, and CGMP's. FDA proposed that manufacturers of this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulation, thus, in this respect, the comments did not suggest a change in the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA proposed that manufacturers of this device be exempt from the CGMP regulations with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comments suggested no changes in the CGMP exemptions in the regulation.

Accordingly, the regulation is being adopted with only a minor clarifying change.

22. Section 890.3920; Docket No. 78N-1226; Wheelchair component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50500), a proposed regulation to classify wheelchair components into class I.

Two comments stated that this device should be exempt from premarket

notification under section 510, records and reports requirements under section 519, and the CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, the 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for wheelchair components. AOPA did not provide the rationale to exempt wheelchair components as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for wheelchair components. The Section disagreed with the comment and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of wheelchair components should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA also believes that manufacturers of wheelchair components should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that manufacturers of wheelchair components be exempt from the CGMP regulations under section 520(f) of the act. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of wheelchair components having defects that could harm users. the agency has, however, previously granted an individual manufacturer's petition (79P-0283) for exemption of its "wheelchair cushion" from the requirements of the CGMP regulations except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* and the discussion under the heading "Exemptions for Class I Devices" for further discussion of exemptions.

Accordingly, the proposed regulation is being adopted without change.

23. Section 890.5275; Docket No. 78N-1239; Microwave diathermy.

FDA published in the **Federal Register** of August 28, 1979; (44 FR 50511), a proposed regulation to classify microwave diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III for use in the treatment of malignancies, because insufficient data exist concerning the safety and effectiveness of the device for this use.

FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because microwave diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, microwave diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III microwave diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of microwave diathermies for the treatment of malignancies or if FDA reclassifies microwave diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5275 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of microwave diathermies or any reclassification. FDA believes that investigations are still being done to show whether microwave diathermies are safe and effective when intended for the teatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established, and the necessary parameters to assure the effectiveness of diathermy may be addressed in the future in a performance standard.

24. Section 890.5290; Docket No. 78N-1241; Shortwave diathermy.

FDA published in the **Federal Register** August 28, 1979 (44 FR 50512), a proposed regulation to classify shortwave diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

One comment objected that "pain" should not be the only specific class II indication for the device's use and suggested that FDA provide details on the "selected medical conditions" that comprise the device's class II indications.

On December 13, 1979, FDA referred the comment to the Section. Also, at this meeting, a representative of Diapulse Corp. presented a brief history of its shortwave device and described the manner in which the device works without producing "therapeutic deep heat" in the tissues. The Diapulse Corp. representative asked the Section to expand the class II identification for shortwave diathermy to include indications for use other than "relief of pain." The Section members agreed that relief of pain is not the only class II indication for use of the device. The Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that shortwave diathermies be classified into class III when used in the treatment of malignancies because insufficient data exist concerning the safety and effectiveness of the device for this use. In determining the final classification for shortwave diathermy, FDA considered the comment received on the proposal.

the Section's recommendation, and the information presented to the Section. FDA has changed the final regulation to clarify the distinction between deep heat threatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because shortwave diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, shortwave diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III shortwave diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of shortwave diathermies for the treatment of malignancies or if FDA reclassifies shortwave diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5290 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of shortwave diathermies or any reclassification. FDA believes that investigations are still being done to show whether shortwave diathermies are safe and effective when intended for the treatment of malignancies. FDA advises that the Diapulse and similar machines which claim to produce therapeutic effect by modes of action other than deep heat are not classified into class II, but are in class III, as stated in this regulation. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat" because the effective therapeutic temperatures for diathermy have been established, and the necessary parameters to assure the effectiveness of diathermy may be addressed in the future in a performance standard.

25. Section 890.5300; Docket No. 78N-1242; Ultrasonic diathermy.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50514), a proposed regulation to classify ultrasonic diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III when used in the treatment of malignancies, because insufficient data exist concerning the safety and effectiveness of the device for this use. FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because ultrasonic diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, ultrasonic diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III ultrasonic diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of ultrasonic diathermies for the treatment of malignancies or if FDA reclassifies ultrasonic diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulations of these uses, the agency will amend § 890.5300 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of ultrasonic diathermies or any reclassification. FDA believes that investigations are still being done to show whether ultrasonic diathermies are safe and effective when intended for the treatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established and are known in the medical community. FDA has already published under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602), a safety performance standard for ultrasonic diathermies, 21 CFR 1050.10 *Ultrasonic therapy products*, that was effective February 17, 1979. FDA may address additional necessary parameters to ensure the effectiveness of diathermy during the development, in the future, of a new or revised performance standard.

26. Section 890.5350; Docket No. 78N-1243; Exercise component.

FDA published in the **Federal Register** August 28, 1979 (44 FR 50515), a proposed regulation to classify exercise components into class I.

a. One comment stated this device should be exempt from premarket notification under section 510 and the CGMP requirements under section 520(f) of the act.

FDA agrees in part with the comment. FDA proposed that this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulation. FDA also proposed that this device be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comment suggested no changes in exemptions. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

b. Eleven comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees in part with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying minor changes in the identification of the device. Accordingly, the proposed regulation is being adopted with these changes.

27. Section 890.5360; Docket No. 78N-1244; Measuring exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50516), a proposed regulation to classify

measuring exercise equipment into class II.

a. One comment stated that odometers and timers should not be included as measuring instrumentation for these devices.

The agency disagrees with this comment. Accurate exercise measurements are necessary for the safe and effective use of therapeutic equipment. Odometers and timers on therapeutic equipment provide information that is used for evaluation and treatment planning purposes.

b. Twelve comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments FDA has made clarifying changes in the identification of the device. Accordingly, the proposed regulation is being adopted with these changes.

28. Section 890.5370; Docket No. 78N-1245; Nonmeasuring exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50517), a proposed regulation to classify nonmeasuring exercise equipment into class I.

a. One comment stated that this device should be exempt from premarket notification under section 510 and CGMP requirements under section 520(f) of the act.

FDA agrees in part with the comment. FDA proposed that the device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations. FDA also proposed that this device be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comment suggested no change in exemptions. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

b. Twelve comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices, and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying changes in the identification of the device. Accordingly, the proposed rule is being adopted with these changes.

29. Section 890.5380; Docket No. 78N-1246; Powered exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50518), a proposed regulation to classify powered exercise equipment into class II.

a. One comment objected to the listing of treadmills and exercise bicycles as examples of powered exercise equipment.

The agency rejects this comment. Powered treadmills and exercise bicycles, when intended for medical purposes, are medical devices.

b. Eight comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices, and that if the regulation is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for §890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying changes in the identification of the device. Accordingly, the proposed rule is being adopted with these changes.

30. Section 890.5410; Docket No. 77P-0328; Powered finger exerciser.

Section 513(f) of the act classifies into class III a device that is first offered for commercial distribution after enactment of the Medical Device Amendments and that is not substantially equivalent to a preamendments device. On May 17, 1977, C. R. Bard, Inc., 700 E. 22d St., Lawrence, KA 66004, submitted to FDA a petition (77P-0328) for reclassification of a device it intended to market, the Ketcham Hand Exerciser, a device classified into class III pursuant to section 513(f) of the act. The Section reviewed the petition and recommended that the device be reclassified into class II.

In the **Federal Register** of November 11, 1977 (42 FR 58787), FDA published a notice of the Section's recommendation and provided a period of 60 days for interested persons to submit comments to FDA. FDA received no comments on the recommendation. Because FDA agreed with the Section's recommendation, FDA granted the petition and reclassified the device into class II by order in the form of a letter to the sponsor dated January 4, 1978.

This regulation codifies the 1978 order. The order and the regulation apply to any powered finger exerciser that is substantially equivalent to the reclassified device. FDA determines substantial equivalence by reviewing premarket notification submissions under section 510(k) of the act and Subpart E of Part 807 of the regulations.

31. Section 890.5500; Docket No. 78N-1248; Infrared lamp.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50519), a proposed regulation to classify infrared lamps into class II.

a. One comment disagreed with the proposal to classify infrared lamps into class II. The comment suggested that the device be classified into class I because the risks to health are "common to all electrical devices incorporating light bulbs." The comment further stated that the skin is able to detect the radiation of the device, thereby preventing burns, and that any electrical device may present a hazard of electrical shock.

The agency agrees that most of the risks to health involved are similar to those of many electrical devices incorporating light bulbs. However, the agency does not agree with the recommendation that infrared lamps intended for topical heating for medical purposes be classified into class I. Not all patients being treated may have a normal sensory system to pain and temperature, and a serious burn can result. The Section recommended classification into class II for all AC-powered devices to ensure compliance with an electrical safety standard. The agency agrees with the Section that a performance standard is necessary for this device and rejects the comment.

b. One comment suggested that the identification of the infrared lamp is too broad.

The agency disagrees with the comment. FDA has attempted to make device identifications sufficiently broad to include all devices that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for further discussion of what is meant by "intended use" of a device.

Accordingly, the proposed regulation is being adopted with only minor clarifying changes.

32. Section 890.5525; Docket No. 78N-1249; Iontophoresis device.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50520), a proposed regulation to classify into class II iontophoresis devices for specialized uses (diagnosis of cystic fibrosis, application of fluoride in dentistry, and for local anesthesia of the intact tympanic membrane) and to classify into class III the device for all other uses.

Three comments were received, each of which objected to proposed § 890.5525(d) classifying into class III iontophoresis devices for uses other than diagnosing cystic fibrosis, application of fluoride in dentistry, or anesthetizing the tympanic membrane. One comment was from a physician who stated that he has safely and successfully used iontophoresis for the transmission of a local anesthetic and a steroid compound. A manufacturer objected specifically to FDA's proposal to classify into class III iontophoresis devices for sweat inhibition. Another manufacturer argued that such classification is unnecessary for current uses and would limit future applications of iontophoresis devices.

On December 12, 1979, FDA held a public meeting of the Section. The Section disagreed with the comment. The Section agreed with FDA's analysis of the literature cited in the preamble to the proposal and emphasized that the device is able to deliver systemically active medications that may be harmful because the dosage level administered to the patient is unpredictable. The Section believes that use of iontophoresis devices in diagnosing cystic fibrosis, applying fluoride to the teeth, and anesthetizing the intact tympanic membrane have been shown in the literature to be both safe and effective. The Section believes there are insufficient data to support other uses of the device. The Section believes that existing data are insufficient to ensure the safety and effectiveness of the device for its use in sweat inhibition.

In addition to regulating medical devices, FDA also regulates the safety and effectiveness of drugs. The classification of the iontophoresis device as a device in no manner affects the regulatory status of drugs that are, or may be, used with the device. Such drugs continue to be regulated under the act as drugs. Any person who intends for a drug to be used with a medical device, such as an iontophoresis device, must assure that the drug is in compliance with all applicable requirements of the act, including the premarket approval required for new drugs and antibiotic drugs.

During the Section's evaluation of the safety and effectiveness of the use of an iontophoresis device with drugs in diagnosing cystic fibrosis, the Section considered the application of the device in conjunction with specific drugs. The Section did not, however, consider whether these drugs are safe and effective. The agency proposed to classify into class II iontophoresis devices for use in the diagnosis of cystic fibrosis, for the dental application of fluoride, and for the local anesthetizing of the intact tympanic membrane. However, this final regulation classifies the iontophoresis device into class II for use in the diagnosis of cystic fibrosis or for other uses only when the labeling of the drug intended for use with the device bears adequate directions for use of the iontophoresis device with that drug. At the present time, the agency is unaware of any marketed drug that has labeling providing adequate directions for its use with an iontophoresis device for the dental application of fluoride or the anesthetizing of the intact tympanic membrane. Therefore, the effect of this change in the identification of the device is to classify into class III iontophoresis devices for these two uses. The agency advises further that § 890.5525 will apply to those iontophoresis devices that were on the market before May 28, 1976, the enactment date of the Medical Device Amendments of 1976, and substantially equivalent devices offered after that date. New, not substantially equivalent devices offered for marketing after May 28, 1976, including devices previously marketed that have been substantially altered (e.g., by providing new indications in the labeling), are classified by statute (21 U.S.C. 360c(f)) into class III and must undergo premarket approval before marketing unless reclassified.

Accordingly, the proposed regulation is being adopted with the noted changes and other minor clarifications in the identification of the device.

33. Section 890.5700; Docket No. 78N-1253; Cold pack.

Section 890.5730; Docket No. 78N-1256; Moist heat pack.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50525 and 44 FR 50528), proposed regulations to classify both the cold pack and the moist heat pack into class I.

A comment stated that both devices should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted comments to the proposals requesting the above exemptions for the cold pack and the moist heat pack. AOPA did not provide the rationale to exempt these devices as it had for the other 40 devices, and the representative stated that AOPA would withdraw its recommendation for exemption of the cold pack and the moist heat pack if the Section believed there was no justification for exemptions. The Section agreed to review and comment on exemptions for the cold pack and the moist heat pack. The Section disagreed with the comment and recommended that manufacturers of both of these devices not be granted exemptions. The Section believes that all general control requirements are necessary to ensure the safety and effectiveness of both of these devices. FDA disagrees in part with the recommendations of the Section. FDA believes that manufacturers of both devices should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of both devices should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of both devices should be exempt from CGMP's in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the two proposed rules are being adopted with these changes and with minor clarifying changes.

34. Section 890.5860; Docket No. 78N-1260; Ultrasound and muscle stimulator.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50531), a proposed regulation to classify ultrasound and muscle stimulators into class II when used for applying therapeutic deep heat and muscle stimulation and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be

made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the ultrasound component of the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III when used in the treatment of malignancies because insufficient data exist concerning the safety and effectiveness of the device for this use. FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because ultrasound and muscle stimulators intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, ultrasound and muscle stimulators intended for treatement of malignancies are subject to premarket approval without the 30-month grace period applicable to class III ultrasound and muscle stimulators of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of ultrasound and muscle stimulators for the treatment of malignancies or if FDA reclassifies ultrasound and muscle stimulators for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5860 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of ultrasound and muscle stimulators or any reclassification. FDA believes that investigations are still being done to show whether ultrasound and muscle stimulators are safe and effective when intended for the treatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established and are known in the medical community. FDA has already published a safety performance standard for ultrasonic diathermies, 21 CFR 1050.10 *Ultrasonic therapy products*, that was effective February 17, 1979. FDA may address additional necessary parameters to ensure the effectiveness of diathermy during the development, in the future, of a new or revised performance standard.

35. Section 890.5925; Docket No. 78N-1263; Traction accessory.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50534), a proposed regulation to classify traction accessories into class I.

a. A comment pointed out that traction accessories are also being reviewed by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel and that the final classification of this device should be postponed until FDA has published its classification of traction accessories in response to the Orthopedic Section's recommendations.

The agency disagrees with the comment to postpone classification of the device. However, the agency realizes that there may be some confusion between the physical medicine and orthopedic traction accessories. Therefore, the agency has made minor changes to the identification of the device to clarify that this rule applies only to those devices that are intended for use with power traction equipment. FDA advises it has published in the **Federal Register** proposed regulations to classify orthopedic devices, including the traction accessories mentioned by the comment (July 2, 1982; 47 FR 29052).

b. Three comments stated that the device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for traction accessories. AOPA did not provide the rationale to exempt this device as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of these devices if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for traction accessories. The Section agreed with the comments and recommended that manufacturers of these devices be exempt from the requirements of premarket notification, records and reports, and CGMP's. FDA only partially agrees with the recommendations of the Section. FDA believes that manufacturers of this device should not be exempt from premarket notification requirements under section 510(k) of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of this device should be exempt from the CGMP's in Part 820 with the exception for § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 of § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these and minor clarifying changes.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 890 to read as follows:

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.
890.1 Scope.

Subpart B—Physical Medicine Diagnostic Devices

890.1175 Electrode cable.
890.1225 Chronaximeter.
890.1375 Diagnostic electromyograph.
890.1385 Diagnostic electromyograph needle electrode.
890.1450 Powered reflex hammer.
890.1575 Force-measuring platform.
890.1600 Intermittent pressure measurement system.
890.1615 Miniature pressure transducer.
890.1850 Diagnostic muscle stimulator.

Sec.
890.1925 Isokinetic testing and evaluation system.

Subpart C—[Reserved]

Subpart D—Physical Medicine Prosthetic Devices

890.3025 Prosthetic and orthotic accessory.
890.3075 Cane.
890.3100 Mechanical chair.
890.3110 Electric positioning chair.
890.3150 Crutch.
890.3175 Flotation cushion.
890.3410 External limb orthotic component.
890.3420 External limb prosthetic component.
890.3450 Mechanical automobile hand and foot driving control.
890.3475 Limb orthosis.
890.3490 Truncal orthosis.
890.3500 External assembled lower limb prosthesis.
890.3520 Plinth.
890.3610 Rigid pneumatic structure orthosis.
890.3640 Arm sling.
890.3665 Congenital hip dislocation abduction splint.
890.3675 Denis Brown splint.
890.3690 Powered wheeled stretcher.
890.3700 Nonpowered communication system.
890.3710 Powered communication system.
890.3725 Powered environmental control system.
890.3750 Mechanical table.
890.3760 Powered table.
890.3790 Cane, crutch, and walker tips and pads.
890.3800 Motorized three-wheeled vehicle.
890.3825 Mechanical walker.
890.3850 Mechanical wheelchair.
890.3860 Powered wheelchair.
890.3880 Special grade wheelchair.
890.3890 Stair-climbing wheelchair.
890.3900 Standup wheelchair.
890.3910 Wheelchair accessory.
890.3920 Wheelchair component.
890.3930 Wheelchair elevator.
890.3940 Wheelchair platform scale.

Subpart E—[Reserved]

Subpart F—Physical Medicine Therapeutic Devices

890.5050 Daily activity assist device.
890.5100 Immersion hydrobath.
890.5110 Paraffin bath.
890.5125 Nonpowered sitz bath.
890.5150 Powered patient transport.
890.5160 Air-fluidized bed.
890.5170 Powered flotation therapy bed.
890.5180 Manual patient rotation bed.
890.5225 Powered patient rotation bed.
890.5250 Moist steam cabinet.
890.5275 Microwave diathermy.
890.5290 Shortwave diathermy.
890.5300 Ultrasonic diathermy.
890.5350 Exercise component.
890.5360 Measuring exercise equipment.
890.5370 Nonmeasuring exercise equipment.
890.5380 Powered exercise equipment.
890.5410 Powered finger exerciser.
890.5500 Infrared lamp.
890.5525 Iontophoresis device.
890.5575 Powered external limb overload warning device.
890.5650 Powered inflatable tube massager.
890.5660 Therapeutic massager.
890.5700 Cold pack.
890.5710 Hot or cold disposable pack.
890.5720 Water circulating hot or cold pack.
890.5730 Moist heat pack.
890.5740 Powered heating pad.
890.5765 Pressure-applying device.
890.5850 Powered muscle stimulator.
890.5860 Ultrasound and muscle stimulator.
890.5880 Multi-function physical therapy table.
890.5900 Powered traction equipment.
890.5925 Traction accessory.
890.5940 Chilling unit.
890.5950 Powered heating unit.
890.5975 Therapeutic vibrator.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine 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 may not show merely that the device is accurately described by the section title and identification provisions 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, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in the Subpart representing one use of the device, rather than in two or more Subparts.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Physical Medicine Diagnostic Devices

§ 890.1175 Electrode cable.

(a) *Identification.* An electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.1225 Chronaximeter.

(a) *Identification.* A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.

(b) *Classification.* Class II (performance standards).

§ 890.1375 Diagnostic electromyograph.

(a) *Identification.* A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.

(b) *Classification.* Class II (performance standards).

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) *Identification.* A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medial purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).

(b) *Classification.* Class II (performance standards).

§ 890.1450 Powered reflex hammer.

(a) *Identification.* A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

(b) *Classification.* Class II (performance standards).

§ 890.1575 Force-measuring platform.

(a) *Identification.* A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

(b) *Classification.* Class II (performance standards).

§ 890.1600 Intermittent pressure measurement system.

(a) *Identification.* An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.

(b) *Classification.* Class II (performance standards).

§ 890.1615 Miniature pressure transducer.

(a) *Indentification.* A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(b) *Classification.* Class II (performance standards).

§ 890.1850 Diagnostic muscle stimulator.

(a) *Identification.* A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity. It is intended for medical purposes, such as to diagnose motor nerve or sensory neuromuscular disorders and neuromuscular function.

(b) *Classification.* Class II (performance standards).

§ 890.1925 Isokinetic testing and evaluation system.

(a) *Identification.* An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(b) *Classification.* Class II (performance standards).

Subpart C—[Reserved]

Subpart D—Physical Medicine Prosthetic Devices

§ 890.3025 Prosthetic and orthotic accessory.

(a) *Identification.* A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3075 Cane.

(a) *Identification.* A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3100 Mechanical chair.

(a) *Identification.* A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.

(b) *Classification.* Class I (general controls).

§ 890.3110 Electric positioning chair.

(a) *Identification.* An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.

(b) *Classification.* Class II (performance standards).

§ 890.3150 Crutch.

(a) *Identification.* A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is also exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3175 Flotation cushion.

(a) *Identification.* A flotation cushion is a device intended for medical purposes that is made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.

(b) *Classification.* Class I (general controls).

§ 890.3410 External limb orthotic component.

(a) *Identification.* An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3420 External limb prosthetic component.

(a) *Identification.* An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3450 Mechanical automobile hand and foot driving control.

(a) *Identification.* A mechanical automobile hand or foot driving control is a device intended for medical purposes to enable persons who have limited use of their arms or legs to drive an automobile. The device allows the hand operation of the gas, brake, and clutch pedals or foot operation of the steering and gear shift.

(b) *Classification.* Class II (performance standards).

§ 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical

purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3490 Truncal orthosis.

(a) *Identification.* A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification precedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3500 External assembled lower limb prosthesis.

(a) *Identification.* An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

(b) *Classification.* Class II (performance standards).

§ 890.3520 Plinth.

(a) *Identification.* A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedure in Subpart E of Part 807. The device is also exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records and § 820.198 with respect to complaint files.

§ 890.3610 Rigid pneumatic structure orthosis.

(a) *Identification.* A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

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

§ 890.3640 Arm sling.

(a) *Identification.* An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3665 Congenital hip dislocation abduction splint.

(a) *Identification.* A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3675 Denis Brown splint.

(a) *Identification.* A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3690 Powered wheeled stretcher.

(a) *Identification.* A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).

(b) *Classification.* Class II (performance standards).

§ 890.3700 Nonpowered communication system.

(a) *Identification.* A nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3710 Powered communication system.

(a) *Identification.* A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen.

(b) *Classification.* Class II (performance standards).

§ 890.3725 Powered environmental control system.

(a) *Identification.* A powered environmental control system is an AC- or battery-powered device intended for medical purposes that is used by a patient to operate an environmental control function. Examples of environmental control functions include the following: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.

(b) *Classification.* Class II (performance standards).

§ 890.3750 Mechanical table.

(a) *Identification.* A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various

positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class I (general controls).

§ 890.3760 Powered table.

(a) *Identification.* A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class II (performance standards).

§ 890.3790 Cane, crutch, and walker tips and pads.

(a) *Identification.* Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3800 Motorized three-wheeled vehicle.

(a) *Identification.* A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons.

(b) *Classification.* Class II (performance standards).

§ 890.3825 Mechanical walker.

(a) *Identification.* A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3850 Mechanical wheelchair.

(a) *Identification.* A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class I (general controls).

§ 890.3860 Powered wheelchair.

(a) *Identification.* A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class II (performance standards).

§ 890.3880 Special grade wheelchair.

(a) *Identification.* A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.

(b) *Classification.* Class II (performance standards).

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.

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

§ 890.3900 Standup wheelchair.

(a) *Identification.* A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.

(b) *Classification.* Class II (performance standards).

§ 890.3910 Wheelchair accessory.

(a) *Identification.* A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories are the following: armboard, lapboard, pusher cuff, crutch and cane holder, restraint, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3920 Wheelchair component.

(a) *Identification.* A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.

(b) *Classification.* Class I (general controls).

§ 890.3930 Wheelchair elevator.

(a) *Identification.* A wheelchair elevator is a motorized lift device intended for medical purposes to provide a means for a disabled person to move a wheelchair from one level to another.

(b) *Classification.* Class II (performance standards).

§ 890.3940 Wheelchair Platform scale.

(a) *Identification.* A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Subpart E—[Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§ 890.5050 Daily activity assist device.

(a) *Identification.* A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5100 Immersion hydrobath.

(a) *Identification.* An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) *Classification.* Class II (performance standards).

§ 890.5110 Paraffin bath.

(a) *Identification.* A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the patient's appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

(b) *Classification.* Class II (performance standards).

§ 890.5125 Nonpowered sitz bath.

(a) *Identification.* A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5150 Powered patient transport.

(a) *Identification.* A powered patient transport is a motorized device intended for medical purposes to assist transfers of patients to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs. This generic type of device does not include motorized threewheeled vehicles or wheelchairs.

(b) *Classification.* Class II (performance standards).

§ 890.5160 Air-fluidized bed.

(a) *Identification.* An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(b) *Classification.* Class II (performance standards).

§ 890.5170 Powered flotation therapy bed.

(a) *Identification.* A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(b) *Classification.* Class II (performance standards).

§ 890.5180 Manual patient rotation bed.

(a) *Identification.* A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.

(b) *Classification.* Class I (general controls).

§ 890.5225 Powered patient rotation bed.

(a) *Identification.* A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.

(b) *Classification.* Class II (performance standards).

§ 890.5250 Moist steam cabinet.

(a) *Identification.* A moist steam cabinet is a device intended for medical purposes that delivers a flow of heated, moisturized air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.

(b) *Classification.* Class II (performance standards).

§ 890.5275 Microwave diathermy.

(a) *Microwave diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* A microwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Microwave diathermy for all other uses*—(1) *Identification.* A microwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

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

§ 890.5290 Shortwave diathermy.

(a) *Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Shortwave diathermy for all other uses*—(1) *Identification.* A shortwave diathermy for all other uses except for the treatment of milignancies is a device that applies to the body electromagnetic engergy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

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

§ 890.5300 Ultrasonic diathermy.

(a) *Ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions*—*Identification.* An ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of

the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasonic diatermy for all other uses*—(1) *Identification.* An ultrasonic diatermy for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

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

§ 890.5350 Exercise component.

(a) *Identification.* An exercise component is a device that is used in conjunction with other forms of exercise and that is intended for medical purposes, such as to redevelope muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exemption of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5360 Measuring exercise equipment.

(a) *Identification.* Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.

(b) *Classification.* Class II (performance standards).

§ 890.5370 Nonmeasuring exercise equipment.

(a) *Identification.* Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in Subpart E of Part 807. The devices also are exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5380 Powered exercise equipment.

(a) *Identification.* Powered exercise equipment consist of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.

(b) *Classification.* Class II (performance standards).

§ 890.5410 Powered finger exerciser.

(a) *Identification.* A powered finger exerciser is a device intended for medical purposes to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.

(b) *Classification.* Class II (performance standards).

§ 890.5500 Infrared lamp.

(a)Identification. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

(b) *Classification.* Class II (performance standards).

§ 890.5525 Iontophoresis device.

(a) *Iontophoresis device intended for certain specified uses*—(1) *Identification.* An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug. When used in the diagnosis of cystic fibrosis, the sweat is collected and its composition and weight are determined.

(2) *Classification.* Class II (performance standards).

(b) *Iontophoresis device intended for any other purposes*—(1) *Identification.* An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified in paragraph (a) of this section.

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

§ 890.5575 Powered external limb overload warning device.

(a) *Identification.* A powered external limb overload warning device is a device intended for medical purposes to warn a patient of an overload or an underload in the amount of pressure placed on a leg.

(b) *Classification.* Class II (performance standards).

§ 890.5650 Powered inflatable tube massager.

(a) *Identification.* A powered inflatable tube massager is a powered device intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

(b) *Classification.* Class II (performance standards).

§ 890.5660 Therapeutic massager.

(a) *Identification.* A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

(b) *Classification.* Class II (performance standards).

§ 890.5700 Cold pack.

(a) *Identification.* A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5710 Hot or cold disposable pack.

(a) *Identification.* A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

(b) *Classification.* Class I (general controls).

§ 890.5720 Water circulating hot or cold pack.

(a) *Identification.* A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

(b) *Classification.* Class II (performance standards).

§ 890.5730 Moist heat pack.

(a) *Identification.* A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (performance standards).

§ 890.5765 Presssure-applying device.

(a) *Identification.* A presssure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

(b) *Classification.* Class I (general controls).

§ 890.5805 Powered muscle stimulator.

(a) *Identification.* A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

(b) *Classification.*

Class II (performance standards).

§ 890.5860 Ultrasound and muscle stimulator.

(a) *Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contactures, but not for the treatment of malignancies. The device also passes electrical currents throught the body area to stimulate or relax muscles.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasound and muscle stimulator for all other uses*—(1) *Identification.* An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

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

§ 890.5880 Multi-function physical therapy table.

(a) *Identification.* A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

(b) *Classification.* Class II (performance standards).

§ 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

(b) *Classification.* Class II (performance standards).

§ 890.5925 Traction accessory.

(a) *Identification.* A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

(b) *Classification.* Class I (general controls). The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(b) *Classification.* Class II (performance standards).

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(b) *Classification.* Class II (performance standards).

§ 890.5975 Therapeutic vibrator.

(a) *Identification.* A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(b) *Classification.* Class II (performance standards).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule in accordance with section 3(g)(1) of Executive Order 12291, 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 to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were 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 are not major rules.

Effective date. This regulation is effective December 23, 1983.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)))

Dated: November 14, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31321 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-01-M

federal register

Wednesday
November 23, 1983

Part IV

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Research; Actions Under the Guidelines

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research; Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, HHS.

ACTION: Notice of Actions under NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth actions taken by the Director, National Institute of Allergy and Infectious Diseases (NIAID), by authority of the Director, NIH, under the June 1983 NIH Guidelines for Research Involving Recombinant DNA Molecules (48 FR 24556).

EFFECTIVE DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. William J. Gartland, Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20205, (301) 496-6051.

SUPPLEMENTARY INFORMATION: Two major actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules are being promulgated today. These proposed actions were published for comment in the **Federal Register** of August 16, 1983 (48 FR 37198), and reviewed and recommended for approval by the Recombinant DNA Advisory Committee (RAC) at its meeting on September 19, 1983. In accordance with Section IV-C-1-b of the NIH Guidelines, these actions have been found to comply with the Guidelines and to present no significant risk to health or the environment.

Part I of this announcement provides background information on the actions.

Part II provides a summary of the actions and additional announcements of the Director, NIAID.

I. Decisions on Actions Under Guidelines

A. Inclusion of S. Mutans in Sublist F of Appendix A

Dr. Francis Macrina of the Medical College of Virginia of the Virginia Commonwealth University requested the *Streptococcus mutans* be included in Sublist F of Appendix A of the NIH Guidelines for Research Involving Recombinant DNA Molecules. Dr. Macrina argued that *S. mutans* should be included in this sublist for the following reasons:

1. A broad host range streptococcal plasmid, pAMβ1 (conferring erythromycin resistance), is conjugatively transmissible to *S. mutans*. Strains of *S. mutans* inheriting this plasmid are able to transmit it via conjugal transfer.

2. The report of non-plasmid associated conjugal transfer of tetracycline resistance from *S. mutans* to other strains of *S. mutans* and to *S. faecalis*, support the claim of natural genetic transfer from *S. mutans* to other streptococci.

3. A tetracycline resistance determinant from a naturally-resistant *S. mutans* clinical isolate shares sequence homology to the Tn916 (Tc^r) conjugative transposon originating in *S. faecalis*.

4. Naturally transformable strains of *S. mutans* are readily transformed with plasmid or chromosomal DNA from other *mutans* as well as *sanguis* strains.

5. *S. mutans* is far less virulent than two of the current members of Sublist F, *S. pneumoniae* and *S. pyogenes*.

The proposal was published in the August 16, 1983 **Federal Register** (48 FR 37199). No comments were received.

The RAC reviewed this proposal at its September 19, 1983, meeting. It was judged that the data supplied by Dr. Macrina showed that *S. mutans* exchanges DNA by known physiological processes with the other organisms already listed in Sublist F of Appendix A of the Guidelines. The RAC recommended that *S. mutans* be included in Sublist F of Appendix A by a vote of 14 in favor, 0 opposed, and 0 abstentions.

I accept this recommendation, and *S. mutans* has been added to Sublist F, Appendix A. Sublist E of Appendix A will remain as previously published as *S. lactis* is included in Sublist E, but not Sublist F.

B. Modification of Appendix L

The RAC Working Group on Revision of the Guidelines at its January 21, 1983, meeting recommended that Guidelines for field experimentation involving plants modified by recombinant DNA techniques be developed for consideration at the April 11, 1983, RAC meeting.

The Guidelines in force at that time required RAC review and NIH approval as well as IBC approval for the "deliberate release into the environment of any organism containing recombinant DNA." The proposal developed by the working group would have changed this so that provided experiments met certain criteria, growing of plants containing recombinant DNA in the field would have been able to proceed without RAC review and NIH approval. IBC approval would have been required as would notification to ORDA.

The RAC considered the proposal at its April 11, 1983, meeting and discussed it extensively. RAC made several modifications in the specific criteria and modified the procedural aspects of the proposal. The RAC recommended that the modified language be incorporated into a new appendix (Appendix L) which would require review and approval of experiments both by the Institutional Biosafety Committee (IBC) and also by the Plant Working Group of the RAC.

The exact language of Appendix L was subsequently developed by NIH Staff based on the recommendations made at the RAC meeting. The United States Department of Agriculture (USDA) Recombinant DNA Committee then reviewed the RAC recommendation, including the proposed wording for Appendix L, and endorsed their adoption.

The NIH accepted the proposed language and incorporated it into the Guidelines as Appendix L (48 FR 24548 and 24580). Subsequently, Dr. Sue Tolin, the liaison member of the Department of Agriculture to the RAC, in consultation with other members of the RAC Plant Working Group, proposed amendments to Appendix L-II-C which gives some of the criteria allowing review by the RAC Plant Working Group without the requirement for full RAC review. Appendix L-II-C currently reads as follows:

> Appendix L-II-C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences causing disease have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method.

Dr. Tolin proposed that Appendix L-II-C be modified to read as follows:

> Appendix L-II-C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences resulting in production of disease symptons have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method. If sequences resulting in production of disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequences before such plants, derivatives, or seed from them can be used in field tests.

The proposal was published in the August 16, 1983, **Federal Register** (48 FR 37199) for comment. No comments were received.

The RAC discussed this proposed modification at its September 19, 1983, meeting. Dr. Tolin noted that, under the June 1, 1983, **Federal Register** language, the Plant Working Group review might have to be conducted using the strictest definition of the word "disease." This may preclude the approval of some plasmid and virus-derived nucleic acids as vectors, since their replication might be construed as a disease process even though no symptoms develop in the plants. Dr. Tolin stated that it is her belief that if all other stipulations of Appendix L are satisfied, this minor change will result in no greater probability of risk of introducing plants containing recombinant DNA into the environment.

Dr. Tolin said sequences causing disease symptoms might be necessary to introduce the recombinant DNA into the plant. There are, however, methods for removing these sequences before the plants are tested in the field. Data showing elimination of these sequences would be evaluated by the Plant Working Group.

The RAC recommended the proposed modification by a vote of 13 in favor, 0 opposed, and 0 abstentions.

I accept this modification and Appendix L-II-C is modified to reflect this change.

II. Summary of Actions

A. Inclusion of S. Mutans in Sublist F of Appendix A

Sublist F of Appendix A is modified to read:

"Sublist F

"1. *Streptococcus sanguis*
"2. *Streptococcus pneumoniae*
"3. *Streptococcus faecalis*
"4. *Streptococcus pyogenes*
"5. *Streptococcus mutans*"

B. Modification of Appendix L—Release Into the Environment of Certain Plants

Appendix L-II-C of Appendix L is modified to read as follows:

Appendix L-II-C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences resulting in production of disease symptoms have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method. If sequences resulting in production of disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequences before such plants, derivatives, or seed from them can be used in field tests.

Additional Announcement of the Director, NIAID

In connection with the incorporation of Appendix K into the Guidelines on June 1, 1983, it was stated in the note in 48 FR 24551 that Section III-B-5 of the Guidelines was to be changed to delete reference to 45 FR 24968 and to add instead a reference to Appendix K. However, due to an error, this change was not made when the Guidelines were published (48 FR 24559). To correct this error, Section III-B-5 of the Guidelines is now modified to read as follows:

III-B-5. *Experiments Involving More Than 10 Liters of Culture.* The appropriate containment will be decided by the IBC. Where appropriate, Appendix K, *Physical Containment for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules*, should be used.

Dated: November 15, 1983.

Richard M. Krause,

Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Note.—OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance*. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every federal research program in which DNA recombinant molecule techniques could be used, it has been determined to be not cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every federal program would be included as many federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

[FR Doc. 83-31428 Filed 11-22-83; 8:45 am]

BILLING CODE 4140-01-M

federal register

Wednesday
November 23, 1983

Part V

Office of Management and Budget

Budget Deferrals

OFFICE OF MANAGEMENT AND BUDGET

Budget Deferrals

To the Congress of the United States:

In accordance with the Impoundment Control Act of 1974, I herewith propose one rescission of $30,000,000 in contract authority for the Department of the Interior and two new deferrals of budget authority totaling $72,164,000 for the Department of Energy.

The details of the proposed rescission and the deferrals are contained in the attached reports.

Ronald Reagan,

The White House, November 17, 1983.

BILLING CODE 3110-01-M

CONTENTS OF SPECIAL MESSAGE
(in thousands of dollars)

Deferral #	Item	Budget Authority
	Department of Energy:	
D84-21	Fossil energy research and development.....	58,364
D84-22	Alternate fuels production.....	13,800
	Department of the Interior	
D84-23	National Park Service, land acquisition and state assistance (contract authority).....	30,000
	Total, deferrals.....	102,164

****

SUMMARY OF SPECIAL MESSAGES
FOR FY 1984
(in thousands of dollars)

	Rescissions	Deferrals
Second special message		
New items.....	---	102,164
Revisions to previous special messages.....	---	---
Effects of second special message.....	---	102,164
Amounts from previous special messages that are changed by this message (change noted above).....	---	---
Subtotal, rescissions and deferrals.....	---	102,164
Amounts from previous special messages that are not changed by this message.....	---	1,924,697
	*********	**********
Total amount proposed to date in all special messages.....	---	2,026,861

Deferral No: D-84-21

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of Energy

Bureau: Energy Programs

Appropriation title & symbol: Fossil Energy, Research and Development 89X0213 1/

New budget authority (P.L. _____) $ 0

Other budgetary resources 80,972,028

Total budgetary resources 80,972,028

Amount to be deferred:
Part of year $ 46,326,000
Entire year 12,038,000

OMB identification code: 89-0213-0-1-271

Legal authority (in addition to sec. 1013):
☐ Antideficiency Act
☐ Other _____

Trust program: ☐ Yes ☒ No

Type of account or fund:
☐ Annual
☐ Multiple-year _____ (expiration date)
☒ No-year

Type of budget authority:
☒ Appropriation
☐ Contract authority
☐ Other _____

Justification: This account provides for research and development activities relating to coal, petroleum, and natural gas. This deferral includes $46.3 million that was deferred pending enactment of the FY 1984 Department of the Interior Appropriations Bill. This Bill would reprogram these funds for appropriate fossil energy research and development activities in FY 1984. This deferral also includes $12.0 million in prior year unobligated balances that are available as a result of the completion of various fossil energy related construction projects. These funds will be used in FY 1985.

Estimated Program Effect: None.

Outlay Effect: This deferral action will shift $12 million in outlays from FY 1984 to FY 1985.

1/ This account was the subject of a similar deferral in FY 1983 (D83-81). This account has been merged with the fossil energy construction account.

Deferral No: D84-22

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of Energy	New budget authority (P.L. _____) $ 0
Bureau: Energy Programs	Other budgetary resources 14,500,000
Appropriation title & symbol: Alternate Fuels Production 89X5180 1/	Total budgetary resources 14,500,000
	Amount to be deferred: Part of year $ 13,000,000
	Entire year 800,000
OMB identification code: 89-5180-0-2-271	Legal authority (in addition to sec. 1012): ☐ Antideficiency Act
Grant program: ☐ Yes ☒ No	☐ Other _____
Type of account or fund: ☐ Annual ☐ Multiple-year _____ (expiration date) ☒ No-year	Type of budget authority: ☒ Appropriation ☐ Contract authority ☐ Other _____

Justification: This program provides for the development and production of alternative fuels. This deferral includes $13.0 million that was deferred pending enactment of the 1984 Department of the Interior Appropriations Bill. This Bill would reprogram these funds for appropriate alternate fuels production projects in FY 1984. This deferral also includes $800 thousand in FY 1983 unobligated balances made available from completed alternative fuels projects that will be used in FY 1985.

Estimated Program Effect: None.

Outlay Effect: This deferral action will shift $800 thousand in outlays from FY 1984 to FY 1985.

1/ This account was the subject of a similar deferral in FY 1983 (D83-77).

[FR Doc. 83-31525 Filed 11-22-83; 8:45 am]

BILLING CODE 3110-01-C

Deferral No: D84-21

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of the Interior	New budget authority (16 U.S.C. 460L-10a) $ 30,000,000
Bureau: National Park Service	Other budgetary resources 128,000,000
Appropriation title & symbol: Land Acquisition and State Assistance 1/ 14X5035	Total budgetary resources 158,000,000
	Amount to be deferred: Part of year 30,000,000
	Entire year _____
OMB identification code: 14-5035-0-2-303	Legal authority (in addition to sec. 1012): ☐ Antideficiency Act
Grant program: ☒ Yes ☐ No 2/	☐ Other _____
Type of account or fund: ☒ Annual 2/ ☐ Multiple-year _____ (expiration date) ☒ No-year	Type of budget authority: ☒ Appropriation ☒ Contract authority (annual) 2/ ☐ Other _____

Justification: This appropriation provides (1) funds to acquire land for inclusion in the National Park system, and (2) grants to States for outdoor recreation purposes.

Under existing law (16 U.S.C. 460L-10a), $30 million in contract authority is made available each fiscal year for use as an anti-cost escalation measure in purchasing authorized Federal recreation land. This authority was last used in 1969 and 1970, and there are no plans to use it in the future. The contract authority lapsed in fiscal years 1971-1981 and was rescinded by Congressional action for fiscal years 1982 (P.L. 97-257) and 1983 (P.L. 98-63). The $30 million in FY 1984 contract authority has been deferred pending final FY 1985 Budget decisions to be submitted by the President to Congress this January.

Estimated Program Effect: None.

Outlay Effect: None.

1/ This account was subject to a similar deferral in FY 1983 (D83-11).
2/ The deferred funding is non-grant contract authority with a one-year availability.

federal register

Wednesday
November 23, 1983

Part VI

Department of Commerce

International Trade Administration

People's Republic of China; Export Control Policy; Placement in Country Group V; Final Rule

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No. 30909-186]

15 CFR Parts 368, 370, 371, 372, 373, 374, 375, 376, 379, 385, 386 and 399

People's Republic of China; Export Control Policy; Placement in Country Group V

AGENCY: Office of Export Administration, International Trade Administration, Commerce.

ACTION: Final rule.

SUMMARY: This rule implements a more liberal export control policy toward the People's Republic of China. The Export Administration Regulations are amended to set forth the new policy, the major feature of which is the removal of China from Country Group P and its placement in Country Group V.

EFFECTIVE DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Archie Andrews, Director, Exporters' Service Staff (telephone: (202) 377-4811).

SUPPLEMENTARY INFORMATION: This rule amends the Export Administration Regulations to reflect a more liberal export control policy toward the People's Republic of China. China is placed in Country Group V, and all references to Country Group P (previously, the People's Republic of China) are removed from the Regulations. Section 385.3, which had outlined special requirements, provisions, and restrictions applicable to Country Group P, is removed. Advisory Notes are added to the Commodity Control List (Supplement No. 1 to § 399.1) setting forth those commodities most likely to be approved for export to China. In addition, special requirements applicable to exports destined for China are added to the Regulations governing the use of certain export licenses and the export of specified commodities and technical data. These special requirements reflect international strategic trade controls and nuclear non-proliferation objectives of the United States.

Rulemaking Requirements and Invitation To Comment

In connection with various rulemaking requirements, the Office of Export Administration has determined that:

1. Since this regulation involves a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, the opportunity for public participation and a delay in effective date are inapplicable.

2. This rule does not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and in some instances, relieves a regulatory burden because of the easing of export licensing restrictions on certain commodities destined for China.

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

4. This rule is exempt from the requirements of Executive Order 12291 (46 FR 13193, February 19, 1981), "Federal Regulation," because it relates to a foreign affairs function of the United States.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects

15 CFR Part 368

Imports, Penalties.

15 CFR Part 370

Administrative practice and procedure.

15 CFR Parts 371 through 376

Exports.

15 CFR Part 379

Exports, Science and technology.

15 CFR Part 385

Communist countries, Exports.

15 CFR Part 386

Exports.

15 CFR Part 399

Exports.

Accordingly, the Export Administration Regulations (15 CFR Parts 368-399) are amended as follows:

PART 368—[AMENDED]

§ 368.2 [Amended]

1. The footnote to § 368.2(a)(9)(i) is amended by revising the phrase "Country Group P, Q, W, Y or Z" to read "the People's Republic of China or a country in Country Group Q, W, Y or Z."

PART 370—[AMENDED]

§ 370.2 [Amended]

2. The definition of *Country Groups* in § 370.2 is amended by revising the first sentence to read: "For export control purposes, foreign countries are separated into seven country groups designated by the symbols Q, S, T, V, W, Y and Z."

3. The definition of *Qualified General License* in § 370.2 is amended by revising the phrase "P, Q, W and Y Country Groups" to read "Q, W and Y Country Groups."

4. Section 370.6 is amended by revising the title of paragraph (a), the title of (a)(2) and that portion of the first sentence of (a)(2) which appears before (i) to read as follows:

§ 370.6 Shipments entering foreign trade zones.

* * * * *

(a) *Country restrictions.*

* * * * *

(2) *Country Group Q or the People's Republic of China.* Shipments to Country Group Q or the People's Republic of China require a validated license—

* * * * *

§ 370.9 [Amended]

5. Section 370.9 is amended by removing the symbol "P," from the first sentence.

§ 370.11 [Amended]

6. Section 370.11 is amended:

A. By revising the phrase "Country Groups P, Q, W, Y and Z" in paragraph (a)(1)(iv) to read "the People's Republic of China and Country Groups Q, W, Y and Z";

B. By revising the phrase "Country Groups P, Q, W and Y" in paragraph (b) to read "the People's republic of China and Country Groups Q, W, and Y";

C. By revising the phrase "Country Groups P, Q, W, and Y" in paragraph (c) to read "the People's Republic of China and Country Groups Q, W, and Y";

D. By removing the phrase "PQWY" in paragraph (c), and

E. By revising the phrase "five weeks" in the last sentence of (c) to read "two months or more."

§ 370.13 [Amended]

7. Section 370.13(l) is amended by revising the phrase "Country Groups P, Q, W and Y" to read "the People's Republic of China and Country Groups Q, W and Y" in the first sentence.

Supplement No. 1—[Amended]

8. Supplement No. 1 to Part 370 "COUNTRY GROUPS," is amended by removing the symbol ' "P," ' in the first sentence of the introductory paragraph, and by removing the Supplement entry reading—

"Country Group P People's Republic of China."

PART 371—[AMENDED]

§ 371.4 [Amended]

9. Section 371.4(a)(3) is amended by revising the phrase "Country Group P or Q" to read "Country Group Q or the People's Republic of China".

§ 371.5 [Amended]

10. Section 371.5 is amended by revising the phrase "GLV $ Value Limits T & V" to read "GLV $ Value Limit" in paragraph (a)(1), and removing the phrase "P or " in paragraph (a)(2).

§ 371.6 [Amended]

11. Section 371.6 is amended by removing the symbol "P," in paragraph (a), and by adding a next-to-last sentence in paragraph (a) reading as follows: "Only commodities not identified by the code letter "A" or "M" may be taken out of the United States to the People's Republic of China under this general license."

§ 371.9 [Amended]

12. Section 371.9(a)(3) is amended by revising the phrase "P,Q,W,Y or Z" to read "Q, W, Y or Z, or the People's Republic of China"; revising the phrase "P,Q,W or Y" to read "Q,W or Y, or the People's Republic of China" (2 revisions); and by revising the phrase "PQWY countries or Cuba" to read "QWY countries or Cuba or the People's Republic of China."

§ 371.10 [Amended]

13. Section 371.10(a)(3) is amended by revising the phrase "P,Q,W,Y or Z (excluding Cuba)" to read "Q,W,Y or Z (excluding Cuba), or the People's Republic of China"; and revising the phrase "P,Q,W or Y" to read "Q,W or Y, or the People's Republic of China" (2 revisions).

§ 371.15 [Amended]

14. Section 371.15(c)(3) is amended by revising the phrase "Country Group P or Q" to read "Country Group Q or the People's Republic of China."

§ 371.16 [Amended]

15. Section 371.16 is amended by removing the symbol "P," from the introductory paragraph.

§ 371.17 [Amended]

16. Section 371.17 is amended by:

A. Adding a sentence at the end of the introductory paragraph reading as follows: "In accordance with § 387.4, no equipment may be serviced if there is reason to know that the equipment was exported or reexported in violation of the Export Administration Regulations.";

B. By removing the symbol "P," from the title of paragraphs (a)(3), (a)(3)(i) (two removals), (a)(4), the title and introductory sentence of (f)(3), and from (f)(3)(iv);

C. By adding a sentence to the end of paragraph (a)(1) reading as follows: "The servicing shall not have improved or changed the basic characteristics, *e.g.*, as to accuracy, capability, performance, or productivity of the commodity as originally authorized for export or reexport."

D. By removing paragraph (a)(3)(i)(B), and redesignating paragraphs (a)(3)(i)(C), (D) and (E) as (a)(3)(i)(B), (C) and (D).

§ 371.18 [Amended]

17. Section 371.18 is amended by removing the symbol "P," from paragraph (b)(1)(ii).

18. Section 371.22 is amended by revising paragraph (c)(1) to read as follows:

§ 371.22 General License GTE; Temporary Exports.

* * * * *

(c) *Exceptions*—(1) *Destinations.* (i) No commodity may be exported under the provisions of this general license to Country Group S or Z;

(ii) Except as further restricted by § 371.22(c)(2), only commodities not identified by the code letter "A," "B," or "M" following the Export Control Commodity Number on the Commodity Control List (Supplement No. 1 to § 399.1) may be exported to Country Group Q, W or Y;

(iii) Only commodities not identified by the code letter "A" or "M" following the Export Control Commodity Number on the Commodity Control List (Supplement No. 1 to § 399.1) may be exported to the People's Republic of China;

(iv) These exceptions apply also to any vessel, aircraft or extraterritorial point under ownership, control, lease, or charter by any country in Country Groups Q, S, W, Y or Z, or the People's Republic of China, or to any national thereof.

* * * * *

PART 372—[AMENDED]

§ 372.2 [Amended]

19. Section 372.2 is amended by removing the symbol "P," from paragraphs (b) (4) and (6), and by revising the first sentence of (b)(3) to read "A 'Distribution License' (§ 373.3) authorizes the export of certain commodities to approved consignees in Country Groups T and V, except the People's Republic of China, during a period of one year."

§ 372.8 [Amended]

20. Section 372.8 is amended by removing the symbol "P," from paragraphs (b)(1) and (c)(2).

21. Section 372.11 is amended by removing the symbol "P," from paragraphs (f)(7)(iii) and (g)(3)(i), by revising the phrase "Country Group T or V port," in (f)(7) to read "Country Group T or V port (except a port in the People's Republic of China)," and by adding a paragraph (g)(3)(vii) reading as follows:

§ 372.11 Amending Export Licenses.

* * * * *

(g) * * *

(3) * * *

(vii) Amendment to increase the quantity of a license for the People's Republic of China (PRC) or to add an intermediate consignee in the PRC.

* * * * *

PART 373—[AMENDED]

22. Section 373.3 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 373.3 Distribution license.

* * * * *

(a) *Eligible countries.* (1) * * *

(ii) All countries in Country Group V, except Afghanistan and the People's Republic of China.

* * * * *

§ 373.4 [Amended]

23. Section 373.4 is amended by removing the symbol "P," from the introductory paragraph and from paragraphs (a) and (b)(1).

§ 373.7 [Amended]

24. Section 373.7 is amended:

A. By revising the phrase "Country Groups P, Q, W and Y and Afghanistan" to read "Country Groups Q, W and Y, Afghanistan and the People's Republic of China" in paragraph (c)(2) (three revisions), the title of (i), and paragraph (i)(6);

B. By removing the letter "P," from paragraphs (d)(1), the footnotes to (h)(1)(i) and (ii), and from paragraph (i)(1);

C. By adding a second sentence to (d)(2)(i) reading "Reexports of spare and replacement parts to, or their use in, the People's Republic of C hina are subject to provisions of § 373.7(d)(2)(ii)(C) and 373.7(i).";

D. By revising the title of (d)(2)(ii) to read "Country Groups Q, W and Y, Afghanistan and the People's Republic of China";

E. By revising the phrase in paragraphs (d)(2)(ii)(*a*) and (i)(2) reading

"the Country Group P, Q, W, or Y destination or Afghanistan" to read "a destination in Country Group Q, W or Y, Afghanistan or the People's Republic of China";

F. By revising the phrase in paragraphs (d)(2)(i) and (h)(1)(ii) reading "Country Group T or V except Afghanistan" to read "Country Group T or V except Afghanistan and the People's Republic of China";

G. By revising the phrase in (h)(1)(ii) reading "Country Group P, Q, W, or Y or Afghanistan" to read "Country Group Q, W or Y, Afghanistan or the People's Republic of China"; and

H. By revising the phrase "P, Q, W, or Y or Afghanistan" to read "Q, W or Y, Afghanistan or the People's Republic of China" in paragraphs (d)(2)(ii), (d)(2)(ii)(c), (i), (i)(4), and (k) (two revisions).

§ 373.8 [Amended]

25. Section 373.8 is amended by removing the symbol "P," from paragraphs (a)(2) and (c)(1), and by adding a last sentence to (c)(1) reading as follows: "If the aircraft or vessel is registered in, or owned or controlled by, or chartered or leased to the People's Republic of China or a national thereof, the supporting documentation must include the location of the service to be performed and the type of aircraft or vessel to be serviced."

PART 374—[AMENDED]

26. Section 374.2 is amended by removing the symbol "P," from paragraphs (a)(4), (a)(4)(i), and (f); and by revising paragraph (i) to read as follows:

§ 374.2 Permissive reexports.

* * * * *

(i) Reexports from COCOM countries to Country Group Q, W or Y or to the People's Republic of China that meet the conditions set forth in § 374.3(e).

§ 374.3 [Amended]

27. Section 374.3 is amended by removing the symbol "P," from paragraph (c)(1)(i); by inserting "China, People's Republic of" between "Afghanistan" and Liechtenstein" in paragraph (c)(1)(ii); by inserting after the phrase "(Supplement No. 1 to § 399.1)" in paragraph (e)(1)(i)(B) the phrase "(the Advisory Notes for the People's Republic of China do *not* apply in meeting this requirement)"; and by revising the phrase "Country Group P, Q, W, or Y" to read "Country Groups Q, W or Y, or the People's Republic of China" in paragraph (e)(1)(iv).

§ 374.5 [Amended]

28. Section 374.5 is amended by removing the symbol "P," from paragraphs (a) and (b).

PART 375—[AMENDED]

§ 375.2 [Amended]

29. Section 375.2 is amended by removing the symbol "P," from paragraph (a).

PART 376—[AMENDED]

§ 376.4 [Amended]

30. Section 376.4 is amended by removing the symbol "P," from the title and from paragraphs (a) and (b) (4) and (5).

§ 376.7 [Amended]

31. Section 376.7 is amended by revising in paragraphs (c) and (d) the phrase "Country Group P, W, Y or Z" to read "Country Group W, Y or Z, or the People's Republic of China".

§ 376.8 [Amended]

32. Section 376.8 is amended by revising the phrase "except Country Group P, Q, W, Y, or Z," to read "except Country Group Q, W, Y or Z," in paragraph (a); by revising the phrase "Group P, Q, S, W, Y or Z country, Afghanistan or Libya" to read "Group Q, S, W, Y of Z country, the People's Republic of China, or Afghanistan" in paragraph (b)(1)(ii); and by revising the phrase "Group P, Q, S, W, Y, or Z country, Afghanistan, or Libya" to read "Group Q, S, W, Y or Z country, or Afghanistan" in paragraph (b)(1)(iii).

§ 376.9 [Amended]

33. Section 376.9 is amended by revising the phrase "Country Group P, Q, S, W, Y, or Z" to read "Country Group Q, S, W, Y or Z, or the People's Republic of China" in paragraph (b)(3)(ii) (3 revisions).

34. Section 376.10 is amended by revising in paragraph (a)(1) the phrase "Country Groups P, Q, W, and Y" to read "Country Groups Q, W, and Y, and the People's Republic of China," and by revising the phrase "P, Q, W, or Y destinations" to read "Q, W, or Y destinations or to the People's Republic of China".

35. Section 376.10 is amended by adding a paragraph (a)(4)(xxiv) reading as follows:

§ 376.10 Electronic computers and related equipment.

* * * * *

(a) *Digital Computers*

* * * * *

(4) Definitions of Terms.

* * * * *

(xxiv) "Fixed point processing data rate" is the sum of—

(A) 0.85 times the "number of bits in a fixed point add instruction";

(B) 0.15 times the "number of bits in a fixed point multiply instruction"; *and*

(C) 0.55 times the "number of bits in a fixed point operand" *divided by* the sum of—

(1) 0.85 times the "execution time" for a fixed point addition; and

(2) 0.15 times the "execution time" for a fixed point multiplication".

* * * * *

§ 376.11 [Amended]

36. Section 376.11 is amended by revising in the introductory paragraph the phrase "Country Groups P, Q, W, and Y" to read "Country Groups Q, W, and Y and the People's Republic of China".

PART 379—[AMENDED]

37. Section 379.4 is amended by removing the symbol "P," from paragraph (b) and its title.

38. Section 379.4(f) is amended:

A. By revising the phrase "Country Group P, Q, S, W,[2] Y or Z Afghanistan" to read "Country Group Q, S, W,[2] Y, or Z, or Afghanistan or the People's Republic of China" in (f)(1);

B. By revising the phrase "Country Group P, Q, S, W, Y, or Z or Afghanistan" to read "Country Group Q, S, W, Y or Z, or Afghanistan or the People's Republic of China" in (f)(1) (3 revisions), (f)(2)(ii)(*a*), and (f)(3);

C. By revising the phrase "Country Group P, Q, S, W,[8] Y, Z or Afghanistan" to read "Country Group Q, S, W,[8] Y or Z, or Afghanistan or the People's Republic of China" in (f)(2)(i)(*a*); and

D. By revising the phrase "Country Group P, Q, S, W, Y, or Afghanistan" to read "Country Group Q, S, W, Y, or Afghanistan or the People's Republic of China" in (f)(2) (i)(*c*) and (ii)(*c*).

39. Section 379.4 is amended by adding a new paragraph (i) reading as follows:

§ 379.4 General License GTDR: Technical Data Under Restriction.

* * * * *

(i) *Additional restrictions applicable to the People's Republic of China.* In addition to the prohibitions in § 379.4 (c) and (d), no technical data related to commodities identified on the Commodity Control List (Supplement No. 1 to § 399.1) as controlled for reasons of national security, nuclear non-proliferation, or crime control may be exported to the People's Republic of China under General License *GTDR*.

This prohibition does not apply, however, to data described in § 379.4(b).

§ 379.5 [Amended]

40. Section 379.5 is amended by revising the phrase "Country Group Q, V, W, Y, or Z, or Afghanistan" to read "Country Group Q, W [2], Y or Z, the People's Republic of China or Afghanistan" in paragraph (e)(1)(vii), and by revising the phrase "Country Group Q, W, Y, Z, or Afghanistan" to read "Country Group Q, W, Y, Z, Or Afghanistan" to read "Country Group Q, W, Y or Z, the People's Republic of China or Afghanistan" in paragraph (e)(2) (two revisions).

41. Section 379.6 is amended by removing the symbol "P," from paragraph (b)(2) and its title, and by adding a paragraph (b)(1)(iii) reading as follows:

§ 379.6 Exports under a validated license.

* * * * *

(b) * * *

(1) * * *

(iii) For exports to the People's Republic of China, the exporter also shall submit a statement indicating the nature of the transaction (*e.g.*, a sale of technical data, performance of technical services, a technical licensing agreement, or a technology exchange agreement).

* * * * *

42. Section 379.8 is amended:

A. By revising the phrase "Country Group P, Q, W, Y, or Z or Afghanistan" to read "Country Group Q, W, Y or Z, the People's Republic of China or Afghanistan" in paragraph (a)(3);

B. By removing the symbol "P," from paragraphs (b)(2) (two removals) and its title, and (c)(3) and its title;

C. By inserting after the phrase "(Supplement No. 1 to § 399.1)" in paragraph (b)(3)(i)(B) the phrase "(the Advisory Notes for the People's Republic of China do *not* apply in meeting this requirement)";

D. By revising the phrase "Country Group P, Q, W, or Y" to read "Country Groups Q, W or Y, or the People's Republic of China" in paragraph (b)(3)(iv); and

E. By adding a paragraph (c)(2)(iii) reading as follows:

§ 379.8 Reexports of technical data and exports of the product manufactured abroad by use of United States technical data.

* * * * *

(c) * * *

(2) * * *

(iii) For exports to the People's Republic of China, a notice also is required indicating the nature of the transaction (*e.g.*, a sale of technical data, performance of technical services, a technical licensing agreement, a technology exchange agreement, or the rendering of technical services).

PART 385—[AMENDED]

§§ 385.3 and 385.5 [Removed and reserved]

43. Section 385.3, "Country Group P: People's Republic of China", and § 385.5, "Country Group T: North America, Central America and South America," are removed and reserved.

44. Section 385.4 is amended by revising the heading, by removing and reserving paragraph (b), by revising paragraph (c), and by adding a paragraph (g) reading as follows:

§ 385.4 Country Groups T & V.

* * * * *

(b) [Reserved]

(c) *People's Republic of China.* (1) The general licensing policy is to consider exports for China under the Country Group T and V policies set forth in paragraph (g) of this section, except that there are certain commodities, data, and end-uses that may require extended review or denial. Of particular concern are exports that would make a direct and significant contribution to nuclear weapons and their delivery systems, electronic and anti-submarine warfare, intelligence gathering, power projection, and air superiority. Licenses may be approved even when the end-user or end-use military. Commodities or data may be approved for export even though they may contribute to Chinese military development.

(2) Each application will be considered individually. The Advisory Notes in the CCL (Supplement No. 1 to § 399.1) headed "Note for the People's Republic of China" provide guidance on equipment likely to be approved most rapidly for China and that for the most part will not require any inter-agency review. Items with higher performance levels than those described in the Advisory Notes may also be approved on a case-by-case basis.

(3) Applications covering commodities and technical data approved by the United States that are controlled by the COCOM international export control system may have to be forwarded to COCOM for consideration in accordance with established procedures before a license is issued.

* * * * *

(g) *Other countries in Groups T and V.* (1) *General policy.* For other countries in Country Groups T and V, the Department of Commerce requires prior approval for the export or reexport of selected commodities and technical data that include—

(i) Commodities the United States and other Free World governments have agreed to control *vis a vis* their export to Communist destinations in Europe and the Far East, and

(ii) Certain other commodities that the United States considers to have high potential for strategic use, including nuclear-related commodities. Technical data relating to a few commodities of particular strategic significance also are subject to the prior approval procedure. (See § 379.4 for technical data controls, which may vary with country of destination and type of data.)

(iii) The policy generally is one of approval of applications unless there is a significant risk that the commodities or data will be used or diverted contrary to the objectives of a specific U.S. export control program.

(2) *Crime control and detection commodities.* In support of U.S. foreign policy to promote the observance of human rights throughout the world, an individual validated export license is required to export any crime control and detection equipment as defined in § 376.14 to any destination in these country groups except Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin,) Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.

(3) *Regional stability commodities and equipment.* In support of U.S. foreign policy to maintain regional stability, an individual validated export license is required to export military vehicles and certain commodities used to manufacture military equipment identified in § 376.16, to any destination in these country groups except Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom. (See § 385.7 for regional stability controls on exports to Libya.)

PART 386—[AMENDED]

§ 386.3 [Amended]

45. Section 386.3 is amended by removing the symbol "P," from paragraphs (k)(1) and (r)(1).

§386.6 [Amended]

46. Section 386.6 is amended by removing the phrase "the People's Republic of China" from paragraphs (d)(2)(i)(*b*) and (d)(3).

PART 399—[AMENDED]

§399.1 [Amended]

47. Section 399.1 is amended by removing the symbol "P," from paragraphs (d)(1) (2 removals) and (f)(3)(ii) and (iii), and the symbol "P," from the list of Country Groups in (f)(2) (5 removals).

Supplement No. 1 to § 399.1—[Amended]

48. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by removing the symbol "P," from the introductory NOTE at the beginning of each of the 10 Commodity Groups (Group 0, Metal-Working Machinery; Group 1, Chemical and Petroleum Equipment, etc.), and by adding the phrase "(except for those exports to the People's Republic of China restricted by § 379.4 of the Regulations)" after the phrase "Country Groups T & V" in the introductory note at the beginning of each of the 10 Commodity Groups.

49. The Commodity Control List is amended by removing the symbol "P," from the *Validated License Required* paragraph in the following entries of the list:

2018A	1203A	1362A	1502A
1075A	4203B	3362A	1505A
1080A	1205A	3363A	1510A
1081A	1206A	4363B	1514A
1086A	3261A	1370A	1516A
1088A	4261B	1371A	4516B
1091A	1305A	2404A	1517A
1093A	1312A	2406A	4517B
4094B	2317A	2409A	1518A
1110A	2319A	4409B	1519A
1118A	3336A	2410A	1520A
2120A	4337B	1416A	1521A
4127B	1352A	1418A	1522A
4128B	1353A	1431A	1526A
1129A	1355A	4431B	1527A
1131A	1356A	1460A	1529A
3131A	1357A	4460B	4529B
1133A	1358A	5480B	4530B
1142A	4360B	1485A	1531A
1145A	1361A	1501A	1532A
1533A	1548A	1561A	1584A
1534A	1549A	1564A	1585A
1537A	1553A	1565A	4585B
1541A	1555A	1568A	1586A
1542A	1556A	4569B	1587A
1544A	1558A	1570A	1588A
1545A	1559A	1571A	4590B
1547A	1560A	1572A	4592B
1595A	1649A	4707B	1760A
4597B	4654B	2708A	1763A
5597B	1658A	3709A	1767A
4601B	1661A	3711A	4778B
2603A	1670A	1715A	1781A
3604A	1671A	4720B	4781B
3605A	1673A	4721B	4782B
3607A	4674B	1746A	4783B
3608A	4675B	4746B	4784B
3609A	4676B	1754A	4799B
2616A	4677B	4754B	1801A
1631A	4678B	1755A	4996B
1635A	5680B	4755B	4997B
4635B	4698B	1757A	4998B
4638B	1701A	4757B	5998B
1648A	1702A	1759A	4999B
			5999B

50. The Commodity Control List (Supplement No. 1 to §399.1) is amended by removing the symbol "P" from the Advisory Note(s) for the following entries:

2018A	1537A
1081A (Note 1 only)	1541A
1091A (Note 1 only)	1544A
2120A	1545A
1131A	1547A
1133A	1548A
1203A	1549A
1205A	1555A
3261A	1556A
1312A	1559A
1353A	1564A (Notes 1 through 4 only)
1355A (Note 1 only)	1565A (Notes 1 2 and 4 through 10 only)
1357A (Note 1 only)	
1361A	1568A
1371A	1572A (Notes 1 through 4 only)
1485A	1584A (Note 1 only)
1501A	1586A
1502A	1587A
1510A	1588A
1519A (Notes 1 2 and 3 only)	1595A
1520A	3604A
1522A	3605A
1526A	1673A
1529A (Notes 1 2 and 3 only)	1754A
1531A (Note 1 only)	1755A
1532A	1757A
1533A (Note 1 only)	1763A
1534A (Notes 1 and 2 only)	1767A

51. The Commodity Control List (Supplement No. 1 to §399.1) is amended by removing the following Advisory Notes:

Advisory Note 2 for 1081A.
Advisory Note 2 for 1091A.
Advisory Note 2 for 1357A.
Advisory Note 4 for 1519A.
Advisory Notes 5 through 8 for 1529A.
Advisory Notes 2 and 3 for 1531A.
Advisory Note 2 for 1533A.
Advisory Note 3 for 1534A.
Advisory Notes 6, 7 and 8 for 1564A.
Advisory Note 12 for 1565A.
Advisory Note 2 for 1568A.
Advisory Note 6 for 1572A.
Advisory Note 3 for 1584A, the Advisory Note for 4590B, and
Advisory Note 2 for 1757A.

52. The Commodity Control List (Supplement No. 1 to §399.1) is amended by revising the *GLV $ Value Limit* paragraph for the following entries—

1093A	1142A	1356A	1371A
1110A	1203A	1357A	2404A
2120A	1205A	1358A	2410A
1129A	1206A	1362A	1505A
1131A	1352A	3363A	1510A
1133A	1353A	1370A	1521A
1522A	1555A	1595A	1701A
1528A	1556A	3604A	1702A
1537A	1558A	3609A	2708A
1541A	1559A	2616A	3709A
1542A	1560A	1631A	3711A
1544A	1564A	1648A	1715A
1545A	1571A	1649A	1755A
1547A	1585A	1658A	1757A
1548A	1586A	1661A	1760A
1549A	1587A	1670A	1767A
1553A	1588A	1671A	1781A
		1673A	1801A

to read as follows—

"GLV $ Value Limit: $500 for Country Groups T & V, except $0 for the People's Republic of China; $0 for all other destinations."

53. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the *GLV $ Value Limit* paragraph for the following entries—

1075A	2317A	1501A	1533A
1080A	2319A	1514A	1534A
1081A	1361A	1517A	1561A
1086A	2409A	1518A	1565A
1088A	1416A	1519A	1568A
1091A	1418A	1520A	1572A
1145A	1431A	1529A	1584A
1305A	1460A	1531A	1635A
1312A	1485A	1532A	1754A

to read as follows—

"GLV $ Value Limit: $1000 for Country Groups T & V, except $0 for the People's Republic of China; $0 for all other destinations."

54. The Commodity Control List (Supplement No. 1 § 399.1) is amended by revising the *GLV $ Value Limit* paragraph for entries 3362, 3605, 3607 and 1746 to read as follows:

"GLV $ Value Limit: $100 for Country Groups T & V, except $0 for the People's Republic of China; $0 for all other destinations."

55. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the *GLV $ Value Limit* paragraph for entries 1570, 3608 and 1763 to read as follows:

"GLV $ Value Limit: $100 for Country Groups T & V, except $0 for the People's Republic of China; $0 for all other destinations."

56. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the *GLV $ Value Limit* paragraph for entry 1355A to read as follows—

1355A Machinery and equipment for the manufacture of electronic equipment, components and materials; related test gear; parts and components and specialized controls and accessories thereof.

* * * *

"GLV $ Value Limit: $100 for commodities defined in paragraphs (b)(2) (i) and (ii) of the Definitive List to Country Groups T & V, except $0 to the People's Republic of China; $500 for other commodities to Country Groups T & V, except $0 to the People's Republic of China; $0 for all other destinations.

* * * * *

57. Group 5 of the Commodity Control List (Supplement No. 1 to § 399.1) is

amended by revising the *GLV $ Value Limit* paragraph for entry 1502A to read as follows—

1502A Communication, detection or tracking equipment of a kind using ultraviolet radiation, infrared radiation or ultrasonic waves.

Controls for ECCN 1502A

* * * * *

"*GLV $ Value Limit:* For police-model infrared viewers, the $ value limit is $500 only to Australia, Japan, New Zealand and members of NATO, and $0 to all other destinations. For items other than police-model infrared viewers, the $ value limit is $500 to Country Groups T & V, except $0 to the People's Republic of China; $0 to all other destinations.

* * * * *

58. The Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the *Validated License Required* paragraph to read—

"*Validated License Required:* Country Groups QSWYZ, Afghanistan and the People's Republic of China"—

for the following entries:

5399D	5568D
5406D	5585D
5431D	5595D
5510D	5596D
5565D	5799D

59. Entry 1091A of Group O of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the phrase "Country Groups P, Q, W, and Y" to read "Country Groups Q, W, and Y, and the People's Republic of China" in the first Note following the *List of Commodities Controlled by ECCN 1091A.*

60. Entry 1355A of Group 3 of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising the Advisory Note 2 to read as follows:

1355A Machinery and equipment for the manufacture of electronic equipment, components and materials; related test gear; parts and components and specialized controls and accessories thereof.

* * * * *

Advisory Notes

1. * * *

2. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following machinery and equipment:

(a) Equipment for deposition of electronic grade polysilicon defined in paragraph (b)(1)(i);

(b) All types of crystal pullers defined in paragraphs (b)(1)(iii) (a) through (e), *except* those that are rechargeable without opening, magnetic, or computer-controlled;

(c) All types of diffusion furnaces deifined in paragraphs (b)(1)(iii) (a) through (e), *except* those types with computer feedback control;

(d) Vacuum induction-heated zone-refining equipment defined in paragraph (b)(1)(iii)(f);

(e) Manual types of magnetically-enhanced sputtering equipment defined in paragraph (b)(1)(vi);

(f) All types of equipment designed for ion implantation, or for ion-enhanced or photo-enhanced diffusion (paragraph (b)(1)(vii)), *except* those having raster scan techniques or an associated computer, or those introduced after January 1, 1980;

(g) All barrel or barrel/planer types of dry-etching equipment defined in paragraph (b)(1)(viii);

(h) Low pressure chemical vapor deposition equipment defined in paragraph (b)(1)(ix);

(i) All automatic wafer sawing equipment defined in paragraph (b)(1)(xi);

(j) Wafer surface finishing equipment defined in paragraph (b)(1)(xii) that is for lapping and single side polishing;

(k) Hard surface coated substrates defined in paragraph (b)(2)(ii) that are 5 x 5 inch or smaller;

(l) Computer-aided design (CAD) software for IC design defined in paragraph (b)(2)(iv) that has been previously approved for export to China;

(m) Photo-optical mask fabrication equipment defined in paragraph (b)(2)(v) that does not exceed the performance capabilities of U.S.-designed photolithographic step and repeat cameras and pattern generator systems introduced in volume into the market before December 31, 1976;

(n) Manual types of mask inspection equipment defined in paragraph (b)(2)(vi);

(o) Photo-optical Contact and Proximity mask align and expose equipment defined in paragraph (b)(2)(vii), and projection aligners that can produce useful pattern sizes no finer than 3 micrometers;

(p) Contact image transfer equipment defined in paragraph (b)(2)(x);

(q) Semiautomated types of digitally controlled wafer and chip inspection equipment defined in paragraph (b)(3);

(r) Auto wire and die bonders defined in paragraph (b)(4);

(s) Wafer probing equipment defined in paragraph (b)(5); and

(t) Analog test equipment TV circuits, OP AMPs and voltage regulators; A/D and D/A circuit test equipment; and digital test equipment with test data rates of 10 MHz or less defined in paragraph (b)(6)(ii).

61. Entry 1529A of Group 5 of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising Advisory Note 4 to read as follows:

1529A Electronic measuring, calibrating counting, testing, and/or time interval measuring equipment, whether or not incorporating frequency standards.

* * * * *

Advisory Notes

* * * * *

4. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following equipment:

(a) Frequency standards equipment defined in paragraph (a) for non-military configurations for quartz and rubidium and appropriate quantities of cesium standards to NBS-type users;

(b) Instruments defined in paragraph (b)(1) up to 40 GHz;

(c) Manual transfer oscillators and frequency converters defined in paragraph (b)(2) up to 40 GHz and comb frequency devices up to 12.5 GHz;

(d) Non-programmable network analyzers defined in paragraph (b)(3)(i) up to 40 GHz and programmable network analyzers up to 18 GHz;

(e) Direct impedence measuring devices defined in paragraph (b)(3)(iii) up to 18 GHz;

(f) Instruments defined in paragraph (b)(3)(iv) up to 18 GHz;

(g) Spectrum analyzers defined in paragraph (b)(4) employing FFT with realtime capability of calculating 512 complex lines in not less than 50 milliseconds and time compression instruments limited to 100 KHz and not capable of calculating complex lines;

(h) Instruments defined in paragraph (b)(5) with memories up to 64 Kbits;

(i) Equipment necessary for maintenance, repair and use of microcircuits and computers described by the Advisory Notes for the People's Republic of China in ECCNs 1564A, 4529A and 1565A;

(j) Digital counters defined in paragraph (c) that perform non-prescaled (direct) countings up to 550 MHz, or prescaled counting up to 1.5 GHz, and counters capable of measuring burst frequencies up to 200 MHz for a burst duration of more than 0.5 milliseconds;

(k) Time interval measuring equipment defined in paragraph (d) capable of measuring 10 nanosecond time intervals for single shot and 0.1

nanoseconds for averaging repetitive time intervals;

(l) Digital voltmeters defined in paragraph (f); and

(m) Transient recorders capable of sampling single input signals at successive intervals of not less than 20 nanoseconds.

62. Entry 4529B Group 5 of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by adding after the Technical Note an Advisory Note reading as follows:

4529B Other instruments, n.e.s. for measuring, indicating, recording, testing, or controlling electronic, electric, or nonelectric quantities that incorporate digital computers defined in ECCN 1565A, paragraphs (d) and (e); and parts and accessories, n.e.s. (Specify by name and model number.)

* * * * *

Technical Note

* * * * *

Advisory Note for the People's Republic of China: The criteria used to evaluate instruments with stand-alone or associated computers are the same as the criteria used to evaluate mainframe computers controlled by ECCN 1565A.

For instruments with embedded microprocessors, the computing facility will be evaluated under the criteria used to evaluate microcomputers controlled by ECCN 1565A.

63. Entry 1564A of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising Advisory Note 5 to read as follows:

1564A Electronic component assemblies, sub-assemblies, printed circuit boards, and microcircuits.

* * * * *

Advisory Note

* * * * *

5. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following equipment:

(a) Printed circuit boards and materials controlled by this ECCN 1564A;

(b) Microcircuits defined in (but not released by) paragraphs (c)(ii) (1), (2), (3), (6), (7), (9) through (20), (22) and (23);

(c) Microprocessors having a word size not exceeding 16 bits and a performance parameter fixed point processing data rate (XPDR) of 26.0 or less (see § 376.10(a)(4)(xxiv) for the definition of "fixed point processing data rate");

(d) Memories that are not specially designed to military standards to be radiation hardened or to operate over military temperature ranges, as follows:

Type	Memory size not exceeding
MOS DRAMS	64k bits.
MOS SRAMS	16k bits.
ROMs	64k bits.
UV EPROMS	64k bits.
EAROMS	16k bits.
E^2 ROMS	32k bits.

(e) All analog to digital and digital to analog converters that are not specially designed to military standards to be radiation hardened or to operate over military temperature ranges, as follows: Analog to digital converters with conversion time to maximum resolution greater than 500 nanoseconds, and digital to analog converters with greater than 500 nanoseconds (voltage) or greater than 25 nanoseconds (current) settling time;

(f) User reprogrammable single chip microcomputers;

(g) Operational amplifiers, sample and hold amplifiers and track and hold amplifiers with slew rates not exceeding 100V/microsecond, provided they are not specially designed to military standards to be radiation hardened or to operate over military temperature ranges;

(h) Microprocessor peripheral chips designed for use with microprocessors that are likely to be approved for export to China under this Advisory Note;

(i) Photo sensitive arrays, including charge-coupled devices (CCDs), not controlled by ECCN 1548A with 2048 elements or less;

(j) Other microcircuits manufactured before October 1, 1983, covered by ECCN 1564A and not included above.

(Unencapsulated monolithic integrated circuits will be considered for export on the same basis as equivalent encapsulated devices.)

64. Entry 1565A of Group 5 of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by removing the symbol "P" from the *Nuclear Non-Proliferation Controls* paragraph and from the NOTE (2 removals) following that paragraph, and by revising Advisory Note 11 to read as follows:

1565A Electronic computers and related equipment.

* * * * *

Advisory Notes

* * * * *

11. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following equipment:

(a) Digital computer systems that do not exceed the following technical limits:

PDR = 155 Mbits/second
Internal Memory = 72 Mbits
TEBTR = 48 Mbits/second
EBTR = 17 Mbits/second
Total Connected Net Capacity of Peripheral Memory Devices (Excluding Magnetic Tape Units) = 74,000 Mbits;

(b) Graphic displays exhibiting all of the following characteristics:

(1) Not exceeding 19 inch diagonal of viewing area,

(2) Not exceeding 1024 x 1024 displayable pixels or picture elements,

(3) Not exceeding 9 megabits of refresh memory, and

(4) Having not more than 256 shades of gray or color (8 bits per pixel);

(c) Plotters and digitizers of the following description:

(1) Having an accuracy not better than 0.002 inches and

(2) Having a table size not exceeding 100 inches x 100 inches;

(d) Array transform processors that meet either of the following requirements:

(1) Maximum rate of multiply operations less than or equal to 2 million per second; or

(2) Not less than 40 milliseconds for performing an FFT for 1024 complex points;

(e) Software that has been approved previously for export to the People's Republic of China and standard commercial packages for business applications, for example:

(1) Operating systems for transaction processing and real time updating,

(2) Relational database management systems; and

(f) 8-bit and 16-bit home, personal and small business microcomputers having a fixed point processing data rate (XPDR) of 26.0 or less, and equipped with peripherals that are standard and normally supplied with the microcomputer (see § 376.10(a)(4)(xxiv) for the definition of "fixed point processing data rate").

65. Entry 1572A of Group 5 of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising Advisory Note 5 to read as follows:

1572A Recording and/or reproducing equipment.

* * * * *

Advisory Notes

* * * * *

5. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following equipment:

(a) Equipment defined in paragraph (c) that are galvanometer-based recorders not incorporating a cathode-ray tube with a fiber optic faceplate;

(b) Equipment defined in paragraph (d) that is specifically designed for tape verification or certification, provided the machines are not designed for certifying high resolution tape; (High resolution tape is tape having 10,000 bits-per-inch (BPI). For analog systems, high resolution tapes refer to tapes having a coating thickness of 120 micro inches or smaller, such as those intended for use with 1-MHz bandwidth instrumentation recorders.)

(c) Analog magnetic instrumentation recorders having bandwidths up to 2-Megahertz for quantities less than ten, and for end uses/end-user types previously approved;

(d) Instrumentation digital recorders (cartridge or cassette) normally incorporated in (equipment and using a quarter-inch tape and having a packing density of 1600 bits-per-inch per channel or less, and having up to four channels;

(e) Magnetic tape designed and appropriate for use with magnetic tape recorders likely to be approved for export to China under this Advisory Note;

(f) Discs for drives designed for equipment likely to be approved for export to China under this Advisory Note; and

(g) Spare parts to support previously-approved seismic recorders, except that a one-for-one exchange is required on critical parts (*e.g.*, servos, heads, basket motors).

66. Entry 1584A of the Commodity Control List (Supplement No. 1 to § 399.1) is amended by revising Advisory Note 2 to read as follows:

1584A Cathode-ray oscilloscopes, and specialized parts * * * therefor including associated plug-in units, external amplifiers, and pre-amplifiers and sampling devices.

* * * * *

Advisory Notes

* * * * *

2. *Note for the People's Republic of China:* Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of the following equipment:

(a) Cathode-ray oscilloscopes having an amplifier bandwidth up to and including 250 MHz;

(b) Cathode-ray oscilloscopes having an amplifier bandwidth between 250 MHz and 350 MHz, provided that the time-base linearity is not better than 2 percent and the end-user/end-use is not nuclear-related;

(c) Cathode-ray tubes having an amplifier bandwidth up to and including 350 MHz, for use only as replacements in previously-approved instruments;

(d) Instruments with characteristics described in paragraph (e) having an effective bandwidth of not more than 5,000 MHz; and

(e) Digital oscilloscopes capable of sampling the input signal at an interval not less than 40 nanoseconds (25 MHz).

Authority: Secs. 203, 206, Pub. L. 95-223, Title II, 91 Stat. 1626, 1628, 50 U.S.C. 1702, 1704; EO 12444 of Oct. 14, 1983 (48 FR 48215, October 18, 1983).

Dated: November 18, 1983.

John K. Boidock,

Director, Office of Export Administration, International Trade Administration.

[FR Doc. 83-31638 Filed 11-22-83; 8:45 am]

BILLING CODE 3510-DT-M

federal register

Wednesday
November 23, 1983

Part VII

Architectural and Transportation Barriers Compliance Board

Authorities and Delegations; Final Rule

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1153

Authorities and Delegations

AGENCY: Architectural and Transportation Barriers Compliance Board (ATBCB).

ACTION: Final rule: Authorities and delegations.

SUMMARY: The Architectural and Transportation Barriers Compliance Board at its July 12, 1983, meeting adopted Authorities and Delegations which set forth the duties and responsibilities of the ATBCB and the ATBCB Chairperson, Vice Chairperson, Executive Director, General Counsel and Committees. The Authorities and Delegations further provide for designation of an Equal Employment Opportunity Director, Chief Procurement Officer and Freedom of Information Officer and require maintenance of records of all delegations. The Authorities and Delegations were issued to clearly delineate the responsibilities and authorities of the above listed officials and are being published so that all affected persons will be fully informed about the responsibilities and authorities of ATBCB officials.

EFFECTIVE DATE: July 12, 1983.

FOR FURTHER INFORMATION CONTACT: Ms. Laurinda Steele, Office of Administration and Management, Architectural and Transportation Barriers Compliance Board, 330 C Street SW., Washington, D.C. 20202, Phone (202) 245-1801 voice or TDD.

SUPPLEMENTARY INFORMATION: Pursuant to Section 502 of the Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 391, as amended, The Architectural and Transportation Barriers Compliance Board (ATBCB or Board) adopted Authorities and Delegations at its July 12, 1983, meeting. This document sets forth the authority, responsibilities and duties of the Board; sets forth the duties and responsibilities of the Board Chairperson and delegates to the Chairperson the authority to carry out those duties and responsibilities; provides in the absence, death or disqualification of the Chairperson that the Vice Chairperson shall have the duties and powers of the Chairperson; sets forth the duties, responsibilities and authority of the ATBCB Executive Director; sets forth procedures for selection of and the duties and responsibilities of the ATBCB General Counsel; and states the duties and responsibilities of ATBCB Committees.

With respect to procurement, the Authorities and Delegations document provides for designation of a Chief Procurement Officer and sets forth his or her duties and responsibilities to be carried out under the ATBCB Federal Procurement Policies, 36 CFR 1151.4 as amended July 12, 1983.

With respect to Equal Employment Opportunity (EEO) responsibilities, the Authorities and Delegations provide for designation of an EEO Director and give the Chairperson the responsibility to make final decisions on EEO complaints.

Section 1153.9 designates the Executive Director as Freedom of Information Officer to carry out the Board's responsibilities under the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552, and the Board's FOIA regulations, 36 CFR Part 1120.

Finally, § 1153.10 requires that all delegations be in writing and that the Executive Director maintain a file of all such delegations.

The Authorities and Delegations also set forth the procedure to be followed when the Board receives requests to participate in litigation as *amicus curiae*. This procedure amends the existing *amicus curiae* policy of the Board set out at 36 CFR 1151.2, which is specifically amended in the **Federal Register** by separate document.

List of Subjects in 36 CFR Part 1153

Authority delegations, Archives and records, Consultants, Equal employment opportunity, Freedom of information, Government procurement, Handicapped, Organization and functions.

For the reasons stated in the preamble, Chapter XI of Title 36, Code of Federal Regulations, is amended by the addition of Part 1153, as set forth below.

PART 1153—AUTHORITIES AND DELEGATIONS

Sec.

1153.1 The Board.
1153.2 Chairperson.
1153.3 Vice Chairperson.
1153.4 Executive Director.
1153.5 General Counsel.
1153.6 Committees of the Board.
1153.7 Chief Procurement Officer.
1153.8 Equal Employment Opportunity.
1153.9 Freedom of Information Officer.
1153.10 Delegations Records.

Authority: 29 U.S.C. 792, Pub. L. 93-112, as amended by Pub. L. 95-602.

§ 1153.1 The Board.

The Board is the governing body of the agency. The composition of the Board and its functions are established by Section 502 of the Rehabilitation Act of 1973. The Board has the following duties and responsibilities, including:

(a) To carry out its responsibilities under Section 502 of the Rehabilitation Act of 1973, as amended. In carrying out these responsibilities, the Board may hold public hearings throughout the country.

(b) To establish policies and issue regulations in accordance with its statutory mandate.

(c) To resolve issues that are within its jurisdiction.

(d) To determine and adopt a contracting and procurement policy for the agency. In carrying out this responsibility, the Board will enter into contracts only in accordance with its contracting and procurement policy, published in the **Federal Register.**

(e)(1) To effect the prompt and efficient disposition of all matters within its jurisdiction. In carrying out this responsibility, the Board may, in accordance with Article VI of its Statement of Organization and Procedures:

(i) By majority vote delegate to the Executive Committee authority to implement its decisions.

(ii) By two-thirds vote delegate to the Executive Committee any other of its authorities, to the extent permitted by law.

(iii) To the extent permitted by law, delegate other duties to its officers, committees, or staff by a vote of two-thirds of the membership of the Board at the time the vote is taken.

(2) A separate delegation is necessary for each action the Board desires the Executive Committee to implement. Unless so permitted in the original delegation, an officer, committee, or staff person shall not redelegate authority.

(f) To make to Congress, at the end of each fiscal year, an annual report of the Board's activities during that fiscal year. The annual report shall include such material as it is required by law to include and such other material as the Board may decide.

(g) To make to the President and Congress such other reports as it is required by law to make, and such recommendations as it considers necessary or desirable to eliminate environmental barriers confronting handicapped individuals.

(h) To allocate funds appropriated by the Congress for such activities as conducting investigations and surveys, initiating public hearings, collecting data on past and current studies, and providing stenographic or other services.

as necessary, appropriate, and in accordance with law.

(i) To determine the jurisdiction of each standing committee of the Board.

§ 1153.2 Chairperson.

The Chairperson has the following duties and responsibilities:

(a) To coordinate and organize the work of the Board in such a manner as to promote the prompt and efficient disposition of all matters within the jurisdiction of the Board. In carrying out these responsibilities, the Chairperson is delegated the authority to:

(1) Supervise the Executive Director.

(2) Direct the Executive Director concerning appropriate action to implement decisions of the Board.

(3) Evaluate the Executive Director's performance.

(4) Authorize domestic travel for the Executive Director, which authority may be delegated, and authorized foreign travel for staff, Board members and the Executive Director, which authority may not be delegated.

(5) Make necessary administrative decisions for the agency and direct the Executive Director concerning implementation of such decisions during periods when the Board is not in session.

(6) Review and approve publication of the Board newsletter and press releases which contain expressions of Board policy.

(7) Appoint members and Chairpersons to the Board's subject matter committees, and appoint the Chairperson of the Executive Committee.

(8) Nominate one or more Board members to serve, with their consent, at each public hearing which may be held by the Board.

(9) Request from departments or agencies represented on the Board such technical, administrative, or other assistance as may be required to carry out the Board's activities.

(b) To preside at all meetings and sessions of the Board.

(c) To represent the Board in all matters relating to congressional testimony and legislative reports. However, any other Board member may present his or her own or minority views on supplemental reports.

(d) To represent the Board in all matters involving submissions of comments on agencies' proposed regulations and responses to published directives of the Office of Management and Budget.

(e) To represent the Board as head of the agency whenever an applicable Federal statute or regulation imposes a duty, or grants a right or authority to the head of the agency. The Chairperson may designate only another member of the Board or the Executive Director to act as head of the agency for a specific purpose.

(f) To call a special meeting of the Board at the request of the Executive Committee, to take action on a request to the Board to enter litigation as *amicus curiae*.

(g) To carry out other duties and responsibilities as may be delegated by the Board.

§ 1153.3 Vice Chairperson.

The Vice Chairperson, shall, in the absence of the Chairperson from a Board meeting, or in the event of his or her death or disqualification, perform the duties and exercise the powers of the Chairperson, and shall generally assist the Chairperson and perform such other duties, as may be directed by the Chairperson or the Board.

§ 1153.4 Executive Director.

The Executive Director is appointed by the Board and is responsible to the Board under the supervision of the Chairperson. He or she has the following duties and responsibilities:

(a) To assist the Chairperson in carrying out the administrative and executive responsibilities of the Chairperson as the administrative head of the agency and, in connection therewith, to plan, direct, coordinate and manage the administrative affairs of the Board. In carrying out these responsibilities, the Executive Director may exercise authority delegated to him or her in accordance with the Board's contracting and procurement policy published in the **Federal Register**. In addition, the Executive Director is delegated the authority to:

(1) Authorize travel expenses for consultants, specialists, experts, witnesses, and other persons whose presence is deemed essential for attendance at Board meetings, hearings, advisory committee meetings or other functions of the Board.

(2) Reimburse members of the Board who are not regular full-time employees of the United States for travel, subsistence, and other necessary expenses incurred in carrying out their duties.

(b) To recommend to the Executive Committee matters that should be considered by the Board or any of its designated committees.

(c) To review with the Board and with heads of the several units and offices, the program and procedures of the Board and to make recommendations thereon as may be necessary to administer Section 502 of the Rehabilitation Act of 1973 most effectively in the public interest.

(d)(1) To provide sustained administrative leadership and management of staff activities in carrying out the policies and decisions of the Board through overall supervision and coordination of such staff. Supervision and assignment of all staff employees includes:

(i) The promoting, firing, reassigning, training, and detailing of employees.

(ii) Approval of performance evaluations.

(iii) Advance approval of work activities which are outside the normal scope of the employee's job duties.

(iv) The utilization and assignment of staff in support of any Board member or Board committee.

(v) All other utilization and assignment of staff.

(2) In carrying out these responsibilities, the Executive Director is delegated the authority to:

(i) Hire all subordinate personnel to fill vacancies on the Board staff. The General Counsel shall be nominated by the Executive Director and confirmed by the Board. Division directors shall be appointed by the Executive Director after he or she consults with the Executive Committee.

(ii) Authorize domestic travel for all staff. All travel for Board staff shall be authorized in advance.

(e) To designate appropriate staff to assist a Board committee or member, to the extent feasible. In carrying out this responsibility, the Executive Director may consult with the Chairperson to determine whether a request for staff support should be met.

(f) To direct compliance and enforcement activities in accordance with the procedures set forth in 36 CFR Part 1150 including:

(1) Issuing citations and determinations not to proceed.

(2) Conducting negotiations for compliance, and entering into agreements for voluntary compliance.

(3) All other actions authorized by law pertaining to compliance and enforcement not otherwise reserved to the Board by 29 U.S.C. 792.

(4) Issuing staff manuals to provide guidance to staff in interpreting the Architectural Barriers Act of 1968 and Section 502 of the Rehabilitation Act of 1973, as amended, and standards and guidelines issued pursuant to those Acts. Positions taken in any such manuals will not be inconsistent with established Board policy, administrative and court rulings, to the maximum extent possible. The manuals will be for staff guidance

and will only be available to the public upon request.

(g) To direct and supervise the development and execution of routine technical assistance and public information programs, as authorized by law. These activities may be carried out in cooperation with state and local government units, other Federal agencies, and interested consumer groups. Public information program initiatives other than routine program activities shall be approved by the Board in advance.

(h) To maintain ongoing liaisons with constituency groups and other organizations, and with staff of interested Congressional committees to keep them informed of general Board policy and activities, and to obtain information for use by the Board in formulating policy, developing budget requests and drafting recommended legislative changes. This does not include expressing any position or working to support or oppose anything relating to pending legislative or Board matters unless approved in advance by the Board. Where, in the judgment of the Executive Director, there is insufficient time to obtain Board approval of a response to a request concerning a position on pending legislative matters, the Chairperson may approve the response. The Executive Director shall furnish a copy of any written response and a full report on any oral or written response to all Board members.

(i) To provide special administrative assistance to the Board at the request of the Chairperson.

(j) To direct investigation and research of initiatives submitted by staff or Board members regarding technical assistance or other Board functions.

(k) To make and implement changes in the functional organization of the Board staff offices, following a disclosure to the Board of the nature of and reasons for the changes.

(l) To submit bi-weekly reports to the Chairperson.

(m) To incorporate proposed revisions in the minutes if corrections or additions have been submitted, and present both the original and the corrected minutes to the Board for full approval. The Executive Director shall distribute the approved minutes within ten (10) days after approval to: (1) Board members; (2) the House Education and Labor Committee, the House Public Works and Transportation Committee, the Senate Labor and Human Resources Committee, and the Senate Environment and Public Works Committee; and make minutes available to others upon request.

(n) To refer correspondence received by the Board which involves a specific department or agency, to that department or agency for reply.

(o) To account to the Board for the administration of program expenditures and keep records which disclose disposition of any funds and the nature and extent of the Board's activities.

(p) To report semi-annually, in writing, to the Board on each procurement regardless of amount entered into to date in the fiscal year, listing each procurement separately with its amount and date. In addition, the report shall list all procurements then in progress that have not been awarded and any procurements being considered for any future time.

(q) To maintain and keep current a separate file containing all delegations of authority, which shall be in writing, and provide copies of all delegations to the Board as they occur.

§ 1153.5 General Counsel.

The General Counsel is nominated by the Executive Director and confirmed by the Board. He or she is responsible to the Board under the supervision of the Executive Director. The General Counsel has the following duties and responsibilities:

(a) To coordinate and organize the work of the legal staff in order to provide prompt and comprehensive legal advice to the Board.

(b) To provide legal interpretation of statutes, regulations, and rules of procedure for the Board's consideration.

§ 1153.6 Committees of the Board.

(a) *Executive Committee.* The Executive Committee has the following duties and responsibilities:

(1) To report directly to the Board on matters submitted to it by members and subject matter committees, and all other matters that are within its jurisdiction.

(2) To review and consider recommendations and proposals from the various subject matter committees, and take appropriate action thereon. This may result in placing a proposal on the Board agenda for Board action, referring it back to the subject matter committee for further refinement of its proposal or revision of its reports, or referring it to another committee for appropriate actions.

(3) To issue recommendations to the Board concerning proposals on the agenda.

(4) To place items of business on the Board's agenda.

(5) To ensure the orderly functioning of the committees' work and the process for reviewing matters that are proposed for the Board's consideration.

(6) To assist the Chairperson in other circumstances at his or her request.

(7) To arrange joint meetings among the appropriate subject matter committees whenever two or more committees have jurisdiction over a matter, or other related responsibilities.

(8)(i) To review requests to the Board to enter litigation as *amicus curiae.*

(ii) In carrying out these responsibilities, the Executive Committee is delegated the authority to disapprove such requests and make recommendations to the Board to approve such requests. Board approval shall be required prior to any *amicus* filing. The Committee may request the Chairperson of the Board to call a special meeting of the Board to expedite Board action on the Committee's recommendations.

(9) To review and make recommendations to the Board to amend or approver the Board's statement of organization and procedures, formal policy statements, and authorities and delegations.

(10) To carry out other duties and responsibilities as may be duly delegated by the Board.

(b) *Subject Matter Committees.* Each subject matter committee studies and reports to the Executive Committee on matters that are within the subject matter committee's province, and has the following duties and responsibilities:

(1) To review and consider recommendations or proposals submitted by Board members, committees, and other individuals and entities.

(2)(i) To identify issues and develop policy recommendations for review by the Executive Committee. This includes further refinement of matters that are referred from the Executive Committee, and submission of reports containing recommendations or proposals on which action is to be taken by the Board.

(ii) In carrying out these responsibilities, each subject matter committee is delegated the authority to arrange briefings, reports, and research by designated staff, experts, or Federal member agency staff through requests to the Chairperson or Executive Director, whichever is appropriate.

(3) To formulate and present projections of matters to be undertaken by the committee to the Planning and Budget Committee.

(4) To project and formulate the need for staff assistance in performing the committee's functions.

(5) To report, at the direction of the Chairperson of the Board or the committee, the status of matters that are

within the committee's particular jurisdiction.

(6) To advise the Executive Committee to forward materials originating within the subject matter committee to other committees with jurisdiction over the matter involved.

(c) *Special Committees.* A Special Committee has the duties and responsibilities specified by its creator, who shall report the names of its members and chairperson to the Chairperson of the Board.

§ 1153.7 Chief Procurement Officer.

The Chief Procurement Officer is designated by the Head of the Procuring Activity in accordance with the Board's contracting and procurement policy published in the **Federal Register.** He or she has the following duties and responsibilities:

(a) To ensure that staff is provided with equipment and other basic supplies and services that are necessary to perform their duties.

(b) To report to the Head of Procuring Activity in all other matters pertaining to the agency's needs for supplies and services.

§ 1153.8 Equal Employment Opportunity.

(a) The Director of Equal Employment Opportunity (EEO Director) is designated by the Executive Director. The EEO Director has the responsibility, on a collateral duty basis, to carry out the functions of the EEO Director, Federal Women's Program Coordinator, Hispanic Employment Program Manager, and Handicap Program Coordinator, in accordance with regulations of the Equal Employment Opportunity Commission.

(b) For the purposes of 29 CFR 1613.221, the Chairperson shall make the final decision of the Board on a complaint based on information in the complaint file. The Chairperson may designate another Board member to discharge this responsibility. A person designated to make the decision for the head of the agency shall be one who is fair, impartial and objective.

§ 1153.9 Freedom of Information Officer.

(a) The Board has the responsibility to disseminate information on matters of interest to the public and to disclose on request all information contained in records in its custody insofar as is compatible with the discharge of its responsibilities and consistent with the Freedom of Information Act, as amended, 5 U.S.C. 552 and the Board regulations "Public Availability of Information" (36 CFR Part 1120).

(b) The Board designates the Executive Director as the Freedom of Information (FOI) Officer. The FOI Officer has the responsibility for implementing policies and procedures to ensure compliance with the requirements of the Freedom of Information Act and the Board regulations. The Executive Director may delegate that responsibility.

§ 1153.10 Delegations Records.

All delegations authorized by these Authorities and Delegations shall be made in writing. Records of all such delegations will be maintained by the Executive Director in a separate file.

Dated: October 27, 1983.

Wm. Bradford Reynolds,

Chairperson.

[FR Doc. 83-29808 Filed 11-22-83; 8:45 am]

BILLING CODE 6820-BP-M

Reader Aids

Federal Register

Vol. 48, No. 227

Wednesday, November 23, 1983

INFORMATION AND ASSISTANCE

PUBLICATIONS

Code of Federal Regulations

CFR Unit	202-523-3419
	523-3517
General information, index, and finding aids	523-5227
Incorporation by reference	523-4534
Printing schedules and pricing information	523-3419

Federal Register

Corrections	523-5237
Daily Issue Unit	523-5237
General information, index, and finding aids	523-5227
Privacy Act	523-4534
Public Inspection Desk	523-5215
Scheduling of documents	523-3187

Laws

Indexes	523-5282
Law numbers and dates	523-5282
	523-5266
Slip law orders (GPO)	275-3030

Presidential Documents

Executive orders and proclamations	523-5233
Public Papers of the President	523-5235
Weekly Compilation of Presidential Documents	523-5235

United States Government Manual	523-5230

SERVICES

Agency services	523-5237
Automation	523-3408
Library	523-4986
Magnetic tapes of FR issues and CFR volumes (GPO)	275-2867
Public Inspection Desk	523-5215
Special Projects	523-4534
Subscription orders (GPO)	783-3238
Subscription problems (GPO)	275-3054
TTY for the deaf	523-5229

FEDERAL REGISTER PAGES AND DATES, NOVEMBER

50295-50500 1
50501-50698 2
50699-50874 3
50875-51140 4
51141-51274 7
51275-51424 8
51425-51604 9
51605-51764 10
51765-51902 14
51903-52024 15
52025-52280 16
52281-52428 17
52429-52564 18
52565-52686 21
52687-52866 22
52867-53078 23

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month, the Office of the Federal Register publishes separately a list of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

1 CFR

3 52265

3 CFR

Administrative Orders:

Notices:

November 4, 1983 51277

Presidential Determinations:

No. 83-10 of September 30, 1983 51607

Executive Orders:

April 15, 1910 (Revoked in part by PLO 6487) 50894

July 2, 1910 (See PLO 6487)

December 28, 1910 (Revoked in part by PLO 6487) 50894

January 24, 1914 (Revoked in part by PLO 6487) 50894

7594 (Revoked in part by PLO 6489) 50895

12170 (Continued by Notice of November 4, 1983) 51277

12433 (Amended by EO 12449) 52687

12448 51281

12449 52687

Proclamations:

2417 (See PLO 6489) 50895

5123 50699

5124 51275

5125 51279

5126 51425

5127 51605

5 CFR

301 52867

315 52867

316 52867

534 52025

7 CFR

2 ..... 50875, 51141

29 50501

371 50295

905 51765

906 50501

907 ..... 51609, 52466

910 ..... 50701, 50877, 51634, 52281, 52429, 52869

927 52027

931 52027

966 52027

971 52027

989 52028

1125 52869

1131 52429

1133 52869

1290 51427

1421 51765

1805 52565

1809 52565

1872 52565

1910 52565

1943 52565

1944 52565

1951 52565

1955 52565

1962 52565

1965 52565

Proposed Rules:

6 52926

42 51635

225 50743

400 51635

424 52067

434 52467

435 52314

436 51638

438 52471

1006 52318

1012 52318

1036 50549

1290 52071

1488 51490

1910 ..... 51312, 52931

1924 ..... 51312, 52931

1930 ..... 51312, 52931

1941 ..... 51312, 52931

1945 ..... 51312, 52931

8 CFR

3 52432

100 52029

103 ..... 51142, 51430

109 51142

204 52689

214 ..... 51283, 52432

238 ..... 51431, 52029

9 CFR

81 ..... 51422, 52420, 52885

91 52689

92 ..... 50701, 52030, 52691

317 52692

318 52692

319 52692

327 50296

Proposed Rules:

201 52474

203 52474

10 CFR

2 52282

50 50878

71 51903

95 51903

761 50296

Proposed Rules:
Ch. I 52931
2 50550
50 50746
51 50746
211 ..... 50824, 52581
440 51068

11 CFR

110 52567
114 ..... 50502, 52432

12 CFR

Ch. VII 52568
7 52567
26 50296
28 52567
30 51283
212 50296
220 51768
330 52030
348 50296
563f 50296
711 50296
Proposed Rules:
Ch. III 50746
304 51155
330 50339
336 51317
337 50339
349 51155
563 51270
564 50339
571 51270
701 52475
744 52588

13 CFR

Proposed Rules:
111 51642

14 CFR

39 ..... 50508, 50879-50886, 51287, 51431, 51432, 52287, 52570-52574
71 ..... 50510, 50887, 51433-51436, 51903-51905, 52287, 52288, 52575, 52698
73 ..... 52287, 52698
75 ..... 50510, 52288, 52699
91 50510
97 ..... 50512, 51609
159 51416
211 51288
316 52887
385 ..... 51144, 52889
Proposed Rules:
Ch. I 50553, 52480
21 52010
23 52010
36 52010
39 ..... 50341, 50899, 52319, 52321
71 ..... 52322, 52323, 52749
73 52749
91 52010
135 52010
380 50900
399 50900
1214 52480

15 CFR

17a 52289
19 52289
30 52700
368 53064
369 52291
370 53064
371 53064
372 53064
373 53064
374 53064
375 53064
376 53064
379 53064
385 53064
386 53064
399 53064
Proposed Rules:
806 52591

16 CFR

3 52576
13 ..... 50702-50704, 51768, 51769
305 52291
1017 50514
1406 ..... 50705, 52889

17 CFR

15 52701
17 52701
18 52701
33 51288
145 50887
200 52576
211 51769
230 52889
270 52433
275 50526
Proposed Rules:
3 50554
10 50554
230 ..... 51155, 51328
240 51930

18 CFR

157 51436
271 ..... 51446, 52031
Proposed Rules:
271 ..... 52482, 52483, 52592-52594

19 CFR

12 52435
111 51288
162 52897
191 52031
Proposed Rules:
10 50342
19 50342
24 50342
113 50342
125 50342
141 ..... 50342, 52596
142 50342
143 50342
144 50342
146 50342
151 51784

20 CFR

200 51447
202 51447
250 51447
259 51447
260 51447
262 51447
350 51447
362 51447
363 51447
396 50308
602 50662
603 50662
604 50662
621 50527
626 52437
651 50662
652 50662
653 ..... 50527, 50662
654 50527
655 50527
656 50527

21 CFR

5 50527
12 51770
74 ..... 50311, 51145
81 ..... 50311, 51145
82 ..... 50311, 51145
133 51906
136 51448
172 ..... 51906, 52899
176 51770
178 51611
182 ..... 51146-51151, 51612-51615, 51906-51910, 52032, 52438-52445
184 ..... 51146-51151, 51612-51617, 51906-51911, 52032, 52438-52447
193 ..... 50528, 51453, 52902
430 51290
436 ..... 51290, 51292, 51912
440 ..... 51292, 51294
442 51292
446 ..... 51290, 51292
448 51292
449 51292
450 51912
452 51292
510 52448
520 50528
522 50887
546 51292
558 50707
561 ..... 50528, 51453, 52902, 52917
876 53012
890 53032
Proposed Rules:
161 51932
182 52323
184 52323
207 50358
210 50358
225 50358
226 50358
341 52079
436 52750
442 52750
501 50358
510 50358
514 50358
558 ..... 50358, 52597
1304 51329

22 CFR

514 50707

23 CFR

650 52292
Proposed Rules:
Ch. 1 51330

24 CFR

26 51295
200 51295
203 ..... 51295, 51455
205 51295
207 ..... 51295, 51455
213 ..... 51295, 51455
215 51619
220 51455
221 ..... 51295, 51455, 51619
232 ..... 51295, 51455
234 51455
236 ..... 51455, 51619
241 ..... 51295, 51455
242 ..... 51295, 51455
244 ..... 51295, 51455
570 51295
841 52297
883 51296
885 50888
890 51619
Proposed Rules:
202 52931
571 51935
865 51785
868 52934
880 52936
881 52936
883 52936
884 52936
885 52941
886 52936
888 52936
899 52936

25 CFR

700 51771

26 CFR

1 ..... 50711, 52033, 52903
4 52033
5 52903
35a 52033
Proposed Rules:
1 ..... 50751, 51330, 51331, 51645, 51788, 51936, 51940, 52079-52087, 52484, 52943
5 52943
5c 51645
6a 50751
11 52081
13 ..... 50567, 51788, 52081
52 50775
301 ..... 51788, 52087

27 CFR

9 52577
178 52908
Proposed Rules:
4 ..... 51333, 52088
9 52597

28 CFR

0 ..... 50712, 50713, 52449
3 50713
8 50713
9 50713
9a 50713
547 50478
548 50478
Proposed Rules:
16 52752

29 CFR

1 50312

4 ... 50529
5 ... 50312
220 ... 52854
1601 ... 51772, 52579
1910 ... 51086

Proposed Rules:
1908 ... 50902
2623 ... 52752

30 CFR
916 ... 52297
913 ... 51619
936 ... 52298
948 ... 52034

Proposed Rules:
901 ... 51941
915 ... 51457
917 ... 52333
920 ... 51158
926 ... 51334
934 ... 51458, 51459
942 ... 51335, 51461, 51646
948 ... 52092
950 ... 51465

31 CFR

Proposed Rules:
209 ... 52603
210 ... 52603

32 CFR
150 ... 51467
199 ... 52910

Proposed Rules:
1-39 ... 50872
95 ... 51490
505 ... 50775

33 CFR
90 ... 51621
165 ... 50714, 51622

Proposed Rules:
110 ... 50359, 50360
117 ... 52334

34 CFR
222 ... 52579

35 CFR
111 ... 52703
133 ... 51472

36 CFR
223 ... 50889
1151 ... 52910, 52911
1153 ... 53074

Proposed Rules:
7 ... 52484

38 CFR
3 ... 50313
17 ... 51913
21 ... 50529
36 ... 51152

Proposed Rules:
18 ... 52485
21 ... 50568, 50569

39 CFR
111 ... 52054, 52300
601 ... 50889
3001 ... 50715, 51337

Proposed Rules:
111 ... 52753

40 CFR
35 ... 51400
51 ... 50686
52 ... 50530, 50568, 51153, 51472, 51480, 51622, 51942, 51944, 52054, 52055, 52302, 52450, 52451, 52712-52716
80 ... 50482
81 ... 50316, 52057
86 ... 52170
120 ... 51400
123 ... 51298
131 ... 51400
180 ... 50317, 50532, 50533, 51485-51487, 52304, 52912, 52914
228 ... 50317
265 ... 52718
271 ... 50889, 52720, 52915
420 ... 51773
434 ... 50321
439 ... 50322
465 ... 52380
468 ... 50717
761 ... 52304

Proposed Rules:
52 ... 51159, 51338, 51339, 51794, 52093, 52094, 52491, 52753
60 ... 50670, 51900
61 ... 51064
81 ... 50361, 51160, 52094
85 ... 50902
122 ... 52279
133 ... 52258, 52272
180 ... 50363, 52097, 52950, 52951
271 ... 50776, 52754, 52952
403 ... 51647
415 ... 52953
420 ... 51647
421 ... 50906, 52604
461 ... 52604
464 ... 52604
471 ... 52604
761 ... 50486, 52402, 52953

41 CFR
Ch. 7 ... 51488
5-2 ... 51299
5-3 ... 51299
5-16 ... 51299
101-36 ... 50890
101-47 ... 50892

Proposed Rules:
1-15 ... 50873
3-1 ... 51648

42 CFR

Proposed Rules:
36 ... 52410
55a ... 50363
71 ... 50777

43 CFR

Public Land Orders:
422 ... 51153
2249 (Revised in part by PLO 6489) ... 50895
6439 ... 50719
6440 ... 50893
6477 ... 50322
6481 ... 51914
6485 ... 50893
6486 ... 50894
6487 ... 50894
6488 ... 50895
6489 ... 50895
6490 ... 50896
8360 ... 52058

44 CFR
64 ... 51914, 52058, 52722
67 ... 50719, 52722
205 ... 51056

Proposed Rules:
67 ... 50366, 50777, 50778, 51945, 52608, 52953
151 ... 50778

45 CFR
96 ... 52059
302 ... 51916
681 ... 52731
684 ... 52731
801 ... 50721

Proposed Rules:
1076 ... 51760

46 CFR
2 ... 50996
31 ... 50996
32 ... 50996
35 ... 50996
37 ... 50996
42 ... 50996
46 ... 50996
56 ... 50996
71 ... 50996
72 ... 50996
73 ... 50996
74 ... 50996
75 ... 50996
78 ... 50996
79 ... 50996
91 ... 50996
93 ... 50996
97 ... 50996
99 ... 50996
106 ... 50996
107 ... 50996
108 ... 50996
109 ... 50996
111 ... 50996
151 ... 50996
153 ... 50996
154 ... 50996
163 ... 50996
167 ... 50996
168 ... 50996
170 ... 50996
171 ... 50996
172 ... 50996
173 ... 50996
174 ... 50996
177 ... 50996
178 ... 50996
179 ... 50996
185 ... 50996
189 ... 50996
190 ... 50996
191 ... 50996
196 ... 50996

Proposed Rules:
10 ... 51650
35 ... 51650
50 ... 50781
52 ... 50781
53 ... 50781
54 ... 50781
63 ... 50781
157 ... 51650
162 ... 50781
175 ... 51650
185 ... 51650
186 ... 51650
187 ... 51650

47 CFR
1 ... 51917
2 ... 50322, 50722, 50897, 51302
5 ... 52733
17 ... 51917
18 ... 51302
21 ... 50322, 50722, 50897
22 ... 50722
23 ... 50722
31 ... 50534, 51154
61 ... 51773
63 ... 52452
64 ... 51773
73 ... 51304, 51623-51627, 51775, 52305
74 ... 50322, 50722, 50897
78 ... 50722
81 ... 50548, 50722
83 ... 50548, 50739
87 ... 50548, 50722, 52464
90 ... 50722, 51917
94 ... 50322, 50722, 50897
97 ... 51917

Proposed Rules:
Ch. I ... 51340
1 ... 51493, 52492
22 ... 51493
61 ... 52492
64 ... 51650
73 ... 50571-50585, 50907 51161, 51652-51663, 52335-52337

48 CFR

Proposed Rules:
5 ... 50907

49 CFR
1 ... 52678
171 ... 50440, 50444
172 ... 50440, 50444, 52306
173 ... 50440, 50444, 52306
174 ... 50440, 50444
175 ... 50444
176 ... 50440
177 ... 50440
178 ... 50440
179 ... 50440
301 ... 52678
387 ... 52679
509 ... 51310
567 ... 51308
571 ... 52061
660 ... 52313
661 ... 52313
831 ... 52739
845 ... 52739
1003 ... 51777
1033 ... 52918
1039 ... 50897, 51311
1043 ... 51777
1084 ... 51777
1118 ... 51627, 52465
1162 ... 51627, 52465

1163.....51627, 52465
1175.....52066
1176.....52066
1180.....52920
Proposed Rules:
Ch. X.....51664
192.....50908
571.....51795, 52098
1162.....51796

50 CFR

17.....52740, 52743
20.....52747
645.....52066
648.....52066
663.....51782
681.....52922
Proposed Rules:
17.....50909, 51736, 52608, 52611
450.....52099
451.....52099
452.....52099
453.....52099
611.....50379, 50586, 50782 52338
649.....52616
665.....51797
672.....50379
675.....50586

LIST OF PUBLIC LAWS

Last Listing November 22, 1983

This is a continuing list of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-275-3030).

H.R. 3348/Pub. L. 98-159

To honor Congressman Leo J. Ryan and to award a special congressional gold medal to the family of the late Honorable Leo J. Ryan. (Nov. 18, 1983; 97 Stat. 992) Price: $1.50