

8-28-79
Vol. 44 No. 168
Pages 50323-50572

Federal Register

Tuesday
August 28, 1979

Highlights

- 50363 Employee Benefit Plans** Labor/P&WBP proposes regulations relating to definition of plan assets and to establishments of trust; comments by 10-29-79
- 50367 Employee Benefit Plans** Labor/P&WBP proposes regulation relating to exemption under Employee Retirement Income Security Act of 1974 for certain acquisitions, sales or leases of property, comments by 10-29-79
- 50558 Labor Organizations in the Federal Sector** Labor/Office of the Assistant Secretary for Labor—Management Relations proposes rules on standards of conduct; comments by 10-29-79 (Part V of this issue)
- 50329 Employment Taxes** Treasury/IRS adopts regulations relating to credit for household and dependent care services expenses; applicable after 12-31-75
- 50540 Allegations of Discrimination** EEOC, MSPB issue interim regulations for processing appealable actions pending before 1-10 and 1-11-79; effective 8-28-79; comments by 10-29-79 (Part III of this issue) (2 documents)
- 50384 Occupational Safety and Health** USDA/Office of Safety and Health Management solicits public views on proposed programs; comments by 10-1-79

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Area Code 202-523-5240

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- 50425 Treasury Notes** Treasury/Office of the Secretary announces interest rate on Notes of Series W-1981
- 50326 Truth in Lending** FRS publishes official staff interpretation regarding disclosures required for credit life, accident, health or loss of income insurance, property damage or liability insurance and single interest insurance; effective 9-27-79
- 50361 Taxation of Bingo Games** Treasury/IRS proposes regulations relating to treatment of proceeds; comments and hearing requests by 10-29-79
- 50339 Veterans** VA amends regulation which grants service connection for disability due proximately to a service-connected disease or injury; effective 8-22-79
- 50544 Migratory Bird Hunting** Interior/FWS prescribes final frameworks for late season hunting regulations; effective 8-29-79 (Part IV of this issue)
- 50458-50536 Physical Medical Devices** HEW/FDA proposes general classification rules and regulations classifying individual devices for human use; comment by 10-29-79 (Part II of this issue) (83 documents)
- 50360 Color Additives** HEW/FDA proposes additional tolerance in specifications for D & C Orange, No. 4; comments by 10-29-79
- 50412, 50414 GRAS Substances** HEW/FDA announces opportunity for public hearing on safety of iron and iron salts, vitamin A acetate, and vitamin A palmitate; requests for oral presentation by 9-27-79 (2 documents)
- 50324 Clinical or Laboratory Testing** NRC authorizes veterinarians to use byproduct material under general license for *in vitro* testing; effective 9-27-79
- 50410, 50412 Drugs for Human Use** HEW/FDA revokes temporary exemption and announces marketing conditions for monobenzone topical ointment; effective 8-28-79; hearing requests by 9-27-79; supplements to NDA's by 10-29-79 (2 documents)

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Rules and Regulations

Federal Register

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 752

Adverse Actions by Agencies

AGENCY: Office of Personnel Management.

ACTION: Final rule; correction.

SUMMARY: This document corrects a legal citation contained in final regulations implementing adverse action provisions of the Civil Service Reform Act of 1978 which were published August 10, 1979 (44 FR 37032).

DATE: Effective date: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Cynthia Field, Workforce Effectiveness and Development Group, Office of Personnel Management, (202) 632-5623.

Office of Personnel Management.

Roderick S. Speer,

Assistant Issuance System Manager.

Accordingly, the Office of Personnel Management is amending 5 CFR 752.401(b)(2) to read as follows:

§ 752.401 Coverage.

* * * * *

(b) * * *

(2) An employee covered by the definition in 5 U.S.C. 7511(a)(1)(B);

* * * * *

(5 U.S.C. 7504, 7514)

[FR Doc. 79-26714 Filed 8-27-79; 8:45 am]

BILLING CODE 5325-01-M

5 CFR Part 930

Appointment, Pay, and Removal of Administrative Law Judges

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This action amends the authority citation for the regulations on the appointment, pay, and removal of administrative law judges.

Section 5335 of title 5, United States Code, was inadvertently omitted from the authority citation of subpart B of Part 930 in the 1968 edition of the Code of Federal Regulations. To correct that omission, section 5335 is now included in the authority citation of that subpart.

The Civil Service Reform Act of 1978 renumbered 5 U.S.C. 5362. That section's new citation is 5 U.S.C. 5372. The authority citation of Part 930, Subpart B is amended to reflect that change.

FOR FURTHER INFORMATION CONTACT: Joseph A. Norris, Office of Administrative Law Judges, EPMD Office of Personnel Management, (202) 632-4638.

Office of Personnel Management.

Roderick S. Speer,

Assistant Issuance System Manager.

Accordingly, the authority citation of Part 930, subpart B is revised to read as follows:

Subpart B—Appointment, Pay, and Removal of Administrative Law Judges

Authority: 5 U.S.C. 1305, 3105, 3344, 5335, 5372, 7521.

* * * * *

[FR Doc. 79-26713 Filed 8-27-79; 8:45 am]

BILLING CODE 5325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1126

Milk in the Texas Marketing Area; CFR Correction

In § 1126.13, the introductory text of paragraph (e) and (e)(1) appearing on page 119 of Title 7, Code of Federal Regulations, Parts 1120 to 1199, revised as of January 1, 1979 is incorrect. The correct text is set forth below:

§ 1126.13 Producer milk.

* * * * *

(e) Diverted from a pool plant to a nonpool plant that is not a producer-handler plant for the account of the handler operating such pool plant or a handler described in § 1126.9(b), subject to the following conditions:

(1) Milk of a dairy farmer shall not be eligible for diversion during any month unless milk of such dairy farmer was physically received as producer milk at a pool plant and the dairy farmer has continuously retained producer status since that time and further, during each of the months of September through January not less than 15 percent of the milk of such dairy farmer is physically received as producer milk at a pool plant. If a dairy farmer loses his producer status under the order (except as a result of a temporary loss of Grade A approval), his milk shall not be eligible for diversion until milk of such dairy farmer has been physically received as producer milk at a pool plant;

* * * * *

BILLING CODE 6820-27-M

Animal and Plant Health Inspection Service

9 CFR Part 73

Scabies in Cattle; Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: The purpose of this amendment is to quarantine a portion of Dona Ana County in New Mexico because of the existence of cattle scabies. An area of the New Mexico State University campus, consisting of 28 acres and enclosed with a chain link fence, is being used to conduct research on pesticides which are used in the scabies program. Scabies infected animals will be used to complete the study. Personnel from the National Veterinary Services Laboratories, Ames, Iowa, as well as other Veterinary Services and New Mexico State personnel will be participating in the study. Therefore, in order to prevent the dissemination of cattle scabies it is necessary to quarantine the area being used for research.

EFFECTIVE DATE: August 22, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. Glen O. Schubert, Chief Staff Veterinarian, Sheep, Goat, Equine, and Ectoparasites Staff, USDA, APHIS, VS, Federal Building, Room 737, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8322.

SUPPLEMENTARY INFORMATION: This amendment quarantines a portion of Dona Ana County in New Mexico because of the existence of cattle scabies. The restrictions pertaining to the interstate movement of cattle from quarantined areas, contained in 9 CFR Part 73, as amended, apply to the quarantined area.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies, is hereby amended in the following respect:

In § 73.1a, a new paragraph (a) relating to the State of New Mexico is added to read:

§ 73.a Notice of quarantine.

(a) Notice is hereby given that cattle in a certain portion of the State of New Mexico are affected with scabies, a contagious, infectious, and communicable disease; and, therefore, the following area in such State is hereby quarantined because of said disease:

A 28-acre area of land containing corrals and open area enclosed with a chain link fence, being a portion of the New Mexico State University located 1.9 miles East and 0.1 mile South of the intersection of Interstate Highway 25 and University Avenue in Sec. 22, T. 23 S., R. 2E., in Las Cruces, Dona Ana County, New Mexico.

(Secs. 4-7; 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, 134f; 37 FR 28464, 28477; 38 FR 19141)

The amendment imposes certain further restrictions necessary to prevent the interstate spread of cattle scabies from such area and must be made effective immediately to accomplish its purpose in the public interest.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this final rule are impracticable and contrary to the public interest and good cause is found for making this final rule effective less than 30 days after publication of this document in the *Federal Register*.

Further, this final rule has not been designated as "significant," and is being published in accordance with the emergency procedures in Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by J. K. Atwell, Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the emergency nature of this final rule warrants publication without

opportunity for public comment or preparation of an impact analysis statement at this time.

This final rule implements the regulations in Part 73. It will be scheduled for review in conjunction with the periodic review of the regulations in that Part required under the provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Done at Washington, D.C., this 22nd day of August 1979.

G. V. Peacock,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 79-28679 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-34-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 31 and 32

Addition of Veterinarians to the In Vitro General License

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to add veterinarians to the groups already authorized to use byproduct material under general license for clinical or laboratory testing done outside the body. The general license is useful for the regulation of a large number of identical or similar uses under circumstances in which the safety of the use is not highly dependent upon the competence of the user or when it is practical to identify a class of users who may be assumed to have the necessary qualifications. This action is in response to a petition for rulemaking.

EFFECTIVE DATE: September 27, 1979.

FOR FURTHER INFORMATION CONTACT: Deborah A. Bozik, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone 301-443-5860).

SUPPLEMENTARY INFORMATION: On April 26, 1979, the Nuclear Regulatory Commission (NRC) published a proposed rule (44 FR 24570) to amend its regulations: (1) To authorize the addition of veterinarians as general licensees to § 31.11 of 10 CFR Part 31, the general license for use of byproduct material for certain *in vitro* (outside the body) clinical or laboratory testing; (2) to add veterinarians to the group of those authorized to receive, acquire, possess and use byproduct material which is manufactured and distributed by persons holding a specific license in

§ 32.71 of 10 CFR Part 32. The public was invited to submit written comments on the proposed rule by June 25, 1979. Nineteen comments were received and seventeen of these approved the proposed rule without qualification. One commenter suggested that a one year changeover period starting from the date of the effective rule should be given to manufacturers of *in vitro* reagents so that manufacturers could use up old stocks of labels and brochures printed prior to this effective rule. The commenter stated that it would be very expensive to destroy all existing labels and brochures simply to add the phrase "veterinarians in the practice of veterinary medicine" to the labels. NRC agrees and this suggestion has been incorporated into the effective rule so that labels authorized by the regulations in effect on the day before the date of this effective rule may be used until one year from the date of the effective rule.

The same commenter suggested that this general license be extended to include other categories of persons or institutions and gave as examples blood banks, poison control centers, forensic laboratories and drug abuse clinics. The NRC does not agree because one of the criteria for issuing a general license is that the user group is well defined with respect to training in ionizing radiation. Physicians and veterinarians fulfill this criterion; however, blood banks, poison control centers, forensic laboratories and drug abuse clinics do not necessarily fulfill this criterion. In discussing this point with the commenter, he stated that this was not a critical problem at this time since these groups could apply for specific licenses to operate.

Another commenter questioned the choice of the proposed wording which limited a veterinarian to "the practice of veterinary medicine." The staff believes that limiting the veterinarian's use of *in vitro* kits to the practice of veterinary medicine is essential because if someone other than a physician sets up a clinical laboratory, the NRC wants that person to apply for a specific license so that their qualifications can be reviewed. The NRC contacted the commenter and he accepted our explanation. The NRC further discussed with him the point that the phrase "veterinarians in the practice of veterinary medicine" does not exclude veterinary research in which this commenter was involved.

Currently, the veterinarian must use byproduct material under a specific license. A specific license is required for any activity in which the safety of the proposed use is highly dependent upon

such factors as the qualifications of the particular licensee and the unique characteristics of the use. Currently, physicians use byproduct material for the same type of tests as the veterinarians; however, physicians use it under a general license. A general license is effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32 are published as a document subject to codification.

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

1. Section 31.11 of 10 CFR Part 31 is amended by changing the prefatory language of paragraph (a), amending paragraph (d)(2) and deleting a footnote no longer pertinent to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:¹

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or

animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE OR IMPORT CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

2. Paragraph (d) of § 32.71 of 10 CFR Part 32 is revised to read as follows:

§ 32.71 Manufacture and distribution of byproduct materials for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacture or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:¹

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

(Secs. 81, 161, Pub. L. 83-703, 68 Stat. 935, 948 (42 U.S.C. 2111, 2201); sec. 201, Pub. L. 93-438, 68 Stat. 1242 (42 U.S.C. 5841))

Dated at Bethesda, MD this 13th day of August 1979.

For the Nuclear Regulatory Commission.

Lee V. Gossick,

Executive Director for Operations.

[FR Doc. 79-26677 Filed 8-27-79; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Commission

10 CFR Part 211

[Docket No. ERA-R-79-23-B]

Mandatory Petroleum Allocation Regulations; Motor Gasoline Allocation Base Period and Adjustments; Deferral of Effective Date of Final Rule

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of deferral of effective date of final rule.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) is deferring the effective date of a final rule which was adopted on July 15, 1979, and which was the subject of corrective amendments issued on July 19, 1979. These amendments were to go into effect on September 1, 1979. They would establish a downward adjustment and certification procedure for wholesale purchaser-resellers of motor gasoline whose supply obligations to retail sales outlets, wholesale purchaser-consumers, or bulk purchasers decrease as a result of such purchasers going out of business or reducing their allocation entitlements. We are deferring the effective date of this rule until October 1, 1979, in order to enable us to receive the written comments already requested on this provision and to enable us to determine what modifications to this provision, if any, are appropriate.

DATES: The effective date of 10 CFR 211.107(d) is deferred until October 1, 1979. Further written comments by September 20, 1979.

ADDRESSES: Written comments to: Office of Hearings Management, Economic Regulatory Administration, Room 2313, Docket No. ERA-R-79-23-B, Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

Robert G. Gillette (Comment Procedures), Economic Regulatory Administration, 2000 M Street NW., Room 2214B, Washington, D.C. 20461, (202) 254-5201.

William Webb (Office of Public Information), Economic Regulatory Administration, 2000 M Street NW., Room B-110, Washington, D.C. 20461, (202) 634-2170.

William Caldwell (Regulations & Emergency Planning), Economic Regulatory Administration, 2000 M Street NW., Room 2304, Washington, D.C. 20461, (202) 254-8034.

¹ Labels authorized by the regulations in effect on September 28, 1979, may be used until one year from September 27, 1979.

Alan Lockard (Office of Petroleum Operations), Economic Regulatory Administration, 2000 M Street NW., Room 6222, Washington, D.C. 20461, (202) 254-7422.

Joel M. Yudson (Office of General Counsel), Department of Energy, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-6744.

SUPPLEMENTAL INFORMATION: On July 15, 1979 we issued a final rule that, among other things, established a downward adjustment procedure for wholesale purchaser-resellers of motor gasoline whose supply obligations to retail sales outlets decrease (44 FR 42549, July 19, 1979). On July 19, 1979, we issued a corrective amendment to that rule to include wholesale purchaser-consumers and bulk purchasers as categories of customers for which wholesale purchaser-resellers of motor gasoline will be required to make downward adjustments when such resellers' supply obligations decrease. We also made a technical amendment to the rule to clarify that the downward adjustment provision applies for marketer decreases in supply obligations that have occurred since the corresponding base period month and not just to prospective decreases (44 FR 43458, July 25, 1979). We continued the rulemaking for the purpose of receiving further written comments until September 20, 1979.

Since the publication of the final rule, we have received many formal and informal comments from several gasoline marketing groups. In general, these commenters have urged that we rescind or modify the downward certification provision contained in § 211.107(d). In particular, several commenters have urged that the allocation regulations be amended to permit a gasoline marketer the flexibility to close one or more of its retail outlets and reallocate or reassign the base period volume of the closed stations among its remaining retail outlets. In light of these comments, we have decided to wait for the receipt of all written comments on the downward certification provision contained in § 211.107(d) before making the rule effective. Therefore, in order to provide adequate time to analyze these comments and to determine whether any modifications are appropriate, we are deferring the effective date of § 211.107(d) until October 1, 1979. If no further action is taken by us before October 1, § 211.107(d) will automatically go into effect on that date.

We wish to emphasize that in the interim a wholesale purchaser-reseller

will not be required to downward adjust its base period volume when its supply obligation has decreased as a result of a retail sales outlet going out of business, but it will be required under § 211.106(d)(2) and Ruling 1974-13 to use all of the supply made available by a customer going out of business to make a corresponding increase in the supply available to its remaining customers, either by increasing its allocation fraction or, if the fraction is at 1.0 or above, by declaring it as surplus product. It is unlawful under both the new downward certification rule and the existing regulations to divert volumes outside of the distribution system established by the mandatory allocation regulations and to sell such volumes on the "spot" market.

(Emergency Petroleum Allocation Act of 1973, 15 U.S.C. 751 et seq., Pub. L. 93-159, as amended, Pub. L. 93-511, Pub. L. 94-99, Pub. L. 94-133, Pub. L. 94-163, and Pub. L. 94-385; Federal Energy Administration Act of 1974, 15 U.S.C. 787 et seq., Pub. L. 93-275, as amended, Pub. L. 94-332, Pub. L. 94-385, Pub. L. 95-70, and Pub. L. 95-91; Energy Policy and Conservation Act, 42 U.S.C. 6201 et seq., Pub. L. 94-163, as amended, Pub. L. 94-385, and Pub. L. 95-70; Department of Energy Organization Act, 42 U.S.C. 7101 et seq., Pub. L. 95-91; E.O. 11790, 39 FR 23185; E.O. 12009, 42 FR 46267)

In consideration of the foregoing, the effective date of § 211.107(d) of Chapter II of Title 10 of the Code of Federal Regulations is deferred until October 1, 1979.

Issued in Washington, D.C., August 22, 1979.

David J. Bardin,

Administrator, Economic Regulatory Administration.

[FR Doc. 79-26869 Filed 8-23-79; 12:35 pm]

BILLING CODE 6450-01-M

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Reg Z; FC-0167]

Official Staff Interpretation

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official Staff Interpretation.

SUMMARY: The Board is publishing the following official staff interpretation of Regulation Z regarding disclosures required for credit life, accident, health or loss of income insurance, property damage or liability insurance, and single interest insurance written in connection with a credit transaction. The agency is taking this action in response to

requests for interpretation of this regulation.

EFFECTIVE DATE: On or after September 27, 1979.

FOR FURTHER INFORMATION CONTACT: Gerald Kell, Section Chief, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 (202-452-3867).

SUPPLEMENTARY INFORMATION: Identifying details have been deleted to the extent required to prevent a clearly unwarranted invasion of personal privacy. The Board maintains and makes available for public inspection and copying a current index providing identifying information for the public subject to certain limitations stated in 12 CFR Part 261.6.

An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR Part 226.1(d)(2)(ii). As provided by 12 CFR Part 226.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 and must be post marked or received by the Secretary's office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

(15 U.S.C. 1640(b)).

12 CFR Part 226, FC-0167—§ 226.4(a)(5), § 226.4(a)(6), and § 226.404 Disclosures required for credit life, accident, health or loss of income insurance, property damage or liability insurance, and single interest insurance written in connection with a credit transaction.

August 8, 1979.

This will reply to your letter of . . . concerning the proper disclosure to be made of the types of insurance discussed in § 226.4(a)(5) and (6) of Regulation Z. Specifically you ask whether credit sale disclosures are required when any of these types of insurance are obtained from or through the creditor in connection with a loan.

Regulation Z, implementing § 106(b) and (c) of the Truth in Lending Act, provides rules for the proper treatment of certain kinds of insurance—credit life, accident, health, or loss of income insurance (§ 226.4(a)(5)); property damage or liability insurance (§ 226.4(a)(6)); and single interest insurance (Board Interpretation § 226.404). Charges for these types of insurance, even though payable directly or indirectly by the customer and imposed directly or indirectly by the creditor as an incident to or as a condition of the extension of credit, are excludable from the finance charge to be disclosed in connection with that extension of credit if the

specific requirements of the relevant sections of the regulation are met.

Where these types of insurance are written in connection with a credit transaction, and the creditor properly excludes the insurance charges from the finance charge for that transaction and finances the purchase of the insurance as part of the transaction, the amount of the insurance charges should be disclosed as a charge included in the "amount financed." It is not necessary to provide a separate set of credit sale disclosures for the insurance premiums.

This is an official staff interpretation of Regulation Z, issued pursuant to § 226.1(d)(2) and limited to the facts and issues discussed herein. It will become effective 30 days after publication in the Federal Register unless a request for public comment, made in accordance with the Board's procedures, is received and granted. We will notify you if the effective date of the interpretation is suspended because such a request is received.

Sincerely,

Nathaniel E. Butler,
Associate Director.

Board of Governors of the Federal Reserve System, August 16, 1979.

Theodore E. Allison,
Secretary of the Board.

[FR Doc. 79-28712 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 161

[Docket No. 75P-0104]

Canned Shrimp; Stay of Standard of Identity and Standard of Fill of Container

AGENCY: Food and Drug Administration.

ACTION: Stay of final rule.

SUMMARY: This document announces that the effective date of the final regulation establishing a standard of identity for canned shrimp is stayed by the filing of objections and requests for a hearing. It also stays the fill of container standard for canned shrimp, as revised, to permit consideration of a question raised regarding the prescribed compliance procedure. The stay of the identity standard is in effect pending a determination of whether a public hearing is necessary to resolve the issues raised by the objections. A notice of hearing specifying any issues on which a hearing is justified and other pertinent information will be published in the Federal Register at a later date. The stay of the revised fill of container standard is in effect pending consideration of the merits of a comment on the procedure for determining compliance with the

drained weight requirement. A notice announcing the outcome of this determination will be published in the Federal Register at a later date.

FOR FURTHER INFORMATION CONTACT: J. David Clem, Bureau of Foods (HFF-417), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, DC 20204, 202-245-1557.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 9, 1978 (43 FR 19837), the agency issued a final regulation establishing a standard of identity (21 CFR 161.173(a)) and revising the fill of container standard (21 CFR 161.173(c)) for canned wet pack shrimp in transparent or nontransparent containers. This action, taken in response to a petition by the American Shrimp Canners Association (ASCA), P.O. Box 50774, New Orleans, LA 70150, was intended to adopt, to the extent practicable, the provisions of the Codex Alimentarius (Codex) standard for canned shrimp.

The final regulation provided that any person who would be adversely affected could, on or before June 8, 1978, file written objections to the final regulation and, if desired, request a hearing on the specific provisions to which there were objections.

Four letters were received in response to the final regulation. They included one objection and request for a hearing from ASCA on three provisions of the standard of identity, two requests for reconsideration from Pacific Northwest shrimp canners concerning the use of the term "cleaned" to identify a style of shrimp, and one comment from ASCA questioning the appropriateness of the procedure for determining compliance with the drained weight requirement described in the fill of container standard.

Objection and Requests for a Hearing

ASCA's objection and request for a hearing concerned:

1. The provision in § 161.173(a)(3)(ii) (21 CFR 161.173(a)(3)(ii)) which limits the tolerance for veins in deveined style shrimp to 5 percent for all sizes of shrimp. ASCA contends that despite the fact that the 5-percent tolerance is in agreement with Codex, it is out of date since it was established almost 40 years ago on large and jumbo size shrimp which were then peeled and deveined by hand. ASCA believes that tolerances based on size of shrimp and the efficiency attainable with mechanical deveining equipment are more appropriate and would be more reflective of what they contend are industry's present day practices.

2. The provision in § 161.173(a)(5)(i), which limits the use of the term

"prawns" in labeling only to shrimp of large or extra large size. ASCA sees no reason for U.S. standard to depart from the Codex standard which, ASCA notes, refers throughout to shrimp or prawns interchangeably.

3. The provision in § 161.173(a)(5)(iv), which establishes a count per 28.4 grams (1 ounce) for deveined-style shrimp on the basis of an 8-percent tolerance for weight loss as a result of the deveining process. ASCA states that this tolerance, as well as the tolerance for veins discussed previously, although in agreement with the Codex standard, was established many years ago on large and jumbo size shrimp which were blanched or cooked and then deveined by hand. ASCA believes the tolerances should be changed to be more reflective of what they contend are present-day industry practices. ASCA maintains that to remain competitive the industry must utilize mechanical deveining equipment which varies in efficiency depending upon the size shrimp being deveined.

Comments

The Washington Fish and Oyster Co., Seattle, WA and the Washington Crab Producers Inc., Westport, WA, requested reconsideration of § 161.173(a)(5)(ii), which restricts the use of the term "cleaned" in labeling to only those shrimp which have been prepared by removing the dark vein from the first five segments by deliberate cutting action. One comment said the veins of Pacific Northwest shrimp are so near the surface that the peeling operation cleans the vein from the shrimp. The comment maintained that the word "cleaned" should be allowed on the labels of Pacific shrimp packs. According to the comment, changing the description of Pacific Northwest shrimp and loss of identification with the word "cleaned" will have a great financial impact. The second comment also said its shrimp are deveined when they are peeled. The comment opposed having to omit the word "cleaned" on labels of its shrimp product because it believes the word is appropriate to its product. The comment suggested that labeling with the words "no dark veins," as permitted by § 161.173(a)(5)(ii), "would not read too well on our product" and speculated that sales would be harmed.

In the preamble to the final rule, FDA observed that "Through long usage in both the frozen and canned shrimp industries, the words 'cleaned' and 'deveined' have become synonymous and are used interchangeably to describe shrimp which have had the back split open and the dorsal tract removed." Although FDA is not persuaded by the comments that this

observation is erroneous, the agency concludes that the comments have sufficient merit to defer a final decision on this matter until such time as FDA rules on the objections received to other provisions of the standards. In the meantime, the persons who comment are invited to submit additional data and information in support of their contention that shrimp devalued by the peeling process should be permitted to be labeled "cleaned."

A letter was received from ASCA after the close of the objection period commenting on the revised fill of container standard. Both the revised standard and Codex require cutout (drained) weight for canned shrimp of not less than 60 percent of the weight of the water required to fill the container. Prior to the revision, 64 percent was required. ASCA pointed out that the procedure in § 161.173(c)(2) for determining compliance with the new drained weight requirement differs from the procedure described in the Codex standard. The revised FDA standard considers each container that falls below the required drained weight as a "defective" unit and limits the permissible number of defectives in a sample according to a prescribed sampling plan. The compliance procedure in Codex is based on the average of the drained weights of the individual containers in the sample. ASCA maintains that the compliance procedure in the revised standard is more stringent than Codex and that if averaging of individual drained weights is not allowed, the reduction from 64 to 60 percent will not be realized by the packers. According to ASCA, with the best modern technology in can filling and weighing machines, it would not be possible to meet the 60-percent drained weight requirement within the allowable tolerance for defective units unless the cans are filled to an average drained weight of 64 percent. The comment from ASCA was the only one received on the fill of container standard during this rulemaking procedure.

The agency notes that the deviation from the Codex compliance procedure was not discussed in the preamble to the proposal as were the other deviations. FDA is, therefore, on its own initiative, staying the revised fill of container standard pending a reconsideration of the procedure for determining compliance with the drained weight requirement.

Regulation Stayed

The objections filed to the final

regulations published in the Federal Register of May 9, 1978 stayed those parts of the regulation to which objections were made. Since the provisions stayed are an integral part of the regulations, the agency considers it appropriate to stay the entire identity standard. FDA is also staying the revised fill of container standard to permit reconsideration of the prescribed procedure for determining compliance with the drained weight requirement. A notice stating any issues on which a hearing is justified and setting out other pertinent information will be published in the Federal Register at a later date. In light of recent communications with ASCA, the agency is delaying a decision regarding the need for a hearing on the above issues to allow time for ASCA to develop and submit data in support of its first and third objections. Copies of these communications have been placed on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. During the period of the stay, the fill of container standard currently in the Code of Federal Regulations will be effective. However, compliance with the revised fill of container standard may have begun on July 10, 1978. Accordingly, the FDA will not take action against products meeting the drained weight requirement of the revised standard as determined by the sampling and acceptance procedure of that standard.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that objections and requests for a hearing under section 701(e) of the act were received and that in § 161.173 *Canned wet pack shrimp in transparent or nontransparent containers*, paragraph (a), the identity standard, is stayed until further notice. On his own initiative, the Commissioner is also staying § 161.173(c), the revised fill of container standard, until further notice.

Dated: August 21, 1979.

Joseph P. Hille,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26646 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 558

[Docket No. 79N-0267]

New Animal Drugs for Use in Animal Feeds; Bambermycins

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of two supplemental new animal drug applications (NADA's) providing for safe and effective use of a higher concentration bambermycins premix for manufacture of chicken and swine feeds and for a new bambermycins dosage range for swine feed. The applications were filed by American Hoechst Corp.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION:

American Hoechst Corp., Route 202-206 North, Somerville, NJ 08876, filed two supplements to NADA 44-759 for (1) a 10-gram-per-pound bambermycins premix in manufacturing a 1-to-2-gram-per-ton chicken feed and a 2-gram-per-ton swine feed to increase the rate of weight gain and improve feed efficiency and (2) a swine feed having a dosage range of 2 to 4 grams of bambermycins per ton to increase rate of weight gain. Previous approvals provided for a 2-gram-per-pound premix to be used as in (1) above and for a 0.4-gram-per-pound premix to be used for manufacture of swine feeds containing only 2 grams per ton.

The Director of the Bureau of Veterinary Medicine concludes that approval of the supplements poses no increased human risk from exposure to residues of bambermycins. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy, published in the Federal Register of December 23, 1977 (42 FR 64367), the approvals did not require a reevaluation of the safety data in the parent application.

In accordance with the provisions of Part 20 (21 CFR Part 20) promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 514.11(e)(2)(ii) of the animal drug

regulations (21 CFR 514.11(e)(2)(ii)), summaries of safety and effectiveness data and information submitted to support approval of these applications are available for public examination at the office of the Hearing Clerk (HFA-305), Rm. 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.95 is amended by revising paragraphs (b), (d) and (e)(2) to read as follows:

§ 558.95 Bambermycins.

(b) *Approvals.* (1) Premix levels of 2 and 10 grams of bambermycins activity per pound and premix have been granted to 012799 in § 510.600(c) of this chapter for use as provided in paragraph (e)(1), and (e)(2)(i) and (ii) of this section.

(2) Premix level of 0.4 gram of bambermycins activity per pound of premix has been granted to 012799 for use as provided in paragraph (e)(2)(i) and (ii) of this section.

(d) *Special consideration.* The following products are not required to comply with the provisions of section 512(m) of the act:

(1) Premixes containing 0.4 or 2.0 grams of bambermycins per pound used to make complete broiler or swine feeds containing bambermycins as the sole drug and conforming to paragraph (e)(1) or (e)(2) of this section.

(2) Feed supplements containing not more than 40 grams of bambermycins per ton used to make finished growing-finishing swine feeds containing bambermycins as the sole drug and conforming to paragraph (e)(2) of this section.

(e) * * *

(2) *Growing-finishing swine feed.* It is used as follows:

(i) *Amount per ton.* 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

(a) *Indications for use.* For increased rate of weight gain.

(b) *Limitations.* Feed continuously as sole ration.

Effective date. This regulation is effective August 28, 1979.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: August 16, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

(FR Doc. 79-26504 Filed 8-27-79; 8:45 am)

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, 301

[T.D. 7643]

Expenses for Household and Dependent Care Services Necessary for Gainful Employment

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to the expenses for household and dependent care services necessary for gainful employment. Changes to the applicable tax law were made by the Tax Reform Act of 1976 and the Revenue Act of 1978. These regulations describe the circumstances under which a credit will be available for expenses for household and dependent care services.

DATE: The amendments apply, in general, to taxable years beginning after December 31, 1975.

FOR FURTHER INFORMATION CONTACT: Walter H. Woo 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) (202-566-3734).

SUPPLEMENTARY INFORMATION:

Background

On September 1, 1978, the Federal Register published proposed amendments to the regulations under sections 44A, 213, 214, 3402, and 6096 of the Internal Revenue Code of 1954. The amendments were proposed to conform the regulations to section 504 of the Tax Reform Act of 1976 (90 Stat. 1563). No public hearing was requested or held. After consideration of all comments regarding the proposed amendments, the attached Treasury decision is adopted.

Additionally, certain revisions in the proposed regulation amendments are made by this Treasury decision in order to conform the regulations to the amendments made to section 44A by section 121 of the Revenue Act of 1978 (92 Stat. 2279). This statutory amendment made only minor changes in the credit for expenses for household

and dependent care services and prescribes rules favorable to taxpayers. For this reason and because there is need for immediate guidance for taxpayers, the relevant provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring further notice of proposed rulemaking, opportunity for public participation, and delay in effective date are found to be inapplicable.

These regulations will be reviewed as necessary on the basis of comments received from offices within the Treasury Department and Internal Revenue Service or from the public.

In General

The Tax Reform Act of 1976 allows taxpayers to claim a credit against tax for certain household and dependent care expenses. The credit is 20 percent of the expenses paid for the care of a child under age 15 or for an incapacitated dependent or spouse, in order for the taxpayer to be gainfully employed. The employment-related expenses on which the credit is based are limited to \$2,000 for the care of one qualifying individual and \$4,000 for the care of more than one qualifying individual.

Definition of Employment-Related Expenses

In response to a comment, § 1.44A-1(a)(4) has been restated to make clear that prepaid expenses will not be deemed employment-related expenses until the services for which the expenses are incurred have been performed.

Paragraph (c) of § 1.44A-1 defines the term "employment-related expenses" contained in section 44A(c)(2). The definition of employment-related expenses is clarified and expanded to include any tax required to be paid by the taxpayer under section 3301 (relating to the Federal Unemployment Tax Act) and similar State payroll taxes.

Earned Income Limitation

Paragraph (b) of § 1.44A-2 provides that the amount of the employment-related expenses during any taxable year which may be taken into account under section 44A cannot exceed the earned income of the taxpayer, or, in the case of married individuals, the earned income of the spouse earning the smaller amount. The rule in paragraph (b)(2) (relating to the definition of earned income) requiring that wages, salaries, tips, and net earnings from self-employment be includible in the eligible individual's gross income is based on § 1.43-1(c)(3) which defines "earned income" for purposes of the earned income credit under section 43. The application of this rule has been limited

to taxable years beginning before January 1, 1979 to reflect the amendment made to section 43(c)(2)(B) (defining earned income) made by section 104(d) of the Revenue Act of 1978.

Paragraph (b)(3) of § 1.44A-2 sets forth the rule under section 44A(e)(2) that for purposes of the earned income limitation a spouse who is a full-time student at an educational institution is deemed to have earned income of not less than \$166 a month if there is one qualifying individual and \$333 a month if there are two or more qualifying individuals. One comment suggested that paragraph (b)(3)(iii) of § 1.44A-2 which provides a cross-reference to § 1.151-3(c) for the definition of "educational institution" be revised to provide instead a cross-reference to section 170(b)(1)(A)(ii) for a definition of "educational organization". This suggestion was not adopted because the term "educational institution" and not "educational organization" appears in section 44A(e)(2) which is the operative provision.

Payments to Related Individuals

Paragraph (a) of § 1.44A-4 provides special rules for determining when payments to related individuals will qualify for the credit. This paragraph is revised to include a new subparagraph (1) to reflect the amendment made to section 44A(f)(6) (relating to payments to related individuals) by section 121 of the Revenue Act of 1978. As amended, section 44A(f)(6) no longer requires that child care services performed by certain relatives constitute employment to come within the exception to the rule generally denying a credit for payments made to relatives.

One comment suggested that § 1.44A-4(a)(3)(ii)(A) be changed to substitute the words "son, daughter, stepson or stepdaughter" for the word "child" to insure inclusion of stepdaughters and stepsons. To achieve this result, the regulations have been clarified to provide that the term "child" means a child as defined in section 151(e)(3).

Drafting Information

The principal author of these regulations is Walter H. Woo 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.

Adoption of amendments to the regulations

Accordingly, 26 CFR Parts 1, 31, and 301 are amended as follows:

Paragraph 1. Section 1.44A-1, as set forth in paragraph 1 of the notice of proposed rulemaking, is amended—

- (1) By revising paragraph (a)(4);
- (2) By revising paragraph (b)(2);
- (3) By revising paragraphs (c) (1)(i), (3)(i), and (5);
- (4) By revising example (3) in paragraph (c)(6);
- (5) By revising paragraphs (d) (2) and (3); and
- (6) By revising paragraph (e), all to read as follows:

§ 1.44A-1 Expenses for household and dependent care services necessary for gainful employment.

(a) *In general.* * * *

(4) Since an expense cannot be an employment-related expense until the services for which the expense was incurred are performed (see paragraph (c) of this section), prepaid expenses may be claimed only in the taxable year in which the services are performed.

* * *

(b) *Qualifying individual.* * * *

(2) *Special dependency test in case of divorced or separated parents.* A child (as defined in section 151(e)(3)) who—

- (i) Is under age 15 or is physically or mentally incapable of self-care,
- (ii) Receives over half of his or her support during the calendar year from his or her parents who are divorced or legally separated under a decree of divorce or separate maintenance or who are separated under a written separation agreement, and
- (iii) Is in the custody of one or both of his or her parents for more than one-half of the calendar year.

is treated for any taxable year beginning in the calendar year as a qualifying individual (described in subdivision (i) or (ii), as the case may be, of paragraph (b)(1) of this section) of that parent who has custody for a longer period during the calendar year than the other parent. Accordingly, a child may be treated as a qualifying individual of a parent even though the parent is not entitled to a dependency exemption for the child. The child cannot be treated as a qualifying individual with respect to more than one parent.

* * *

(c) *Employment-related expenses—(1)*

Gainful employment—(i) In general.

Expenses are considered to be employment-related expenses only if they are incurred to enable the taxpayer to be gainfully employed and are paid for household services or for the care of one or more qualifying individuals. The expenses must be incurred while the taxpayer is gainfully employed or is in active search of gainful employment. The employment may consist of service either within or without the home of the taxpayer and may include self-employment. An expense is not considered to be employment-

related merely because it is incurred while the taxpayer is gainfully employed. The purpose of the expense must be to enable the taxpayer to be gainfully employed. Volunteer work for a nominal salary does not constitute gainful employment. Whether the purpose of an expense is to enable the taxpayer to be gainfully employed depends upon the facts and circumstances of the particular case. Any tax required to be paid by the taxpayer under sections 3111 (relating to the Federal Insurance Contributions Act) and 3301 (relating to the Federal Unemployment Tax Act), or under similar State payroll taxes, in respect of any wages which otherwise constitute employment-related expenses is considered to be an employment-related expense.

* * *

(3) *Care of qualifying individual—(i) In general.* The primary purpose of expenses for the care of a qualifying individual must be to assure that individual's well-being and protection. Not all benefits bestowed upon a qualifying individual are considered as provided for the individual's care. Accordingly, amounts paid to provide food, clothing, or education are not expenses paid for the care of a qualifying individual. However, where the manner of providing care is such that the expense which is incurred includes expenses for other benefits which are incident to and inseparably a part of the care, the full amount of the expense is considered to be incurred for care. Thus, for example, the full amount paid to a nursery school in which a qualifying child is enrolled is considered as being for the care of the child, even though the school also furnishes lunch and educational services. Educational expenses incurred for a child in the first or higher grade level are not expenses incurred for the care of a qualifying individual. Expenses incurred for transportation of a qualifying individual described in paragraph (b)(1)(i) of this section between the taxpayer's household and a place outside the taxpayer's household where services for the care of the qualifying individual are provided are not incurred for the care of a qualifying individual.

* * *

(5) *Allocation of expenses.* Where a portion of an expense is for household services or for the care of a qualifying individual and a portion of such expense is for other purposes, a reasonable allocation must be made and only the portion of the expense paid which is attributable to such household services or care is considered to be an employment-related expense. No allocation is required to be made, however, if the portion of expense for the other purpose is minimal or insignificant. An allocation must be made, for example, if a servant performs household duties, cares for the qualifying children of the taxpayer, and also performs social services for the taxpayer (for which a deduction is not allowable) or clerical services in the office of the taxpayer outside the home (for which a deduction may be allowable under section 162). Employment-related expenses include household service expenses which are provided in conjunction with the care of a qualifying individual. Thus, if an expense is in part attributable to the care of a qualifying

individual and in part to household services, no allocation is required.

(6) *Illustrations.* * * *

Example (3). The taxpayer, in order to be gainfully employed, employs a full-time housekeeper who cares for the taxpayer's two children, aged 9 and 15 years, respectively, performs regular household services of cleaning and cooking, and chauffeurs the taxpayer to and from his place of employment. The chauffeuring service never requires more than 30 minutes out of the total period of employment each day. No allocation is required for purposes of determining the portion of the expense attributable to the chauffeuring (not a household service expense) since it is *de minimis*. Further, no allocation is required for the purpose of determining the portion of the expense attributable to the care of the 15 year old child (not a qualifying individual) since the household expense is in part attributable to the care of the 9 year old child, who is a qualifying individual. Accordingly, the entire expense of employing the housekeeper is an employment-related expense. However, the total amount of employment-related expenses taken into account would be limited to the amount allowable for one qualifying individual.

(d) *Maintenance of a household.* * * *

(2) *Two or more families.* Solely for purposes of section 44A and this section, if two or more families occupy living quarters in common, each of the families is treated as constituting a separate household, and the taxpayer who provides more than one-half of the costs of maintaining such a separate household is treated as maintaining that household. Thus, for example, if two unrelated taxpayers each with children occupy living quarters in common and each taxpayer pays more than one-half of the household costs incurred by each respective family, each taxpayer will be treated as maintaining a separate household.

(3) *Costs of maintaining a household.* The costs of maintaining a household are the expenses incurred for the mutual benefit of the occupants thereof by reason of its operation as the principal place of abode of the occupants. The expenses of maintaining a household include property taxes, mortgage interest, rent, utility charges, upkeep and repairs, property insurance, and food consumed on the premises. These expenses do not include the cost of clothing, education, medical treatment, vacations, life insurance, or transportation or payments on mortgage principal or for the purchase, permanent improvement, betterment, or replacement of property. Further, the costs of maintaining a household do not include the value of services performed in the household by a qualifying individual described in paragraph (b) of this section. An expense incurred by a taxpayer which is paid or reimbursed by another is not considered as a cost of maintaining a household.

(e) *Substantiation.* A taxpayer claiming a credit under paragraph (a) of this section for employment-related expenses must substantiate by adequate records or other sufficient evidence any credit taken under this section. For example, if requested, the

taxpayer must furnish information as to the nature and period of the physical or mental incapacity of any dependent or spouse in respect of whom a credit is claimed, including necessary information from the attending physician as to the nature of the physical or mental incapacity.

Par. 2. Section 1.44A-2, as set forth in paragraph 1 of the notice of proposed rulemaking, is amended by revising paragraphs (b) (1) and (2) to read as follows:

§ 1.44A-2 *Limitations on amount creditable.*

* * * * *

(b) *Earned income limitation—(1) In general.* The amount of employment-related expenses incurred during any taxable year which may be taken into account under § 1.44A-1(a) cannot exceed—

(i) For an individual not married at the close of the year, the individual's earned income for the year, or

(ii) For an individual married at the close of the year, the lesser of the individual's earned income or the earned income of his or her spouse for the year.

For purposes of this paragraph (b)(1), the earned income of only the spouse to whom the taxpayer is married at the close of the year is taken into account (and not the earned income of another spouse who died or was divorced from the taxpayer during the year). Further, the spouse's earned income for the entire year is taken into account, even though the taxpayer and his or her spouse were married for only a part of the year. For purposes of this paragraph (b), certain married individuals legally separated or living apart are treated as not married (see § 1.44A-3 (b) and (c), respectively).

Earned income. For purposes of this section, earned income means—

(i) Wages, salaries, tips, other employee compensation, and

(ii) Net earnings from self-employment (within the meaning of section 1402(a) and the regulations thereunder).

For taxable years beginning before January 1, 1979, earned income includes only amounts described in subdivision (i) or (ii) of this paragraph (b)(2) which are includible in the eligible individual's gross income for the taxable year of the individual in which the credit is claimed. For all taxable years, however, earned income is computed without regard to any community property laws which may otherwise be applicable. Earned income is reduced by any net loss in earnings from self-employment. Earned income does not include amounts received as a pension or an annuity, or an amount to which section 871 (a) and the regulations thereunder apply (relating to income of nonresident alien individuals not connected with United States business).

Par. 3. Section 1.44A-4, as set forth in paragraph 1 of the notice of proposed rulemaking, is amended by revising paragraph (a) to read as follows:

§ 1.44A-4 *Other special rules relating to employment-related expenses.*

(a) *Payments to related individuals—(1) Taxable years beginning after December 31, 1978.* For taxable years beginning after December 31, 1978, a credit is not allowed under section 44A with respect to the amount of any employment-related expenses paid by the taxpayer to an individual—

(i) With respect to whom for the taxable year a deduction under section 151(e) (relating to deduction for personal exemptions for dependents) is allowable either to the taxpayer or his or her spouse, or

(ii) Who is a child of the taxpayer (within the meaning of section 151(e)(3)) who is under age 19 at the close of the taxable year.

For purposes of this paragraph (a)(1), the term "taxable year" means the taxable year of the taxpayer in which the service is performed.

(2) *Taxable years beginning before January 1, 1979.* For taxable years beginning before January 1, 1979, except as otherwise provided in paragraph (a)(3) of this section, a credit is not allowed under section 44A with respect to the amount of any employment-related expenses paid by the taxpayer to an individual who bears to the taxpayer any relationship described in section 152(a) (1) through (8). These relationships are those of a son or daughter or descendant thereof; a stepson or stepdaughter; a brother, a sister, stepbrother, or stepsister; a father or mother or an ancestor of either; a stepfather or stepmother; a nephew or niece; an uncle or aunt; or a son-in-law, daughter-in-law, father-in-law, mother-in-law, brother-in-law, or sister-in-law. In addition, no credit is allowed with respect to the amount of any employment-related expenses paid by the taxpayer to an individual who qualifies as a dependent of the taxpayer for the taxable year within the meaning of section 152(a)(9), which relates to an individual (other than the taxpayer's spouse) whose principal place of abode for the taxable year is the home of the taxpayer and who is a member of the taxpayer's household.

(3) *Exception for payments to certain related individuals.* For taxable years beginning before January 1, 1979, a credit is allowed for the amount of any employment-related expenses paid by the taxpayer to an individual provided that neither the taxpayer nor his or her spouse is entitled to a deduction under section 151(e) (relating to deduction for personal exemptions for dependents) with respect to such individual for the taxable year in which the service is performed; and the service with respect to which the amount is paid constitutes employment within the meaning of section 3121(b). The following services performed for a taxpayer by a relative who is an employee of the taxpayer may qualify as employment within the meaning of section 3121(b):

(i) Services performed by the taxpayer's child age 21 or over.

(ii) Domestic services in the taxpayer's home performed by the taxpayer's parent if—

(A) The taxpayer has living in his or her home a child (as defined in section 151(e)(3)) who is under age 18 or who has a physical or mental condition requiring the personal care

of an adult during at least four continuous weeks in the calendar quarter, and

(B) The taxpayer is a widow or widower or is divorced, or has a spouse living in the home who, because of a physical or mental condition, is incapable of caring for his or her child during at least four continuous weeks in the calendar quarter in which services are rendered.

(iii) Services of all relatives other than a child, spouse, or parent of the taxpayer. For taxable years beginning before January 1, 1979, a credit is not allowed under section 44A with respect to employment-related expenses paid by the taxpayer to a relative for services which do not constitute employment under section 3121(b). Services performed by a relative do not constitute employment if they relate to the relative's trade or business the income from which is includible in computing the relative's net earnings for purposes of the self-employment tax under section 1401.

(4) *Payments to entities or partnerships.* If the services are performed by an entity or partnership, paragraphs (a) (1) and (2) of this section is normally not applicable. If, however, the entity or partnership is established or maintained primarily to avoid the application of paragraph (a) (1) or (2) in order to permit the taxpayer to obtain the credit with respect to employment-related expenses, for purposes of this paragraph (a), the payments of employment-related expenses shall be treated as made directly to each owner of the entity or partner in proportion to his or her share of the entity or partnership. A factor to consider for purposes of determining whether an entity or partnership is so established or maintained is whether the entity or partnership is set up solely to care for the taxpayer's qualifying individual and to provide household services to the taxpayer.

(5) *Illustrations.* The application of this paragraph may be illustrated by the following examples:

Example (1). For A's taxable year ending December 31, 1978, A, a divorced taxpayer, pays \$5,000 of employment-related expenses to his mother for the care of his child age 5. A's mother cares for the child in her home. The services performed by A's mother do not constitute employment under section 3121(b). Accordingly, A is not allowed a credit with respect to the amounts paid to the mother for the care of his child.

Example (2). Assume the same facts as in example (1) except that A's taxable year under consideration begins after December 31, 1978. A is not entitled to a deduction under section 151(e) for his mother. Accordingly, A is allowed a credit with respect to the amounts paid to the mother for the care of his child, even though the services performed by A's mother do not constitute employment under section 3121(b).

Example (3). For B's taxable year ending December 31, 1978, B, a divorced taxpayer, pays \$6,000 of employment-related expenses to his sister (who is not a dependent of the taxpayer) for the care of his child. The services performed by B's sister in the care of his child constitute a trade or business the income from which is includible in computing net earnings for purposes of the self-

employment tax under section 1401. Accordingly, B is not allowed a credit with respect to the amounts paid to the sister for the care of his child.

Example (4). Assume the same facts as in example (3) except that B's taxable year under consideration begins after December 31, 1978. B is allowed a credit with respect to the amounts paid to the sister for the care of his child, even though the services performed by B's sister do not constitute employment under section 3121(b).

(Sec. 7805, Internal Revenue Code of 1954 (68A Stat. 917; (26 U.S.C. 7805)).)

Jerome Kurtz,

Commissioner of Internal Revenue.

Approved: August 14, 1979.

Donald C. Lubick,

Assistant Secretary of the Treasury.

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The following new sections are added immediately after § 1.44-5:

§ 1.44A-1 Expenses for household and dependent care services necessary for gainful employment.

(a) *In general.* (1) This section applies only for expenses incurred in taxable years beginning after December 31, 1975. For deductibility of expenses incurred in taxable years beginning before January 1, 1972, see § 1.214-1. For deductibility of expenses incurred in taxable years beginning after December 31, 1971, and before January 1, 1976, see §§ 1.214A-1 through 1.214A-5.

(2) Section 44A allows a credit against the tax imposed by chapter 1 of the Code to an individual who maintains a household (within the meaning of paragraph (d) of this section) which includes as a member one or more qualifying individuals (as defined in paragraph (b) of this section). The amount of the credit is equal to 20 percent of the employment-related expenses (as defined in paragraph (c) of this section) paid by the individual during the taxable year (but subject to the limits prescribed in § 1.44A-2(a)). However, the credit cannot exceed the tax imposed by chapter 1, reduced by the sum of the allowable credits enumerated in section 44A(b).

(3) Generally, the credit for employment-related expenses is allowable, regardless of the taxpayer's method of accounting, only for expenses which are actually paid during the taxable year and which are incurred during the taxable year or were incurred during a prior taxable year beginning after December 31, 1975. If the expenses are incurred but not paid during the

taxable year, no credit may be taken for that year on account of those expenses. Thus, if an expense is incurred in the last month of a taxable year but not paid until the following taxable year, a credit for the expense is not allowed for the earlier taxable year but is allowed for the following taxable year. However, if an expense is incurred in a taxable year beginning before January 1, 1976, and paid in a later taxable year, no credit is allowed with respect to the expense under section 44A. Section 214 and the regulations thereunder are applicable in determining whether a deduction for the expense is allowed in the year of payment.

(4) Since an expense cannot be an employment-related expense until the services for which the expense was incurred are performed (see paragraph (c) of this section), prepaid expenses may be claimed only in the taxable year in which the services are performed.

(5) The requirements of section 44A, this section and §§ 1.44A-2 through 1.44A-4 are applied to expenses as of the time they are incurred regardless of when they are paid.

(6) For special rules relating to employment-related expenses which also qualify as medical expenses deductible under section 213, see § 1.44A-4(b).

(7) For substantiation of the credit, see paragraph (e) of this section.

(b) *Qualifying individual.*—(1) *In general.* A person is considered to be a qualifying individual if he or she is—

(i) The taxpayer's dependent who is under the age of 15 and is an individual for whom the taxpayer is entitled to a deduction for a personal exemption under section 151(e);

(ii) The taxpayer's dependent (not described in subdivision (i)) who is physically or mentally incapable of self-care; or

(iii) The taxpayer's spouse who is physically or mentally incapable of self-care.

The term "dependent," as used in this paragraph (b)(1), includes any individual who is a dependent within the meaning of section 152. However, see paragraph (b)(2) of this section for special rules for determining which parent may treat a child as a qualifying individual where the parents are divorced, legally separated, or separated under a written separation agreement.

(2) *Special dependency test in case of divorced or separated parents.* A child (as defined in section 151(e)(3)) who—

(i) Is under age 15 or is physically or mentally incapable of self-care,

(ii) Receives over half of his or her support during the calendar year from

his or her parents who are divorced or legally separated under a decree of divorce or separate maintenance or who are separated under a written separation agreement, and

(iii) Is in the custody of one or both of his or her parents for more than one-half of the calendar year.

is treated for any taxable year beginning in the calendar year as a qualifying individual (described in subdivision (i) or (ii), as the case may be, of paragraph (b)(1) of this section) of that parent who has custody for a longer period during the calendar year than the other parent. Accordingly, a child may be treated as a qualifying individual of a parent even though the parent is not entitled to a dependency exemption for the child. The child cannot be treated as a qualifying individual with respect to more than one parent.

(3) *Qualification on a daily basis.* The status of a person as a qualifying individual is determined on a daily basis. Thus, if a dependent or spouse of a taxpayer ceases to be a qualifying individual on September 16, the dependent or spouse is treated as a qualifying individual through September 15 only.

(4) *Physical or mental incapacity.* An individual is considered to be physically or mentally incapable of self-care if as a result of a physical or mental defect the individual is incapable of caring for his or her hygienical or nutritional needs, or requires full-time attention of another person for his or her own safety or the safety of others. The fact that an individual, by reason of a physical or mental defect, is unable to engage in any substantial gainful activity, or is unable to perform the normal household functions of a homemaker or to care for minor children, does not of itself establish that the individual is physically or mentally incapable of self-care. An individual who is physically handicapped or is mentally defective, and for such reason requires constant attention of another person, is considered to be physically or mentally incapable of self-care.

(c) *Employment-related expenses—*
(1) *Gainful employment—(i) In general.* Expenses are considered to be employment-related expenses only if they are incurred to enable the taxpayer to be gainfully employed and are paid for household services or for the care of one or more qualifying individuals. The expenses must be incurred while the taxpayer is gainfully employed or is in active search of gainful employment. The employment may consist of service either within or without the home of the taxpayer and may include self-

employment. An expense is not considered to be employment-related merely because it is incurred while the taxpayer is gainfully employed. The purpose of the expense must be to enable the taxpayer to be gainfully employed. Volunteer work for a nominal salary does not constitute gainful employment. Whether the purpose of an expense is to enable the taxpayer to be gainfully employed depends upon the facts and circumstances of the particular case. Any tax required to be paid by the taxpayer under section 3111 (relating to the Federal Insurance Contributions Act) and 3301 (relating to the Federal Unemployment Tax Act), or under similar State payroll taxes, in respect of any wages which otherwise constitute employment-related expenses is considered to be an employment-related expense.

(ii) *Determination of period of employment on a daily basis.* An allocation of expenses is required on a daily basis when the expenses cover any period during part of which the taxpayer is gainfully employed or is in active search of gainful employment and during the other part of which there is no employment or active search for gainful employment. Thus, for example, if a taxpayer incurs during each month of the taxable year \$60 of expenses which would be employment-related if he or she were gainfully employed all year, and the taxpayer is gainfully employed, or in active search of gainful employment, for only 2 months and 10 days during such year, the amount of employment-related expenses is limited to \$140.

(2) *Household services.* Expenses are considered to be paid for household services if they are paid for the performance in and about the taxpayer's home of ordinary and usual services necessary to the maintenance of the household. However, expenses are not considered as paid for household services unless the expenses are attributable in part to the care of the qualifying individual. Thus, amounts paid for the services of a domestic maid or cook are considered to be expenses paid for household services if a part of those services is provided to the qualifying individual. Amounts paid for the services of an individual who is employed as a chauffeur, bartender, or gardener, however, are not considered to be expenses paid for household services.

(3) *Care of qualifying individual—(i) In general.* The primary purpose of expenses for the care of a qualifying individual must be to assure that individual's well-being and protection.

Not all benefits bestowed upon a qualifying individual are considered as provided for the individual's care. Accordingly, amounts paid to provide food, clothing, or education are not expenses paid for the care of a qualifying individual. However, where the manner of providing care is such that the expense which is incurred includes expenses for other benefits which are incident to and inseparably a part of the care, the full amount of the expense is considered to be incurred for care. Thus, for example, the full amount paid to a nursery school in which a qualifying child is enrolled is considered as being for the care of the child, even though the school also furnishes lunch and educational services. Educational expenses incurred for a child in the first or higher grade level are not expenses incurred for the care of a qualifying individual. Expenses incurred for transportation of a qualifying individual described in paragraph (b)(1)(i) of this section between the taxpayer's household and a place outside the taxpayer's household where services for the care of the qualifying individual are provided are not incurred for the care of a qualifying individual.

(ii) *Manner of providing care.* The manner of providing the care need not be the least expensive alternative available to the taxpayer. For example, the taxpayer's mother may reside at the taxpayer's home and be available to provide adequate care at no cost for the taxpayer's wife who is physically or mentally incapable of caring for herself. Nevertheless, the expenses incurred in providing a nurse for the wife may be an expense for the care of the wife. See paragraph (c)(1)(i) of this section with respect to the requirement that the expense must be for the purpose of permitting the taxpayer to be gainfully employed.

(4) *Services outside the taxpayer's household.* The credit is allowed under section 44A with respect to employment-related expenses incurred for services performed outside the household of the taxpayer only if the expenses are incurred for the care of one or more qualifying individuals of the taxpayer who are under the age of 15. Otherwise, the credit is only allowed with respect to employment-related expenses incurred for services performed in the household of the taxpayer. Thus for example, if a taxpayer places his or her invalid father in a nursing home, the taxpayer is not entitled to a credit with respect to employment-related expenses incurred for the father's care provided by the nursing home. If, however, the father remains in the taxpayer's

household, the taxpayer is allowed a credit with respect to employment-related expenses attributable to the care for the father.

(5) *Allocation of expenses.* Where a portion of an expense is for household services or for the care of a qualifying individual and a portion of such expense is for other purposes, a reasonable allocation must be made and only the portion of the expense paid which is attributable to such household services or care is considered to be an employment-related expense. No allocation is required to be made, however, if the portion of expense for the other purpose is minimal or insignificant. An allocation must be made, for example, if a servant performs household duties, cares for the qualifying children of the taxpayer, and also performs social services for the taxpayer (for which a deduction is not allowable) or clerical services in the office of the taxpayer outside the home (for which a deduction may be allowable under section 162). Employment-related expenses include household service expenses which are provided in conjunction with the care of a qualifying individual. Thus, if an expense is in part attributable to the care of a qualifying individual and in part to household services, no allocation is required.

(6) *Illustrations.* The application of this paragraph (c) may be illustrated by the following examples:

Example (1). The taxpayer lives with her mother who is physically incapable of caring for herself. In order to be gainfully employed the taxpayer hires a practical nurse whose sole duty consists of providing for the care of the mother in the home while the taxpayer is at work. All amounts spent for the services of the nurse are employment-related expenses.

Example (2). The taxpayer has a dependent child 10 years of age who has been attending public school. The taxpayer, who has been working part time, is offered a position involving full-time employment which she can accept only if the child is placed in a boarding school. The taxpayer accepts the position and the child is sent to a boarding school. The expenses paid to the school must be allocated between that part of the expenses which represents care for the child and that part which represents tuition for education. The part of the expense representing care of the child is incurred for the purpose of permitting the taxpayer to be gainfully employed.

Example (3). The taxpayer, in order to be gainfully employed, employs a full-time housekeeper who cares for the taxpayer's two children, aged 9 and 15 years, respectively, performs regular household services of cleaning and cooking, and chauffeurs the taxpayer to and from his place of employment. The chauffeuring service never requires more than 30 minutes out of the total period of employment each day. No

allocation is required for purposes of determining the portion of the expense attributable to the chauffeuring (not a household service expense) since it is *de minimis*. Further, no allocation is required for the purpose of determining the portion of the expense attributable to the care of the 15-year-old child (not a qualifying individual) since the household expense is in part attributable to the care of the 9-year-old child, who is a qualifying individual. Accordingly, the entire expense of employing the housekeeper is an employment-related expense. However, the total amount of employment-related expenses taken into account would be limited to the amount allowable for one qualifying individual.

(d) *Maintenance of a household—(1) In general.* An individual is considered to have maintained a household for the taxable year (or lesser period) only if the individual (and his or her spouse if the individual is married) have furnished over one-half of the cost incurred for such taxable year (or lesser period) in maintaining the household. The household must actually constitute for the taxable year the principal place of abode of the taxpayer and the qualifying individual or individuals described in paragraph (b) of this section. It is not sufficient that the taxpayer maintain the household without being its occupant. A physical change in the location of the home does not, however, prevent the home from constituting the principal place of abode of the taxpayer and a qualifying individual. The fact that an individual is born or dies during the taxable year does not prevent a home from constituting his or her principal place of abode for such year. An individual is not considered to have terminated a household as his or her principal place of abode merely by reason of temporary absences therefrom by reason of illness, education, business, vacation, military service, or a custody agreement.

(2) *Two or more families.* Solely for purposes of section 44A and this section, if two or more families occupy living quarters in common, each of the families is treated as constituting a separate household, and the taxpayer who provides more than one-half of the costs of maintaining such a separate household is treated as maintaining that household. Thus, for example, if two unrelated taxpayers each with children occupy living quarters in common and each taxpayer pays more than one-half of the household costs incurred by each respective family, each taxpayer will be treated as maintaining a separate household.

(3) *Costs of maintaining a household.* The costs of maintaining a household are the expenses incurred for the mutual benefit of the occupants thereof by

reason of its operation as the principal place of abode of the occupants. The expenses of maintaining a household include property taxes, mortgage interest, rent, utility charges, upkeep and repairs, property insurance, and food consumed on the premises. These expenses do not include the cost of clothing, education, medical treatment, vacations, life insurance, or transportation or payments on mortgage principal or for the purchase, permanent improvement, betterment, or replacement of property. Further, the costs of maintaining a household do not include the value of services performed in the household by a qualifying individual described in paragraph (b) of this section. An expense incurred by a taxpayer which is paid or reimbursed by another is not considered as a cost of maintaining a household.

(4) *Monthly proration of annual costs.* In determining the cost incurred for a period of less than a taxable year in maintaining a household, the cost incurred during the entire taxable year must be prorated on the basis of the number of calendar months within such lesser period. For this purpose a period of less than a calendar month will be treated as a calendar month. Thus, for example, if the cost of maintaining a household for a taxable year is \$6,600, and the period in respect of which a determination is being made under section 44A is from June 20 to December 31, the taxpayer must furnish more than \$1,925 $[(\$6,600 \times \frac{1}{12}) \times 50 \text{ percent}]$ in maintaining the household from June 1 to December 31.

(e) *Substantiation.* A taxpayer claiming a credit under paragraph (a) of this section for employment-related expenses must substantiate by adequate records or other sufficient evidence any credit taken under this section. For example, if requested, the taxpayer must furnish information as to the nature and period of the physical or mental incapacity of any dependent or spouse in respect of whom a credit is claimed, including necessary information from the attending physician as to the nature of the physical or mental incapacity.

§ 1.44A-2 Limitations on amount creditable.

(a) *Annual dollar limit on amount creditable.* The amount of the employment-related expenses incurred during any taxable year which may be taken into account under § 1.44A-1(a) cannot exceed—

- (1) \$2,000 if there is one qualifying individual with respect to the taxpayer at any time during the taxable year, or
- (2) \$4,000 if there are two or more qualifying individuals with respect to

the taxpayer at any one time during the taxable year.

For example, a calendar year taxpayer whose only qualifying individual reaches age 15 on April 1, 1976, is subject for 1976 to the entire annual dollar limit of \$2,000, without proration of the \$2,000 limit. However, only expenses incurred prior to the child's 15th birthday may be employment-related expenses.

(b) *Earned income limitation*—(1) *In general.* The amount of employment-related expenses incurred during any taxable year which may be taken into account under § 1.44A-1(a) cannot exceed—

(i) For an individual not married at the close of the year, the individual's earned income for the year, or

(ii) For an individual married at the close of the year, the lesser of the individual's earned income or the earned income of his or her spouse for the year.

For purposes of this paragraph (b)(1), the earned income of only the spouse to whom the taxpayer is married at the close of the year is taken into account (and not the earned income of another spouse who died or was divorced from the taxpayer during the year). Further, the spouse's earned income for the entire year is taken into account, even though the taxpayer and his or her spouse were married for only a part of the year. For purposes of this paragraph (b), certain married individuals legally separated or living apart are treated as not married (see § 1.44A-3 (b) and (c), respectively).

(2) *Earned income.* For purposes of this section, earned income means—

(i) Wages, salaries, tips, other employee compensation, and

(ii) Net earnings from self-employment (within the meaning of section 1402(a) and the regulations thereunder).

For taxable years beginning before January 1, 1979, earned income includes only amounts described in subdivision (i) or (ii) of this paragraph (b)(2) which are includible in the eligible individual's gross income for the taxable year of the individual in which the credit is claimed. For all taxable years, however, earned income is computed without regard to any community property laws which may otherwise be applicable. Earned income is reduced by any net loss in earnings from self-employment. Earned income does not include amounts received as a pension or an annuity or an amount to which section 871(a) and the regulations thereunder apply (relating to income of nonresident alien individuals not connected with United States business).

(3) *Special rule for spouse who is a student or incapable of self-care.* (i) For purposes of this section, a spouse is deemed, for each month during which the spouse is a full-time student or is a qualifying individual described in § 1.44A-1(b)(1)(iii), to be gainfully employed and to have earned income of not less than—

(A) \$166, if there is one qualifying individual with respect to the taxpayer at any time during the taxable year, or

(B) \$333, if there are two or more qualifying individuals with respect to the taxpayer at any one time during the taxable year.

However, in the case of any husband and wife, this subparagraph shall apply with respect to only one spouse for any one month.

(ii) A "full-time student" is an individual who is enrolled at and attends an educational institution during each of 5 calendar months of the taxable year of the taxpayer for the number of course hours which is considered to be a full-time course of study. The enrollment for 5 calendar months need not be consecutive. School attendance exclusively at night does not constitute a full-time course of study. However, a full-time course of study may include some attendance at night.

(iii) For the definition of "educational institution", see § 1.151-3(c).

(4) *Illustrations.* The application of this paragraph may be illustrated by the following examples:

Example (1). During the taxable year, A, a married taxpayer, incurs and pays employment-related expenses of \$4,000 for the care of a qualifying individual. A's earned income for the taxable year is \$20,000 and his wife's earned income is \$1,500. Under these circumstances, the amount of employment-related expenses for the year which may be taken into account under § 1.44A-1(a) is \$1,500, determined as follows:

Employment-related expenses incurred during taxable year (\$4,000, but limited to \$2,000 by paragraph (a)(1) of this section).....	\$2,000
Application of paragraph (b)(1)(ii) of this section (employment-related expenses, may not exceed wife's earned income of \$1,500).....	1,500
Employment-related expenses taken into account.....	1,500

Example (2). Assume the same facts as in example (1) except that A's wife is a full-time student for nine months of the taxable year and earns no income for the year. Under these circumstances, the amount of employment-related expenses for the year which may be taken into account under § 1.44A-1(a) is \$1,494, determined as follows:

Employment-related expenses incurred during taxable year (\$4,000, but limited to \$2,000 by paragraph (a)(1) of this section).....	\$2,000
Application of paragraph (b)(3) of this section (employment-related expenses may not exceed wife's earned income of \$1,494 (\$166 x 9)).....	1,494
Employment-related expenses taken into account.....	1,494

§ 1.44A-3 Special rules applicable to married individuals.

(a) *Joint return requirement.* This section applies only if the taxpayer is married at the close of a taxable year in which employment-related expenses are paid. In such a case the credit provided by section 44A with respect to employment-related expenses is allowed only if for the taxable year the taxpayer and his or her spouse file a joint return. If either spouse dies during the taxable year and a joint return may be made for the year under section 6013(a)(2) for the survivor and the deceased spouse, the credit is allowed for the year only if a joint return is made. If, however, the surviving spouse remarries before the end of the taxable year in which his or her first spouse dies, a credit is allowed on the separate return which is made for the decedent spouse. For purposes of this section, certain married individuals legally separated or living apart are treated as not married, as provided in paragraphs (b) and (c), respectively, of this section.

(b) *Marital status.* For purposes of section 44A, an individual legally separated from his or her spouse under a decree of divorce or of separate maintenance is not considered as married.

(c) *Certain married individuals living apart.* For purposes of section 44A, an individual who is married within the meaning of section 143(a) is treated as not married for the entire taxable year, if the individual—

(1) Files a separate return for the year,

(2) Maintains as his or her home a household which constitutes for more than one-half of the taxable year the principal place of abode of a qualifying individual, and

(3) Furnishes over one-half of the cost of maintaining the household for the year, and if the individual's spouse is not a member of the household at any time during the last 6 months of the year. Thus for example, an individual who is married during the taxable year, but is treated as not married by reason of this paragraph, may determine the earned income limitation upon the amount of employment-related expenses without taking into account the earned income of his or her spouse under § 1.44A-2(b).

§ 1.44A-4 Other special rules relating to employment-related expenses.

(a) *Payments to related individuals—*

(1) *Taxable years beginning after December 31, 1978.* For taxable years beginning after December 31, 1978, a credit is not allowed under section 44A with respect to the amount of any employment-related expenses paid by the taxpayer to an individual—

(i) With respect to whom for the taxable year a deduction under section 151(e) (relating to deduction for personal exemptions for dependents) is allowable either to the taxpayer or his or her spouse, or

(ii) Who is a child of the taxpayer (within the meaning of section 151(e)(3)) who is under age 19 at the close of the taxable year.

For purposes of this paragraph (a)(1), the term "taxable year" means the taxable year of the taxpayer in which the service is performed. (1943)

(2) *Taxable years beginning before January 1, 1979.* For taxable years beginning before January 1, 1979, except as otherwise provided in paragraph (a)(3) of this section, a credit is not allowed under section 44A with respect to the amount of any employment-related expenses paid by the taxpayer to an individual who bears to the taxpayer any relationship described in section 152(a) (1) through (8). These relationships are those of a son or daughter or descendant thereof; a stepson or stepdaughter; a brother, a sister, stepbrother, or stepsister; a father or mother or an ancestor, of either; a stepfather or stepmother; a nephew or niece; an uncle or aunt; or a son-in-law, daughter-in-law, father-in-law, mother-in-law, brother-in-law, or sister-in-law. In addition, no credit is allowed with respect to the amount of any employment-related expenses paid by the taxpayer to an individual who qualifies as a dependent of the taxpayer for the taxable year within the meaning of section 152(a)(9), which relates to an individual (other than the taxpayer's spouse) whose principal place of abode for the taxable year is the home of the taxpayer and who is a member of the taxpayer's household.

(3) *Exception for payments to certain related individuals.* For taxable years beginning before January 1, 1979, a credit is allowed for the amount of any employment-related expenses paid by the taxpayer to an individual provided that neither the taxpayer nor his or her spouse is entitled to a deduction under section 151(e) (relating to deduction for personal exemptions for dependents) with respect to such individual for the taxable year in which the service is performed; and the service with respect to which the amount is paid constitutes employment within the meaning of section 3121(b). The following services performed for a taxpayer by a relative who is an employee of the taxpayer may qualify as employment within the meaning of section 3121(b):

(i) Services performed by the taxpayer's child age 21 or over.

(ii) Domestic services in the taxpayer's home performed by the taxpayer's parent if—

(A) The taxpayer has living in his or her home a child (as defined in section 151(e)(3)) who is under age 18 or who has a physical or mental condition requiring the personal care of an adult during at least 4 continuous weeks in the calendar quarter, and

(B) The taxpayer is a widow or widower or is divorced, or has a spouse living in the home who, because of a physical or mental condition, is incapable of caring for his or her child during at least 4 continuous weeks in the calendar quarter in which services are rendered.

(iii) Services of all relatives other than a child, spouse, or parent of the taxpayer.

For taxable years beginning before January 1, 1979, a credit is not allowed under section 44A with respect to employment-related expenses paid by the taxpayer to a relative for services which do not constitute employment under section 3121(b). Services performed by a relative do not constitute employment if they relate to the relative's trade or business the income from which is includible in computing the relative's net earnings for purposes of the self-employment tax under section 1401.

(4) *Payments to entities or partnerships.* If the services are performed by an entity or partnership, paragraph (a) (1) and (2) of this section is normally not applicable. If, however, the entity or partnership is established or maintained primarily to avoid the application of paragraph (a) (1) or (2) in order to permit the taxpayer to obtain the credit with respect to employment-related expenses, for purposes of this paragraph (a), the payments of employment-related expenses shall be treated as made directly to each owner of the entity or partner in proportion to his or her share of the entity or partnership. A factor to consider for purposes of determining whether an entity or partnership is so established or maintained is whether the entity or partnership is set up solely to care for the taxpayer's qualifying individual and to provide household services to the taxpayer.

(5) *Illustrations.* The application of this paragraph may be illustrated by the following examples:

Example (1). For A's taxable year ending December 31, 1978, A, a divorced taxpayer, pays \$5,000 of employment-related expenses to his mother for the care of his child age 5. A's mother cares for the child in her home. The services performed by A's mother do not constitute employment under section 3121(b).

Accordingly, A is not allowed a credit with respect to the amounts paid to the mother for the care of his child.

Example (2). Assume the same facts as in example (1) except that A's taxable year under consideration begins after December 31, 1978. A is not entitled to a deduction under section 151(e) for his mother.

Accordingly, A is allowed a credit with respect to the amounts paid to the mother for the care of his child even though the services performed by A's mother do not constitute employment under section 3121(b).

Example (3). For B's taxable year ending December 31, 1978, B, a divorced taxpayer, pays \$6,000 of employment-related expenses to his sister (who is not a dependent of the taxpayer) for the care of his child. The services performed by B's sister in the care of his child constitute a trade or business the income from which is includible in computing net earnings for purposes of the self-employment tax under section 1401. Accordingly, B is not allowed a credit with respect to the amounts paid to the sister for the care of his child.

Example (4). Assume the same facts as in example (3) except that B's taxable year under consideration begins after December 31, 1978. B is allowed a credit with respect to the amounts paid to the sister for the care of his child, even though the services performed by B's sister do not constitute employment under section 3121(b).

(b) *Expenses qualifying as medical expenses.* An expense which may constitute an amount otherwise deductible under section 213, relating to medical, etc., expenses, may also constitute an expense with respect to which a credit is allowable under section 44A. In such a case, that part of the amount with respect to which a credit is allowed under section 44A will not be considered as an expense for purposes of determining the amount deductible under section 213. On the other hand, where an amount is treated as a medical expense under section 213 for purposes of determining the amount deductible under that section, it may not be treated as an employment-related expense for purposes of section 44A. The application of this paragraph may be illustrated by the following examples:

Example (1). A taxpayer pays \$5,000 of employment-related expenses during the taxable year for the care of his child when the child is physically incapable of self-care. These expenses are incurred for services performed in the taxpayer's household and are of a nature which qualify as medical expenses under section 213. The taxpayer's adjusted gross income for the taxable year is \$100,000. Of the total expenses, the taxpayer may take \$2,000 into account under section 44A; the balance of the expenses, or \$3,000, may be treated as medical expenses to which section 213 applies. However, this amount does not exceed 3 percent of the taxpayer's adjusted gross income for the taxable year and is thus not allowable as a deduction under section 213.

Example (2) Assume the same facts as in example (1). It is not proper for the taxpayer first to determine his deductible medical expenses of \$2,000 (\$5,000—[\$100,000×3 percent]) under section 213 and then claim the \$3,000 balance as employment-related expenses for purposes of section 44A. This is because the \$3,000 balance has been treated as a medical expense in computing the amount deductible under section 213.

Example (3) A taxpayer incurs and pays \$12,000 of employment-related expenses during the taxable year for the care of his child. These expenses are incurred for services performed in the taxpayer's household, and they also qualify as medical expenses under section 213. The taxpayer's adjusted gross income for the taxable year is \$18,000. The taxpayer takes \$2,000 of such expenses into account under section 44A. The balance, or \$10,000, he treats as medical expenses for purposes of section 213. The allowable deduction under section 213 for the expenses is limited to the excess of the balance of \$10,000 over \$540 (3 percent of the taxpayer's adjusted gross income of \$18,000), or \$9,460.

§ 1.213 and Historical Note [Deleted]

Par. 2. Section 1.213 and the historical note are deleted.

Par. 3. Paragraph (f) of § 1.213-1 is revised to read as follows:

§ 1.213-1 Medical, dental, etc., expenses.

(f) *Exclusion of amounts allowed for care of certain dependents.* Amounts taken into account under section 44A in computing a credit for the care of certain dependents shall not be treated as expenses paid for medical care.

§ 1.214 and Historical Note [Deleted]

Par. 4. Section 1.214 and the historical note are deleted.

Par. 5. Paragraph (a)(1) of § 1.214-1 is revised to read as follows:

§ 1.214-1 Expenses for the care of certain dependents incurred during taxable years beginning before January 1, 1972.

(a) *General rule.* (1) This section applies only for expenses incurred during taxable years beginning before January 1, 1972. For expenses incurred in taxable years beginning after December 31, 1971, and before January 1, 1976, see §§ 1.214A-1 through 1.214A-5.

§ 1.214A and Historical Note [Deleted]

Par. 6. Section 1.214A and the historical note are deleted.

Par. 7. Section § 1.214A-1 is amended by revising the heading thereto and by revising so much of paragraph (a)(1) thereof as precedes subdivision (i) to read as follows:

§ 1.214A-1 Certain expenses to enable individuals to be gainfully employed incurred during taxable years beginning after December 31, 1971, and before January 1, 1976.

(a) *In general.* For expenses incurred during taxable years beginning after December 31, 1971, and before January 1, 1976, section 214 allows (subject to the requirements of this section and §§ 1.214A-2 through 1.214A-5) a deduction for employment-related expenses (as defined in paragraph (c) of this section) which are paid during the taxable year by an individual who maintains a household (within the meaning of paragraph (d) of this section) that includes as a member one or more qualifying individuals (as defined in paragraph (b) of this section). The deduction for expenses allowed under section 214 may be taken only as an itemized deduction and may not be taken into account in determining adjusted gross income under section 62. No deduction shall be allowed under section 214 in respect of any expenses incurred during a taxable year beginning after March 29, 1975, and before January 1, 1976, for which the taxpayer's adjusted gross income is \$44,600 or more (or incurred during a taxable year beginning after December 31, 1971, and before March 30, 1975, for which the taxpayer's adjusted gross income is \$27,600 or more). Expenses which are taken into account in determining the deduction under section 214—

Par. 8. Section 1.214A-2 is amended by revising so much of paragraph (c)(1) thereof as precedes example (3) to read as follows:

§ 1.214A-2 Limitations on deductible amounts.

(c) *Taxpayer's income limitation—(1)* *In general.* This paragraph applies only if the adjusted gross income of the taxpayer for the taxable year exceeds the amount of \$35,000, in the case of a taxable year beginning after March 29, 1975, and before January 1, 1976 (or the amount of \$18,000 in the case of a taxable year beginning after December 31, 1971, and before March 30, 1975). In either case, in determining the deduction allowable under § 1.214A-1(a) for employment-related expenses, the amount of the expenses incurred during any calendar month of the taxable year must be reduced by an amount equal to the excess of the adjusted gross income of the taxpayer for the taxable year over the applicable income limitation (\$35,000 or \$18,000 as the case may be) divided by twice the number of calendar months in the taxable year. For purposes of

applying the taxpayer's income limitation a period of less than a calendar month will be treated as a calendar month. The limitation provided by this paragraph must be applied after making the reduction in the amount of employment-related expenses provided by paragraph (a) of § 1.214A-3 and after the application of the limitations upon the amount deductible provided by paragraph (a) of § 1.214A-3 and after the application of the limitations upon the amount deductible provided by paragraphs (a) and (b) of this section. The application of this subparagraph may be illustrated by the following examples:

Example (1). A, a single individual who uses a fiscal year ending March 31 as the taxable year, incurs (and pays) during May 1975 employment-related expenses of \$600. He has adjusted gross income of \$41,000 for the fiscal year ending March 31, 1976. Under these circumstances the amount of employment-related expenses for the month of May 1975 which may be taken into account under paragraph (a) of § 1.214A-1 is \$150, determined as follows:

Employment-related expenses incurred during May (\$600, but not to exceed \$400 under paragraph (a) of this section)	\$400
Less: Reduction under this subparagraph:	
Adjusted gross income for taxable year	\$41,000
Less: Taxpayer's income limitation applicable to taxable year beginning after March 29, 1975	35,000
Excess adjusted gross income over income limitation	6,000
Excess divided by twice the number of calendar months in taxable year ($6,000 \div [2 \times 12]$)	250
Employment-related expenses to be taken into account	150

Example (2). Assume the same facts as in example (1) except that A incurs employment-related expenses of only \$200 during May 1975. Under these circumstances no amount of employment-related expenses may be taken into account for the month of May under paragraph (a) of § 1.214A-1 because the expenses of \$200 for the month are fully offset by the reduction of \$250 required under this subparagraph.

PART 31—EMPLOYMENT TAXES; APPLICABLE ON AND AFTER JANUARY 1, 1955

§ 31.3402 [Amended]

Par. 19. Section 31.3402(m) and the historical note are deleted.

PART 301—PROCEDURE AND ADMINISTRATION

§ 301.6096 and Historical Note [Deleted]

Par. 10. Section 301.6096 and the historical note are deleted.

Par. 11. Paragraph (b) of § 301.6096-1 is amended to read as follows:

§ 301.6096-1 Designation by individuals for taxable years beginning after December 31, 1972.

(b) *Income tax liability.* For purposes of paragraph (a) of this section, the income tax liability of an individual for any taxable year is the amount of the tax imposed by chapter 1 on such individual for the taxable year (as shown on his or her return) reduced by the sum of the credits (as shown on his or her return) allowable under sections 33, 37, 38, 40, 41, 42, 44, and 44A.

[FR Doc. 79-26743 Filed 8-27-79; 8:45 am]
BILLING 4830-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Safety and Health Standards; Occupational Exposure to Lead; Correction

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Correction to final standard for occupational exposure to lead.

SUMMARY: OSHA's final standard for occupational exposure to lead was published in the Federal Register on November 14, 1978 (43 FR 52952). Corrections to the regulation were published in the Federal Register on January 26, 1979 (44 FR 5446). This notice corrects the language of the standard's exemption for construction work to avoid any possible ambiguity in the scope of the exemption.

DATES: This correction is effective August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Gail Brinkerhoff, OSHA Office of Compliance Programming, U.S. Department of Labor, Room N3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: OSHA's final standard for occupational exposure to lead, 29 CFR 1910.1025, published on November 14, 1978 (43 FR 52952), exempted the construction industry from coverage by the new standard. The preamble to the standard, at 43 FR 52986, discussed the arguments that had been made during the rule-making proceeding in support of a construction industry exemption and articulated OSHA's rationale for incorporating this exemption in the final standard. Briefly, OSHA reviewed the arguments that the

unique nature of the construction industry, rendered many of the provisions of the standard infeasible or meaningless, i.e., the mobility and transient nature of employees, worksites and working conditions. OSHA concluded that the record before it was insufficient to resolve the issues raised by the uniqueness of the construction industry and therefore exempted the industry from the standard pending submission of the issues to the Construction Advisory Committee for its recommendations.

In incorporating the construction industry exemption into the lead standard, paragraph (a)(2) provided that the section "does not apply to construction work as defined in 29 CFR 1910.12(b)." Several interested persons, including parties in the current appellate litigation concerning the lead standard, have brought to OSHA's attention that the phrase "construction work as defined in 29 CFR 1910.12(b)" may be interpreted as exempting from the protection of the standard industrial workers in a plant producing or using lead whenever they perform tasks falling under the rubric of "construction work." In view of the broad interpretation given to the term "construction work" by the Occupational Safety and Health Review Commission, there is merit to the suggestion that this term is susceptible to an interpretation which would exempt from coverage a class of employees whom OSHA never intended to exclude. It is therefore necessary to conform the language of the standard to OSHA's intent, expressed in the preamble, to exempt the "construction industry," but to provide protection for workers employed in the lead industry even when they may be performing "construction work."

Since this correction is minor and merely conforms the regulatory language to OSHA's clear intent, we find that there is no purpose or need for notice and public procedure or for a delayed effective date within the meaning of 5 U.S.C. 553(b) and (d) and 29 CFR 1911.5.

Accordingly, pursuant to section 6(b) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 29 U.S.C. 655), 5 U.S.C. 553, Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911, paragraph (a)(2) of 29 CFR 1910.1025 is amended to read as follows:

§ 1910.1025 Lead.

(a) * * *

(2) This section does not apply to the construction industry or to agricultural operations covered by 29 CFR Part 1928.

Signed at Washington, D.C. this 23 day of August, 1979.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 79-26739 Filed 8-27-79; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF DEFENSE

Corps of Engineers

33 CFR Part 209

[ER 1140-1-210]

Laboratory Investigations and Materials Testing

AGENCY: Corps of Engineers, DOD

ACTION: Final rule.

SUMMARY: This regulation imposes restrictions on non-Corps work that may be undertaken at Corps of Engineers laboratories other than research and development laboratories. Increasing requests from other Governmental agencies and private firms for investigation and testing services were tending to divert laboratory resources from Corps work, and improperly placing the Corps in competition with private industry. This regulation will prevent unfair competition between Government and private sector materials investigations and testing organizations.

EFFECTIVE DATE: August 31, 1979.

FOR FURTHER INFORMATION CONTACT: James A. Rhodes, Chief, Concrete Section, Office, Chief of Engineers, Washington, DC 20314, (202) 272-0219.

Accordingly, 33 CFR Part 209 is amended by revising § 209.340 to read as follows:

§ 209.340 Laboratory investigations and materials testing.

(a) *Purpose.* The purpose of this section is to define and establish policies and procedures applicable to the performance of investigations and tests at Corps of Engineers laboratory installations for other governmental agencies and private organizations.

(b) *Applicability.* This regulation applies to Corps of Engineers Divisions and Districts operating soils, concrete, water quality and hydraulic laboratories, and to the Inter-Agency Sedimentation Project.

(c) *References.* (1) AR 37-20.

(2) AR 37-27.

(3) ER 1-1-6.

(4) ER 10-1-3, Appendix XIII.

(5) ER 1110-1-8100.

(6) ER 1140-2-303.

(d) *Policy.* Subject to the authority limitations contained in paragraph (f) of

this section, laboratory investigations and materials testing may be performed for other agencies of the Federal Government, State and local units of government, foreign governments and private firms under the following conditions:

(1) The work will be performed on a cost reimbursable basis.

(2) Work may be performed for State and local units of government, foreign governments or private firms only when it is firmly established that private commercial laboratory facilities capable of performing such work are not available, or because of location or for other reasons it is clearly impractical to utilize such private commercial laboratory services. The requesting entity must further certify that such services cannot be procured reasonably and expeditiously through ordinary business channels.

(3) Performance of the work will not interfere with provisions of services essential to the mission of the Corps.

(4) Performance of the work will not require an increase in the permanent staff of the facility.

(5) Performance of the work will not require expansion of normal facilities.

(6) The work is within the scope of authorized activities of the laboratory at which the work is to be performed.

(7) Performance of the work will not be adverse to the public interest.

(8) Prior to undertaking laboratory investigations or materials testing for private firms, written certification will be obtained from such firms stating that the results of the work will not be used in litigation or for promotional purposes.

(e) *Terms of providing reimbursement for work performed.* (1) *Federal agencies.* Reimbursement for work for the Department of Defense, the Department of the Army, and other Federal Agencies will be in accordance with the procedures prescribed in AR 37-27.

(2) *State and Local units of Government.* Funds to cover the total estimated cost of the work or an initial increment of the estimated cost based on an approved schedule of payment will be deposited with the installation performing the work before any obligations or expenses in connection with the work are incurred; and when funds are being deposited on an approved schedule no obligations or expenses will be incurred in connection with the work in excess of funds on deposit.

(3) *Private concerns and foreign governments.* Funds will be deposited in advance of the work as required in paragraph (e)(2) of this section. Charges shall include a surcharge of 15 percent

of all applicable costs, except under the following conditions:

(i) When the final product will directly contribute to a specific planning, design, or construction activity which derives its principal support from Federal funds in the form of a grant or otherwise.

(ii) Where an exception is granted based on a direct benefit to the Government. Adequate justification, outlining the direct benefits which are expected to accrue to the Government, will be forwarded to HQDA (DAEN-CWE-DC) Washington, DC 20314, for review and approval prior to deletion of the surcharge.

(f) *Authority.* The following delegations of authority to perform laboratory investigations and materials testing apply.

(1) *Division materials laboratories.* Division Engineers are delegated the authority to approve laboratory work for Federal, State and local units of government when the total estimated cost of each investigation or test project is \$15,000 or less. Division Engineers are also delegated the authority to approve laboratory work for private firms and foreign Governments when the total estimated cost of each investigation or test project is \$5,000 or less. Approval is required when the estimated or actual costs exceed those delegations of authority. Requests for approval shall be addressed to DAEN-CWE-DC.

(2) *Hydraulic Laboratories.* Division Engineers and District Engineers operating hydraulic laboratories or hydraulic model laboratories are delegated the authority to approve laboratory work for others within the same limitations and in accordance with the same procedures as apply to Division Materials Laboratories.

(3) *Inter-Agency Sedimentation Project.* St. Anthony Falls Laboratory, University of Minnesota, Minneapolis, Minnesota. The District Engineer, St. Paul is authorized to perform work required in procurement, testing and calibration of specialized sediment sampling equipment developed at the Inter-Agency Sedimentation Project. Equipment of this nature will be made available to Federal, State and local governmental agencies at cost. The District Engineer, St. Paul, is also authorized to approve the performance of testing and calibration work for U.S. private firms that fabricate this specialized equipment for commercial sale when the estimated cost for services of Corps personnel is \$5,000 or less for a single order. Approval is required when the estimated single order cost for a private firm exceeds \$5,000 and when the total cost of work during a fiscal year for any one private

firm exceeds \$15,000. Requests for approval shall be addressed to HQDA (DAEN-CWE-HY) Washington, DC 20314.

(g) *Reports of testing results.* Final reports of results will be submitted in accordance with instructions provided by the sponsoring organization, with two copies to HQDA (DAEN-CWE-DC) Washington, DC 20314.

Copies of reports of scientific or technical activities of a research and development nature will be transmitted to the Defense Documentation Center as required by AR 70-31. (RCS OSD-1366).

Authority: (Sec. 3012, 70A Stat. 157; 10 U.S.C. 3012)

Source: ER 1140-1-210.

Dated: August 21, 1979.

Forrest T. Gay, III,
Colonel, Corps of Engineers, Executive
Director, Engineer staff.

[FR Doc. 79-28645 Filed 8-27-79; 8:45 am]

BILLING CODE 3710-92-M

VETERANS ADMINISTRATION

38 CFR Part 3

Pension, Compensation, and Dependency and Indemnity Compensation; Proximate Results, Secondary Conditions

AGENCY: Veterans Administration.

ACTION: Final Regulations.

SUMMARY: The Veterans Administration has amended its regulation which grants service connection for a disability which is proximately due to a service-connected disease or injury. This amendment results from a report made by the National Academy of Sciences. The effect of this action is to grant service connection for ischemic heart disease or other cardiovascular disease developing in a veteran who has a service-connected amputation of one lower extremity at or above the knee or service-connected amputations of both lower extremities at or above the ankles.

EFFECTIVE DATE: August 22, 1979.

FOR FURTHER INFORMATION CONTACT: T.H. Spindle, Jr. (202-389-3005).

SUPPLEMENTARY INFORMATION: On pages 26762-63 of the Federal Register of May 7, 1979, there was published a proposed amendment to 38 CFR 3.310.

Interested persons were given 30 days to submit comments, suggestions, or objections to the proposed amendment. Three comments were received.

One commentator wants us to presume that cardiovascular disease developing in veterans who have

suffered a single below-the-knee amputation is service-connected. We are unable to adopt this suggestion since the National Academy of Sciences (NAS) study shows that only unilateral above-the-knee amputations result in a significant increase in the incidence of cardiovascular disease.

Another commentator feels that service connection should be presumed for cardiovascular disease developing in a veteran who has suffered a unilateral below-the-knee amputation and who had to be hospitalized while in service for a prolonged period to treat numerous other disabilities or who has a service-connected disability evaluated as 30 percent or more disabling in the other leg. Since these situations were not dealt with in the NAS report we are unable to favorably consider these suggestions.

The third commentator expressed concern that the NAS report failed to adequately deal with the incidence of cardiovascular disease developing in veterans who suffered arm amputations or who suffered unilateral leg amputations above the ankle but below the knee. The commentator felt that it is wrong for the Veterans Administration to adopt strict regulations without more study of veterans who have suffered these kinds of amputations.

The NAS report shows that only unilateral above-the-knee amputations and amputations of both lower extremities result in a significant increase in the incidence of cardiovascular disease. The amendment of § 3.310, which implements this finding, does not, however, preclude further amendment if it is subsequently shown that other types of amputations also result in a significant increase in the incidence of cardiovascular disease. In this regard the amendment of § 3.310 is not meant to be restrictive.

The amendment of § 3.310 is adopted without change and is set forth below.

Approved: August 22, 1979.

By direction of the Administrator.

Rufus H. Wilson,
Deputy Administrator.

Section 3.310 is revised to read as follows:

§ 3.310 Proximate results, secondary conditions.

(a) *General.* Disability which is proximately due to or the result of a service-connected disease or injury shall be service connected. When service connection is thus established for a secondary condition, the secondary condition shall be considered a part of the original condition.

(b) *Cardiovascular disease.* Ischemic heart disease or other cardiovascular disease developing in a veteran who has a service-connected amputation of one lower extremity at or above the knee or service-connected amputations of both lower extremities at or above the ankles, shall be held to be the proximate result of the service-connected amputation or amputations. (38 U.S.C. 210(c), 310.331)

[FR Doc. 79-26678 Filed 8-27-79; 8:45 am]

BILLING CODE 8320-01-M

**GENERAL SERVICES
ADMINISTRATION**

41 CFR Chapter 101

**Federal Property Management
Regulations; Standard Form 149, U.S.
Government National Credit Card**

AGENCY: Transportation and Public Utilities Service, General Services Administration.

ACTION: Temporary regulations.

SUMMARY: These regulations modify GSA policies and procedures concerning the acquisition, use, and control of Standard Form 149, U.S. Government National Credit Card, to provide tighter management controls over the issuance, accountability, and disposition of the credit card.

DATES: Effective date: October 1, 1979. Expiration date: July 31, 1980, unless sooner revised or superseded.

FOR FURTHER INFORMATION CONTACT: Lowell Stockdale, Acting Director, Federal Fleet Management Division (703-557-1327).

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that these regulations will not impose unnecessary burdens on the economy or on individuals and, therefore, are not significant for the purposes of Executive Order 12044. (Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

**Subchapter E—Supply and
Procurement**

Appendix—Temporary Regulations

[FPMR Temp. Reg. E-184]

In 41 CFR Chapter 101, the following temporary regulation is added to the appendix at the end of Subchapter E to read as follows:

**Federal Property Management Regulations,
Temporary Regulation E-184**

To: Heads of Federal agencies.

Subject: Standard Form 149, U.S. Government National Credit Card.

1. *Purpose.* This regulation provides revised policy and procedures concerning the acquisition and use of Standard Form 149, U.S. Government National Credit Card.

2. *Effective date.* This regulation is effective October 1, 1979.

3. *Expiration date.* This regulation expires on July 31, 1980, unless sooner revised or superseded.

4. *Background.* A notice of proposed rulemaking, published on November 3, 1978 (43 FR 51429), announced that the General Services Administration would amend the Federal Property Management Regulations to revise the information concerning the acquisition and use of Standard Form 149, U.S. Government National Credit Card. However, developments in the program during the preparation of the amendment led to a decision to issue a temporary regulation to implement the new policies and procedures quickly. (See attachment A.) Before the expiration date, this regulation will be codified in the permanent regulations of the General Services Administration appearing in Title 41 CFR, Public Contracts and Property Management.

5. *Effect on other directives.* This temporary regulation supersedes the information contained in §§ 101-26.406-1 (a) and (b) and 101-26.406-5.

Dated: August 15, 1979.

R. G. Freeman III,
Administrator of General Services.

**1. Use of Standard Form 149, U.S.
Government National Credit Card.**

a. Standard Form 149, U.S. Government National Credit Card, is authorized for use by Federal agencies to obtain authorized services or supplies at service stations dispensing items provided by the contractors listed in the Defense Fuel Supply Center publication "Your Guide to Service Stations for Gasoline, Oil, and Lubrication" (DFSC H 4280.1). Activities requiring copies of the publication should submit requests to: Commander, Defense Fuel Supply Center, Attention: DFSC:OD, Cameron Station, Alexandria, VA 22314.

b. Standard Form 149 is the only Government-wide credit card approved for use by Federal agencies for the procurement of gasoline and services at service stations dispensing items provided by the contractors listed in the Defense Fuel Supply Center publication referenced in subpar. a. However, agencies that operate motor vehicles for purposes of which identification as Government vehicles would interfere with the performance of the functions for which the vehicles were acquired and are used (see § 101-38.602) need not use Standard Form 149 for those specific vehicles.

**2. Methods of obtaining Standard Form 149,
U.S. Government National Credit Card.**

a. Agency requests for embossed Standard Forms 149 shall be forwarded to the contractor in the format specified in Federal Supply Schedule 75 Part VII. Request should be submitted on GSA Form 300, Purchase

Order; DD1155, Order for Supplies or Services Request for Quotation; or the purchase order form normally used by the agency. In accordance with the procedures contained in FPMR Temporary Regulation G-144, each request shall include the following information for each Standard Form 149 requisitioned:

- (1) The billing code;
- (2) The complete address for billing purposes, and the name and commercial telephone number of an employee in the office ordering the credit card;
- (3) The vehicle tag number or serial number. If a serial number is furnished instead of a vehicle tag number, it shall be restricted to four characters, all numeric, with zeros used to fill blank positions;
- (4) The agency identifier. This is a one-line entry with a maximum of 22 characters identifying the agency or agency department (no Government employee's name will be embossed on the credit card) that is authorized to use the Standard Form 149; and
- (5) The replacement code if the request is for a replacement for a previously issued Standard Form 149. The replacement code used shall be as follows: A, address or billing account number has changed; B, broken; C, cracked; D, debossed; E, expired; L, lost; or S, stolen.

b. Any order that does not include all of the required data elements or that contains inaccurate information will be returned to the sender.

c. The requesting agency may furnish an expiration date (month and year, not to exceed 2 years from the date of the request) for each credit card. If an expiration date is not furnished by the agency, the contractor will emboss an expiration date of 2 years from the date of the request.

d. The contractor will bill the ordering agencies directly.

e. The type font to be used when embossing Standard Forms 149 shall conform with the requirements of the Federal Supply Schedule contract.

f. Instructions for requisitioning Standard Forms 149 by means of electronic data transmission will be made available upon request to the General Services Administration (TM), Washington, DC 20408.

Subchapter G—Transportation and Motor Vehicles

Appendix—Temporary Regulations

[FPMR Temp. Reg. G-144]

In 41 CFR Chapter 101, the following temporary regulation is added to the appendix at the end of Subchapter G to read as follows:

Federal Property Management Regulations, Temporary Regulation G-144

To: Heads of Federal agencies.

Subject: Standard Form 149, U.S. Government National Credit Card.

1. *Purpose.* This regulation provides revised policy and procedures concerning the preparation and control of Standard Form 149, U.S. Government National Credit Card.

2. *Effective date.* This regulation is effective October 1, 1979.

3. *Expiration date.* This regulation expires on July 31, 1980, unless sooner revised or superseded.

4. *Background.* A notice of proposed rulemaking, published on November 3, 1978 (43 FR 51429), announced that the General Services Administration would amend the Federal Property Management Regulations to revise the information concerning the acquisition and use of Standard Form 149, U.S. Government National Credit Card. However, developments in the program during the preparation of the amendment led to a decision to issue a temporary regulation to implement the new policies and procedures quickly. (See attachment A.) Before the expiration date, this regulation will be codified in the permanent regulations of the General Services Administration appearing in Title 41 CFR, Public Contracts and Property Management.

5. *Effect on other issuances.* This temporary regulation supersedes the information contained in §§ 101-38.1200 through 101-38.1203.

Dated: August 15, 1979.

R. G. Freeman, III,

Administrator of General Services.

1. General information.

a. Standard Form 149, U.S. Government National Credit Card, is authorized for use by Federal agencies to obtain services and supplies at service stations dispensing items provided by contractors listed in the Defense Fuel Supply Center publication "Your Guide to Service Stations for Gasoline, Oil, and Lubrication" (DFSC H 4280.1). Activities requiring copies of the publication should submit requests to: Commander, Defense Fuel Supply Center, Attention: DFSC:OD, Cameron Station, Alexandria, VA 22314.

b. Procedures for obtaining Standard Form 149, U.S. Government National Credit Card, are in attachment A to FPMR Temporary Regulation E-184.

2. *Billing code.* The billing code is a 10-digit number and is embossed on the first line of the Standard Form 149.

a. The first nine digits shall be assigned by the using agency in accordance with the following instructions:

(1) The first three digits of the billing code shall always be 000 for all Federal agencies other than the General Services Administration, the Department of Agriculture, and the Department of Defense. The Department of Defense shall use 002, and the Department of Agriculture shall use 003, as will the General Services Administration.

(2) The fourth digit may be used by civilian agencies to designate the vehicle class or for other purposes to meet the agency's requirements. If not used for any designation, the fourth digit shall be zero. Components of the Department of Defense shall use the following in the fourth position: 1, Navy; 2, Army; 3, Air Force; 4, Marine Corps; 7, Defense Logistics Agency; and 0, all independent Department of Defense agencies.

(3) The fifth and sixth digits for all civilian agencies shall be the agency code unless otherwise authorized by GSA. Agency codes are shown in the Department of the Treasury booklet "Federal Account Symbols and Titles." For all Department of Defense

activities the fifth through the ninth digits shall be the station accounting number for the particular activity authorized to use the credit card.

(4) For civilian agencies the seventh, eighth, and ninth digits indicate the agency billing address code number unless otherwise authorized by GSA. Each agency shall assign its own billing address code numbers when the seventh, eighth, and ninth digits are used for that purpose.

b. The tenth digit is the validation number for use in automatic billing operations of the contractor. This number is not assigned by the agency but will be determined by the embossing contractor listed in Federal Supply Schedule FSC 75 Part VII. The validation number will be computed in accordance with American National Standard X4.13-1971, Section 5.3.

3. *Billing address.* The billing address is the name of the agency and the address to which contractors should send statements or invoices covering the purchase of supplies and services by the user of the Standard Form 149, U.S. Government National Credit Card. The billing address will not be embossed on the SF 149 but shall be maintained on file by the contractor providing the credit cards and by the petroleum contractors listed in the Defense Fuel Supply Center publication "Your Guide to Service Stations for Gasoline, Oil, and Lubrication" (DFSC H 4280.1).

4. *Agency identifier.* The agency identifier is a one-line entry of a maximum of 22 characters embossed on the third line of the Standard Form 149. It identifies the agency or agency department which is authorized to use the Standard Form 149. No Government employees' name will be embossed on the card.

5. Administrative control of credit cards.

a. It is essential that Federal agencies ensure that supplies and services procured with Standard Form 149, U.S. Government National Credit Card, are for the official use of the agency involved and that administrative control is maintained to prevent unauthorized use of credit cards. Administrative control shall include the following as a minimum:

(1) A replacement series mark will be embossed on the fifth line at the extreme right side to indicate the number-of-times a credit card has been replaced as a result of being reported lost or stolen (e.g., R-1); and

(2) The license tag number of a vehicle or a four-digit serial number shall be embossed on the fourth line of the credit card. When the license tag number is embossed on the fourth line, the card is to be used to procure supplies and services for that vehicle only. If a serial number is embossed, the credit card may be used to obtain supplies and services for any properly identified U.S. Government vehicle, boat, small aircraft, nonvehicular equipment, or motor vehicle that is leased or rented for 60 continuous days or more and is officially identified in accordance with § 101-38.305.

b. Agencies shall establish procedures to provide for the following:

(1) Prompt notification to the credit card contractor of lost or stolen credit cards (notifications shall include the date each card was initially reported lost or stolen);

(2) Prompt notification to the credit card contractor of changes or deletions to billing account numbers and/or addresses;

(3) Issuance of requests for replacement of credit cards (requests shall include the reason for replacement for each credit card, indicated by use of the following replacement codes: A, address or billing account number has changed; B, broken; C, cracked; D, debossed; E, expired; L, lost; or S, stolen);

(4) Prompt and positive destruction of all credit cards that have been replaced for any reason, and of lost or stolen credit cards recovered after being reported and/or replaced; and

(5) Destruction of credit cards bearing an expiration date that has passed or credit cards bearing an invalid license tag number; e.g., the number of a tag that has been replaced or destroyed.

6. *Expiration date.* An expiration date (month and year) not to exceed 2 years will be embossed on the extreme right side of the fourth line of the credit card by the contractor. An expiration date of less than 2 years may be requested by the agency.

7. *Centralized administrative control of credit cards.*

a. GSA will provide centralized management and control of the Standard Form 149, U.S. Government National Credit Card program. Inquiries concerning the policy and administration of this program shall be directed to GSA (TMM), Washington, DC 20406.

b. Agency requests for credit cards shall be submitted to the contractor and shall conform to the requirements of this temporary regulation. Changes in billing codes and addresses shall also be furnished promptly to the contractor so that there will be proper control of billing procedures.

c. After the determination has been made that the billing code(s) and billing address(es) submitted are correct and are not duplicates, the contractor will process the request and emboss and issue the credit cards.

R. G. Freeman,

Administrator of General Services.

[FR Doc. 79-26639 Filed 8-27-79; 8:45 a.m.]

BILLING CODE 6820-AM-M

41 CFR Part 101-36

[FPMR Amdt. F-38]

Compilers and Data Standards

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: This regulation extends the requirement for validation of COBOL compilers to those compilers used in conjunction with the acquisition of COBOL programs and/or programming services. This action is the result of the requirement in Federal Information Processing Standards Publication (FIPS PUB) 21-1 that all COBOL compilers offered or used by vendors to meet Federal agency requirements must be

validated. This regulation also notes the change in the name of the Federal COBOL Compiler Testing Service (FCCTS) to the Federal Compiler Testing Center (FCTC) and the transfer of its operation from the Department of the Navy to the General Services Administration. The regulation also reflects the Department of Commerce revision of FIPS PUB 10-1 to FIPS PUB 10-2 and the issuance of FIPS PUBS 58 and 59 applicable to the interchange of machine processable data between and among agencies.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: L. Perlman, Procurement Policy and Regulations Branch, Policy and Evaluation Division, Office of Policy and Planning (202-566-0834).

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that this regulation will not impose unnecessary burdens on the economy or on individuals and, therefore, is not significant for the purposes of Executive Order 12044.

Subpart 101-36.13—Implementation of Federal Information Processing and Federal Telecommunication Standards Into Solicitation Documents

Section 101-36.1305-1 is amended to revise paragraph (a); to revise the second clause prescribed in paragraph (b); to revise paragraphs (c), (c)(1), and (c)(3) through (c)(7); and to revise the first paragraph of the clause prescribed in paragraph (d), as follows:

§ 101-36.1305-1 FIPS PUB 21-1, Federal Standard COBOL.

(a) FIPS PUB 21-1 specifies the use of the American National Standard Programming Language COBOL X3.23-1974 as the Federal Standard COBOL. The purpose of FIPS 21-1 is to promote a high degree of interchangeability of programs for use on a wide variety of information processing systems. All COBOL compilers brought into the Federal Government inventory and those used to develop computer programs for the Government when providing programming services must be validated in accordance with paragraph (c).

(b) The standard terminology for use in solicitation documents is:

Acquisition of COBOL Compilers

* * * * *

Acquisition of COBOL Programs and/or Programming Services

Business-oriented computer application programs (i.e., those applications or programs that emphasize the manipulation of characters, files, and input/output as

contrasted with those concerned primarily with computation of numeric values) offered or prepared as a result of the requirements set forth in this solicitation will be written using one of the levels of Federal Standard COBOL as defined in FIPS PUB 21-1 including optional language elements, if any, as specified herein. If services provided include compilation(s), compilers used to perform these services shall be validated in accordance with Federal Property Management Regulations (FPMR) 101-36.1305-1(c).

(c) COBOL compilers that are asserted to conform with one or more levels specified in FIPS PUB 21-1 and are offered to the Federal Government for purchase or lease and those used to develop computer programs when providing programming services or compilations shall be validated. The term "validation" as used in this section is the process of testing a given COBOL compiler against predetermined conditions and specifying which, if any, conditions are not met.

(1) COBOL compilers which are offered or used by vendors as a result of requirements set forth by Federal agencies in solicitations must implement the language elements of a designated level of the Federal Standard COBOL. To confirm that an implementation meets the specifications of the designated level of the Federal Standard COBOL, test routines have been developed and approved for use in testing COBOL compilers. These routines are known as the COBOL Compiler Validation System (CCVS). A Federal Compiler Testing Center (FCTC), operated by the General Services Administration, provides a validating service for Federal agencies.

(3) Requests for and questions on validations should be sent to:

Federal Compiler Testing Center (CFT),
General Services Administration,
Washington, DC 20405.

(4) When a request for validation service requires that compiler testing be performed, the requester is responsible for providing the necessary test facilities.

(5) In response to a request for validation service, the FCTC will provide a Validation Summary Report (VSR) summarizing the test results.

(6) Validation is performed on a cost-reimbursable basis. The FCTC will send the requester an estimate of validation costs for approval before beginning the validation process.

(7) Unresolved questions and/or any ambiguities that are identified by the FCTC or by the requester shall be referred to the NBS in accordance with FIPS PUB 29.

(d) The standard terminology for use in solicitation documents is:

Validation of COBOL Compilers

In addition to the specified mandatory COBOL compiler requirements stated in the specification portion of this solicitation, all COBOL compilers brought into the Federal inventory as a result of this solicitation and those compilers used to develop programs when providing services, the most recent release of which has not been previously tested, must be tested using the official COBOL Compiler Validation System (CCVS). Validation shall be in accordance with Federal Property Management Regulation (FPMR) 101-36.1305-1(c). The results of the validation shall be used to confirm that the compiler meets the specified requirements of the designated level of FIPS PUB 21-1, Federal Standard COBOL. To be considered responsive, the vendor shall:

* * * * *

Section 101-36.1307-1(b) is revised to read as follows:

§ 101-36.1307-1 FIPS PUBS applicable to the interchange of machine processable data between and among agencies.

* * * * *

(b) The standard terminology for use in solicitation documents is:

All application programs (software and machine sensible data) resulting from this solicitation that have been identified as those that will be interchanged with Federal agencies, State and local governments, industry, and the public must implement the following applicable approved Federal Information Processing Standards (FIPS):

- FIPS PUB 4 Calendar Date.
- FIPS PUB 5-1 States and Outlying Areas of the United States.
- FIPS PUB 6-2 Counties and County Equivalents of the States of the United States.
- FIPS PUB 8-4 Standard Metropolitan Statistical Areas.
- FIPS PUB 9 Congressional Districts of the United States.
- FIPS PUB 10-2 Countries, Dependencies and Areas of Special Sovereignty.
- FIPS PUB 58 Representations of Local Time of the Day for Information Interchange.
- FIPS PUB 59 Representations of Universal Time, Local Time Differentials, and United States Time Zone References for Information Interchange.

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

Dated: August 16, 1979.

R. G. Freeman III,

Administrator of General Services.

[FR Doc. 79-28637 Filed 8-27-79; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 2

Records and Testimony; Bureaus and Offices of the Department of the Interior

AGENCY: Department of the Interior.

ACTION: Final Rule.

SUMMARY: This action amends appendix B of 43 CFR Part 2 to reflect current offices and addresses of the Department of the Interior.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: John D. Trezise, Office of the Solicitor, U.S. Department of the Interior, Washington, DC 20240, (202) 343-5216.

SUPPLEMENTARY INFORMATION:

Background

Appendix B of 43 CFR Part 2 lists the addresses of bureau heads and offices of the Department of the Interior. It was originally published on February 19, 1975 (40 FR 7310), and has not since been revised. Changes of address and Departmental reorganization have rendered the current appendix B obsolete.

Authorship

The primary author of this document is Jane Albrecht, Office of the Solicitor, (202) 343-5216.

Significance

The Department of the Interior has determined that this document is not a significant rule and does not require a regulatory analysis under Executive Order 12044 and 43 CFR Part 14.

Waiver of 30 Day Waiting Period

Good cause exists to waive the 30 day waiting period normally allowed before a regulation takes effect. The amendments to appendix B do not implement change; they merely reflect it. The information in Appendix B, as amended, has been in effect for quite some time prior to this publication.

(5 USC 552)

Dated: August 21, 1979.

Larry E. Meierotto,

Assistant Secretary of the Interior.

Appendix B of 43 CFR Part 2, is hereby amended to read as follows:

Appendix B—Bureaus and Offices of the Department of the Interior

1. Bureaus and Offices of the Department of the Interior. (The address for all bureaus and offices, unless otherwise indicated, is

U.S. Department of the Interior, Washington, DC 20240.)

Secretary of the Interior, Office of the Secretary

Commissioner, Bureau of Indian Affairs
Director, Heritage Conservation and Recreation Service, The Pension Building, 440 "G" Street, N.W., Washington, DC 20007

Director, U.S. Fish and Wildlife Service
Director, National Park Service
Commissioner, Bureau of Reclamation
Director, Bureau of Land Management
Director, Bureau of Mines, Columbia Plaza, 2401 "E" Street, N.W., Washington, D.C. 20241

Director, Geological Survey, The National Center, Reston, VA 22092

Director, Office of Surface Mining—Reclamation and Enforcement

Director, Office of Public Affairs
Director, Office of Congressional and Legislative Affairs

Director, Office of Youth Programs

Director, Office for Equal Opportunity

Director, Office of Hearings and Appeals, 4015 Wilson Blvd., Arlington, VA 22203

Director, Office of Territorial Affairs
Inspector General, Office of the Inspector General

Director, Office of Water Research and Technology

Director, Office of Coal Leasing, Planning and Coordination

Director, Office of Minerals Policy and Research Analysis

Administrator, Ocean Mining Administration
Superintendent, National Mine Health and Safety Academy, P.O. Box 1166, Beckley, WV 25801

Director, Office of ADP and

Telecommunications Management

Director, Office of Aircraft Services, 3905 Vista Avenue, Boise, ID 83705

Director, Office of Administrative Services

Director, Office of Administrative and Management Policy

Director, Office of Budget

Director, Office of Environmental Project Review

Director, Office of Library and Information Services

Director, Office of Outer Continental Shelf Program Coordination

Director, Office of Personnel

Director, Office of Policy Analysis

Solicitor, Office of the Solicitor

2. Public Information Officers of the Department of the Interior. (The address for all public information officers, unless otherwise indicated, is U.S. Department of the Interior, Washington, DC 20240.)

Director, Office of Public Affairs, U.S.

Department of the Interior

Director, Public Information Staff, Bureau of Indian Affairs

Chief, Office of Public Affairs, Bureau of Land Management

Chief, Office of Mineral Information, Bureau of Mines, Columbia Plaza, 2401 E Street, N.W., Washington, DC 20241

Director, Office of Public Affairs, Bureau of Reclamation

Chief, Office of Public Affairs, Heritage Conservation and Recreation Service, The

Pension Building, 440 G Street, N.W.,
Washington, DC 20243
Chief, Office of Public Affairs, National Park
Service

Public Affairs Officer, Office of Surface
Mining—Reclamation and Enforcement
Assistant Director, Public Affairs, U.S. Fish
and Wildlife Service

Information Officer, U.S. Geological Survey,
The National Center, Reston, VA 22092

3. Office of Hearings and Appeals—Field
Offices:

Alaska Native Claims Appeal Board, P.O.
Box 2433, Anchorage, AK 99510

Administrative Law Judge, 2020 Hurley Way,
Suite 170, Sacramento, CA 95825

Administrative Law Judge, 6432 Federal
Building, Salt Lake City, UT 84138

Administrative Law Judge, 530 Gay Street,
S.W., Knoxville, TN 37902

Administrative Law Judge, Rm. 3408A,
Federal Building, 500 Quarrier Street,
Charleston, WV 25301

Administrative Law Judge, 1052C Federal
Building, 600 Federal Place, Louisville, KY
40202

Administrative Law Judge, Federal Office
Building, Suite 1603, 1000 Liberty Avenue,
Pittsburgh, PA 15222

Administrative Law Judge, Indian Probate,
Mayer Central Building, Suite 412, 3033 N.
Central Avenue, Phoenix, AZ 85012

Administrative Law Judge, Indian Probate,
2020 Hurley Way, Suite 150, Sacramento,
CA 95825

Administrative Law Judge, Indian Probate,
Federal Building and Courthouse, Rm. 3329,
316 N. 28th Street, Billings, MT 59101

Administrative Law Judge, Indian Probate,
301 Federal Building, Hill and 3rd Street,
Gallup, NM 87301

Administrative Law Judge, Indian Probate,
P.O. Box 3064, Tulsa, OK 74101

Administrative Law Judge, Indian Probate,
1425 N.E. Irving Street, Building 100, Suite
112, Portland, OR 97232

Administrative Law Judge, Indian Probate,
Federal Building, Rm. 674, Fort Snelling,
Twin Cities, MN 55111

Administrative Law Judge, Indian Probate,
Federal Building, Rm. 688, Fort Snelling,
Twin Cities, MN 55111

4. Office of the Solicitor—Field Offices:

Anchorage Region

Regional Solicitor, U.S. Department of the
Interior, 510 L Street, Suite 408, Anchorage,
AK 99501

Atlanta Region

Regional Solicitor, U.S. Department of the
Interior, Richard B. Russell Building, Rm.
1328, 75 Spring Street, S.W., Atlanta, GA
30303

Boston Region

Regional Solicitor, U.S. Department of the
Interior, Suite 306, One Gateway Center,
Newton Corner, MA 02158

Field Solicitor, U.S. Department of the
Interior, 686 Federal Building, Fort Snelling,
Twin Cities, MN 55111

Field Solicitor, U.S. Department of the
Interior, 950 E. Kanawha Boulevard,
Charleston, WV 25301

Field Solicitor, U.S. Department of the
Interior, Suite 505, Federal Bldg. and U.S.

Courthouse, 46 East Ohio Street,
Indianapolis, IN 46204

Denver Region

Regional Solicitor, U.S. Department of the
Interior, P.O. Box 25007, Denver Federal
Center, Denver, CO 80225

Field Solicitor, U.S. Department of the
Interior, P.O. Box 549, Aberdeen, SD 57401

Field Solicitor, U.S. Department of the
Interior, P.O. Box 1538, Billings, MT 59103

Portland Region

Regional Solicitor, U.S. Department of the
Interior, Lloyd 500 Building, Suite 607, 500
N.E. Multnomah Street, Portland, OR 97232

Field Solicitor, U.S. Department of the
Interior, Box 020, Federal Building, U.S.
Courthouse, 550 West Fort Street, Boise, ID
83724

Sacramento Region

Regional Solicitor, U.S. Department of the
Interior, Room E-2753, 2800 Cottage Way,
Sacramento, CA 95825

Field Solicitor, U.S. Department of the
Interior, Box 36064, 450 Golden Gate
Avenue, Rm. 14126, San Francisco, CA
94102

Field Solicitor, U.S. Department of the
Interior, Window Rock, AZ 86515

Field Solicitor, U.S. Department of the
Interior, P.O. Box 427, Park Street, Boulder
City, NV 89005

Field Solicitor, U.S. Department of the
Interior, Valley Bank Center, Suite 2080,
201 North Central Avenue, Phoenix, AZ
85073

Field Solicitor, U.S. Department of the
Interior, 3610 Central Avenue, Suite 104,
Riverside, CA 92506

Salt Lake City Region

Regional Solicitor, U.S. Department of the
Interior, Suite 6201, Federal Building, 125
South State Street, Salt Lake City, UT 84138

Tulsa Region

Regional Solicitor, U.S. Department of the
Interior, P.O. Box 3156, Tulsa, OK 74101

Field Solicitor, U.S. Department of the
Interior, Room 7102, Federal Building and
Courthouse, 500 Gold Avenue, S.W.,
Albuquerque, NM 87101

Field Solicitor, U.S. Department of the
Interior, Box H-4393, Herring Plaza, 317
East Third, Amarillo, TX 79101

Field Solicitor, U.S. Department of the
Interior, P.O. Box 397, W.C.D. Office
Building, Route 1, Anadarko, OK 73005

Field Solicitor, U.S. Department of the
Interior, P.O. Box 1508, Room 319, Federal
Building, 5th and Broadway, Muskogee, OK
74401

Field Solicitor, U.S. Department of the
Interior, c/o Osage Agency, Grandview
Avenue, Pawhuska, OK 74056

Field Solicitor, U.S. Department of the
Interior, Room 224, U.S. Courthouse,
Federal Place and Washington Street,
Santa Fe, NM 87501

Field Solicitor, U.S. Department of the
Interior, 950 E. Kanawha Boulevard,
Charleston, WV 25301

[PR Doc. 79-26963 Filed 8-27-79; 8:45 am]

BILLING CODE 4310-10-M

Bureau of Land Management

43 CFR Public Land Order 5679

[NM-28111 and NM-29710]

New Mexico; Partial Revocation of Executive Orders Nos. 6143, 6276, and 6583

AGENCY: Bureau of Land Management,
Interior.

ACTION: Final rule.

SUMMARY: This order will restore
approximately 919 acres of public land
to operation of the public land laws and
to location for nonmetalliferous
minerals.

EFFECTIVE DATE: September 25, 1979.

FOR FURTHER INFORMATION CONTACT:

Louis B. Bellesi, 202-343-8731.

By virtue of the authority contained in
section 204 of the Act of October 21,
1976, 90 Stat. 2751, 43 U.S.C. 1714, it is
ordered as follows:

1. The Executive Orders No. 6143 of
May 23, 1933; No. 6276 of September 8,
1933, and No. 6583 of February 3, 1934,
which withdrew public lands in New
Mexico to aid the State in making
exchange selections as provided by the
Act of June 15, 1926, 44 Stat. 746-748, are
hereby revoked so far as they affect the
following described lands:

New Mexico Principal Meridian

T. 19 S., R. 13 W.,

Sec. 27, SW $\frac{1}{4}$ NW $\frac{1}{4}$.

T. 29 S., R. 19 W.,

Sec. 5, lots 3, 4, S $\frac{1}{2}$ NW $\frac{1}{4}$ and E $\frac{1}{2}$ SW $\frac{1}{4}$;

Sec. 6, S $\frac{1}{2}$ NE $\frac{1}{4}$ and NW $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 8, SW $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ NW $\frac{1}{4}$
and W $\frac{1}{2}$ SW $\frac{1}{4}$

T. 30 S., R. 19 W.,

Sec. 12, NE $\frac{1}{4}$ SE $\frac{1}{4}$.

T. 27 S., R. 20 W.,

Sec. 21, N $\frac{1}{2}$ SE $\frac{1}{4}$;

Sec. 24, S $\frac{1}{2}$ N $\frac{1}{2}$.

The area described aggregates 918.59
acres in Grant and Hidalgo Counties.

The land is gently rolling open
grassland used for grazing.

2. At 10 a.m. on September 25, 1979,
the lands shall be open to operation of
the public land laws generally subject to
valid existing rights, the provisions of
existing withdrawals, and the
requirements of applicable law. All
valid applications received at or prior to
10 a.m. on September 25, 1979, shall be
considered as simultaneously filed at
that time. Those received thereafter
shall be considered in the order of filing.

3. The lands have been and continue
to be open to applications and offers
under the mineral leasing laws and to
location under the United States mining
laws for metalliferous minerals. They
will be open to location for

nonmetalliferous minerals at 10 a.m. on September 25, 1979.

Inquiries concerning the lands should be addressed to the Chief, Division of Technical Services, Bureau of Land Management, P.O. Box 1449, Santa Fe, New Mexico 87501.

Guy R. Martin,
Assistant Secretary of the Interior.

August 20, 1979.

[FR Doc. 79-26604 Filed 8-27-79; 8:45 am]

BILLING CODE 4310-84-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 79-97; RM-3220]

Television Broadcast Station in Marion, Va.; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Report and order.

SUMMARY: Action taken herein assigns a first UHF television channel to Marion, Virginia, in response to a petition filed by Blue Ridge ETV Association, Inc. The proposed station could provide an unserved area in Virginia with its first noncommercial educational television service.

EFFECTIVE DATE: October 1, 1979.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Report and Order—Proceeding Terminated

Adopted: August 17, 1979.

Released: August 23, 1979.

In the matter of amendment of § 73.606(b), *Table of Assignments*, Television Broadcast Stations. (Marion, Virginia), BC Docket No. 79-97, Rm-3220.

1. The Commission herein considers the *Notice of Proposed Rule Making*, 44 FR 28029, inviting comments on a petition filed by Blue Ridge ETV Association, Inc. ("petitioner"), licensee of noncommercial educational television Stations WBRA-TV (Channel *15), Roanoke, Virginia, and WSVN-TV (Channel *47), Norton, Virginia. The petition proposed the assignment and reservation of UHF television Channel *52 to Marion, Virginia, for

noncommercial educational television use. The only comments received were from the petitioner in support of its proposal.

2. Marion (pop. 8,158), seat of Smyth County (pop. 31,349),¹ is located in western Virginia, approximately 145 kilometers (95 miles) west of Roanoke, Virginia. There are no television assignments in Marion.

3. Petitioner claims there is an area, encompassing Smyth County and parts of Washington, Tazewell, Bland, Grayson and Wythe Counties, which does not receive noncommercial educational television service. It proposes to bring service to this area by establishing a satellite of its Roanoke, Virginia, station (WBRA-TV). It states that the proposed station would essentially complete coverage in Virginia by educational television.

4. We believe the public interest would be served by assigning television Channel *52 to Marion, Virginia. The proposed station would provide the community and surrounding area with a first noncommercial educational television service.

5. Authority for the adoption of the amendment contained herein appears in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281 of the Commission's rules.

6. Accordingly, it is ordered, That effective October 1, 1979, the Television Table of Assignments (§ 73.606(b) of the Commission's rules) is amended as follows for the community listed below:

City	Channel No.
Marion, Virginia	*52

7. It is further ordered, that this proceeding is terminated.

8. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; (47 U.S.C. 154, 155, 303).)

Federal Communications Commission.

Richard J. Shiben,

Chief, Broadcast Bureau.

[FR Doc. 79-26627 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

¹ Population figures are taken from the 1970 U.S. Census.

47 CFR Part 73

[BC Docket No. 79-89; RM-3274]

Television Broadcast Station in Allen, S. Dak.; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Report and order.

SUMMARY: Action taken herein assigns a UHF television channel to Allen, South Dakota, in response to a petition filed by Oglala Sioux Broadcasting Company. The proposed station could bring a first local television service to the Pine Ridge Indian Reservation on which Allen is located.

EFFECTIVE DATE: September 29, 1979.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Report and Order—Proceeding Terminated

Adopted: August 15, 1979.

Released: August 22, 1979.

In the matter of amendment of § 73.606(b), *Table of Assignments*, Television Broadcast Stations. (Allen, South Dakota), BC Docket No. 79-89, RM-3274.

1. The Commission has before it the *Notice of Proposed Rule Making*, 44 FR 24587, in response to a petition filed by the Oglala Sioux Broadcasting Company ("petitioner"), proposing the assignment of UHF television Channel 22 to Allen, South Dakota. Supporting comments¹ were filed by petitioner in which it reaffirmed its intention to file an application for the proposed channel, if assigned. No oppositions to the proposal were received.

2. Allen (pop. 100),² an unincorporated community in Bennett County (pop. 3,088), is located on the Pine Ridge Reservation in southwest South Dakota, approximately 140 kilometers (90 miles) southeast of Rapid City, South Dakota. The only television assignment in the area is educationally reserved Channel

¹ Petitioner filed a Motion to accept late-filed comments in support of its proposal. Since there has been no objection to our acceptance of these comments, and not other parties would be affected thereby, we are granting petitioner's motion and will accept its comments.

² The community does not appear in the 1970 U.S. Census. Petitioner estimates the population to be 100 and the population of Pine Ridge Reservation to be 16,000, 2,000 of whom are non-Indians.

*8, used by Station KZSD-TV, at Martin, the seat of Bennett County. Martin is located approximately 19 kilometers (12 miles) southeast of Allen.

3. As we indicated in the Notice, the proposed assignment meets the distance separation requirements and other technical criteria. Petitioner submitted information with respect to Allen and its need for a first television channel assignment. Through use of the channel, television service can be brought to many residents of the Reservation.

4. In view of the foregoing, we conclude that it would be in the public interest to make the requested assignment to provide a first local television service to Allen, South Dakota.

5. Accordingly, it is ordered, That effective September 29, 1979, the Television Table of Assignments, § 73.606(b) of the Commission's rules, is amended with regard to the city listed below:

City	Channel No.
Allen, South Dakota	22*

6. Authority for the action taken herein is found in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and § 0.281 of the Commission's rules.

7. It is further ordered, that this proceeding is terminated.

8. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; (47 U.S.C. 154, 303, 307).)

Federal Communications Commission.

Richard J. Shiben,
Chief, Broadcast Bureau.

[FR Doc. 79-28030 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

Hunting; National Wildlife Refuges in Idaho

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulations.

SUMMARY: The Director has determined that the opening to hunting of certain National Wildlife Refuges in Idaho is compatible with the objectives for which these areas were established, will utilize

a renewable natural resource, and will provide additional recreational opportunity to the public. This document establishes special regulations effective for the upcoming hunting seasons for migratory game birds, upland game, and big game.

DATES: September 1, 1979 to January 31, 1980.

ADDRESSES: Contact the Refuge Manager at the address and/or telephone number listed below in the body of Special Regulations. For Further Information Contact: L. A. Mehrhoff, Area Manager, U.S. Fish and Wildlife Service, 4620 Overland Road, Room 238, Boise, Idaho 83705, Phone: 208-384-1960.

SUPPLEMENTARY INFORMATION: The Refuge Recreation Act of 1962 (16 U.S.C. 460k) authorizes the Secretary of the Interior to administer such areas for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. In addition, the Refuge Recreation Act requires (1) that any recreational use permitted will not interfere with the primary purpose for which the area was established; and (2) that funds are available for the development, operation, and maintenance of the permitted forms of recreation.

The recreational use authorized by these regulations will not interfere with the primary purposes for which these National Wildlife Refuges were established. This determination is based upon consideration of, among other things, the Service's Final Environmental Statement on the Operation of the National Wildlife Refuge System published in November 1976. Funds are available for the administration of the recreational activities permitted by these regulations.

Hunting is permitted on the National Wildlife Refuges indicated below in accordance with 50 CFR Part 32, and the following special regulations. Portions of refuges which are open to hunting are designated by signs and/or delineated on maps. No vehicle travel is permitted except on designated roads and trails. Special conditions applying to individual refuges are listed on the reverse side of maps available at refuge headquarters and from the office of the Regional Director, Fish and Wildlife Service, Lloyd 500 Bldg., Suite 1692, 500 N.E. Multnomah Street, Portland, OR 97232.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

1. Migratory game birds may be hunted on the following refuge areas:

Camas National Wildlife Refuge, Hamer, Idaho 83425, phone 208-662-5423.

Special Conditions: Dove hunting is prohibited.

Deer Flat National Wildlife Refuge, Snake River Island Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Special Conditions: (1) Waterfowl and coot hunters are required to use native materials for hunting blind construction. (2) Hunting is on a first-come-first-served basis. Kootenai National Wildlife Refuge, Star route #1, Box 160, Bonners Ferry, Idaho 83805, phone 208-267-3888.

Special Conditions: (1) Hunting is permitted on Saturdays, Sundays, Tuesdays and Thursdays. (2) Dove hunting is prohibited. (3) Hunters are required to use native materials for blind construction.

2. Migratory game birds except doves and common snipe may be hunted on the following refuge areas:

Bear Lake National Wildlife Refuge, P.O. Box 9, Montpelier, Idaho 83254, phone 208-847-1757.

Special Regulations: Air-thrust boats are prohibited.

Deer Flat National Wildlife Refuge, Lake Lowell Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Special Conditions: (1) Goose hunting is prohibited. (2) Hunters are required to use native materials for hunting blind construction.

Grays Lake National Wildlife Refuge, P.O. Box 837, Soda Springs, Idaho 83276, phone 208-547-4996.

Special Conditions: (1) Air-thrust boats are prohibited. (2) Entry to the hunting area is limited to foot travel only. Minidoka National Wildlife Refuge, Route 4, Rupert, Idaho 83350, phone 208-436-3580.

§ 32.22 Special regulations; upland game; for individual wildlife refuge areas.

Bear Lake National Wildlife Refuge, P.O. Box 9, Montpelier, Idaho 83254, phone 208-847-1757.

Camas National Wildlife Refuge, Hamer, Idaho 83425, phone 208-662-5423.

Deer Flat National Wildlife Refuge, Lake Lowell and Snake River Sectors, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Minidoka National Wildlife Refuge, Route 4, Rupert, Idaho 83350, phone 208-436-3589. Special Conditions: Upland game may be hunted on the public hunting area during the waterfowl season only.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

Deer Flat National Wildlife Refuge, Snake River Island Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Grays Lake National Wildlife Refuge, P.O. Box 837, Soda Springs, Idaho 83276, phone 208-547-4996.

Special Conditions: (1) Entry to the hunting area is by foot travel only. (2) Horses may

only be used to retrieve bagged animals. Kootenai National Wildlife Refuge, Star route #1, Box 160, Bonners Ferry, Idaho 83805, phone 208-267-3888.

Special Conditions: Only that portion of the refuge west of the west side road is open to big game hunting.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally and which are set forth in Title 50, Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

Note.—The Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11494 and OMB Circular A-107.

Dated: August 20, 1979.

C. Joe Packham,
Boise Area Acting Manager.

[FR Doc. 79-26895 Filed 8-27-79; 8:45 am]
BILLING CODE 4310-55-M

50 CFR Part 32

Hunting; National Wildlife Refuges in Oregon

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulations.

SUMMARY: The Director has determined that the opening to hunting of certain National Wildlife Refuges in Oregon is compatible with the objectives for which these areas were established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public. This document establishes special regulations effective for the upcoming hunting seasons for migratory game birds, upland game, and big game.

DATES: September 1, 1979 to January 31, 1980.

ADDRESS: Contact the Refuge Manager at the address and/or telephone number listed below in the body of Special Regulations.

FOR FURTHER INFORMATION CONTACT: L. A. Mehrhoff, Area Manager, U.S. Fish and Wildlife Service, 4820 Overland Road, Room 238, Boise, Idaho 83705, 208-384-1960.

SUPPLEMENTARY INFORMATION: The Refuge Recreation Act of 1962 (16 U.S.C. 460k) authorizes the Secretary of the Interior to administer such areas for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. In addition, the Refuge Recreation Act

requires (1) that any recreational use permitted will not interfere with the primary purpose for which the area was established; and (2) that funds are available for the development, operation, and maintenance of the permitted forms of recreation.

The recreational use authorized by these regulations will not interfere with the primary purposes for which these National Wildlife Refuges were established. This determination is based upon consideration of, among other things, the Service's Final Environmental Statement on the Operation of the National Wildlife Refuge System published in November 1976. Funds are available for the administration of the recreational activities permitted by these regulations.

Hunting is permitted on the National Wildlife Refuges indicated below in accordance with 50 CFR Part 32, and the following special regulations. Portions of refuges which are open to hunting are designated by signs and/or delineated on maps. No vehicle travel is permitted except on designated roads and trails. Special conditions applying to individual refuges are listed on the reverse side of maps available at refuge headquarters and from the office of the Regional Director, Fish and Wildlife Service, Lloyd 500 Bldg., Suite 1692, 500 N.E. Multnomah Street, Portland, OR 97232.

§ 32.12 Special Regulations; migratory game birds; for individual wildlife refuge areas.

1. Migratory game birds may be hunted on the following refuge areas:

Ankeny National Wildlife Refuge, Route 1, Box 198, Jefferson, Oregon 97352, phone 503-327-2444.

Special Conditions: (1) Mourning dove and band-tailed pigeon hunters must check in and out of the refuge by use of self-service permits. (2) Waterfowl, coot, and snipe hunting is permitted on Wednesdays, Saturdays and Sundays from opening shooting time until 12 noon during the authorized season. (3) A Federal permit is required for waterfowl, coot, and snipe hunting and will be issued on an advanced reservation basis. Applications for reservations will be accepted between September 15 and October 15. (4) Steel shot only may be possessed or used on the refuge while hunting waterfowl, coot, and snipe. (5) Waterfowl, coot, and snipe hunters are limited to the possession and use of twenty (20) shells per day.

Baskett Slough National Wildlife Refuge, 10995 Highway 22, Dallas, Oregon 97338, phone 503-623-2749.

Special Conditions: (1) Dove and pigeon hunting is prohibited. (2) Waterfowl, coot, and snipe hunting is permitted on Wednesdays, Saturdays and Sundays from opening shooting time until 12 noon during the authorized season. (3) A Federal permit

is required for waterfowl, coot, and snipe hunting and will be issued on an advanced reservation basis. Application for reservations will be accepted between September 15 and October 15. (4) Steel shot only may be possessed or used on the refuge while hunting waterfowl, coot, and snipe. (5) Waterfowl, coot, and snipe hunters are limited to the possession and use of twenty (20) shells per day.

Deer Flat National Wildlife Refuge, Snake River Island Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Special Conditions: (1) Waterfowl and coot hunters are required to use native materials for hunting blind construction. (2) Hunting is on a first-come-first-served basis.

Malheur National Wildlife Refuge, P.O. Box 113, Burns, Oregon 97720, phone 503-493-2323.

Special Conditions: (1) That portion of the refuge in the Blitzen Valley west of Highway 205, south of Diamond Lane will be open to dove and pigeon hunting concurrent with the regular state season, as posted. (2) Part of Malheur Lake will be open to waterfowl, coot and snipe hunting concurrent with the state season as posted. (3) Use of motors on boats, construction or use of permanent blinds and use of all terrain vehicles is prohibited.

William L. Finley National Refuge, Route 2, Box 208, Corvallis, Oregon 97330, phone 503-757-7236.

Special Conditions: (1) Band-tailed pigeon hunting is prohibited. (2) Dove hunters are required to check in and out of the refuge daily by use of self-service permits. (3) Waterfowl, coot and snipe hunting is permitted on Wednesdays, Saturdays and Sundays from opening shooting time until 12 noon during the authorized season. (4) A Federal permit is required for waterfowl, coot and snipe hunting and will be issued on an advanced reservation basis. Applications for reservations will be accepted between September 15 and October 15. (5) Steel shot only may be possessed or used on the refuge while hunting waterfowl, coot and snipe. (6) Waterfowl, coot and snipe hunters are limited to the possession and use of twenty (20) shells per day.

2. Migratory game birds, except doves, pigeons and common snipe, may be hunted on the following refuge areas:

Cold Springs National Wildlife Refuge, Hermiston, Oregon, P.O. Box 239, Umatilla, Oregon 97882, phone 503-822-3232.

Klamath Forest National Wildlife Refuge (Headquarters: Klamath Basin National Wildlife Refuges, Route 1, Box 74, Tule Lake, California 96134, phone 916-667-2231).

Special Conditions: (1) Boats with or without motors are permitted except air-thrust and inboard water-thrust are prohibited. (2) All decoys, boats and other personal property must be removed from the refuge at the close of each day. (3) No person may possess any weapon or ammunition that may not be legally used for taking waterfowl.

Lewis and Clark National Wildlife Refuge, Route 1, Box 378C, Cathlamet, Washington 98612, phone 206-795-4915.

Special Conditions: Posted portions of the refuge in Clatsop County will be closed to waterfowl and coot hunting.

Lower Klamath National Wildlife Refuge (Headquarters: Klamath Basin National Wildlife Refuges, Route 1, Box 74, Tule Lake, California 96134, phone 916-667-2231).

Special Conditions: (1) Posted retrieving zones are established on certain hunting units. Possession of firearms in these retrieving zones is prohibited, except, unloaded firearms may be taken through these zones when necessary to reach or leave hunting areas. Decoys may not be set in retrieving zones. (2) Boats with or without motors are permitted. Air-thrust and inboard water-thrust boats are prohibited. (3) All decoys, boats, and other personal property must be removed at the close of each day.

McKay Creek National Wildlife Refuge, Pendleton, Oregon (Headquarters: Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882, phone 503-922-3232).

Special Conditions: Hunting is permitted on Wednesdays, Saturdays, Sundays and State holidays, except Christmas.

Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882, phone 503-922-3232.

Special Conditions: (1) Waterfowl and coot hunting is permitted on Wednesdays, Saturdays, Sundays and State holidays, except Christmas. (2) A Federal permit is required and will be issued on an advance reservation basis. Successful applicants may bring one guest and must arrive at check station at least one hour before shooting time or reservation is cancelled. (3) Applications will be accepted during two sign-up periods. Permits are non-transferable. (4) Steel shot only may be possessed or used during waterfowl and coot hunting. (5) Waterfowl and coot hunting will be from blinds only.

Upper Klamath National Wildlife Refuge (Headquarters: Klamath Basin National Wildlife Refuges, Route 1, Box 74, Tule Lake, California 96134, phone 916-667-2231).

Special Conditions: (1) Boats with or without motors are permitted. Air-thrust and inboard water-thrust boats are prohibited. (2) All decoys, boats and other personal property must be removed from the refuge at the close of each day. (3) No person may possess any weapon or ammunition that may not be legally used for taking waterfowl.

§ 32.22 Special Regulations; upland game, for individual wildlife refuge areas.

Upland game may be hunted on the following refuge areas:

Ankeny National Wildlife Refuge, Route 1, Box 198, Jefferson, Oregon 97352, phone 503-327-2444.

Special Conditions: (1) Only pheasant and quail may be hunted. (2) No upland game hunting is permitted after November 4, 1979. (3) All hunters must check in and out of the refuge daily by use of self-service permits. (4) Hunters on the area served by

each registration station will be limited to 50 at any one time.

Baskett Slough National Wildlife Refuge, 10995 Highway 22, Dallas, Oregon 97338, phone 503-623-2749.

Special Conditions: (1) Only pheasant and quail may be hunted. (2) No upland game hunting is permitted after November 4, 1979. (3) All hunters must check in and out of the refuge daily by use of self-service permits. (4) Hunters on the area served by each registration station will be limited to 50 at any one time.

Cold Springs National Wildlife Refuge, Hermiston, Oregon (Headquarters: Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882, phone 503-922-3232).

Deer Flat National Wildlife Refuge, Snake River Island Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Hart Mountain National Wildlife Refuge, P.O. Box 11, Lakeview, Oregon 97630, phone 503-947-3315.

Lower Klamath National Wildlife Refuge (Headquarters: Klamath Basin National Wildlife Refuges, Route 1, Box 74, Tule Lake, California 96134, phone 916-667-2231).

Malheur National Wildlife Refuge, P.O. Box 113, Burns, Oregon 97720, phone 503-493-2323.

Special Conditions: (1) Pheasant, quail and partridge hunting will be permitted on the upland game hunting area during the last nine days of the state season. (2) Pheasant, quail and partridge hunting will be permitted on the waterfowl hunting area during the waterfowl season. (3) Hunting will be permitted in the Blitzen Valley west of Highway 205 concurrent with the regular state season as posted.

McKay Creek National Wildlife Refuge, Pendleton, Oregon (Headquarters: Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882, phone 503-922-3232).

Special Conditions: (1) Hunting is permitted on Wednesdays, Saturdays, Sundays and State holidays, except Christmas.

Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882, phone 503-922-3232.

Special Conditions: (1) A Federal advanced reservation permit is required to hunt pheasants on the opening weekend of pheasant season. (2) Hunting is permitted from 12 noon until closing time on Wednesdays, Saturdays, Sundays and State holidays, except Christmas. (3) Pheasant hunters are required to check in and out of the refuge at check stations.

William L. Finley National Wildlife Refuge, Route 2, Box 208, Corvallis, Oregon 97330, phone 503-757-7326.

Special Conditions: (1) Only pheasant and quail may be hunted. (2) Hunters are required to check in and out of the refuge by use of self-service permits. (3) Upland game hunting is prohibited after November 4, 1979. (4) Each registration station is limited to 100 hunters at any one time.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

Deer Flat National Wildlife Refuge, Snake River Island Sector, Route 1, Box 1457, Nampa, Idaho 83651, phone 208-467-9278.

Hart Mountain National Wildlife Refuge, P.O. Box 111, Lakeview, Oregon 97630, phone 503-947-3315.

Special Conditions: (1) Hunters are required to check in and out of the refuge. (2) Antelope and sheep hunters are required to attend a prehunt indoctrination session.

Malheur National Wildlife Refuge, P.O. 113, Burns, Oregon 97720, phone 503-947-3315.

Special Conditions: (1) That portion of the refuge in the Blitzen Valley west of Highway 205 will be open as posted to deer hunting concurrent with the regular State season.

William L. Finley National Wildlife Refuge, Route 2, Box 208, Corvallis, Oregon 97330, phone 503-757-7326.

Special Regulations: (1) Hunters are required to check in and out of the refuge by use of self-service permits. (2) The use of rifles is prohibited.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally and which are set forth in Title 50, Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

Note.—The Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11949 and OMB Circular A-107.

Dated: August 20, 1979.

C. Joe Packham,
Boise Area Acting Manager.

[FR Doc. 79-26696 Filed 8-27-79; 8:45 am]

BILLING CODE 4310-55-M

50 CFR Part 32

Hunting; National Wildlife Refuges in Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special Regulations.

SUMMARY: The Director has determined that the opening to hunting of certain National Wildlife Refuges in Washington is compatible with the objectives for which these areas were established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public. This document establishes special regulations effective for the upcoming hunting seasons for migratory game birds, upland game, and big game.

DATES: September 1, 1979 to June 30, 1980.

ADDRESSES: Contact the Refuge Manager at the address and/or

telephone number listed below in the body of Special Regulations.

FOR FURTHER INFORMATION CONTACT:

Joseph R. Blum, Area Manager, U.S. Fish and Wildlife Service, 2625 Parkmont Lane, Olympia, Washington 98502, Telephone: FTS 434-9578 or 9579, Com'l 206-753-9578 or 9579.

SUPPLEMENTARY INFORMATION: Hunting is permitted on the National Wildlife Refuges indicated below in accordance with 50 CFR 32 and the following Special Regulations. Portions of refuges which are open to hunting are designated by signs and/or delineated on maps. No vehicle travel is permitted except on maintained roads and trails. Special conditions applying to individual refuges are listed on the reverse side of maps available at refuge headquarters and from the office of the Regional Director, U.S. Fish and Wildlife Service, Lloyd 500 Building, 500 N.E. Multnomah Street, Portland, Oregon 97232. Hunting shall be in accordance with all applicable State regulations subject to the following conditions:

The Refuge Recreation Act of 1962 (16 U.S.C 460k) authorizes the Secretary of the Interior to administer such areas for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. In addition, the Refuge Recreation Act requires (1) that no area of the refuge system is used for forms of recreation not directly related to the primary purposes for which the area was established; and (2) that funds are available for the development, operation, and maintenance of the permitted forms of recreation.

The recreational use authorized by these regulations will not interfere with the primary purposes for which the National Wildlife Refuge(s) were established. This determination is based upon consideration of, among other things, the Service's Final Environmental Statement on the Operation of the National Wildlife Refuge System published in November 1976. Funds are available for the administration of the recreational activities permitted by these regulations.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

1. Doves, pigeons, ducks, coots, and common snipe may be hunted on the following refuge areas:

Conboy Lake National Wildlife Refuge, Box 5, Glenwood, Washington 98619. Contact Refuge Manager at 509-364-3410

2. Ducks, geese, coots, and common snipe may be hunted on the following refuge areas:

Columbia National Wildlife Refuge, P.O.

Drawer F, Othello, Washington 99344. Contact Refuge Manager at 509-488-3831

Special Conditions: (1) Hunters using field 226-227 near Royal Lake must register before hunting and may shoot from designated sites only. (2) On Crab Creek and impoundments from Goose Lake Road to Goldeneye Lake, hunting will be permitted on Wednesday and Saturday only.

Toppenish National Wildlife Refuge, Route 1, Box 1300, Toppenish, Washington 98948. Contact Refuge Manager at 509-865-2405

Special Condition: Hunters using the upper Jensen and Robbins Road areas must register at respective parking areas and may shoot from designated sites only.

Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882. Contact Refuge Manager at 503-922-3232

Columbia White-Tailed Deer National Wildlife Refuge, Route 1, Box 376C, Cathlamet, Washington 98612. Contact Refuge Manager at 206-795-3915

Ridgefield National Wildlife Refuge, P.O. Box 457, Ridgefield, Washington 98642. Contact Refuge Manager at 206-887-4071

Special Conditions: (1) Hunting will be allowed on Saturday, Sunday, and Wednesday during the regular waterfowl season. Hunting will not be allowed on Federal holidays. (2) A Federal permit, available from the refuge office, is required to enter the public hunting area. Permits will be issued only by mail on a first come, first served basis. Only one regular permit may be held by a hunter at any one time. (3) Hunters may shoot only from blinds assigned by drawing at the check-in station. A recreational use fee of \$3.00 will be charged for each hunter's use of a blind. Fee for holders of Golden Age Passport is \$1.50. (4) Steel shot only may be possessed or used on the refuge hunting area. (5) Hunters may possess and use not more than twenty (20) shells on the north hunting area or twelve (12) shells on the south hunting area per hunter per day.

3. Ducks, geese, and coots may be hunted on the following refuge areas:

McNary National Wildlife Refuge, P.O. Box 308, Burbank, Washington 99323. Contact Refuge Manager at 509-547-4942

Special Conditions: (1) Hunters are required to park vehicles in designated parking areas only. (2) On Burbank Slough, hunting will be permitted on Wednesday, Saturday, Sunday and Thanksgiving Day only. No additional hunting will be permitted during the State extended goose hunting season. In the north and south one-thirds of hunting area, hunting is from marked sites only. Reservations are required for use of goose hunting sites in fields 5 and 6. (3) On the Hanford Island Division, hunting is permitted only on the five upstream islands from opposite the Hanford 300 area—Sagemoor Road upstream to BPA powerline crossing. The Hanford Island offshore from Graduate Center, Sprout Road is closed to hunting. (4) All public use

on the Strawberry Island Division is prohibited.

Willapa National Wildlife Refuge, Ilwaco, Washington 98624. Contact Refuge Manager at 206-484-3482
Lewis and Leadbetter Point Units

Special Conditions: Hunter registration is required. Leadbetter Point is the only refuge unit open to black brant hunting after close of general season.

Riekkola Unit

Special Conditions: (1) Hunter registration is required. (2) Hunting will be permitted on Wednesday and Saturday only. (3) Hunting will not be permitted on Federal holidays. (4) Hunting will be from designated blinds only with no more than three (3) hunters per blind. Blind selection is by drawing each hunt morning at check station. (5) Hunters may possess and use not more than ten (10) shells per hunter per day. (6) This area closes at the end of the regular waterfowl season. No extension of the season is provided for the hunting of black brant.

§ 32.22 Special regulations; upland game; for individual wildlife refuge areas.

Upland game birds and rabbits may be hunted on the following refuge areas:

Columbia National Wildlife Refuge, P.O.

Drawer F, Othello, Washington 99344. Contact Refuge Manager at 509-488-3831

Special Conditions: (1) Open to the hunting of rabbits in addition to game birds. (2) Upland game birds and rabbits may be hunted during State seasons running concurrently with the waterfowl season. (3) Hunters using field 226-227 near Royal Lake must register before hunting and may shoot from designated sites only. (4) On Crab Creek and impoundments from Goose Lake Road to Goldeneye Lake hunting will be permitted on Wednesday and Saturday only.

Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882. Contact Refuge Manager at 503-922-3232

Special condition: No rabbit hunting permitted.

Conboy Lake National Wildlife Refuge, Box 5, Glenwood, Washington 98619. Contact Refuge Manager at 509-364-3410

Special Condition: Rabbits and upland game birds may only be hunted during that part of the State season concurrent with the waterfowl hunting season.

Toppenish National Wildlife Refuge, Route 1, Box 1300, Toppenish, Washington 98948. Contact Refuge Manager at 509-865-2405

Special Condition: Rabbits and upland game birds may only be hunted during that part of the State season concurrent with the waterfowl hunting season.

Willapa National Wildlife Refuge, Ilwaco, Washington 98624. Contact Refuge Manager at 206-484-3282

Long Island Unit

Special Conditions: (1) Archery hunting for blue and ruffed grouse only. (2) Permits for the opening weekend will be limited and obtained in advance. Applications are available from the Refuge Manager. (3) After opening weekend, hunters must possess

regular hunting permit available at refuge headquarters and at the Nahcotta Dock. (4) All nonburnable garbage must be removed from the island.

McNary National Wildlife Refuge, P.O. Box 308, Burbank, Washington 99323. Contact Refuge Manager at 509-547-4942

Special Conditions: (1) Pheasants only may be hunted during the first half of the State's split season or through November 6, whichever is earlier. (2) Pheasant hunting will be restricted to Wednesday, Saturday, and Sunday. (3) Hunters are required to park vehicles in designated parking areas only.

§ 32.32 Special regulations; big game; for individual wildlife refuge areas.

1. Big game hunting is permitted on the following refuge area:

Little Pend Oreille National Wildlife Refuge, Route 1, Box 443, Colville, Washington 99114. Contact Refuge Manager at 509-684-2824

2. Deer hunting only is permitted on the following refuge areas:

Columbia National Wildlife Refuge, P.O. Drawer F, Othello, Washington 99344. Contact Refuge Manager at 509-488-3831
Conboy Lake National Wildlife Refuge, Box 5, Glenwood, Washington 98619. Contact Refuge Manager at 509-364-3410
Umatilla National Wildlife Refuge, P.O. Box 239, Umatilla, Oregon 97882. Contact Refuge Manager at 503-922-3232

3. Bear, deer, and elk may be hunted on the following refuge areas:

Willapa National Wildlife Refuge, Ilwaco, Washington 98624. Contact Refuge Manager at 206-484-3482
Long Island Unit

Special Conditions: (1) Archery hunting only is permitted. (2) Permits for opening weekend will be limited and obtained in advance. Applications are available from the Refuge Manager. (3) After opening weekend, hunters must possess regular hunting permit available at refuge headquarters and at the Nahcotta Dock. (4) Use of bait or baiting for bears is prohibited. (5) All non-burnable garbage must be removed from the island.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally and which are set forth in Title 50 Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

The Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11949 and OMB Circular A-107.

The primary author of this document is Joseph R. Blum, Area Manager: Telephone FTS 434-9578 or 9579, com'l 206-753-9578 or 9579.

Dated: August 21, 1979.

David L. Bartling,

Acting Area Manager, U.S. Fish and Wildlife Service.

[FR Doc. 79-26097 Filed 8-27-79; 8:45 am]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register

Vol. 44, No. 168

Tuesday, August 28, 1979

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[9 CFR Part 92]

Importation of Animals From Mexico

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend certain requirements relating to the importation of certain animals into the United States from Mexico. This action is needed to clarify the requirements of the regulations and to relieve certain restrictions, which may no longer be necessary, governing the importation of such animals. The intended effect of this action is to clarify the regulations relating to the importation of poultry from Mexico for slaughter, and those relating to the importation of swine which are ineligible to enter the United States from Mexico. Additionally, the proposal would provide for cattle, otherwise qualified for entry, to be imported into the United States from any area of Mexico in lieu of restricting such imports to specific States of origin in Mexico, and would provide for horses to be imported into the United States from Mexico for slaughter without detention at the port of entry and testing for specific diseases as is required for all other horses imported into the United States from Mexico.

DATE: Comments on or before October 29, 1979.

ADDRESS: Written comments to Deputy Administrator, USDA, APHIS, VS, Room 815, Federal Building, Hyattsville, MD 20782.

FOR FURTHER INFORMATION CONTACT: Dr. D. E. Herrick, USDA, APHIS, VS, Federal Building, Room 815, Hyattsville, Maryland 20782. (301) 436-8170.

SUPPLEMENTARY INFORMATION: Notice is hereby given in accordance with the

administrative procedure provisions in 5 U.S.C. 553, that, pursuant to section 2 of the Act of February 2, 1903, as amended; and sections 2, 3, 4, and 11 of the Act of July 2, 1962 (21 U.S.C. 111, 134a, 134b, 134c, and 134f), the Animal and Plant Health Inspection Service is considering amending Part 92, Title 9, Code of Federal Regulations.

When the importation of ruminants into the United States from Mexico was resumed following the successful foot-and-mouth disease eradication program (1947-1953), only ruminants from certain specified northern States of Mexico were permitted entry into the United States because of the use of foot-and-mouth disease vaccine in southern Mexico as a part of the eradication program. Since that time, all ruminants in Mexico which may have been vaccinated with foot-and-mouth disease vaccine during the eradication program apparently have been eliminated from the livestock population. In view of this, the provision of the regulations in § 92.31(a) which provides that ruminants from specified States in northern Mexico only may be imported into the United States without an import permit at specified ports under certain conditions would be amended to provide that ruminants otherwise eligible for importation may be imported from any area of Mexico without an import permit at specified ports and in accordance with specified conditions.

Therefore, clause (1) of the proviso in § 92.31(a) would be deleted. The clause numbered (2) would be renumbered (1) and would be amended to delete the reference to "Mexican States other than those listed." Clauses (3) and (4) would be renumbered (2) and (3) respectively, and amended to delete the references to the permit requirements, as those references would no longer apply. Instead of referring to permit requirements, the regulations would be amended to refer to those countries listed in § 94.1(a)(1) as infected with foot-and-mouth disease and rinderpest. Since animals from such countries constitute a threat to transmit such diseases, ruminants coming in contact with such animals must not be permitted entry into the United States.

The provisions of § 94.10 of this chapter prohibit the importation of swine from countries where hog cholera is determined to exist. As Mexico is a country where hog cholera exists, the

references in § 92.33 for inspection at the port of entry for swine imported from Mexico would be deleted. This action would remove conflicts in the regulations of this chapter and delete procedures that are not presently applicable.

In § 92.34 the provisions in paragraph (b) relating to cattle and other ruminants would be deleted. As this rulemaking document proposes that cattle and other ruminants may be imported from all areas of Mexico without an import permit, the provisions that require cattle from Mexico which previously would have required a permit to be quarantined at the port of entry for 15 days would likewise be deleted.

Also, because Mexico is considered to be affected with VVND, the 15-day quarantine period for poultry from Mexico in § 92.34(b) conflicts with the provisions of § 92.11(c) which requires that poultry from VVND-affected countries be quarantined for not less than 30 days and be negative to specified tests for that disease.

Section 92.34(a) would be redesignated as a new § 92.35(a) and be amended by deleting the listed Mexican States, since such distinctions would no longer apply. Further, § 92.34(c) would be redesignated as a new § 92.39(b).

This rearrangement of § 92.34 is intended to clarify the regulations governing the importation of animals from Mexico, by listing the requirements by species of animals.

Paragraphs (a), (b) and (c) of § 92.35 would be redesignated as paragraphs (b), (c) and (d) respectively, because former § 92.34(a) would be designated as a new § 92.35(a). Further, the third sentence in new § 92.35(b) (former paragraph (a)) would be amended by deleting the phrase "or quarantined" because of the changes deleting the quarantine period in § 92.34 for cattle and other ruminants as noted above.

For the aforementioned reasons, and conformity with the other proposed changes in this document, § 92.40 would be amended to delete references to specific Mexican States, poultry and ruminants.

The regulations now require that all horses imported into the United States from Mexico through land border ports be held at the port of entry and tested for specific diseases before being released for importation into the United States. Since horses imported for

slaughter are required to be certified by a Mexican official as being free of evidence of communicable diseases and be moved directly to approved slaughter establishments for slaughter under Federal or State inspection within two weeks from the date of entry, no useful purpose would appear to be served by requiring that they be detained at the port of entry and tested before entry, as is required for all other horses. Therefore, all provisions of the regulations which require the detention and testing of slaughter horses imported from Mexico through land border ports would be deleted.

The regulations in § 92.11(c) provide that poultry and eggs for hatching imported in to the United States from all countries of the world, except Canada, must be quarantined for not less than 30 days and meet certain testing requirements as a condition for entry. Because of the existence of exotic Newcastle disease in Mexico, poultry and hatching eggs from that country must meet the provisions of § 92.11(c) to be eligible for entry into the United States. However, § 92.34 provides that poultry from Mexico be quarantined for not less than 15 days at the port of entry. Further, poultry from Mexico intended for immediate slaughter need not be quarantined (See § 92.40). Therefore, to remove the conflict between the provisions concerning poultry contained in §§ 92.11(c), 92.34(b) and 92.40, the references to poultry in § 92.34(b) and § 92.40 would be deleted.

The provisions for the importation of swine from Mexico would be deleted as such importations are prohibited from countries not considered free of hog cholera.

Certain other minor editorial changes have been made for clarity and ease of reading.

Accordingly, Part 92, Title 9, Code of Federal Regulations, would be amended in the following respects:

1. In § 92.31, paragraph (a) would be amended to read:

§ 92.31 Import permits and applications for inspection for animals and animal semen.

(a) For ruminants, poultry, and animal semen intended for importation from Mexico, the importer shall first apply for and obtain from Veterinary Services an import permit as provided in § 92.4; *Provided*, That an import permit is not required for a ruminant offered for entry at a land border port designated in § 92.3(c), if such animal:

(1) Was born in Mexico or the United States, and has been in no country other than Mexico or the United States, and

(2) Has not, during the preceding 60 days been corralled, pastured, or held with, or bred by, or inseminated with semen from any ruminant which has been imported into Mexico from a country designated in § 94.1(a)(1) as infected with foot-and-mouth disease or rinderpest, and

(3) Is not pregnant as a result of having been bred by, or artificially inseminated with semen from a ruminant imported into Mexico from countries designated in § 94.1(a)(1) as infected with foot-and-mouth disease or rinderpest.

§ 92.33 [Amended]

2. In § 92.33(a), the term "swine" in the first sentence and the term "and swine" in the third sentence would be deleted.

§ 92.34 [Amended]

3. All of § 92.34 would either be deleted or moved to other sections. Paragraph (b) of § 92.34 would be deleted. Paragraph (a) of § 92.34 would be redesignated as a new paragraph (a) in § 92.35. Paragraph (c) of § 92.34 would be redesignated as a new paragraph (b) in § 92.39.

4. In § 92.35, paragraphs (a), (b), and (c) would be redesignated as paragraphs (b), (c), and (d) respectively; former § 92.34(a) would be added as a new paragraph (a); and the third sentence in new paragraph (b) [former paragraph (a)] would be amended to delete the phrase "or quarantined". New § 92.35 (a) and the third sentence in new paragraph (b) would be amended to read as follows:

§ 92.35 Cattle from Mexico.

(a) Cattle and other ruminants imported from Mexico, except animals being transported in bond for immediate return to Mexico or animals imported for immediate slaughter, may be detained at the port of entry, and there subjected to such disinfection, blood tests, other tests, and dipping as required in this part to determine their freedom from any communicable disease or infection of such disease. The importer shall be responsible for the care, feed, and handling of the animals during the period of detention.

(b) * * * Notwithstanding such certificates, such cattle shall be detained as provided in paragraph (a) of this section and shall be dipped at least once, under the supervision of an inspector, in one of the permitted dips listed in § 72.13(b) of this chapter. * * *

5. Section 92.39 would be amended to read:

§ 92.39 Horses from Mexico.

(a) Horses offered for entry from Mexico shall be inspected as provided in § 92.8(a) and § 92.33; shall be accompanied by a certificate and otherwise handled as provided in § 92.17; and shall be quarantined and tested as provided in paragraph (b) of this section; *Provided*, That horses offered for importation from tick-infested areas of Mexico shall be chute inspected, unless in the judgment of the inspector a satisfactory inspection can be made otherwise. If upon inspection they are found to be apparently free from fever ticks, before entering the United States they shall be dipped once in a permitted arsenical solution or be otherwise treated in a manner approved by the Deputy Administrator, Veterinary Services.

(b) Horses intended for importation from Mexico, except horses certified for immediate slaughter, shall be quarantined at a port designated in § 92.3 until they qualify for release from such quarantine. In order to qualify for such release, all horses while so detained shall test negative to an official test for dourine, glanders, equine piroplasmiasis, equine infectious anemia,⁷ and such other tests that may be required by the Deputy Administrator to determine their freedom from other communicable diseases. Such horses shall also be subjected to such other inspections and disinfections deemed necessary by the Deputy Administrator to prevent the introduction of communicable disease and they shall be released from quarantine only if found to be free from communicable disease upon inspection.

6. Section 92.40 would be amended to read:

§ 92.40 Animals for immediate slaughter.

Ruminants, other than sheep and goats, and horses may be imported from Mexico, subject to the applicable provisions of §§ 92.31, 92.32, 92.33 and 92.35(b)(2) for immediate slaughter if accompanied by a certificate of a salaried veterinarian of the Mexican Government stating that he has inspected such animals on the premises of origin and found them free of

⁷ In view of the fact that official tests for dourine and glanders are run exclusively at the Veterinary Services Laboratory, Beltsville, Maryland, protocols for these tests have not been published and are therefore not available; copies of "Protocol for the Complement-Fixation Test for Equine Piroplasmiasis" and "Protocol for the Immuno-Diffusion (Coggins) Test for Equine Infectious Anemia" may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, Hyattsville, Maryland 20782, filed as part of the original document.

evidence of communicable disease, and that, so far as it has been possible to determine, they have not been exposed to any such disease common to animals of their kind during the preceding 60 days, and if the animals are shipped by rail or truck, the certificate shall further specify that the animals were loaded into cleaned and disinfected cars or trucks for transportation directly to the port of entry. Such animals shall be consigned from the port of entry to a recognized slaughtering establishment and there slaughtered within 2 weeks from the date of entry. Such animals shall be moved from the port of entry in conveyances sealed with seals of the United States Government. Sheep and goats from any part of Mexico may be imported only in compliance with other applicable sections in this part.

All written submissions made pursuant to this notice will be made available for public inspection at the Federal Building, 6505 Belcrest Road, Room 824, Hyattsville, Maryland, during regular hours of business (8 a.m. to 4:30 p.m., Monday to Friday, except holidays) in a manner convenient to the public business (7 CFR 1.27(b)).

Comments submitted should bear a reference to the date and page number of this issue in the *Federal Register*.

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Draft Impact Analysis has been prepared and is available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301-436-8695.

Done at Washington, D.C., this 21st day of August 1979.

G. V. Peacock,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 79-26509 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-34-M

NUCLEAR REGULATORY COMMISSION

[10 CFR Part 9]

Privacy Act Regulations; Notice of Proposed Exemptions

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing exemptions as provided under the Privacy Act of 1974. The proposed amendment of the Commission's regulation "Public Records" would exempt from certain requirements of the

Privacy Act portions of a proposed new system of records "Document Control System."

DATE: Comments must be received by September 27, 1979.

ADDRESSES: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Ellen Whitlow, FOIA/PA Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301)-492-8133.

SUPPLEMENTARY INFORMATION: The Commission is publishing a notice to establish a proposed new system of records, identified as Document Control System, NRC-29. The proposed new system will incorporate the existing system NRC-26 with the Document Control System. Upon establishment of the new system, the existing system NRC-26 will be deleted.

The proposed amendment of § 9.95 of 10 CFR Part 9 set forth below would exempt from certain requirements of the Privacy Act portions of the proposed system of records NRC-29.

Specific exemptions from the requirements of the Privacy Act pertaining to proposed NRC-29 are intended to prevent access to records that contain information specifically authorized under Executive Order (E.O. 12065) to be kept secret in the interest of the national defense and foreign policy.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a, and 553 of Title 5 of the United States Code, as amended, notice is hereby given that adoption of the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9 is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch by September 27, 1979. Copies of comments received will be available for public inspection and copying at the Commission's Public Document Room, 1717 H Street NW, Washington, DC.

1. Section 9.95 of 10 CFR Part 9 is amended by deleting paragraph (j) and by adding a new paragraph (j) to read as follows:

§ 9.95 Specific exemptions.

Pursuant to 5 U.S.C. 552a(k), portions of the following NRC systems of records are exempt from 5 U.S.C. 552a(c)(3); (d); (e)(1); (e)(4)(G), (H) and (I) and (F) and are subject to the provisions of § 9.61 of this part:

* * * * *

(j) Document Control System

* * * * *

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841); 5 U.S.C. 552a).

Dated at Bethesda, Maryland this 13th day of August 1979.

For the Nuclear Regulatory Commission,
Lee V. Gossick,

Executive Director for Operations.

[FR Doc. 79-26507 Filed 8-27-79; 8:45 am]

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FEDERAL TRADE COMMISSION

[16 CFR Part 13]

[File No. 792 3038]

Montgomery Ward & Co., Inc.; Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, accepted subject to final Commission approval, among other things, would require a Chicago, Ill. firm, engaged in the operation of a chain of department and catalog stores, to cease making unsubstantiated safety-related claims regarding the installation, operation or maintenance of wood-burning heaters and Franklin fireplaces; or any representation that contradicts the requirements of prevailing model building or fire protection codes. The company would be required to include in its catalogs a conspicuous notice providing minimum distances from adjacent combustible walls at which heating devices can be safely and properly installed; and advising consumers that such information has been previously misstated; that improperly installed heating devices are fire hazards and should be immediately relocated; and that Ward, at its own expense, will reinstall improperly installed heaters and provide shields for previously purchased Franklin fireplaces. Additionally, the company would have six months in which to revise and reprint promotional and instructional material as required to comply with the terms of the order, and

provide its sales personnel with corrected installation information.

DATE: Comments must be received on or before October 29, 1979.

ADDRESS: Comments should be directed to: Office of the Secretary, Federal Trade Commission, 6th St. and Pennsylvania Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Paul W. Turley, Director, 3R, Chicago Regional Office, Federal Trade Commission, 55 East Monroe St., Suite 1437, Chicago, Ill. 60603. (312) 353-4423.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist and an explanation thereof, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(14) of the Commission's Rules of Practice (16 CFR 4.9(b)(14)).

[File No. 792-3038 Agreement Containing Consent Order]

In the matter of Montgomery Ward & Co., Incorporated, a corporation.

The Federal Trade Commission having initiated an investigation of certain acts and practices of Montgomery Ward & Co., Incorporated (hereinafter "proposed respondent"), a corporation, and it now appearing that proposed respondent is willing to enter into an agreement not to engage in the acts and practices being investigated;

It is hereby agreed by and between proposed respondent, by its duly authorized officer and its counsel, and counsel for the Federal Trade Commission that:

1. Proposed respondent Montgomery Ward & Co., Incorporated is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its principal executive offices located at Montgomery Ward Plaza, Chicago, Illinois 60671.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint here attached.

3. Proposed respondent waives: (a) Any further procedural steps; (b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and (c)

All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become a part of the official record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released; and such acceptance may be withdrawn by the Commission if comments or views submitted to the Commission disclose facts or considerations which indicate the order contained in the agreement is inappropriate, improper or inadequate.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent of any of the facts stated, or that the law has been violated as alleged, in the draft of complaint here attached.

6. This agreement contemplates that if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, then the Commission may, without further notice to the proposed respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order shall have the same force and effect and shall become final and may be altered, modified or set aside in the manner and within the same time provided by statute for other orders. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby, and understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order, and that it may be liable for a civil penalty in the amount provided by law for each violation of the order after it becomes final.

8. Proposed respondent agrees that mailing of the complaint and decision containing the agreed-to order to its address stated in this agreement constitutes service, and proposed respondent waives any right it may have

to any other manner of service. Proposed respondent further understands that the effective date of this order shall be the date of such service.

Order

I

It is ordered, That respondent Montgomery Ward & Co., Incorporated (hereinafter "respondent"), a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale or distribution in or affecting commerce of any woodburning heaters or Franklin fireplaces, forthwith cease and desist from, directly or indirectly:

A. Making any representation to consumers regarding the safe or proper installation clearances for any woodburning heater or Franklin fireplace from adjacent combustible walls, where such representation contradicts the general clearance requirements from combustible walls contained in prevailing model building, mechanical and fire protection codes, unless prior to the time such representation is first made, respondent possesses and relies upon a competent scientific test which substantiates such representation. Provided, that for purposes of this Order, a "competent scientific test" shall mean:

A test in which one or more persons, qualified by professional training, education and experience, formulate and conduct a test and evaluate its results in an objective manner using testing procedures which are generally accepted in the profession to attain valid and reliable results. The test may be conducted or approved by (a) a reputable and reliable organization which conducts such tests as one of its principal functions, or (b) with the exception of the specific tests required by Paragraph III. A below, by persons employed by respondent, if they are qualified by professional training, education and experience and can conduct and evaluate the test in an objective manner.

B. Making any safety-related representation to consumers regarding the installation (other than clearances from adjacent combustible walls), operation or maintenance of any woodburning heater or Franklin fireplace, unless prior to the time such representation is first made, respondent possesses and relies upon competent and reliable evidence which substantiates such representation, including but not limited to competent scientific tests or competent and reliable opinions of scientific, engineering or other experts, including employees of

respondent, who are qualified by professional training or experience to render competent judgments in such matters.

C. Making any representation to consumers regarding any woodburning heater or Franklin fireplace, which misstates or misrepresents the results or applicability of any test, listing or approval by any third party.

II

It is further ordered, That respondent shall include as a full page located in the center of its October 1979 catalog house clearance books, and as a full page located immediately preceding the first page of the Index in its Spring & Summer 1980 semi-annual general catalog, the following notice, conspicuously displayed:

IMPORTANT SAFETY NOTICE TO OWNERS OF WARDS WOODBURNING HEATERS AND FRANKLIN FIREPLACES

Some recent Wards catalogs, fireplace booklets, descriptive manuals, owner's guides, or sales person statements understated some of the minimum recommended clearances between some Wards woodburning heaters and Franklin fireplaces and adjacent combustible walls (see the list of model numbers below). If you purchased one of these heaters or fireplaces and installed it closer to combustible walls than the distances shown in the chart below, it should be relocated IMMEDIATELY. Failure to relocate the heater or fireplace to these distances, or (if needed) to install a protective heat shield between it and combustible walls, COULD CAUSE A FIRE.

Clearances for models 5722, 7377, 7387, 21015, and 21017:

Stove model	Distance from rear	Distance from sides
5722 (circulating wood heater)	36 inches from back of stove	30 inches from sides of stove.
7377 (comfort heater)	30 inches from back of stove	36 inches from sides of stove.
7387 (parlor heater)	30 inches from back of stove	36 inches from sides of stove.
21015 (Franklin fireplace)	18 inches from back of fireplace, with heat shield installed on the inside back wall of fireplace.	36 inches from sides of firebox opening.
21017 (Franklin fireplace)	18 inches from back of fireplace, with heat shield installed on the inside back wall of fireplace.	36 inches from sides of firebox opening.

If you have installed one of the above heaters or fireplaces at less than the distances from combustible walls shown above, or without a heat shield where a heat shield is needed, Wards will help you by either relocating the heater or fireplace to the correct distance or by providing or installing the heat shield, at Wards' expense.

Clearances for models 21335, 21336, and 21337:

Stove model	Distance from rear	Distance from sides
"Little Ben" Franklin fireplace (Wards model 21335; Hearth Craft model 220).	18 inches from back of fireplace, with heat shield installed on back of fireplace.	12 inches from sides of cast iron hearth.
"Big Ben" Franklin fireplace (Wards model 21336; Hearth Craft model 280).	18 inches from back of fireplace, with heat shield installed on back of fireplace.	12 inches from sides of cast iron hearth.
"Giant Ben" Franklin fireplace (Wards model 21337; Hearth Craft model 300).	18 inches from back of fireplace, with heat shield installed on back of fireplace.	12 inches from sides of cast iron hearth.

If you have purchased one of the above three Franklin fireplaces from Wards and installed it without a heat shield, Wards will provide or install a heat shield at Wards' expense.

For further information, write: Mr. Donald C. Gutmann, Customer Relations Manager, 4-N, Montgomery Ward & Co., Incorporated, Montgomery Ward Plaza, Chicago, Illinois 60671.

To enable us to assist you promptly, please try to include the following information in your letter, if known: your name, address and telephone number, the unit you own, the distance from the back and sides of your unit to adjacent combustible walls, whether your unit is installed with a heat shield, and the address where your unit is located.

III

It is further ordered, That:

A. Respondent shall promptly submit the following of its models of woodburning heaters to one or more independent product testing laboratories

approved for this purpose by the Federal Trade Commission or its delegees, for determination by competent scientific tests, as defined in Paragraph I.A. above, of the minimum recommended installation clearances for such models from adjacent combustible walls: models 5718, 7326 and 7336, as offered in respondent's Spring & Summer 1978 catalog, and models 7366, 7386 and 7396, as offered in respondent's Fall & Winter 1977 catalog.

B. If the results of the tests required by Paragraph III.A above on respondent's models 5718, 7326, 7336, 7366, 7386 and 7396, show that respondent has understated the minimum recommended clearances for any such model from adjacent

combustible walls, in any of its current or past catalogs, fireplace booklets, descriptive manuals or owner's guides, respondent shall include in the notice required by Paragraph II above notification of the clearances determined by such test and an offer to relocate the model to such clearances at respondent's expense.

IV

It is further ordered, That respondent shall take all such steps as are necessary to carry out its obligations described in the notice required by Paragraphs II and III.B above to relocate certain woodburning heaters and Franklin fireplaces, or provide or install protective heat shields where needed, at respondent's expense. *Provided*, That:

A. Respondent may, at its election, have the necessary work performed by persons selected by it, including its own employees, who are competent to perform such work.

B. Respondent shall, if relocation of a particular heater or fireplace, or installation of the necessary heat shield on its Franklin fireplace models 21335, 21336 and 21337, is not acceptable to the consumer, offer instead to remove the unit, refund the full purchase price paid by the consumer for the unit (including shipping and handling charges), and make reasonable repairs to the consumer's premises necessitated by such removal, at respondent's expense.

C. Respondent may, at its election, if it concludes that relocating a particular heater or fireplace, or installing the necessary heat shield on its Franklin fireplace model 21015, 21017, 21335, 21336 or 21337, would not be feasible, instead offer to remove the unit, refund the full purchase price paid by the consumer for the unit (including shipping and handling charges), and make reasonable repairs to the consumer's premises necessitated by such removal, at respondent's expense.

D. Respondent may, as regards its Franklin fireplace models 21335, 21336 and 21337, require the consumer to submit proof of purchase satisfactory to respondent showing that the consumer purchased his or her unit from respondent, before respondent must approve any remedy under this Order

for said consumer, which approval by respondent shall not be unreasonably withheld.

V

It is further ordered, That:

A. Respondent shall send to each of its retail sales departments involved in the sale of any woodburning heater or Franklin fireplace, prior to or contemporaneously with the selling of such item in that department, descriptive manual pages or other written information for the department's sales personnel setting forth the clearance requirements from adjacent combustible walls, and the heat shield requirements, if any, for the installation of that item.

B. For a period of six (6) months from the effective date of this Order (plus such additional time as may be necessary to conduct competent scientific tests and to print the materials), respondent shall send to all company retail and catalog stores, as available based upon competent scientific tests, written point of sale material for distribution to consumers inquiring about any of the woodburning heaters or Franklin fireplaces which are covered by the notice requirements of Paragraphs II and III.B of this Order, and which respondent is then offering for sale to consumers, setting forth the clearance requirements from adjacent combustible walls, and the heat shield requirements, if any, for the installation of such items.

VI

It is further ordered, That respondent shall have a period of six (6) months from the effective date of this Order to revise and reprint all printed materials as required to comply with this Order, including but not limited to owner's guides, advertising copy, catalog copy and descriptive materials, and shall not be in violation of this Order because of the existence of owner's guides packaged with products prior to the effective date of this Order. Provided, that during such period, respondent shall use its best efforts to advise customers and consumers of the installation information contained in the notice required by Paragraphs II and III.B above of this Order, and to include with the woodburning heaters and Franklin fireplaces covered by such notice corrected installation information concerning recommended clearances from adjacent combustible walls.

VII

It is further ordered, That respondent shall:

A. Sixty (60) and two hundred forty (240) days after the effective date of this Order, file with the Commission reports in writing setting forth in detail the manner and form in which it has complied with this Order.

B. Maintain files of all persons making written requests to respondent to have woodburning heaters or Franklin fireplaces covered by the notice required by Paragraphs II and III.B of this Order relocated, or installed or provided with heat shields, where respondent has refused such requests, which files shall contain the names and addresses of such persons and the information on which each such refusal was based, including all correspondence from the consumer concerning the consumer's request. Such files shall be made available for inspection and copying, upon reasonable notice, by a duly authorized agent of the Commission during respondent's regular business hours.

C. Forthwith distribute a copy of this Order to each of its operating divisions which is involved in the sale or offering for sale of, or the selection, evaluation or preparation of materials regarding, woodburning heaters or Franklin fireplaces.

D. Notify the Commission at least thirty (30) days prior to any proposed change in the respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the respondent which may affect compliance obligations arising out of this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Montgomery Ward & Co., Incorporated, Montgomery Ward Plaza, Chicago, Illinois. The Agreement culminates an investigation conducted under FTC File 792-3038 by the Commission's Chicago Regional Office and involving Wards' sale of woodburning heaters and Franklin fireplaces.*

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the

*Woodburning heaters and Franklin fireplaces are freestanding heating appliances that burn wood to heat the rooms in which they are placed. Common examples of these devices include the "pot belly stove", the "parlor heater" and the "Ben Franklin fireplace stove."

agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The Commission's complaint alleges that respondent, Wards, has made false, inconsistent and unsubstantiated representations to consumers with respect to the minimum distances at which woodburning heaters and Franklin fireplaces can safely and properly be installed from adjacent combustible walls and has misrepresented the results and applicability of third party product tests, listings, and approvals. The complaint further alleges that these representations, included in catalog advertising, descriptive manuals, owner's guides and oral sales presentations, had the capacity to induce consumers to install the devices in a manner contrary to established safety standards (in the form of mechanical and fire protection codes in effect in states, counties and municipalities throughout the nation), and at distances less than those determined in product safety tests run by or for the company itself. Installing the devices with insufficient clearances from combustible walls could subject consumers to potential fire loss and risks of personal injury and property damage.

Part I of the proposed order prohibits Wards from making any representation concerning installation clearances for any woodburning heater or Franklin fireplace from combustible walls that contradicts the general clearance requirements of prevailing model building, mechanical or fire protection codes, unless Wards possesses and relies upon a competent scientific test to substantiate that representation. Wards is also prohibited from making any safety-related representation to consumers regarding the installation, operation or maintenance of heaters or fireplaces, without prior substantiation by competent scientific tests, expert opinion, or other competent and reliable evidence. Finally, Part I of the order prohibits Wards from making any misrepresentation concerning the results or applicability of any third party test, listing or approval.

Part II of the proposed order requires Wards to place a conspicuous notice in its October, 1979 catalog house clearance books, and in its Spring & Summer 1980 semi-annual general catalog, informing consumers of its misstatements in the past of recommended clearances for certain of its woodburning heaters and fireplaces and of the proper installation distances required between the devices and

adjacent combustible walls. (A general notice was required in widely circulated company media because Wards does not retain records of individual past purchasers.) The notice informs consumers that the devices should be relocated immediately if they have been installed at less than required distances from adjacent combustible walls or without a protective heat shield, which is required in some instances. Furthermore, Wards must offer to compensate consumers who have installed the devices improperly by either re-installing them at the company's expense or providing or installing heat shields where appropriate. The notice also informs purchasers of three (3) models of franklin fireplaces that if the devices have been installed without a heat shield, one will be provided by Wards at no additional cost. (Clearances for these three franklin fireplaces that appeared in promotional and instructional materials were proper if a heat shield, which should have been included with the product but oftentimes was not, was installed on the device.)

The notice required by the proposed order does not describe Ward's additional obligation (see Part IV discussed more fully below) to offer dissatisfied consumers the option of removing the device, refunding the full purchase price and repairing any damage to the premises.

Part III of the proposed order requires Wards to submit several models of woodburning heaters to an independent product testing laboratory for testing to determine safe and proper installation clearances from adjacent combustible walls. The models included are those for which Wards has made representations concerning proper installation clearances but respecting which no scientific tests have as yet been conducted to establish minimum safe clearances. (The models specifically listed in the notice required by Part II of the order, in contrast, are those for which representations were made that were contradicted by actual scientific tests already performed on the devices.) Should the tests performed under Part III of the order determine that Wards has in fact understated the proper clearances for any of these models in any of its current or past promotional or instructional materials, the company will include the proper clearances for those models in the notice required by Part II of the order and make the same offer to relocate the devices at Wards' expense.

Part IV of the proposed order requires Wards to fulfill the redress obligations

described in the notice to consumers discussed above. Part IV provides:

(1) that the necessary work may be performed by persons selected by the company, including its own employees, so long as they are competent to perform such work;

(2) that if relocation of the device or installation of a heat shield is unacceptable to the consumer, Wards will offer to remove the unit, refund the full purchase price (including shipping and handling charges) and make repairs to the premises at Wards' expense. This offer does not apply to installation of a heat shield on two of the fireplace models because the heat shield would be located inside the unit and would have no effect on the model's appearance or location;

(3) that if relocation of the device or installation of the heat shield is not feasible (for example, there is not enough room to relocate the unit), the company will make the same refund offer described immediately above; and

(4) that Wards may require proof of purchase on three (3) franklin fireplace models, since these models are also marketed by other retailers. Approval may not, however, be unreasonably withheld.

Part V of the proposed order requires Wards to provide materials to sales personnel setting forth the clearance or heat shield requirements for any woodburning heater or franklin fireplace sold in applicable retail sales departments. Wards is also required to provide such information in point of sale materials for consumers for a period of six (6) months from the effective date of the order.

Part VI of the proposed order gives Wards six (6) months to revise and reprint promotional and instructional materials. It provides that the company will not be in violation of the order if owner's guides packaged with the products before the effective date of the order are distributed after the date of the order (it would not be feasible to locate and open all such packages), but requires that correct instructions be included with any unit sold.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

James A. Tobin,
Acting Secretary.

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DEPARTMENT OF LABOR

Office of the Secretary

[20 CFR Chapters I, IV, V, VI, and VII]

[29 CFR Subtitle A and Chapters II, IV, V, XVII, and XXV]

[30 CFR Ch. I]

Improving Government Regulations Schedule for Semiannual Agenda, Supplemental Agenda, and List of Regulatory Review Panel Members

AGENCY: Department of Labor.

ACTION: Schedule For the Publication of the next Semiannual Agenda, Supplemental Agenda, and Listing of Regulatory Review Panel Members.

SUMMARY: The Department of Labor's Guidelines implementing Executive Order 12044 require the Department to publish in the *Federal Register*, a semiannual agenda of significant regulations which will be considered for review or development during the coming six month period. The Guidelines also provide for the publication of supplemental agenda when appropriate, and give notice of the dates on which forthcoming agenda will be published. This document contains a notice of the revised dates for publication of the Department's Agenda. It also contains a Supplemental Agenda indicating which of the regulations contained in the Department's January 26, 1979 Agenda have been published in final form. And finally it contains the membership of the Regulatory Review Panel established by the Department in accordance with the Guidelines.

DATES: The next Department of Labor semiannual agenda of regulations will be published by October 1, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. Judith Sorum, Special Assistant to the Secretary, Room S2018, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523-8656, or Seth D. Zinman, Associate Solicitor for Legislation and Legal Counsel, Room N2428, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523-8201.

SUPPLEMENTARY INFORMATION: On January 26, 1979 the Department of Labor published in the *Federal Register*, its Guidelines for implementing Executive Order 12044, its First Semiannual Agenda of Regulation Selected for Development and Review and a notice indicating that further agenda would be published on August 30, 1979 and at six month intervals thereafter (44 FR 5570-5590).

Following a careful review by the Department's Regulatory Review Panel of the status of all regulations listed on the January, 1979 Agenda and of the regulatory activity expected during the coming year, it has been determined that changing the date for the next semiannual agenda to October 1, 1979 will result in a more thorough and useful listing of the significant regulations to be addressed by the Department in the coming months. In addition this change in the Agenda publication date will permit the Department to coordinate the publication of the Agenda with the publication by the Regulatory Council of its Calendar of Major Regulations, thus reducing duplication of effort.

The Regulatory Review Panel also determined that the Publication of a Supplemental Agenda listing the regulatory activity completed since the January, 1979 Agenda was published, would be useful to the interested public and would indicate the progress made to July 1, 1979. Each regulation which is listed on the Supplemental Agenda has as indicated either been published in final form or has been removed from Department of Labor jurisdiction, and will not appear on the October 1, 1979 Agenda unless it is once again selected for review.

With respect to any other regulation listed on the January 26, 1979 Agenda, interested persons may determine the status of any such regulation by contacting the person whose name, address, and phone number appears following the listing of the regulation in the January, 1979 Agenda. The October 1, 1979 Agenda will detail the progress made in connection with each regulation still pending.

The Department also indicated in the January 26, 1979 Guidelines that the names of the members of the Regulatory Review Panel would be published in the *Federal Register*. This document sets forth the members of the Panel.

Accordingly—

A. The next Department of Labor Semiannual Agenda of Regulations Selected for Development and Review will be published by October 1, 1979 and subsequent agenda will be published at 6 month intervals thereafter.

B. The following regulations which appeared on the Department of Labor's January 26, 1979 Semiannual Agenda were published in final form or removed from Department of Labor jurisdiction on or before July 1, 1979 and are removed from the Department's Agenda.

29 CFR Parts 94-99—Comprehensive Employment and Training

Regulations which implement the Comprehensive Employment and Training Act as amended.

Basis for Action: A review of existing regulations from 29 CFR Part 94 to 29 CFR Part 99 was necessary in order to operate existing programs under the Comprehensive Employment and Training Act of 1973, as amended in 1978, to provide for a smooth transition from existing to new legislation, and to prepare new regulations under the reauthorized CETA legislation.

Contact: Robert Anderson, Administrator, Office of Comprehensive Employment Development, Employment and Training administration, U.S. Department of Labor, Patrick Henry Building, Room 6000, 601 D Street, N.W., Washington, D.C. 20213 (202) 376-6254.

Regulatory Analysis: A regulatory analysis was not required.

Action: A final regulation was published.

29 CFR Part 800—Equal Pay for Equal Work under the Fair Labor Standards Act

Interpretations regarding the meaning and application of Equal Pay Act provisions prohibiting discrimination on the basis of sex in the payment of wages for work which is substantially equal.

Basis for Action: With respect to insurance and other employee benefit plans, the current interpretations provide that the Act is not violated where either the plan provides equal benefits to both men and women or the employer makes equal contributions to the plan. On the basis of decisions of the U.S. Supreme Court and other courts and a thorough review of the legislative history and purposes of the Equal Pay Act, the Department has determined that the "either-or-rule" is an incorrect interpretation. Thus, proposed modifications in §§ 800.110 and 800.116(d) of the Equal Pay interpretations, as proposed on August 25, 1978 in the *Federal Register*, would make clear that employee benefits are "wages" within the meaning of the Equal Pay Act, that any differential in such benefits based on sex-based differential in required employee contributions toward equal benefits violates the Act.

Regulatory Analysis: A regulatory analysis was not prepared.

Action: Responsibility transferred to the Equal Employment Opportunity Commission.

29 CFR Part 850—Age Discrimination in Employment—Records to be Made or Kept Relating to Age, Notices to be Posted, Administrative Exemptions

Recordkeeping and posting requirements for employers, employment agencies and labor organizations subject to the Age Discrimination in Employment Act, and administrative exemptions pursuant to Section 9 of the Act.

Basis for Action: The interpretations must be revised to implement the Age Discrimination in Employment Act Amendments of 1978. Proposed interpretations relating to employee benefit plans (Section 860.120) were published in the *Federal Register* on September 22, 1978, and the final version was published in the *Federal Register* on May 25, 1979. Proposed interpretations concerning limited exemptions affecting certain bona fide executive or high policymaking employees and tenured employees at institutions of higher education were published in the *Federal Register* on December 12, 1978. Proposed interpretations concerning the prohibition of mandatory retirement up until age 70 are also necessary; and to conform with changes in ADEA coverage under the Fair Labor Standards Act Amendments of 1974 and the 1978 ADEA amendments, minor proposed revisions are needed in sections of these interpretations concerning the definitions of "employer" and discrimination within the age range covered under the Act.

Contact: Francis V. LaRuffa, Chief, Branch of Age Discrimination, Wage and Hour Division, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S3502, Washington, D.C. 20210 (202) 523-7640.

Regulatory analysis: A regulatory analysis was not prepared.

Action: Responsibility transferred to the Equal Employment Opportunity Commission.

4. 29 CFR Part 860—Age Discrimination in Employment—Interpretations

Interpretations which guide the Department in the enforcement and administration of the Age Discrimination in Employment Act of 1967.

Basis for Action: The interpretations needed to be revised to implement the Age Discrimination in Employment Act Amendments of 1978. Proposed interpretations relating to employee benefit plans (§ 860.120) were published in the *Federal Register* on September 22, 1978. Proposed interpretations concerning limited exemptions affecting certain bona fide executive or high

polymaking employees and tenured employees at institutions of higher education were published in the *Federal Register* on December 12, 1978. Proposed interpretations concerning the prohibition of mandatory retirement up until age 70 may be expected in the near future. Also to conform with changes in ADEA coverage under the Fair Labor Standards Act Amendments of 1974 and the 1978 ADEA amendments, minor proposed revisions may be expected (early next year) in sections of these interpretations concerning the definitions of "employer" and discrimination within the age range covered under the Act.

Contact: Francis V. LaRuffa, Chief, Branch of Age Discrimination, Wage and Hour Division, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S3502, Washington, D.C. 20210 (202) 523-7640.

Regulatory Analysis: A regulatory analysis was not prepared.

Action: Responsibility transferred to the Equal Employment Opportunity Commission.

29 CFR Part 2520—Elimination of Form EBS-1.

A revision of certain reporting requirements will be proposed to eliminate the need for employee benefit plans to file a Plan Description Form EBS-1 with the Department.

Basis for Action: The revision is intended to eliminate duplicative reporting and reduce the paperwork burden imposed by ERISA.

Contact: Peter Straub, Pension and Welfare Benefit Programs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room N4472, Washington, D.C. 20210 (202) 523-8377.

Regulatory Analysis: A regulatory analysis was not required.

Action: A final regulation was published.

29 CFR 92.1-92.9—Labor Management Services Administration Regulations to be Issued Governing Employee Benefit Payments Under the Redwood National Park Expansion Act (Pub. L. 95-250)

These provisions will define the eligibility criteria which employees must meet in order to receive benefits under the Act.

Basis for action: These regulations were necessary to implement Section 102(b) and Sections 103(d)-103(i) of title I and all of title II of Pub. L. 95-250.

Contact: Ron Glass, Division of Employee Protections, Labor-Management Services Administration, U.S. Department of Labor, Room N5641, 200 Constitution Avenue, N.W., Washington, D.C. 20210 (202) 523-6495.

Regulatory Analysis: A regulatory analysis was not required.

Action: A final regulation was published.

30 CFR Part 46—State Grants Regulations

Basis for Action: To improve regulations implementing Sections 503 of FMSHA.

Contact: Frank A. White, Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203 (703) 235-1910.

Regulatory Analysis: A regulatory analysis was not required.

Action: A final regulation was published.

30 CFR Parts 55, 56, and 57—Miscellaneous Amendments Including Standards for Exposure to Radon Daughters (Part 57 only)

Basis for action: To implement improved safety and health standards under Section 301 of the Amendments Act.

Contact: Frank A. White, Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203 (703) 235-1910.

Regulatory Analysis: A regulatory analysis was not required.

Action: Final regulation was published.

C. The following officials shall serve on the Department of Labor's Regulatory Review Panel:

Chair: The Under Secretary of Labor.

Members:

The Solicitor of Labor;
The Assistant Secretary for Labor-Management Standards;
The Assistant Secretary for Employment Standards;
The Assistant Secretary for Policy Evaluation and Research;
The Assistant Secretary for Employment and Training;
The Assistant Secretary for Occupational Safety and Health;
The Assistant Secretary for Mine Safety and Health;
The Assistant Secretary for Administration and Management;
The Inspector General;
The Commissioner of Labor Statistics;
The Deputy Under Secretary for International Labor Affairs; and
The Deputy Under Secretary for Legislation and Intergovernmental Relations.

Executive Secretary: A designated Special Assistant to the Secretary.

Signed this 22nd day of August, 1979 at Washington, D.C.

Ray Marshall,
Secretary of Labor.

[FR Doc. 79-26755 Filed 8-27-79; 8:45 am]

BILLING CODE 4510-23-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 16, 56, 71, 171, 180, 310, 312, 314, 320, 330, 361, 430, 431, 601, 630, 1003, and 1010]

[Docket No. 77N-0350]

Protection of Human Subjects; Standards for Institutional Review Boards for Clinical Investigations; Waiver of Requirement

AGENCY: Food and Drug Administration.

ACTION: Waiver of Requirement.

SUMMARY: The Food and Drug Administration (FDA) is waiving the requirement for submitting a summary of the presentation as part of the written notice of participation for a public hearing on "Standards for Institutional Review Boards for Clinical Investigations" for the scheduled September 18, 1979 hearing in Bethesda, MD. The agency is also correcting the date for the San Francisco hearing by changing the date from October 2, 1979 to October 3, 1979.

DATES: Public hearings on September 18, October 3, and October 16, 1979. Written notices of participation required by September 4, September 18, and October 2, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John C. Petricciani, Bureau of Biologics (HFB-4), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20205, 301-496-9320.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 14, 1979 (44 FR 47699), FDA announced public hearings on proposed standards for institutional review boards (IRB's) for clinical investigations. One of these public hearings is scheduled for Bethesda, MD, on September 18, 1979.

Under the requirements of 21 CFR 15.21, a written notice of participation must be filed with the FDA Hearing Clerk. The written notice of participation requires the name, address, and telephone number of the

person desiring to make a statement, along with any business affiliation, a summary of the scope of the presentation with references to the appropriate subpart of the proposed regulations, and the approximate amount of time requested for the presentation. The written notices of participation were required to be submitted not later than September 4, 1979 for the Bethesda, MD, hearing.

The agency received telephoned comments from persons interested in participating in the September 18, 1979 hearing at Bethesda, MD, indicating that there is inadequate time to prepare and submit the required summary of the presentation by the September 4, 1979 deadline.

The agency agrees with these comments and is therefore waiving the requirement to submit a summary of the presentation for the September 18, 1979 hearing in Bethesda, MD, only. Because the San Francisco and Houston hearings are scheduled for October 3 and October 16, respectively, persons interested in participating in the other hearings have sufficient time to prepare a summary and will be required to submit this information with the notice of participation required for those hearings.

This action is not expected to have any adverse effect on the scheduled September 18, 1979 hearing at Bethesda, MD, for either the public or the agency.

The agency is also correcting the date for the San Francisco hearing specified in the August 14, 1979 *Federal Register* announcement. This announcement inadvertently identified the date for the San Francisco hearing as October 2, 1979. The correct date for this hearing is October 3, 1979.

Dated: August 23, 1979.

Joseph P. Hille,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26795 Filed 8-24-79; 11:11 am]

BILLING CODE 4110-03-M

[21 CFR Part 74]

[Docket No. 77C-0276]

Listing of Color Additives Subject to Certification; D&C Orange No. 4

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to revise the specifications for D&C Orange No. 4 by adding a tolerance for 4,4'-(diazamino)-dibenzene-sulfonic acid. This revision is necessary because a tolerance for 4,4'-(diazamino)-

dibenzene-sulfonic acid was inadvertently omitted in the listing regulation for D&C Orange No. 4.

DATE: Comments by October 29, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Gerald L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the *Federal Register* of September 30, 1977 (42 FR 52395) listed D&C Orange No. 4 for use in externally applied drugs and cosmetics (see §§ 74.1254 and 74.2254 (21 CFR 74.1254 and 74.2254)). A final rule published in the *Federal Register* of April 7, 1978 (43 FR 14641) confirmed the effective date of November 1, 1977 for the "permanent" listing of D&C Orange No. 4, and also revised the specifications for total color and the sum of volatile matter and chlorides and sulfates (as sodium salts) in response to two objections to the regulation. The revision became effective on April 7, 1978.

The agency has recently become aware that the specifications for D&C Orange No. 4 do not include a tolerance for 4,4'-(diazamino)-dibenzene-sulfonic acid (DAADBSA). A tolerance of not more than 0.1 percent DAADBSA was inadvertently omitted from the specifications when the final regulation was published in the *Federal Register*. FDA has determined, consistent with its policy on the certification of color additives, as well as with the requirement necessary to establish the safety of D&C Orange No. 4, that the tolerance of DAADBSA should be included as originally intended in the specifications for D&C Orange No. 4.

After reviewing the analytical data, FDA has concluded that a tolerance of not more than 0.1 percent for DAADBSA can be met when good manufacturing practices are employed in the production of D&C Orange No. 4.

FDA has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399-403 as amended (21

U.S.C 376(b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 74 be amended in § 74.1254 by inserting, after the entry for "subsidiary colors" in the specifications in paragraph (b), a new entry to read as follows:

§ 74.1254 D&C Orange No. 4.

* * * * *

(b) * * *
4,4'-(diazamino)-dibenzene-sulfonic acid, not more than 0.1 percent.
* * * * *

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office, between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 17, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26647 Filed 8-27-79; 8:45 am]

BILLING 4110-03-M

[21 CFR Part 184]

[Docket No. 78N-0369]

Whey, Whey Products, and Hydrogen Peroxide; Affirmation of GRAS Status as Direct Human Food Ingredients; Extension of Comment Period

AGENCY: Food and Drug Administration.
ACTION: Extension of Comment Period.

SUMMARY: The agency extends the comment period on its proposal to affirm the generally recognized as safe (GRAS) status of whey and whey products as direct human food ingredients and hydrogen peroxide for use as an antimicrobial agent in cheesemaking and whey processing. This action is taken in response to a request for extension of the comment period.

DATE: Written comments by September 20, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 22, 1979 (44 FR 36416), the Food and Drug Administration proposed to affirm the GRAS status of whey and whey products as direct human food ingredients and of hydrogen peroxide for use as an antimicrobial agent in cheesemaking and whey processing. Interested persons were invited to submit comments on the proposal by August 21, 1979.

Kraft Co., Chicago, Illinois, requested a 30-day extension of the comment period, to September 20, 1979, to allow sufficient time to prepare comments on the proposal.

The agency considers the opportunity to comment on GRAS affirmation proposals to be an important part of the GRAS review process. It has determined that an extension of the comment period for this proposal would be appropriate, and that the additional time should be extended to all interested persons.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), the comment period for the GRAS affirmation proposal for whey, whey products, and hydrogen peroxide is extended to September 20, 1979.

Interested persons may, on or before September 20, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 23, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26766 Filed 6-24-79; 11:11 am]

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

[CC:EE-180-78]

Income tax; Treatment of Proceeds From Bingo Games

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the treatment of proceeds from bingo games. Changes to the applicable tax law were made by the Act of October 21, 1978. The regulations would provide the public with the guidance needed to comply with that Act and would affect exempt organizations and political organizations that conduct bingo games.

DATES: Written comments and requests for a public hearing must be delivered or mailed by October 29, 1979. The amendments are proposed to be effective for exempt organizations for taxable years beginning after December 31, 1969, and for political organizations for taxable years beginning after December 31 1974.

ADDRESS: Send comments and request for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T:EE-180-78, Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Charles Kerby of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, Attention: CC:LR:T:EE-180-78, 202-566-3422, (Not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under sections 513 and 527 of the Internal Revenue Code of 1954, as amended by sections 301 and 302 of the Act of October 21, 1978 (P.L. 95-502; 92 Stat. 1702). The amendments are to be issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

Exempt Organizations

A tax exempt organization is generally taxed on the income received from any "unrelated trade or business" conducted by the organization. Under prior law, a bingo game conducted by an exempt organization generally constituted an unrelated trade or business. Under Pub. L. 95-502, the term "unrelated trade or business" does not include the conducting of bingo games.

Political Organizations

A political organization is taxed on the income it receives that is not "exempt function income." Under prior law, proceeds from bingo games were not exempt function income and were, therefore, included in the taxable income of a political organization. Pub. L. 95-502 redefines the term "exempt function income" to include proceeds from bingo games.

Comments and Requests for a Public Hearing

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

Drafting Information

The principal author of these proposed regulations was Charles Kerby of the Employee Plans and Exempt Organizations Division of the Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

Proposed Amendments to the Regulations

The proposed amendments to 26 CFR Part 1 are as follows:

Paragraph 1. There is added in the appropriate place the following new section:

§ 1.513-5 Certain bingo games not unrelated trade or business.

(a) *In general.* Under section 513(f), and subject to the limitations in paragraph (c) of this section, in the case of an organization subject to the tax imposed by section 511, the term "unrelated trade or business" does not include any trade or business that

consists of conducting bingo games (as defined in paragraph (d) of this section).

(b) *Exception.* The provisions of this section shall not apply with respect to any bingo game otherwise excluded from the term "unrelated trade or business" by reason of section 513(a)(1) and § 1.513-1(e)(1) (relating to trades or businesses in which substantially all the work is performed without compensation).

(c) *Limitations.*—(1) *Bingo games must be legal.* Paragraph (a) of this section shall not apply with respect to any bingo game conducted in violation of State or local law.

(2) *No commercial competition.* Paragraph (a) of this section shall not apply with respect to any bingo game conducted in a jurisdiction in which bingo games are ordinarily carried out on a commercial basis. Bingo games are "ordinarily carried out on a commercial basis" within a jurisdiction if they are regularly carried on (within the meaning of § 1.513-1 (c)) by for-profit organizations in any part of that jurisdiction. Normally, the entire State will constitute the appropriate jurisdiction for determining whether bingo games are ordinarily carried out on a commercial basis. However, if State law permits local jurisdictions to determine whether bingo games may be conducted by for-profit organizations, or if State law limits or confines the conduct of bingo games by for-profit organizations to specific local jurisdictions, then the local jurisdiction will constitute the appropriate jurisdiction for determining whether bingo games are ordinarily carried out on a commercial basis.

(3) *Examples.* The application of this paragraph is illustrated by the following examples:

Example (1). (i) Rescue Squad X ("X") a tax-exempt organization, conducts weekly bingo games in State M. The bingo games are operated by individuals who are compensated by X for their services and are, therefore, not excluded from the term "unrelated trade or business" under section 513(a)(1).

(ii) State M has a statutory provision that prohibits all forms of gambling including bingo games. However, that law is not enforced by State officials against local charitable organizations such as X that conduct bingo games to raise funds. Since bingo games are illegal under State law, X's bingo games constitute unrelated trade or business regardless of whether, or to what degree, the State law is enforced.

Example (2). (i) Veterans' organizations Y ("Y") and X ("X"), both tax-exempt organizations, conduct weekly bingo games in State N. The bingo games are operated by individuals who are compensated for their services by Y and X and are, therefore, not

excluded from the term "unrelated trade or business" under section 513(a)(1).

(ii) State N has a statutory provision that permits bingo games to be conducted by tax-exempt organizations. In addition, State N permits bingo games to be conducted by for-profit organizations in city S, a resort community located in county R. Several for-profit organizations conduct nightly bingo games in city S. Y conducts its weekly bingo games in city S. X conducts its weekly bingo games in county R outside of city S. Since State law confines the conduct of bingo games by for-profit organizations to city S, and since bingo games are regularly carried on there by those organizations, Y's bingo games conducted in city S constitute unrelated trade or business. However, X's bingo games conducted in county R outside of city S do not constitute unrelated trade or business.

(d) *Bingo game defined.* A bingo game is a game of chance played with cards that are generally printed with five rows of five squares each. Participants place markers over randomly called numbers on the cards in an attempt to form a preselected pattern such as a horizontal, vertical, or diagonal line, or all four corners. The first participant to form the preselected pattern wins the game. As used in this section, the term "bingo game" means any game of bingo of the type described above in which wagers are placed, winners are determined, and prizes or other property is distributed in the presence of all persons placing wagers in that game. The term "bingo game" does not refer to any game of chance (including, but not limited to, keno games, dice games, card games, and lotteries) other than the type of game described in this paragraph.

(e) *Effective date.* Section 513(f) and this section apply to taxable years beginning after December 31, 1969.

Par. 2. Section 1.527-3(b)(1) is revised to read as follows:

§ 1.527-3 Political organization taxable income.

(b) *Exempt function income defined.*—

(1) *In general.* For purposes of section 527 and these regulations the term "exempt function income" means any amount received as—

(i) A contribution of money or other property;

(ii) Membership dues, fees, or assessments from a member of a political organization;

(iii) Proceeds from a political fund raising or entertainment event, or proceeds from the sale of political campaign materials, which are not received in the ordinary course of any trade or business; and

(iv) Proceeds from the conduct of any bingo game (as defined in section 513 (f) (2)) unless the proceeds were held on

October 21, 1978, by the political organization that conducted the bingo game and thereafter were used by that organization to make a contribution or expenditure (as defined in section 301 (e) and (f) of the Federal Election Campaign Act of 1971; 2 U.S.C. 431 (e), (f)) in connection with an election held before January 1, 1979.

to the extent such amount is segregated for use only for the exempt function of the political organization. (See also § 1.527-4 regarding the treatment of expenditures for a judicially determined illegal activity.)

Jerome Kurtz,

Commissioner of Internal Revenue.

(FR Doc. 79-26742 Filed 8-27-79; 8:46 am)

BILLING CODE 4830-01-M

Bureau of Alcohol, Tobacco and Firearms

[27 CFR Parts 6, 8, 10, 11]

[Reference Notice 327]

Unlawful Trade Practices Under the Federal Alcohol Administration Act

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

ACTION: Notice of public hearing—changed date; Notice of extension of period for filing written comments.

SUMMARY: On August 1, 1979, the Bureau of Alcohol, Tobacco and Firearms published a notice of proposed rulemaking, and notice of hearing in the Federal Register (44 FR 45298). That notice proposed regulations implementing the unlawful trade practice provisions of the Federal Alcohol Administration Act, and set dates for public hearings to consider the proposed regulations, and for submitting written comments.

A number of industry members have requested more time to prepare for these public hearings, and to submit their written comments. The Director believes that extending these deadlines will give more people adequate time to prepare their written and oral comments.

DATES: Written comments must be received by December 17, 1979.

The public hearing formerly scheduled for September 6 and 7 in Washington, DC is now scheduled to be held October 22 and 23, 1979. Requests to testify at this hearing must be received no later than October 12, 1979.

Other public hearings will be held as originally scheduled as follows:

September 10, 11—Hartford, Connecticut.
September 13, 14—Atlanta, Georgia.

September 17, 18—Chicago, Illinois.
September 19, 20—San Francisco, California.

Requests to testify at these hearings must be received no later than September 4, 1979.

ADDRESSES: Send written comments and requests to testify at public hearings to: Director, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044, Attn: Chief, Regulations and Procedures Division.

DATES AND ADDRESSES: PUBLIC HEARINGS

Public Hearing, Hartford, CT

Dates: From 10 a.m. until 5 p.m. on September 10 and 11, 1979.

Address: Plaza Room, Hotel Sonesta, 5 Constitution Plaza.

Public Hearing, Atlanta, GA

Dates: From 10 a.m. until 5 p.m. on September 13 and 14, 1979.

Address: Holiday Hall I and II, Holiday Inn Downtown, 175 Piedmont Avenue, NE.

Public Hearing, Chicago, IL

Dates: From 10 a.m. until 5 p.m. on September 17 and 18, 1979.

Address: Monroe Ballroom, 6th Floor—(September 17); Crystal Ballroom, 3rd Floor (September 18); Palmer House Hotel, State and Monroe Streets.

Public Hearing, San Francisco, CA

Dates: From 10 a.m. until 5 p.m. on September 19 and 20, 1979.

Address: Room 503, U.S. Customs House, 555 Battery Street.

Public Hearing, Washington, DC

Dates: From 10 a.m. until 5 p.m. on October 22 and 23, 1979.

Address: Room 5041, Federal Building, 12th & Pennsylvania Avenue, NW.

Evening Public Hearings

Public hearings will be held in the evenings to accommodate persons unable to attend daytime hearings, if demand is great enough. Evening hearings will begin at 7 p.m. and be held in each city at a location to be announced. Evening hearings are scheduled as follows: Hartford, Connecticut on September 10; Atlanta, Georgia on September 13; Chicago, Illinois on September 17; San Francisco, California on September 20, and Washington, DC on October 22.

FOR FURTHER INFORMATION CONTACT: Charles N. Bacon, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, telephone: 202-566-7626.

SUPPLEMENTARY INFORMATION:

Requests To Testify; Rules Governing Public Hearings

Persons requesting to testify at any of these hearings shall indicate the city in their request. These persons shall also indicate a preference for the date and time of day in which they request to testify; to the extent possible, ATF will

honor these preferences. The request to testify must include an outline of the topic or topics on which a person desires to speak. Testimony will be limited to 10 minutes per speaker, but additional time may be granted for answering questions. Persons testifying should be prepared to respond to questions concerning their testimony, the outline of their testimony, or to any matters relating to written comments which they may have submitted. Written comments relating to Notice of Proposed Rulemaking No. 327, or to the advance notice of proposed rulemaking will be available at each hearing for public inspection. Persons not scheduled to testify may be allowed to testify if time permits at the conclusion of each hearing.

ATF will notify all persons requesting to testify and will confirm dates and times. ATF will prepare an agenda, listing speakers and their topics, for each hearing, and will make this agenda available at the hearing.

All public hearings held pursuant to this notice will be conducted under ATF's procedural rules at 27 CFR 71.41(a)(3).

Disclosure of Comments

Comments on this notice of proposed rulemaking may be inspected in the ATF Reading Room, Office of Public Affairs, Room 4408, Benjamin Franklin Post Office Building, 12th and Pennsylvania Avenue, NW, Washington, DC during normal business hours.

Authority and Issuance

This notice is issued under the authority contained in section 5 of the Federal Alcohol Administration Act, 49 Stat. 981, as amended (27 U.S.C. 205).

Signed: August 23, 1979.

G. R. Dickerson,
Director.

[FR Doc. 26744 Filed 8-27-79; 8:46 am]

BILLING CODE 4810-31-M

DEPARTMENT OF LABOR

Pension and Welfare Benefit Programs [29 CFR Part 2550]

Rules and Regulations for Fiduciary Responsibility; Proposed Regulations Relating to Definition of Plan Assets and to Establishment of Trust

AGENCY: Department of Labor.

ACTION: Proposed Rule Making and Withdrawal of Previous Proposed Regulation.

SUMMARY: This document contains a proposed regulation clarifying what will

be regarded as assets of an employee benefit plan under the Employee Retirement Income Security Act of 1974 (the Act). The document also (1) contains a proposed regulation providing certain exemptions from the requirement that assets of an employee benefit plan be held in trust, and (2) withdraws a previous proposed regulation concerning that subject.

DATES: Written comments concerning the proposed regulations must be received on or before October 29, 1979. The proposed regulations would be effective 30 days after they are adopted.

ADDRESSES: Interested persons are invited to submit written data, views, or arguments concerning either or both of the proposed regulations set forth in this document to: Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20216, marked to the attention of "Plan Asset Regulations," on or before the date indicated above. All such submissions will be open to public inspection in the Public Documents Room, Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Robert R. Bitticks, Esq., Office of the Solicitor, U.S. Department of Labor, Washington, D.C. (202) 523-8620.

SUPPLEMENTARY INFORMATION: Section 403(a) of the Act requires that, in general, assets of employee benefit plans be held in trust by one or more trustees. Certain exceptions to this requirement are set forth in section 403(b) of the Act. One such exception is contained in section 403(b)(4), which provides that the requirements of section 403(a) will not apply to a plan which the Secretary of Labor exempts from those requirements, and which is not subject to part 2 of Title I of the Act (relating to participation and vesting), part 3 of Title I (relating to funding), or Title IV (relating to plan termination insurance). The category of plans to which the exemptive authority extends thus includes all welfare plans and certain types of pension plans.¹

¹ The classes of pension plans which the Secretary of Labor has the authority to exempt from the trust requirement are, generally, (1) excess benefit plans; (2) plans established and maintained by a society, order, or association described in section 501(c)(8) or (9) of the Internal Revenue Code of 1954 if there are no employer contributions made to the plan; (3) trusts described in section 501(c)(18) of the Code; and (4) plans established or maintained by a labor organization described in section 501(c)(5) of the Code which do not provide for employer contributions.

Pursuant to the exemptive authority contained in section 403(b)(4), the Department of Labor (Department) published proposed regulation 29 CFR 2552.1, which would have provided an exemption from the trust requirements of section 403(a) of the Act for certain unfunded employee welfare benefit plans.² A number of the public comments received in response to that proposed regulation expressed the view that the class of welfare plans to which the exemption would apply was too limited. It was also suggested by commentators that, in connection with adopting regulations regarding the trust requirement of the Act, the Department should clarify what constitutes "assets" of an employee benefit plan within the meaning of the Act.

Upon consideration of those comments and other relevant matters, the Department has determined to withdraw the proposed regulation published in December 1974, and to propose in its stead the regulations described below. One of the regulations now being proposed, 29 CFR 2550.401b-1, would define the meaning of "plan assets" under the Act.³ The other regulation now being proposed, would in part provide, at 29 CFR 2550.403b-1(e), a limited exemption from the trust requirement of the Act with respect to welfare plans.

Proposed Regulation With Regard to What Constitutes "Assets" of a Plan

The Act does not explicitly define the types of property which will be regarded as "assets" of an employee benefit plan. However, the Act in section 401(b) describes certain types of property which will *not* be regarded as plan assets even though a plan might be viewed as having an interest in such property. Specifically, section 401(b) provides that, where a plan invests in a security issued by an investment company which is registered under the Investment Company Act of 1940, or where a plan invests in a contract or policy of insurance which is issued by

and funded through the general account of an insurer,⁴ the assets of the plan will be deemed to include such security, contract or policy, but will not necessarily be deemed to include any assets of the investment company or insurer.

The existence of these explicit exceptions in section 401(b) of the Act suggests that, except where such an exception is applicable, the assets of a pooled investment vehicle which is not a registered investment company or an insurer issuing certain contracts or policies of insurance would, in many cases, constitute plan assets where a plan invests in the pooled investment vehicle. Such a conclusion is consistent not only with the logical implication of the provisions of section 401(b), but also with the intent of Congress as expressed in the legislative history of the Act. That is, in enacting the exception relating to securities issued by a registered investment company, Congress relied largely upon the fact that such securities are broadly held, and that the issuers of such securities are subject to regulation under the Investment Company Act of 1940.⁵ The exception for contracts or policies issued by insurers and funded by insurers' general accounts also appears to be based upon the fact that the plan benefits provided under such contracts or policies are insured by an entity which is subject to state regulation designed to assure the entity's ability to pay benefits specified in the policies when due.⁶ Obviously, such protections are not available with respect to some other types of pooled investment.

Furthermore, a functional analysis leads to the conclusion that with respect to a wide variety of pooled investment vehicles, when a plan invests some or all of its assets in a pooled investment vehicle, the plan is, as a practical matter, retaining the management of that investment vehicle to manage the portion of the plan's assets which is so invested. It would be unreasonable to suppose that Congress intended that the protections of the fiduciary responsibility provisions of the Act which are applicable where a plan

retains a manager of its investments directly would not be applicable where the manager is retained indirectly, through investment by the plan in a pooled investment vehicle. Therefore, it seems to the Department that Congress intended that, where a plan invests in a pooled investment vehicle, the assets of that vehicle are properly viewed as plan assets, and must be managed in accordance with the fiduciary responsibility provisions of the Act, unless circumstances exist which make application of those provisions inappropriate or unnecessary.

On the other hand, it seems clear that the Act does not contemplate that its fiduciary responsibility provisions will govern the management of every business in which a plan happens to have an interest. For example, as the Department has previously recognized,⁷ investment by a plan in equity securities of a corporation or partnership which is an operating company (*i.e.*, whose primary activity is the production, provision, or sale of a product or service, rather than mere investment) does not, solely by reason of such investment, cause the assets of the company to be plan assets.⁸ Normally, a plan or other investor which purchases an interest in such a company may be thought to base its decision upon the expectation that the company's operating activity will produce a profit, and the belief that investment by the company in plant, inventory, or other items is in furtherance of its operating activity. Moreover, making the fiduciary responsibility provisions of the Act applicable to the management of an operating company in which a plan holds an interest could unreasonably restrict the operations of the company. The Department has found no basis for believing that Congress intended such a result.

Moreover, the Department is of the view that, even where a plan holds an interest in a corporation, partnership, or

² Interpretive Bulletin 75-2, issued February 6, 1975, 29 CFR 2509.75-2.

³ Interpretive Bulletin 75-2 does not explicitly state that the principles enunciated therein are confined to operating companies. However, in proposing a class exemption relating to insurance company pooled separate accounts (42 FR 54886, October 11, 1977), the Department and the Internal Revenue Service indicated their view that, where a plan invests in such an entity, the assets of that entity would constitute plan assets. The class exemption was later granted (43 FR 59915, December 22, 1978). As discussed hereinafter, the assets held by other forms of pooled investment vehicles in which employee benefit plans invest may or may not be plan assets depending on several factors. To the extent that the regulation proposed herein might be viewed as inconsistent with Interpretive Bulletin 75-2, the regulation will, if adopted, supersede the Interpretive Bulletin.

⁴ 39 FR 44458, December 24, 1974.

⁵ If adopted, this proposed regulation would supersede ERISA IB 75-2 (29 CFR § 2509.75-2) to the extent that anything in IB 75-2 is inconsistent with this regulation, and would clarify the meaning of "plan assets" not only for purposes of the trust requirement of the Act, but for purposes of all provisions of Title I of the Act where that term is relevant. In addition, the question of what constitutes plan assets is relevant with respect to certain provisions of the Internal Revenue Code of 1954 (the Code) which are under the administration of the Department. See section 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713 (October 17, 1978). The Department contemplates that, if it adopts proposed § 2550.401b-1, it will apply the same meaning to the term "plan asset" in administering section 4975 of the Code.

⁶ The language in section 401(b)(2) of the Act which sets forth this exception refers to a "guaranteed benefit policy." The Department has previously interpreted this provision to mean generally that assets held in an insurer's general account to support benefits under a contract purchased by a plan are not plan assets, but that assets held for the same purpose in the insurer's separate account are plan assets. See 29 CFR 2509.75-2.

⁷ See H.R. Rep. No. 93-1280, 93d Cong., 2d Sess., 296 (1974) [Conference Report]. See also S. Rep. No. 93-383, 93d Cong., 1st Sess. 103 (1973).

⁸ See Conference Report at 296.

other entity which is a pooled investment vehicle rather than an operating company, there are cases, in addition to those described in section 401(b) of the Act, where the assets of the pooled investment vehicle should not be viewed as constituting plan assets. Specifically, the Department believes that, where shares of such a company are publicly traded, freely transferable and widely held, as in the case, for example, of some real estate investment trusts (REITs), application of the fiduciary responsibility provisions of the Act to the management of the REIT could unreasonably restrict the activities of the company. In such a case it might be virtually impossible for the company's management to know whether plans hold shares of the company at any particular time, and what persons are parties in interest with respect to such plans. To this extent, application of the fiduciary responsibility provisions of the Act to publicly held REITs and other companies with similar characteristics might have the practical effect of forcing such companies to cease operation. The Department does not believe that Congress intended such a result. Moreover, the fact that shares of such companies are publicly traded would seem to afford plans investing therein some of the same protection which led Congress to provide explicitly in section 401(b) of the Act that the assets of a registered investment company do not constitute plan assets merely because a plan owns shares of the company. That is, the management of the company is generally subject to oversight by a large number of investors in addition to the plan, and such oversight is facilitated by the disclosure and reporting requirements of the Securities Act of 1933 and the Securities Exchange Act of 1934.

The Department's view that plan assets do not necessarily include the assets of operating companies or of certain types of pooled investment vehicles in which plans invest is reflected in proposed § 2550.401b-1. This proposed regulation provides in effect that plan assets include any property, tangible or intangible, in which a plan has a beneficial ownership interest, and that plan assets include the assets of a company in which a plan invests unless the company is (1) an operating company; (2) a company whose assets are not plan assets because of the provisions in section 401(b) of the Act; or (3) a company whose assets would otherwise be deemed plan assets only by virtue of a plan's ownership of the company's equity securities, when such

securities are freely transferable,⁹ widely held,¹⁰ and are either registered under section 12 of the Securities Act of 1934 or registered under the Securities Act of 1933 when sold to the plan and are thereafter registered under section 12 of the Securities Exchange Act of 1934.

Certain of the public comments filed in response to the prior proposed regulation raised the question whether the general assets of an employer or an employee organization which is the plan sponsor should be deemed to constitute plan assets when, under the terms of the plan, benefits are provided from such general assets. In the usual case, a plan would have no beneficial ownership interest in the assets of a plan sponsor, even when benefits are or may be provided from such assets, and thus the assets would not constitute plan assets under the proposed regulation.¹¹ This would be true even if the employer or the employee organization set aside some of its general assets in a segregated account for the purpose of providing benefits under the plan. However, if the employer, the employee organization or the plan took steps which caused the plan to gain a beneficial ownership interest in such assets, those assets would then be deemed plan assets under the regulation.

Furthermore, the Department believes that there are certain circumstances under which assets should be regarded as plan assets regardless of whether the plan would be deemed to have a beneficial ownership interest in those assets. Specifically, the proposed regulation provides that, if an employer or employee organization represents to participants or beneficiaries that certain assets of the employer or employee organization (respectively) will be used only for the purpose of providing benefits under the plan, then those assets are to be deemed plan assets. For example, it appears that the

constitutions and by-laws of some employee organizations provide that certain of the organization's assets will be used only to pay benefits under a plan. Such specified assets would constitute plan assets under proposed § 2550.401b-1. Under proposed § 2550.403a-1 (discussed below), such assets would have to be held in trust. The proposed regulation also provides that if the obligation of the employer or employee organization to make contributions to a plan is limited under the plan to particular assets, then those assets will be deemed plan assets. For example, if an employer's obligation to make contributions to a plan were limited under the plan to assets which were set aside in a separate bank account, that account would constitute plan assets under proposed § 2550.401b-1, and would have to be held in trust pursuant to proposed § 2550.403a-1, discussed below.

Another question raised in public comments submitted in response to the previously proposed regulation is whether employee contributions to a plan constitute plan assets when such contributions are deducted by an employer from the employees' salaries, or are otherwise received by the employer. The Department would regard a plan as obtaining a beneficial ownership interest in such contributions when they are made,¹² and the contributions would constitute plan assets at that time.¹³ Where employee contributions are made with respect to a welfare plan, a limited exemption from the trust requirement would be provided in proposed § 2550.403b-1, discussed below.

In addition to circumstances where property should be regarded as plan assets without regard to whether a plan has a beneficial ownership interest in that property, it is the Department's view that in the following circumstances certain property should not be regarded as plan assets even if a plan has or may have a beneficial ownership interest in the property: Where a plan invests in an interest-bearing security which evidences a participation in certain

⁹ Generally, the Department would not view interests to be freely transferable if there were restrictions on the transfer of such interests imposed by the issuer (e.g., a right of first refusal).

¹⁰ The question of how many interest holders a company must have in order for interests in the company to be "widely held" might vary from case to case. Normally, however, the Department would not view interests in a company to be widely held for purposes of the proposed regulation if they were held by fewer than 100 persons.

¹¹ It should be noted that a transaction may be prohibited under the provisions of section 406 of the Act and section 4975 of the Code regardless of whether the transaction involves plan assets. For example, the prohibited transaction provisions may be applicable, under certain circumstances, where a plan sponsor directly pays a party in interest for services rendered by the party in interest to the plan.

¹² In the case of employee payroll deductions the contribution is made at the time payment by cash or check is made or required to be made to an employee of an amount less than that to which he would otherwise be entitled, the lesser amount being justified on the ground that a deduction is being made in respect of a plan.

¹³ It might be noted that the Department's temporary bonding regulation under section 412 of the Act, 29 CFR § 2550.412-1, accords somewhat different treatment to the question of whether employee contributions received by employers constitute plan assets for purposes of bonding. The proposed regulation would not affect the temporary bonding regulation.

underlying property and which was issued by an agency or instrumentality of the United States, and where repayment of the principal investment and payment of the interest thereon is guaranteed or otherwise assured by the United States or an agency or instrumentality thereof, even if the security conveys a beneficial ownership interest in the underlying property, the security but not the underlying property would be an asset of the plan. It appears that assurance of payment by the United States or an agency or instrumentality of the United States generally provides the basis upon which such securities are evaluated by investors. Furthermore, the consequences of considering the underlying property to be plan assets could result in impairment of the function mandated by Congress to be performed by the agency or instrumentality of the United States which issues such securities. Provision for this circumstance is set forth in proposed § 2550.401b-1(b).

Proposed Regulation Relating to Trust Requirement

Proposed § 2550.403a-1 provides that, with certain exceptions, all assets of an employee benefit plan must be held in trust by one or more trustees pursuant to a written trust instrument. The proposed regulation contains provisions regarding the powers of the trustee which are substantially identical to provisions contained in section 403(a) of the Act.¹⁴

The exceptions to the trust requirement are set forth in proposed § 2550.403b-1. Some of these exceptions are the same ones set forth in section 403(b) of the Act. That is, the proposed regulation provides that the trust requirement of the Act will not apply to (a) any assets of a plan which consist of insurance contracts or policies issued by an insurance company qualified to do business in a state, (b) any assets of such an insurance company or any assets of a plan which are held by such an insurance company, (c) a plan some or all of the participants of which are employees described in section 401(c)(1) of the Code or which consists of one or more individual retirement accounts described in section 408 of the Code where certain requirements are met, or

(d) a contract established and maintained under section 403(b) of the Code where certain requirements are met.

In addition, subsection (e) of the proposed regulation provides that employee contributions to a welfare plan which are temporarily held by an employer or employee organization need not be held in trust, provided that: (1) no such contributions, and no income or profits derived therefrom, are held by the employer or employee organization or any agent of the employer or employee organization for more than three months; (2) all such contributions, and any income or profits derived therefrom, are, while in the possession of the employer or employee organization, maintained in a segregated account which is clearly identified as containing assets of the plan; and (3) the employer or employee organization acknowledges in writing to the plan that it holds such assets in its capacity as a fiduciary of such plan and will be liable for any losses of such contributions or income or profits while such property is in the possession of the employer or employee organization.

The Department believes that the proposed exemption relating to welfare plans described above will avoid unnecessary expense on the part of employers, while at the same time containing conditions sufficient to protect the interests of plan participants and beneficiaries.

The regulations proposed herein do not meet the criteria for significant regulations set forth in Department of Labor guidelines (44 FR 5570, January 26, 1979) issued to implement Executive Order 12044 (43 FR 12661, March 23, 1978).

(The regulations are proposed, and the previous proposed regulation is withdrawn, pursuant to sections 401, 403, and 505 of the Act (29 U.S.C. 1101, 1103, and 1135).)

In consideration of the matters discussed above, the Department hereby withdraws proposed regulation 29 CFR 2552.1 published on December 24, 1974 at 39 FR 44456, and proposes to amend part 2550 of Chapter XXV of Title 29 of the Code of Federal Regulations in the manner set forth below.

1. Adopt regulation 29 CFR 2550.401b-1, to provide as follows:

§ 2550.401b-1 Definition of "plan assets."

(a) Except as otherwise provided in this section, the assets of an employee benefit plan shall, for purposes of Title I of the Act, include all property, tangible or intangible:

(1) In which the plan has any beneficial ownership interest;

(2) Which is the property of an employer or employee organization sponsoring the plan and which such employer or employee organization represents to plan participants or beneficiaries can or will be used only to provide plan benefits;

(3) Which constitutes an identified portion less than the whole of the assets of an employer or employee organization sponsoring the plan, and which under the terms of a plan constitutes the sole source of contributions to such plan by such employer or employee organization; or

(4) Which constitutes employee contributions to the plan.

(b) Notwithstanding the provisions of subsection (a), where an employee benefit plan invests in interest-bearing securities representing an interest in certain underlying property, which securities

(1) Are issued by an agency or instrumentality of the United States,

(2) Provide that the plan, by reason of its investment, has or may have a beneficial ownership interest in the underlying assets, and

(3) Are guaranteed or otherwise assured as to repayment of principal and payment of interest by the United States or an agency or instrumentality thereof,

then such securities shall constitute assets of the plan but the property underlying such securities shall not.

(c) Notwithstanding the provisions of subsection (a), in the case of a plan which invests in any security issued by an investment company registered under the Investment Company Act of 1940, the assets of such plan shall be deemed to include such security but shall not, solely by reason of such investment, be deemed to include any assets of such investment company.

(d) Notwithstanding the provisions of subsection (a), in the case of a plan which is funded in whole or in part by a contract or policy of insurance issued by an insurer, the assets of the plan shall include the contract or policy under which the benefits are insured but shall not, solely by reason of the issuance of such contract or policy, include the assets of the insurer issuing the contract or policy except to the extent that such assets are maintained by the insurer in one or more separate accounts and do not constitute surplus in any such account. For purposes of this paragraph, the term "insurer" means an insurance company, insurance service, or insurance organization, qualified to conduct business in a State.

(e) Notwithstanding the provisions of subsection (a), in the case of a plan

¹⁴ In this connection, the Department has received inquiries as to whether it is permissible for securities in which a plan has invested to be registered in the name of a broker-dealer or the broker-dealer's nominee, sometimes referred to as "street name" registration. The Department would generally view such a practice under the proposed regulation as violating the requirement of section 403(a) of the Act that plan assets must be held in trust, except under those circumstances where the broker-dealer holds the securities as trustees for the plan pursuant to an executed trust agreement.

which invests in any equity security which is not issued by an investment company registered under the Investment Company Act of 1940, the assets of such plan shall be deemed to include such security and the assets of the issuer of such security, unless:

- (1) The issuer of such security is engaged primarily in the provision, production, or sale of a product or service other than the investment of capital; or
- (2) Such security is:
 - (i) Freely transferable;
 - (ii) Widely held; and
 - (iii) Either (A) registered under section 12(b) or 12(g) of the Securities Exchange Act of 1934; or (B) sold to the plan as part of an offering of such securities to the public pursuant to an effective registration statement under the Securities Act of 1933, and the security is registered under section 12(b) or 12(g) of the Securities Exchange Act of 1934 within 120 days (or such later time as may be allowed by the Securities and Exchange Commission) after the end of the fiscal year of the issuer during which the offering of such securities to the public occurred.

2. Adopt regulations 29 CFR 2550.403a-1 and 29 CFR 2550.403b-1, to provide as follows:

§ 2550.403a-1 Establishment of trust.

Except as provided in § 2550.403b-1, all assets of an employee benefit plan shall be held in trust by one or more trustees pursuant to a written trust instrument. Such trustee or trustees shall be either named in the trust instrument or in the plan instrument described in section 402(a) of the Act, or appointed by a person who is a named fiduciary (within the meaning of section 402(a)(2) of the Act), and upon acceptance of being named or appointed, the trustee or trustees shall have exclusive authority and discretion to manage and control the assets of the plan, except to the extent that:

(a) The plan instrument or the trust instrument expressly provides that the trustee or trustees are subject to the direction of a named fiduciary who is not a trustee, in which case the trustees shall be subject to proper directions of such fiduciary which are made in accordance with the terms of the plan and which are not contrary to the provisions of Title I of the Act or Chapter XXV of this Title, or

(b) Authority to manage, acquire, or dispose of assets of the plan is delegated to one or more investment managers (within the meaning of section 3(38) of the Act) pursuant to section 402(c)(3) of the Act.

§ 2550.403b-1 Exemptions from Trust Requirement.

The assets of an employee benefit plan shall not be required to be held in trust to the extent that such assets consist of:

- (a) Insurance contracts or policies issued by an insurance company qualified to do business in a State;
- (b) Assets held by an insurance company qualified to do business in a State;
- (c) Assets of a plan—
 - (1) Some or all of the participants of which are employees described in section 401(c)(1) of the Internal Revenue Code of 1954 (the Code); or
 - (2) Which plan consists of one or more individual retirement accounts described in section 408 of the Code, to the extent that such assets are held in one or more custodial accounts which qualify under section 401(f) or 408(h) of the Code, whichever is applicable;
- (d) Contracts established and maintained under section 403(b) of the Code, to the extent that the assets of the contract are held in one or more custodial accounts pursuant to section 403(b)(7) of the Code; or
- (e) Employee contributions to an employee welfare benefit plan which are, pursuant to an arrangement between an employer or an employee organization and the participants in the plan, either periodically paid by such participants to such employer or employee organization or deducted by such employer from the salaries of participating employees, provided that the following conditions are met:

(1) No such contributions, and no income or profits derived therefrom, are held by the employer or employee organization or any agent of the employer or employee organization for more than three months;

(2) All such contributions, and any income or profits derived therefrom, are, while in the possession of the employer or employee organization, maintained in a segregated account which is clearly identified as containing assets of the plan; and

(3) The employer or employee organization acknowledges in writing to the plan that it holds such assets in its capacity as a fiduciary of such plan and will be liable for any losses of such contributions or income or profits while such property is in the possession of the employer or employee organization.

Signed at Washington, D.C., this 22d day of August 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

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[29 CFR Part 2550]

Rules and Regulations for Fiduciary Responsibility; Proposed Regulation Relating to the Statutory Exemption for Certain Acquisitions, Sales, or Leases of Property

AGENCY: Department of Labor.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This document contains a proposed regulation under the Employee Retirement Income Security Act of 1974 (Act) relating to certain acquisitions, sales, or leases of property by an employee benefit plan. The proposed regulation is intended to clarify the scope of provisions of the Act which exempt such transactions if certain conditions are met. If adopted, the regulation might affect participants and beneficiaries of employee benefit plans, plan fiduciaries, employers and other persons who engage in these transactions.

DATES: Written comments concerning the proposed regulation must be received by the Department of Labor (the Department) on or before October 29, 1979. The regulation, if adopted, would be effective as of January 1, 1975.

ADDRESS: Interested persons are invited to submit written comments concerning the proposed regulation to: Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, Washington, D.C. 20216, Attention: Proposed regulation § 2550.408e. All submissions will be open to public inspection at the Public Documents Room, Pension and Welfare Benefit Programs, Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Jay S. Neuman, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, D.C. 20216, telephone (202) 523-9141. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Department proposes to adopt a regulation under section 408(e) of the Act. A discussion of the provisions of the proposed regulation are set forth below.

A. Background

Section 406(a) of the Act generally prohibits a fiduciary¹ with respect to an employee benefit plan from causing the plan to engage in certain types of transactions with a party in interest.² These prohibited transactions include, among others, loans, leases and sales or exchanges of property between a plan and a party in interest. Moreover, section 406(b) of the Act prohibits a fiduciary from, among other things, dealing with plan assets in his own interest or engaging in a transaction involving a conflict of interest.

In addition, section 406(a) of the Act, together with section 407(a), describe the circumstances under which a plan may acquire or hold real property which is leased to an employer of employees covered by the plan, and securities which are issued by such employer, without violating the prohibited transaction provisions.

However, section 408(e) of the Act provides an exemption for any acquisition or sale by a plan of "qualifying employer securities",³ and

¹ Section 3(21)(A) of the Act provides in relevant part that a person is a fiduciary with respect to a plan to the extent he (i) exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, (ii) renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to do so, or (iii) has any discretionary authority or discretionary responsibility in the administration of such plan.

² The term "party in interest" is defined in section 3(14) of the Act to include fiduciaries, employers of individuals covered by the plan, and persons or organizations having other relationships with the plan which are described in that section.

³ Section 407(d)(5) of the Act defines the term "qualifying employer security" to mean an "employer security" which is stock or a "marketable obligation".

Section 407(d)(1) of the Act defines the term "employer security" to mean, with certain exceptions, a security issued by an employer of employees covered by the plan, or by an affiliate of such employer. Under section 3(20) of the Act, a "security" has the same meaning as such term has under section 2(1) of the Securities Act of 1933 (15 USC 77b(1)).

Section 407(e) of the Act defines the term "marketable obligation" to mean a bond, debenture, note, or certificate, or other evidence of indebtedness (hereinafter referred to as "obligation") if—

(1) Such obligation is acquired—

(A) On the market, either (i) at the price of the obligation prevailing on a national securities exchange which is registered with the Securities and Exchange Commission, or (ii) if the obligation is not traded on such a national securities exchange, at a price not less favorable to the plan than the offering price for the obligation as established by current bid and asked prices quoted by persons independent of the issuer;

(B) From an underwriter, at a price (i) not in excess of the public offering price for the obligation as set forth in a prospectus or offering circular filed with the Securities and Exchange Commission, and

any acquisition, sale or lease by a plan of "qualifying employer real property",⁴ from or to a party in interest if certain conditions are met. These conditions are (1) the acquisition, sale or lease must be for adequate consideration, (2) no commission may be charged with respect thereto, and (3) in the case of an acquisition of qualifying employer securities and an acquisition or lease of qualifying employer real property by a plan other than an "eligible individual account plan,"⁵ such acquisition or lease must comply with the

(ii) at which a substantial portion of the same issue is acquired by persons independent of the issuer; or

(C) Directly from the issuer, at a price not less favorable to the plan than the price paid currently for a substantial portion of the same issue by persons independent of the issuer;

(2) Immediately following acquisition of such obligation—

(A) Not more than 25 percent of the aggregate amount of obligations issued in such issue and outstanding at the time of acquisition is held by the plan, and

(B) At least 50 percent of the aggregate amount referred to in subparagraph (A) is held by persons independent of the issuer; and

(3) Immediately following acquisition of the obligation, not more than 25 percent of the assets of the plan is invested in obligations of the employer or an affiliate of the employer.

⁴ Section 407(d)(2) of the Act defines the term "employer real property" to mean real property (and related personal property) which is leased to an employer of employees covered by the plan, or to an affiliate of such employer.

The term "qualifying employer real property" is defined in section 407(d)(4) of the Act to mean parcels of employer real property—

(A) If a substantial number of the parcels are dispersed geographically;

(B) If each parcel of real property and the improvements thereon are suitable (or adaptable without excessive cost) for more than one use;

(C) Even if all of such real property is leased to one lessee (which may be an employer, or an affiliate of an employer); and

(D) If the acquisition and retention of such property comply with the provisions of Part 4 of Title I of the Act (other than section 404(a)(1)(B) to the extent it requires diversification, and sections 404(a)(1)(C), 406, and section 407(a)).

⁵ Under section 407(d)(3) of the Act, the term "eligible individual account plan" means an individual account plan which is (i) a profit-sharing, stock bonus, thrift, or savings plan; (ii) an employee stock ownership plan; or (iii) a money purchase plan which was in existence on the date of enactment of the Act and which on such date invested primarily in qualifying employer securities. Such term excludes an individual retirement account or annuity described in section 408 of the Internal Revenue Code of 1954 (Code). A plan is treated as an eligible individual account plan with respect to the acquisition or holding of qualifying employer real property or qualifying employer securities only if such plan explicitly provides for the acquisition and holding of qualifying employer securities or qualifying employer real property (as the case may be). The Department has requested public comments with respect to questions which have arisen in connection with the development of a regulation to clarify the applicability of the term "eligible individual account plan" to certain arrangements. See 44 FR 34517, June 15, 1979.

requirements of section 407(a) of the Act and the regulations thereunder.⁶

B. Scope

1. Section 406(b)

Section 408(e) provides an exemption from the prohibitions of section 406(a) for certain acquisition, sale and lease transactions if the conditions in that section are satisfied.

In its consideration of the proposed regulation, it appeared to the Department that section 408(e) also provides an exemption from the restrictions of section 406(b)(1) of the Act (relating to fiduciaries dealing with the assets of plans in their own interest or for their own account) and section 406(b)(2) of the Act (relating to fiduciaries in their individual or any other capacity acting in any transaction involving the plan on behalf of party (or representing a party) whose interests are adverse to the interest of the plan or the interests of its participants or beneficiaries). This is because, in the Department's view, section 408(e), by its terms, is intended to provide relief for transactions between a plan and, among others, an employer of employees who are covered by the plan,⁷ and the employer often is a fiduciary with respect to the plan. However, the Department interprets section 408(e) as not providing an exemption from section 406(b)(3) of the Act (relating to fiduciaries receiving consideration for their own personal account from any party dealing with a plan in connection with a transaction involving assets of the plan). The Department considers the receipt of such consideration a separate transaction not described in the statutory exemption.⁸ This position is consistent with one of the requirements of section 408(e)—that no commission be charged with respect to transactions covered by the exemption. Accordingly, the proposed regulation has been drafted to reflect these views.

2. *Sales by plans other than eligible individual account plans.* The proposed regulation states that under section 408(e) and the regulation, an exemption is provided for the sale of qualifying employer securities and qualifying employer real property by all plans, including those which are not eligible individual account plans.

Section 408(e), in the Department's view, provides an exemption for the

⁶ See 29 CFR §§ 2550.407a-1 through 2550.407a-4.

⁷ See H.R. Rep. No. 93-1280, 93d Cong., 2d Sess. 318 (1974).

⁸ The Department has adopted a similar approach in regulations under other sections of the Act which provide statutory exemptions. See 29 CFR §§ 2550.408b-3(b)(1), 2550.408b-4(a), and 2550.408b-6(a).

acquisition or sale by a plan of qualifying employer securities, or the acquisition, sale or lease of qualifying employer real property, if certain conditions are satisfied. One of the conditions is that the plan be an eligible individual account plan. Another condition, found in section 408(e)(3)(B), is that, in the case of a plan which is not an eligible individual account plan, the acquisition or lease of qualifying employer real property or the acquisition of qualifying employer securities not be prohibited by section 407(a). While section 408(e)(3)(B) could be interpreted to limit the applicability of the exemption so that it would not apply to sale transactions unless they were made by eligible individual account plans, in the Department's view the section should not be construed to limit the scope of the exemption in that manner. Rather, section 408(e)(3)(B) makes clear that, for plans which are not eligible individual account plans, no relief is provided from the percentage restrictions of section 407(a). Thus, an acquisition by such a plan which otherwise meets the requirements of section 408(e) (adequate consideration; no commission charged) must also satisfy section 407(a). Sales by such plans of qualifying employer securities and qualifying employer real property, since they would not be prohibited by section 407(a) of the Act, are not affected by the terms of section 408(e)(3).

This interpretation is consistent with the purpose of section 407(a)(2), which is to limit the acquisition of qualifying employer securities and qualifying employer real property. The restrictions in section 407(a) were designed in part to minimize an employee's dependence on the employer's financial condition for the payment of a promised benefit.⁹ It also appears to be consistent with one of the principal purposes of section 408(e), which is to facilitate the disposition of qualifying employer securities and qualifying employer real property. Since Congress intended to limited investments in qualifying employer securities and qualifying employer real property by plans other than eligible individual account plans, it is consistent with that intent to interpret section 408(e) to permit sales of such securities and property by such plans to parties in interest. Otherwise, these plans would be restricted in their ability to dispose of the very type of investment that Congress intended to discourage. It would be illogical to assume that Congress would allow eligible

individual account plans, which under certain circumstances may invest up to 100% of their assets in qualifying employer securities and qualifying employer real property, to sell freely to parties in interest, but would limit the ability of plans other than eligible individual account plans to sell such investments to parties in interest to the situations described in the transitional rule in section 414(c)(5) of the Act.¹⁰

3. Transactions not covered by section 408(e)

Section 408(e) does not exempt any separate transaction, such as an extension of credit, which is related to an exempt acquisition, sale or lease. Thus, although section 408(e) may permit a plan to sell qualifying employer securities to a party in interest if the plan receives adequate consideration and no commission is charged with respect to the sale, that section does not provide an exemption to allow the plan to accept a note or other promise to pay from the party in interest in exchange for the qualifying employer securities.¹¹ The extension of credit by the plan to the party in interest would constitute a separate transaction prohibited under section 406(a) and not exempt under section 408(e).¹²

⁹ Section 414(c)(5) provides that section 406 of the Act shall not apply with respect to a sale, exchange or other disposition by a plan to a party in interest of certain employer securities and employer real property, if the plan is required to dispose of such securities or property in order to comply with the provisions of section 407(a) of the Act and if the plan receives not less than adequate consideration.

¹¹ The stated general proposition is subject to an exception in the case where the obligation of the party in interest is itself a qualifying employer security (i.e., a marketable obligation), and its acquisition would not contravene the restrictions of section 407(a) of the Act.

¹² In this regard, however, section 408(a) of the Act empowers the Secretary of Labor to grant administrative exemptions from the prohibited transaction provisions of sections 406 and 407(a) of the Act if the Secretary finds that the exemption is administratively feasible, in the interest of the plan and its participants and beneficiaries and protective of the rights of plan participants and beneficiaries. Section 4975(c)(2) of the Internal Revenue Code of 1954 (Code) contains substantially similar provisions regarding administrative exemptions from the prohibited transaction provisions of section 4975(c)(1) of the Code. If a transaction does not meet the conditions, or is not within the scope, of section 408(e), but the plan fiduciary believes that an exemption would satisfy the criteria of section 408(a) of the Act and section 4975(c)(2) of the Code, an application for an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code may be filed with the Department, which has authority to grant exemptions under both the Act and the Code. It should be noted that effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue such exemptions to the Secretary of Labor. Applications for administrative exemption should be filed in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975).

Because section 408(e) refers only to transactions involving qualifying employer securities and qualifying employer real property, it does not provide any exemption (whether or not the plan involved is an eligible individual account plan) from the prohibitions of sections 406(a)(1)(E), 406(a)(2), and 407(a)(1) of the Act, insofar as they relate to the acquisition, disposition or holding of employer securities which are not qualifying employer securities, or employer real property which is not qualifying employer real property.

It should be noted that applicability of section 408(e) to a transaction does not relieve a fiduciary with respect to the plan from the general fiduciary responsibility provisions of section 404 of the Act which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interests of plan participants and beneficiaries and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act;¹³ nor does it affect the requirement of section 401(a) of the Code that a plan must be operated for the exclusive benefit of employees and their beneficiaries. The provisions of section 408(e) are further limited by section 408(d) of the Act (relating to transactions with owner-employees and related persons).

C. Other Matters

1. *Acquisition.* The proposed regulation contains a definition of the term "acquisition" for purposes of section 408(e). This definition is similar to the definition of "acquisition" for purposes of section 407(a) set forth in 29 CFR § 2550.407a-2(b).¹⁴

2. *Adequate consideration.* Under the proposed regulation, an acquisition, sale or lease must be for "adequate consideration." That term is defined, in the case of a marketable obligation, as a price not less favorable to the plan than the price determined under section 407(e)(1) of the Act. For all other property, it is a price not less favorable to the plan than the price determined under section 3(18) of the Act, which specifically defines the term "adequate

¹³ Thus, while a plan may be able to acquire qualifying employer securities under the provisions of section 408(e) and this regulation, if the acquisition were not prudent (because, for example, of the poor financial condition of the employer), the appropriate plan fiduciaries would remain liable for any loss resulting from a breach of fiduciary responsibility. See H.R. Rep. No. 93-1280, 93d Cong., 2d Sess. 320 (1974).

¹⁴ It should be noted that an acquisition of securities pursuant to a conversion of securities may also be exempt from the prohibited transaction provisions of the Act by virtue of section 408(b)(7). To date, no regulations implementing that section have been issued.

⁹ See, for example, S. Rep. No. 93-383, 93d Cong., 1st Sess. 100 (1973).

consideration." A determination as to whether a particular transaction is for adequate consideration should be made by the appropriate plan fiduciaries on the basis of relevant facts and circumstances; the Department generally will not issue advisory opinions with respect to what constitutes adequate consideration.¹⁵

3. *Commissions.* Under the proposed regulation, generally, no commission, fee, or similar charge may be paid in connection with the transaction. However, in accordance with Congressional intent,¹⁶ the proposal provides that when a purchase is made from an underwriter who assumes the risk of market fluctuations after the award date, the underwriter's margin would be specifically excluded from the definition of "commission" for purposes of section 408(e).

In this regard, the Department is considering, and invites comment on, whether there are additional types of charges which should be excluded from the definition of "commission" for purposes of section 408(e). Under one such approach, for example, the term "commission" would be defined to exclude: fees paid by a party other than the plan to a "managing dealer" in connection with a public tender or exchange offer; or the underwriter's margin in a public offering of securities registered under the Securities Act of 1933 (whether or not the offering is made pursuant to a firm commitment by the underwriter); or both. It appears to the Department that these exclusions may be appropriate because the transactions do not present the type of abuse with which the prohibition on the payment of commissions was intended to deal. The fees described above do not result from private, negotiated transactions between, for example, a plan and the sponsoring employer, where there would be no apparent justification for the payment of a commission; the transactions are public in nature, with unrelated persons participating on the same terms as the plan. Moreover, the amount paid or received by a plan generally would be unaffected by the payment of any fee described in the exclusions. Finally, the managing dealer or underwriter who would receive the fee from the offeror or issuer has a significant role in the transaction regardless of the plan's decision to acquire or dispose of

securities.¹⁷ It appears to the Department that these exclusions may be consistent with the Congressional intent underlying section 408(e) to facilitate the disposition, and, in some cases, the acquisition, by plans of qualifying employer securities; and may be consistent with the express Congressional intent regarding certain underwritings.

4. *Relationship to class exemptions.* The Department is aware that certain types of transactions which may be exempt under section 408(e) and this proposed regulation may also be exempt under Prohibited Transaction Exemption 75-1. The conditions of the class exemption, however, vary in some respects from those of the statutory exemption as interpreted by this proposed regulation. Thus, if the regulation were adopted, a transaction might be exempt by virtue of the class exemption or section 408(e), or both. In such cases, a plan fiduciary could rely upon either the statutory or administrative exemption, provided the relevant conditions are satisfied.¹⁸

5. *Relationship to transitional rules.* Certain transactions which may be exempt under section 408(e) and this proposed regulation may also be exempt under section 414(c)(3) of the Act.¹⁹ Section 414(c)(3) provides that, before July 1, 1984, section 406 of the Act shall not apply with respect to a sale, exchange or other disposition of certain property between a plan and a party in interest if certain conditions are met.

¹⁵ In this latter regard, the Department notes that a soliciting dealer in a tender or exchange offer generally receives a fee per share of securities tendered through his firm and accepted by the offeror. Unlike the situation of the managing dealer, it does not appear that there would be any justification for permitting this type of charge in cases where an employee benefit plan tenders shares of qualifying employer securities.

¹⁶ For example, Prohibited Transaction Exemption 75-1, Part II would exempt from section 408(a) the purchase by a plan of qualifying employer securities from a registered broker-dealer who is not a plan fiduciary if: the broker-dealer customarily purchases and sells securities for its own account in the ordinary course of its business; the transaction is at least as favorable to the plan as an arm's-length transaction with an unrelated party would be; the broker-dealer is a party in interest with respect to the plan solely by reason of section 3(14)(B) of the Act; and certain records are kept. This exemption would, therefore, permit the broker-dealer to receive a commission in connection with certain principal transactions with a plan. Section 408(e) would exempt from sections 406(a) and 406(b)(1) and (2) the purchase by a plan of qualifying employer securities from a party in interest, including a plan fiduciary, if: the purchase is for adequate consideration; no commission is charged with respect to the transaction; and the acquisition complies with the requirements of section 407(a).

¹⁷ On April 27, 1979, the Department published in the *Federal Register* (44 FR 24876) proposed regulation 29 CFR § 2550.414c-3, which would interpret this section.

The conditions of section 414(c)(3), however, vary in some respects from those of section 408(e) as interpreted by this proposed regulation. A transaction would be exempt from relevant prohibited transaction provisions of the Act if the conditions of either section 414(c)(3) or section 408(e) were met. Similarly, certain transactions which may be exempt under section 408(e) and this proposed regulation may also be exempt under section 414(c)(5) of the Act.

This proposed regulation is not "significant" under the criteria prescribed by Executive Order 12044 and the Department's Guidelines implementing the Order (44 FR 5570, January 26, 1979).

(The proposed regulation set forth herein is issued pursuant to sections 408(e) and 505 of the Act)

Proposed Regulation: In consideration of the matters discussed above, it is proposed to amend Part 2550 of Chapter XXV of Title 29 of the Code of Federal Regulations by adding in the appropriate place the following § 2550.408e.

§ 2550.408e Statutory exemption for acquisition or sale of qualifying employer securities and for acquisition, sale or lease of qualifying employer real property.

(a) *General.* Section 408(e) of the Employee Retirement Income Security Act of 1974 (the Act) exempts from the prohibitions of sections 406(a) and 406(b)(1) and (2) of the Act any acquisition or sale by a plan of qualifying employer securities (as defined in section 407(d)(5) of the Act), or any acquisition, sale or lease by a plan of qualifying employer real property (as defined in section 407(d)(4) of the Act), from or to a party in interest, if certain conditions are met. These conditions are that

(1) The acquisition, sale or lease must be for adequate consideration (as defined in paragraph (d) of this section);

(2) No commission may be charged with respect to the transaction; and

(3) In the case of an acquisition or lease of qualifying employer real property, or an acquisition of qualifying employer securities, by a plan other than an eligible individual account plan (as defined in section 407(d)(3) of the Act), the acquisition or lease must comply with the requirements of section 407(a) of the Act.

(b) *Acquisition.* For purposes of section 408(e) and this section, an acquisition by a plan of qualifying employer securities or qualifying employer real property shall include but not be limited to, an acquisition by purchase, by the exchange of plan assets, by the exercise of warrants or

¹⁵ See section 5 of ERISA, Proc. 76-1, the Department's Advisory Opinion Procedure (41 FR 36281, August 7, 1976).

¹⁶ See H.R. Rep. No. 93-1280, 93d Cong., 2d Sess. 318 (1974).

rights, by the conversion of a security, by default of a loan where the qualifying employer security or qualifying employer real property was security for the loan, or in connection with the contribution of such securities or real property to the plan. However, an acquisition of a security shall not be deemed to have occurred if a plan acquires the security as a result of a stock dividend or stock split.

(c) *Sale.* For purposes of section 408(e) and this section, a sale of qualifying employer real property or qualifying employer securities shall include any disposition for value.

(d) *Adequate Consideration.* For purposes of section 408(e) and this section, adequate consideration means:

(1) In the case of a marketable obligation, a price not less favorable to the plan than the price determined under section 407(e)(1) of the Act; and

(2) In all other cases, a price not less favorable to the plan than the price determined under section 3(18) of the Act.

(e) *Commission.* For purposes of section 408(e) and this section, the term "commission" includes any fee, commission or similar charge paid in connection with a transaction, other than the underwriter's margin when a purchase is made from an underwriter who assumes the risks of market fluctuations after the award date.

Signed at Washington, D.C., this 22nd day of August, 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 79-26536 Filed 8-22-79; 12:56 pm]

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ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 1305-8]

State Implementation Plans; General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment Areas—Supplement (on Revised Schedules for Submission of Volatile Organic Compound Ract Regulations)

AGENCY: Environmental Protection Agency.

ACTION: General Preamble for proposed rulemaking—Supplement.

SUMMARY: Provisions of the Clean Air Act enacted in 1977 requires States to revise their State Implementation Plans for all areas that have not attained

National Ambient Air Quality Standards. States are to have submitted the necessary plan revisions to EPA by January 1, 1979. The Agency is now publishing proposals inviting public comment on whether each of the submittals should be approved. In the April 4, 1979 issue of the *Federal Register*, EPA published a General Preamble identifying and summarizing the major considerations that will guide EPA's evaluation of the submittals (44 FR 20372). Today's Supplement provides information on the revised schedule for adoption of regulations for source categories emitting volatile organic compounds (VOC) covered by the second set of Control Technique Guidelines (CTGs).

FOR FURTHER INFORMATION CONTACT:

The appropriate EPA Regional Office listed on the first page of the General Preamble (44 FR 20372) or the following Headquarters office: G. T. Helms, Chief, Control Programs Operations Branch, Control Programs Development Division, EPA Office of Air Quality Planning and Standards (MD-15), Research Triangle Park, North Carolina 27711, (919) 541-5365 or 541-5228.

SUPPLEMENTARY INFORMATION: The background is set out at length in the April 4 General Preamble. This Supplement address an issue that needs explanation.

The Administrator's memorandum of February 24, 1978, published in the *Federal Register* at 43 FR 21673 (May 19, 1978), stated that the 1979 plan submission for ozone nonattainment areas, "... must include, as a minimum, legally enforceable regulations to reflect the application of reasonably available control technology (RACT) to those sources for which EPA has published a Control Technique Guideline (CTG) by January 1978, and provide for the adoption and submittal of additional legally enforceable RACT regulations on an annual basis beginning in January 1980 for those CTGs that have been published by January of the preceding year."

It is now apparent that the regulatory adoption process may be more lengthy than first anticipated. Additional time may be necessary to accommodate public, administrative, and legislative review. In order to realistically address this problem, yet to continue meeting our responsibilities to attain the ambient standards as expeditiously as practicable, EPA is revising by six months the deadlines for submittal of the RACT regulations for the second set of CTGs. The SIPs should now provide for the adoption and submittal of additional legally enforceable

regulations by July 1, 1980 for the following source categories:

Factory Surface Coating of Flatwood Paneling
Petroleum Refinery Fugitive Emission (Leaks)
Pharmaceutical Manufacture
Rubber Tire Manufacture
Surface Coating of Miscellaneous Metal Parts and Products
Graphic Arts (Printing)
Dry Cleaning, Perchloroethylene
Gasoline Tank Trucks, Leak Prevention
Petroleum Liquid Storage, Floating Roof Tanks

If this revision to the adoption schedule of RACT regulations requires alteration of any comments on a plan for which the comment period has already ended, the commenter should contact the appropriate EPA Regional Office immediately so that the issue can be appropriately dealt with.

Note.—Under Executive Order 12044 EPA is required to judge whether a regulation is "significant" and, therefore, subject to the procedural requirements of the order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044. [Secs. 110(a), 172, Clean Air Act, as amended (42 U.S.C. 7410(a), 7502)].

Dated: August 21, 1979.

Edward F. Tuerk,

Acting Assistant Administrator for Air, Noise, and Radiation.

[FR Doc. 79-26750 Filed 8-27-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 63 and 64]

[CC Docket No. 78-95; CC Docket No. 78-96; FCC 79-481]

Graphnet Systems, Inc.; Regulatory Policies Concerning the Provision of Domestic Public Message Services by Entities Other Than the Western Union Telegraph Co.

AGENCY: Federal Communications Commission.

ACTION: Order on Reconsideration released in CC Dockets 78-95/96, *Domestic Public Message Services.*

SUMMARY: The Commission clarified its decision in *Domestic Public Message Services*, 71 FCC 2d 471 (1979), by saying that the earlier decision did not apply to service in Alaska. Acting on a reconsideration request, the Commission also found that certain provisions in the contracts between Graphnet Systems, Inc. and three international record

carriers were unfair and contrary to the public interest.

DATES: Non-Applicable.

ADDRESS: Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Leonard Sawicki, (202) 632-6363, or Thomas Casey, (202) 632-3855, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION:

Order on Reconsideration

Adopted: August 1, 1979.

Released: August 23, 1979.

By the Commission: Commissioner Lee absent; Commissioner Jones not participating.

In the matter of Domestic Public Message Services, Graphnet Systems, Inc., Application to participate in the Hinterland Delivery of International Communications Messages, CC Docket No. 78-95, File No. W-P-C 1430; Regulatory Policies Concerning the Provision of Domestic Public Message Services by Entities Other than the Western Union Telegraph Company and Proposed Amendment to Parts 63 and 64 of the Commission's Rules, CC Docket No. 78-96. See also 44 FR 30168, May 24, 1979.

1. The Commission has before it a Petition for Clarification filed by RCA Alaska Communications, Inc. (RCA Alascom) and a Petition for Reconsideration filed by TRT Telecommunications Corporation (TRT) of our Order in *Domestic Public Message Services*, 71 FCC 2d 471 (1979), CC Dockets 78-95 and 78-96. Graphnet, Inc. and RCA Global Communications, Inc. (RCA Globcom) filed oppositions to the TRT Petition for Reconsideration and Western Union Telegraph Company (WU) filed a "Partial Opposition." TRT offered a Reply Memorandum to the opposition petitions and also filed a Motion to Expedite.

I. Comments of the Parties Concerning Reconsideration

2. TRT's major points are that the agreements between Graphnet and ITT and RCA¹ together constitute an "anticompetitive reciprocal dealing arrangement" and that the Commission should have imposed the international formula on Graphnet as a condition of its Section 214 application. TRT specifically requests that Graphnet's application be so conditioned. TRT alleges that the nature of the Graphnet

agreements (tying the distribution of outbound messages to inbound messages Graphnet receives from the international record carriers) creates incentives for the parties to the agreements "to deal with one another, regardless of either the price or quality of the service which they provide" (TRT Comments, p. 9). Because ITT and RCA control so much inbound message traffic, they can force Graphnet to send the vast majority of its traffic via ITT and RCA even if Graphnet desired to send it via one of the other international record carriers (IRCs). TRT continues by noting that if Graphnet ever controls a large portion of outbound traffic, it could coerce the IRC to deal with it. TRT adds that "it is inauspicious to say the least to sanction Graphnet's entry into PMTS pursuant to a scheme which systematically bars carriers from fairly competing for interconnection arrangements" (TRT Comments, p. 10). TRT argues that the Commission "must scrutinize closely anticompetitive or potentially anticompetitive practices of the entities it regulates" (TRT Comments, p. 11). Since the anticompetitive effects of the Graphnet agreements were identified by TRT, the Commission should have conditioned Graphnet's application to prevent such effects.

3. TRT avers that the Commission departed without explanation from its policy stated in the *International Formula* proceeding, 67 FCC 2d 877 (1978), with respect to WU's outbound international message traffic. The Commission erred by this departure, TRT argues, especially since the Second Circuit's decision in *RCA Global Communications Inc. v. FCC*, 574 F.2d 727 (2d Cir. 1978) found the Commission's reasons for a new formula "sound and logical." TRT contends that these reasons are "equally 'sound and logical' for applying the International Formula to the distribution of unrouted traffic originating on the Graphnet system, particularly when contrasted with the anticompetitive and unfair mechanism that Graphnet has worked out with ITT and RCA" (TRT Comments, p. 14). Because the foreign correspondents control interconnection rights as well as which IRCs handle messages originating in the foreign country, TRT argues that the Graphnet agreements with ITT and RCA result in the foreign correspondents determining who gets the U.S.-originated outbound traffic. This is because ITT and RCA have the bulk of inbound traffic and have tied the proportion of inbound traffic to Graphnet's distribution of outbound traffic. Therefore, by controlling the distribution of inbound

traffic, the foreign correspondents indirectly control the distribution of U.S. outbound message traffic.

4. Graphnet argues that TRT's petition is without merit and should be denied. It also argues that TRT's proposal is a "thinly-veiled effort to impose marketplace restraints designed for TRT's benefit," and that by proposing to subject Graphnet to the international formula, "TRT would be guaranteed a portion of all competing domestic carriers' international traffic" (Graphnet Opposition, p. 3, emphasis in original). Graphnet notes that the formula requirements may have been appropriate in a domestic monopoly environment, but they have no place in a competitive market.

5. For a number of reasons, Graphnet argues that the Commission has no proper basis for conditioning its application as TRT requests. Graphnet points out that the application in question only covered its proposal for hinterland delivery of inbound international messages, not outbound. Further, TRT's initial objections to the Graphnet agreements (the ITT Worldcom agreement has been effective since January 1, 1977) were untimely when raised in November 1977 and their reiteration at this time does not cure the initial untimeliness. Graphnet continues by contesting the TRT petition on its merits by arguing that Section 222(e)(1) applies only to a consolidated or merged carrier (WU) which Graphnet is not. Also, contrary to TRT's contentions, "there has been no Commission 'policy' with which Graphnet's interconnection arrangements is inconsistent" (Graphnet Opposition, p. 6). No formula has been imposed on domestic carriers other than WU and, Graphnet adds, "with the elimination of Western Union's monopoly, there is no need for such constraints with respect to international message traffic."

6. Graphnet avers that TRT has not given any indication that the traffic distribution approach in the Graphnet agreements is not in the public interest and in fact "the Commission has previously found * * * that an arbitrarily imposed formula designed to assure any carrier a guaranteed quota of traffic is unjust and unreasonable" (Graphnet Opposition, p. 8). Further, before the merger of WU and Postal Telegraph (analogous to today's competitive situation), each of the domestic carriers had exclusive contracts with only certain of the IRCs. TRT has failed to show why the Commission should interfere with its existing contract provisions and how TRT would be damaged by such

¹ Graphnet has also entered into a similar arrangement with Western Union International (WUI).

contracts. Graphnet views TRT's request as a plea for "Commission-sponsored strengthening of TRT's bargaining position abroad" with foreign carriers by assuring TRT the largest possible portion of outbound Graphnet traffic.

7. Calling TRT's assertions of anticompetitive reciprocal dealing "untimely and frivolous," Graphnet reproaches TRT for advancing the theory "for the first time on reconsideration." Graphnet characterizes its IRC interconnect as a "unitary, joint offering which the Commission has permitted for decades" (Graphnet Opposition, p. 11). The antitrust concept of reciprocity has no applicability in this context, says Graphnet. Graphnet notes TRT's failure to quantify any adverse effects, the freedom of IRCs to use Graphnet's services or not, Graphnet's willingness to negotiate agreements with all IRCs, and TRT's alleged voluntary choice not to explore an agreement with Graphnet, instead preferring guarantees of traffic under the formula.

8. RCA Globcom discusses the origin of the international formula and concludes that it should not be applied to Graphnet. At the time of the WU-Postal Telegraph merger, Congress saw that WU could use its domestic position to favor its own international operations and therefore required divestiture through Section 222(c)(2). Globcom continues by noting that "[I]n order to further protect the international carriers against arbitrary allocation of unrouted messages and to insure that the merged carrier divided such traffic fairly, Congress enacted Section 222(e)(1) * * * (RCA Globcom Opposition, p. 3). The international formula which is a "highly specialized provision" of Section 222 was intended to deal with a "unique industry problem" unrelated to the present situation. The present situation is distinguishable, RCA continues, because (1) Graphnet is not a consolidated or merged carrier within the meaning of Section 222; (2) Graphnet is not in a position to favor one carrier over another, and (3) the Commission had determined in *Graphnet Systems, Inc.*, 63 FCC 2d 402, 409 (1977) that the IRCs are free to interconnect with any nonaffiliated domestic carriers.

9. RCA Globcom calls TRT's arguments unsupported, because contrary to TRT's contentions, the Graphnet agreements specifically state that neither party is precluded from entering into agreements with other parties, the agreements are greatly concerned with service quality, and

foreign correspondents will not dictate domestic message distribution because the correspondents do not care who handles the messages in the U.S. as long as the service is timely and efficient. Globcom adds that TRT is seeking to obtain an advantage through the regulatory process which it is unable to gain in the marketplace.

10. Western Union filed a "Partial Opposition," agreeing with TRT that the Commission should have considered "formula" issues in the order, but disagreeing with TRT's request for relief. Western Union seeks amendment of the international formula so that it will have "the same flexibility as Graphnet with respect to the distribution of unrouted traffic" (WU Opposition, p. 2), that is, as competitive conditions require. It is argued that (1) the "circumstances heretofore justifying the promulgation of a detailed formula no longer exist, and (2) the continuation of such a formula would be antithetical to the Commission's findings in this proceeding" (WU Opposition, p. 5). The existing formula is no longer just, reasonable, equitable or in the public interest.

11. Reasoning that the international formula was conceived as a device to protect against anticompetitive behavior on the part of a domestic monopolist which could favor its own international arm or, after divestiture of its own international operations, play favorites among the IRCs, Western Union argues that the circumstances no longer exist which led to the adoption of Section 222(e) and the present prescribed formula. Today's situation is much like the pre-1943 merger period with two competing carriers in existence. WU adds that the "continued imposition of a detailed traffic distribution formula also would be inconsistent with the Commission's basic decision in this proceeding * * * that the public interest will best be served by reliance on the marketplace rather than competition" (WU Opposition, p. 8).

12. TRT replies to the opposition pleadings by arguing that none of the parties have refuted its "characterization of the nature of the policy established by the Commission in the *International Formula* proceeding" (TRT Reply, p. 3). The Commission does have "unquestioned authority" to apply the general policy of the *International Formula* proceeding and Graphnet and RCA did not argue why it is not applicable to Graphnet, says TRT. TRT devotes the largest portion of its Reply to the question of whether the "Graphnet-ITT/RCA contract" constitutes "an improper reciprocal

dealing arrangement." TRT argues that the Commission has an obligation to correct anticompetitive arrangements concluding that "the Graphnet-ITT/RCA arrangement represents a *per se* violation of Section 1 of the Sherman Act. By any measure, a 'not unsubstantial' amount of interstate commerce is effected by these arrangements." RCA and ITT exercise significant economic power over inbound traffic and will be in a position "to demand that Graphnet give to them, and thereby deny to TRT or other IRCs, the lion's share of the outbound traffic picked up on the Graphnet system." (TRT Reply, p. 10).

II RCA Alascom's Petition for Clarification

13. RCA Alaska Communications, Inc. (RCA Alascom) seeks clarification of our Order on the basis that "the FCC has failed to confirm that the terms and conditions governing the provision of public message services to, from and within Alaska are beyond the scope of this proceeding and are, therefore, unchanged by the Commission's decision" (RCA Alascom Petition, p. 1). RCA Alascom points out that the factual record and discussion and the analyses in the *Domestic PMS* proceeding "focus squarely and exclusively upon Western Union" (RCA Alascom Petition, p. 3) and that WU has never been authorized to serve Alaska, Alascom's authority to provide service for Alaska was the subject of entirely independent FCC proceedings and decisions, and no participant in the WU proceeding opposed Alascom's petition. Alascom requests that we clarify our Order by stating that the situation with respect to Alaskan service remains unchanged.

14. We shall grant RCA Alascom's request for clarification. The general tenor and specific wording of our order can only be read to encompass Western Union services. However, we are compelled to point out that, although our Order did not apply to Alaska service, we do not intend to foreclose the possibility of competition in Alaskan service perpetually, and we intend to examine whether such competition would be beneficial. For now, we have no reason to change our existing policy.

III. Procedural Matters

15. Graphnet argues that TRT's initial objections to the Graphnet agreements were untimely raised in November 1977 because Graphnet's agreement with ITT has been effective since January 1, 1977. Thus, Graphnet claims that reiteration in this proceeding does not cure the initial untimeliness. Even though TRT may have untimely raised its arguments, the

Commission may on its own motion consider matters that affect the public interest. Because of the importance of the allegations of anticompetitive activity, we will consider the issues raised in TRT's petition.

16. Graphnet also argues that prior to the merger of WU and Postal Telegraph, each of the domestic carriers had exclusive contracts with only certain of the IRCs and that TRT has failed to show why the Commission should interfere with Graphnet's existing contract provisions. We find that the existence of contracts over 35 years ago has no bearing on the validity of entirely different contracts existing today. Furthermore, the case law concerning unlawful voluntary reciprocal dealing arrangements is of recent vintage, see paragraph 27 below, and we must consider current dealings between carriers in the context of current legal developments.

IV. Application of the International Formula

17. The basic issue here is whether the present international formula for the distribution of outbound unrouted international messages should be applied to Graphnet as well as Western Union, only Western Union or if it should be amended to allow Western Union to distribute its unrouted traffic as competitive circumstances warrant. The other question, raised by TRT, is the Commission's alleged unexplained departure from the policy of the *International Formula* proceeding. We should point out that the basic issue of applicability of the present formula will be handled by the Commission in the Notice of Inquiry and Proposed Rulemaking in CC Docket No. 78-96, FCC No. 79-442, released July 23, 1979. In that Notice, we propose altering of the present formula and seek wider comments on TRT's proposal to expand the coverage of the international formula. We believe that the rulemaking proceeding is a more appropriate forum in which to address such issues and thereby gauge the public interest. There is no need here to reiterate our arguments in support of our proposal. However, we do wish to address TRT's petition to the fullest extent possible in this order.

18. In answer to the claim that we departed from our policy in *International Record Carriers Scope of Operation* (International Formula), 67 FCC 2d 877 (1978),² we must emphasize

that the decision did only and could only apply to the distribution of outbound unrouted international messages filed with the Western Union. This case was decided long before our findings in the instant PMs proceeding which authorized Graphnet's entry. The principles of *International Record Carriers Scope of Operation* could only have been developed in the light of the market structure of the time; that is, a Western Union domestic PMS monopoly. Faced with that market structure, the Commission did prescribe a formula which was "just, equitable, reasonable and in the public interest" which served as an incentive to the IRCs to "strive to improve service efficiency and to keep charges as low as feasible." 67 FCC 2d at 889. The market structure is no longer the same, and in any event, we did not depart from our international formula policy, for that prescription is still effective in respect to the principle parties involved; that is, WU and the IRCs.

19. As it now stands, the international formula does not apply to Graphnet, nor is it our present disposition for it to do so. However, in our rulemaking proceeding, we do wish to hear more arguments on the matter and if convinced that some sort of relief is warranted, we do have authority to impose conditions on the operations of Graphnet and the IRCs under the broad authority granted this Commission under Sections 201-205 of the Communications Act. We also reaffirm our statements in our order that we seek to treat domestic PMS carriers in the most equitable, even-handed manner possible.

20. Thus, we reject TRT's argument that the international formula should have been applied to Graphnet through a condition on its Section 214 authorization. Our regulatory control of subject carriers' terms and conditions of service does not end at the point of facility authorization. Therefore, we have the option of imposing some sort of international formula on Graphnet at a later time, if appropriate.

V. Graphnet's Agreements with the IRCs

21. As noted in the summary of comments above, TRT has characterized the "Graphnet-ITT/RCA arrangement" as an anticompetitive reciprocal dealing arrangement. TRT argues that these agreements raise issues of *actual* reciprocal dealing arrangements under the Sherman Act (Section 1) rather than issues of *potential* reciprocity raised by mergers examined under the Clayton Act (Section 7). TRT concluded that the Graphnet-ITT/RCA arrangement represents a *per se* violation of Section 1

of the Sherman Act.³ (TRT Reply, pp. 5-10.)

22. At the outset, we must observe that Graphnet has *separate* agreements (not a single "arrangement") with ITT Worldcom, RCA Globcom and, as of January 9, 1979, with Western Union International (WUI). These agreements are similar in nature, but separately reached with the three mentioned IRCs. Each of the agreements has two major parts, an inter-carrier interconnection agreement and an operating agreement which implements the inter-carrier one. The inter-carrier agreement discusses service standards in some detail either directly in the agreement or through reference to Graphnet's tariff.⁴

23. The provision of each of the agreements that TRT complains of provides that the outbound unrouted message traffic forwarded by Graphnet to each IRC shall be distributed to the IRCs in the same proportion as the amount of each IRC's unrouted inbound traffic handled by Graphnet.⁵ Thus, Graphnet's distribution of outbound traffic to the IRCs is based upon each IRC's distribution of inbound traffic to Graphnet.

24. Looking to the practical effect of this provision we note that in 1977, RCA carried 41.9 percent of the inbound traffic, ITT 29.0 percent, WUI 24.7 percent, and TRT only 2.8 percent.⁶ Thus, RCA, ITT and WUI together carried 95.6 percent of the inbound international traffic.⁷ In other words, if we allow this provision to stand, RCA, ITT, and WUI, by handling 95.6 percent of the inbound PMS traffic, can control the distribution of up to 95.6 percent of Graphnet's outbound unrouted traffic, giving them an anticompetitive advantage for Graphnet's unrouted outbound traffic.

25. TRT could be foreclosed from 95.6 percent of Graphnet's unrouted outbound traffic, even if TRT were to offer better prices or service than the

² Section 1 of the Sherman Antitrust Act, reads in pertinent part, every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal * * * 15 U.S.C.A. § 1.

³ See, RCA-Graphnet Inter-carrier Interconnection Agreement, par. 2, pp. 2-4; ITT-Graphnet Inter-carrier Interconnection Agreement, par. 2, pp. 2-5; WUI-Graphnet Inter-carrier Interconnection Agreement, par. 2, pp. 2-5.

⁴ See, RCA-Graphnet Agreement, par. 3.b, pp. 4-5; ITT-Graphnet Agreement par. 12, pp. 11-12; WUI-Graphnet Agreement, par. 3.b, pp. 5-6.

⁵ These statistics are derived from data found in semi-annual traffic reports filed by each of the IRCs pursuant to Section 43.61 of the Commission's Rules. The reports are on file with the Commission.

⁶ The statistics are not very much different from 1976, 1975, or 1974 where the totals for the three carriers were 95.8 percent, 96.0 percent and 96.2 percent, respectively.

⁷ This was our order on remand from the Court of Appeals decision in *RCA Global Communications v. FCC*, 559 F.2d 881 (2d Cir.), rehearing granted, 563 F.2d 1 (1977).

other carriers.⁸ This is particularly troublesome in view of the fact that in 1977 TRT handled 7.1 percent of the outbound traffic, but only 2.8 percent of the inbound traffic.⁹ Thus, if distribution of outbound unrouted traffic is based on inbound, TRT could lose some of its outbound traffic. In view of the fact that the amount of inbound traffic handled has no relationship to the price and quality that can be offered for outbound traffic, we find that the contract clauses linking outbound traffic to inbound traffic are unfair and contrary to the public interest.¹⁰

26. On the other hand, if the contract provision at issue is deleted, normal marketplace forces will assure a fair distribution of the outbound traffic. Graphnet would be able to distribute outbound unrouted traffic according to price and quality of service. Even if there was no variation in price or quality among the IRCs, Graphnet would still have an incentive to seek some method of distribution because each of the IRCs is a source of traffic (and revenues). It makes sense that Graphnet would attempt to keep all of the IRCs satisfied in some evenhanded fashion. The same is true for inbound traffic. Each IRC would be able to distribute traffic to domestic carriers according to price and quality considerations. If Graphnet's prices and service are more attractive than its competitor's the IRCs will want to use Graphnet. In each case, if price and quality of service is comparable, each carrier would be motivated to distribute traffic on a fair and equitable basis, and if any carrier uses its control over a portion of the market to unfairly obtain more than its

fair share of the traffic, we have authority to entertain complaints and take appropriate action. In this way the operations of the market will act to supplement our regulatory authority.

27. Our view is that the contractual provision at issue is unfair, anticompetitive, and contrary to the public interest. This finding is consistent with decisions under the antitrust laws regarding reciprocal dealing arrangements. As one antitrust court has put it:

A reciprocal dealing arrangement exists when two parties face each other as both buyer and seller. One party offers to buy the other party's goods, but only if the second party buys other goods from the first party.¹¹

That is essentially the type of arrangement we have here. Each IRC, i.e., RCA, ITT, and WUI, has agreed with Graphnet to interconnect for the delivery of domestic PMS traffic.¹² More importantly, however, Graphnet has agreed to deliver "unrouted" ¹³ outbound international PMS traffic to each IRC "in the same proportion as the amount of each such (international) carrier's discretionary inbound communications" handled by Graphnet bears to the total of such communications handled by Graphnet for all such carriers.¹⁴ In other words, there is present here the characteristic prerequisite of reciprocal dealing in the antitrust context—one party's agreement to provide business to another party only if that party provides business to it. True, the agreement here is not the sort of mutual sale/purchase agreement for goods or services typically involved in the antitrust cases, but rather a mutual arrangement to provide component elements of an interconnected international communications service. Nevertheless, the "good" or "service," so to speak,

¹¹ *Spartan Grain & Mill Co. v. Ayers*, 581 F.2d 419, 424 (5th Cir. 1978).

¹² Indeed, as an implementing provision the IRCs have agreed that so long as Graphnet's charges for domestic PMS delivery are "at least 10% below" the charges of other domestic PMS carriers, then the IRC will distribute to Graphnet a portion of the IRC's "discretionary" inbound PMS traffic "at least equal to that distributed by (the IRC) to any other domestic United States carrier." In this context, "discretionary" means that the IRC has the discretion to select a domestic U.S. carrier for PMS delivery. It refers to "those communications destined for the (U.S.) hinterland as to which the originator has not designated a domestic delivery carrier by name." See paragraphs of parties' interconnection agreements cited in footnote.⁸ *supra*. See RCA-Graphnet Inter-carrier Interconnection Agreement, par. 12, p. 10; ITT-Graphnet Inter-carrier Interconnection Agreement, par. 13, p. 12; WUI-Graphnet Inter-carrier Interconnection Agreement, par. 12, pp. 12-13.

¹³ In this context, "unrouted" means that Graphnet's originating customer has not specified which IRC should be used.

¹⁴ See footnote.⁸ *supra*, for citations to relevant paragraphs of parties' interconnection agreements.

which each IRC has agreed to "sell" to Graphnet, i.e., the opportunity to provide hinterland delivery of certain inbound messages for compensation, is distinctly different from the "good" or "service" which Graphnet has agreed to "sell" to the IRC's, i.e., the opportunity to provide international transmission of certain outbound messages for compensation. While the messages may be fungible as far as the carriers are concerned, the business which each party is affording the other is not substitutable *inter sese*. The deemed for each type of business is different; the customers may well be different; certainly those authorized to offer the service are different as is the market structure in which the competitors function. In sum, Graphnet's assertion that "(a)ntitrust concepts of reciprocity simply have neither meaning nor applicability in this context" (Opposition, p. 11) is incorrect.

28. The antitrust cases which have considered reciprocity have done so generally in two contexts: (1) Where a conglomerate merger is challenged under Section 7 of the Clayton Act, 15 U.S.C. 18, on the ground that the combined firm will probably engage in reciprocal buying, thus lessening competition; ¹⁵ and (2) where a bilateral reciprocal agreement, or a course of dealing from which such an agreement may be inferred, is challenged as a restraint of trade under Section 1 of the Sherman Act, 15 U.S.C. 1. In one merger case, *FTC v. Consolidated Foods Corp.*, 380 U.S. 592 (1965), the Supreme Court held that reciprocity

is one of the congeries of anticompetitive practices at which the antitrust laws are aimed. The practice results in "an irrelevant and alien factor" * * * intruding into the choice among competing products, creating at the least "a priority on the business at equal prices." * * * Reciprocal trading may ensure not from bludgeoning or coercion but from more subtle arrangements. A threatened withdrawal of orders if products of an affiliate cease being bought, as well as a conditioning of future purchases on the receipt of orders for products of that affiliate, is an anticompetitive practice. (380 U.S. at 594.)

Having ruled that even non-coercive reciprocity can be anticompetitive, the Court then upheld the FTC's finding that the particular merger would probably result in reciprocal practices and substantial lessening of competition. In

¹⁵ *E.g., Gulf & Western Industries, Inc. v. Great Atlantic & Pacific Tea Co.*, 476 F.2d 687, 693-94 (2d Cir. 1973); *Allis-Chalmers Mfg. Co. v. White Consolidated Industries, Inc.* 414 F.2d 506, 518-19 (3d Cir. 1969); *United States v. Int'l Tel. & Tel. Corp.*, 306 F. Supp. 766 (D. Conn. 1969), appeal dismissed, 404 U.S. 801 (1971); *United States v. Penick & Ford, Ltd.*, 242 F. Supp. 518 (D.N.J. 1965); *United States v. Ingersoll-Rand Co.*, 18 F. Supp. 530, 552 (W.D. Pa.), aff'd, 320 F.2d 509 (3d Cir. 1963).

⁸ We recognize that these statistics are derived from data for all traffic and are not specifically for "discretionary" traffic to the hinterland. However, the differences in percentages between TRT and the other carriers is so large, that even if the data varied somewhat for "discretionary" traffic to the hinterland, we would expect similar results. "Discretionary" inbound traffic, as referred to in the agreements, is that traffic destined for the U.S. which does not designate a specific domestic carrier to deliver the message.

⁹ Although the disparity between inbound and outbound traffic was not as much in prior years as for 1977 (for 1976, TRT handled 4.8 percent of the outbound and 2.6 percent of the inbound, for 1975 it was 4.2 percent outbound and 2.4 percent inbound, and for 1974 it was 3.9 percent outbound and 2.3 percent inbound), it can nevertheless be seen that TRT consistently handles more outbound than inbound traffic.

¹⁰ We are not in any way guaranteeing a share of the market to TRT. We are taking this step to assure that TRT, and other IRCs are not foreclosed from increasing their market shares. It should be stressed that the ultimate effects on any single carrier depend on a number of things, including Graphnet's market share of total outbound traffic, the nature of Western Union's operations, the results of our gateway proceeding (Docket 19660) and the total amount of unrouted outbound messages available for distribution by all domestic carriers.

United States v. General Dynamics, 258 F. Supp. 36 (S.D.N.Y., 1966), a district court not only invalidated a merger under Clayton § 7 because of reciprocity potential, but also found the merger agreement itself a restraint of trade under Sherman § 1 because of the parties' proven intent to employ reciprocity after the merger. While not clearly necessary to the court's result, the court found "that reciprocity, whether coercive in nature or based on mutual patronage (i.e., not based on unequal bargaining power or leverage), is an anticompetitive practice." 258 F. Supp. at 59.

29. Despite the foregoing precedents, it is still somewhat uncertain whether a non-coercive unleveraged reciprocity agreement (or course of dealing from which such an agreement can be inferred) necessarily and in every case is anticompetitive and a Sherman § 1 violation. The *General Dynamics* decision seemed to say that all reciprocal dealing agreements are *per se* unlawful by analogy to "tie-in" arrangements which are unquestionably *per se* unlawful if a not insubstantial amount of commerce is affected. 258 F. Supp. at 66, citing Supreme Court "tie-in" cases.¹⁶ The theory is that even though neither party to the mutual patronage agreement is being "forced" to buy on terms it otherwise would find unacceptable, third-party competitors are inevitably adversely affected and barriers to entry are raised. In the instant context, even if Graphnet and the three IRC's find the agreements mutually acceptable, a fourth IRC (TRT) is necessarily foreclosed from a portion of Graphnet's unrouted outbound traffic for which it (TRT) might otherwise compete, i.e., that portion already allocated to RCA, ITT, and WUI on the basis of their inbound traffic market shares. Cutting against the idea that mutual patronage reciprocity is unlawful *per se* without regard to possible redeeming virtues are several factors. First, commentators have theorized that in certain market settings, reciprocity may be a procompetitive means of achieving needed entry or real

purchasing and selling economies.¹⁷ Second, the Supreme Court has recently cautioned against imposing a *per se* standard of illegality where the economic consequences of an arrangement in all contexts are not clear and, indeed, has overruled one of its own pronouncements of *per se* illegality.¹⁸ Third, reciprocal buying agreements have frequently been analogized to tying arrangements; but the courts have recently made it clear that economic power in the tying product is an essential feature of a *per se* unlawful tie-in.¹⁹

30. In the present case, we need not resolve whether a reciprocity arrangement may be held *per se* unlawful absent evidence that one party has unequal bargaining power relative to the other party. Here, RCA, WUI and ITT, have vastly more power than Graphnet. The international record carrier market is a tight oligopoly; the three firms together control 95.6 percent of the inbound PMS traffic. (See paragraph 22 above.) Graphnet is dependent on them for any substantial share of discretionary inbound traffic. Graphnet, as a generator of overseas-bound PMS traffic, is minuscule compared to Western Union and has no market power as yet. Plainly, the IRC's have buying power to use as leverage against Graphnet. One manifestation of this is the fact that under the agreement Graphnet has to undercut Western Union by 10 percent in order to assure mere parity with Western Union in the delivery of discretionary inbound international PMS messages. (see paragraph 27 above.) the extent to which this leveraged reciprocity arrangement would actually result in substantial detriment to TRT and other small IRC's depends, of course, on the domestic market share for outbound traffic which Graphnet might ultimately obtain. Suffice it to say, for present purposes, that the potential Graphnet share would be significant enough so that the long-run effect of the challenged

reciprocity provision on TRT and other small IRC's would not be de minimis.²⁰

31. In view of the foregoing, it can be seen that the clauses in the contracts between Graphnet and RCA, WUI, and ITT that link outbound to inbound traffic constitute reciprocal trading agreements portend a violation of Section 1 of the Sherman Act and are also unfair and contrary to the public interest. Thus, we will grant TRT's request by granting Graphnet authority to domestically distribute international PMS on the condition that the clauses linking outbound to inbound traffic be deleted from the three contracts. This will allow Graphnet to go into operation and at the same time avoids enforcement of a contract provision deleterious to the public interest.

32. Accordingly, it is ordered, that the Petition for Reconsideration of our order in *Domestic Public Message Service*, CC Dockets No. 78-95 and 78-96, filed by TRT Telecommunications Corporation IS GRANTED to the extent indicated herein and in other respects IS DENIED.

33. It is further ordered, that the Petition for Clarification filed by RCA Alaska Communications, Inc. is granted to the extent indicated herein and in all other respects is denied.

34. It is further ordered, pursuant to Section 214 of the Communications Act of 1934, as amended, that our grant of authority to Graphnet Systems, Inc., as stated in *Domestic Public Message Services*, CC Dockets 78-95 and 78-96, 71 FCC 2d 471 (1979), is modified and additionally conditioned as follows:

(A) Paragraph 3.b of the RCA Globcom-Graphnet Interconnect Agreement executed on February 24, 1977 shall be deleted.

(B) Paragraph 12 of the ITT Worldcom-Graphnet Interconnect Agreement executed on June 3, 1976 shall be deleted.

(C) Paragraph 3.b of the Western Union International-Graphnet Interconnect

²⁰ We might even find the challenged provision anticompetitive and contrary to the public interest on another ground as well. Although the standard reciprocity provision appears in three separate agreements, it is obvious from the way the provision reads that the IRC's intended Graphnet to act as their intermediary to achieve a horizontal market allocation agreement between competitors (the IRC's). The provision on its face constitutes an agreement by Graphnet as to what language it will place in its agreements with other IRC's. Horizontal market allocation agreements are *per se* unlawful under Sherman § 1. *United States v. Topco Associates, Inc.*, 405 U.S. 596 (1972). Such an agreement between competitors, even though accomplished through parallel agreements or consciously parallel conduct with a third party, is unlawful. See *United States v. Sealy, Inc.*, 388 U.S. 350 (1967); *Interstate Circuit, Inc. v. United States*, 306 U.S. 208 (1939). Here Graphnet's involvement is of even greater concern because Graphnet itself is a potential entrant into international record carriage and, thus, a potential horizontal competitor of the IRC's.

¹⁶ Several decisions finding no antitrust violations or no right to recover damages have simply assumed that bilateral agreements to engage in mutual patronage reciprocity are *per se* Sherman § 1 violations. E.g., *Columbia Nitrogen Corp. v. Royster Co.*, 451 F. 2d 3, 14-15 (4th Cir. 1971); *Ryals v. National Car Rental System, Inc.*, 404 F. Supp. 481, 485-86 (D. Minn. 1975); *United States v. Airco, Inc.*, 386 F. Supp. 915, 921 (S.D.N.Y. 1974). The D.C. Circuit, however, has indicated that it may still be an open question whether non-coercive reciprocity, where neither party has leverage over the other, is a *per se* violation of Sherman § 1. *Fidelity Television, Inc. v. FCC*, 515 F. 2d 684, 698 (panel majority), 720 n. 59 (Bazelon dissenting to denial of rehearing en banc) (D.C. Cir. 1975).

¹⁷ See Peter O. Steiner, *Mergers: Motives, Effects, Policies* (1975) at 231-32. Even "tie-ins," which are generally thought to be *per se* unlawful, may be justifiable for a time in permitting entry into a new business. *United States v. Ferrol Electronics Corp.*, 187 F. Supp. 545, 557, 560 (E.D. Pa. 1960), aff'd per curiam, 365 U.S. 587 (1961); ABA, Section of Antitrust Law, *Antitrust Law Developments* (1975) at 42.3.

¹⁸ *Continental T.V. Inc. v. GTE Sylvania, Inc.*, 443 U.S. 36 (1977); see *Broadcast Music, Inc. v. ASCAP*, 47 U.S.L.W. 4359, 4361-62 (U.S. 1979) (declining to apply *per se* rule).

¹⁹ *United States Steel Corp. v. Fortner Enterprises*, 429 U.S. 610, 619-22 (1977); *Spartan Grain & Mill Co. v. Ayers*, supra, 581 F. 2d.

Agreement executed on December 9, 1978 shall be deleted.

Such authorization is explicitly subject to possible revocation or modification as a result of any findings, rules, requirements or other actions which may result from or be promulgated by, the proceedings in Common Carrier Docket No. 78-72, In the Matter of MTS and WATS market Structure, FCC 78-144 (March 3, 1978) and in Common Carrier Docket No. 78-96, In the Matter of Domestic Public Message Services, FCC 79-442 (July 23, 1979). The grantee is afforded 30 days from the release of this order to decline this authorization as conditioned. Failure to respond within this period will constitute formal acceptance of the authorization as conditioned.

35. It is further ordered, that the hearing to investigate whether grant of the above-captioned application is in the public interest, convenience and necessity, which was instituted in our Memorandum Opinion and Order and Notice of Inquiry and Proposed Rulemaking, 67 F.C.C. 2d 1059 (1978), is hereby terminated.

Federal Communications Commission.

William J. Tricarico,
Secretary.

[FR Doc. 79-26738 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

[47 CFR Parts 63 and 64]

[CC Docket No. 78-96]

Regulatory policies concerning the provision of Domestic Public Message Services by entities other than the Western Union Telegraph Company and proposed amendments to parts 63 and 64 of the Commission's Rules; Order extending time for filing comments and reply comments

AGENCY: Federal Communications Commission.

ACTION: Time limits for filing comments extended in CC Docket 78-96 (*Domestic Public Message Services*).

SUMMARY: On July 23, 1979, the Federal Communications Commission released a Notice in CC Docket No. 78-96 proposing changes in rules and policies for domestic public message services. Comments on that Notice were originally due on August 27, 1979. The date for filing comments has now been extended to September 7, 1979. Reply comments are due September 24, 1979.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Leonard Sawicki, Common Carrier Bureau (202) 632-6363.

SUPPLEMENTARY INFORMATION:

Order

Adopted: August 20, 1979.
Released: August 21, 1979.

In the matter of Regulatory Policies Concerning the Provision of Domestic Public Message Services by Entities Other than the Western Union Telegraph Company and Proposed Amendments to Parts 63 and 64 of the Commission's rules, CC Docket No. 78-96.¹

1. On August 15, 1979 Western Union International, Inc. (WUI) filed a request for an extension of time for filing comments and reply comments on the Commission's *Notice of Inquiry and Proposed Rulemaking* (Notice) in CC Docket 78-96, released July 23, 1979 (FCC 79-442). WUI seeks to have the filing dates extended two weeks from the release of the *Order on Reconsideration* in CC Dockets 78-95 and 78-96, which was adopted at the Commission's August 1, 1979 open meeting. Citing the close relationship between the two items, WUI argues that it would be allowed "a wholly insufficient period of time" to review the *Order on Reconsideration* before August 27, 1979 when the comments are due on the Notice.

2. Because of the relationship between the two proceedings and their importance, the request appears reasonable and in the public interest. We shall grant the request for extension of time for the filing of comments and reply comments in this matter.

3. Accordingly, it is ordered, pursuant to § 0.291 of the Commission's rules on delegation of authority, that the request for extension of time for all parties to file comments and reply comments in CC Docket No. 78-96 is granted. Comments shall be filed on or before September 7, 1979, and reply comments shall be filed on or before September 24, 1979.

Philip L. Verveer,

Acting Chief, Common Carrier Bureau.

[FR Doc. 79-26632 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

[47 CFR Part 73]

[Docket No. 20902; RM-2642]

Rescinding Report and Order and Denying Petition for Rulemaking

AGENCY: Federal Communications Commission.

ACTION: Memorandum opinion and order.

SUMMARY: Action taken herein rescinds a previous action which assigned and reserved television Channel 46 at St. Louis, Missouri, for noncommercial educational use. Since then, one of the two applicants for television Channel *40 at St. Louis, has withdrawn its application. As a result, the Commission sees no need for an additional noncommercial educational television channel since the remaining applicant can be accommodated on Channel 40.

DATE: Not applicable.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Memorandum Opinion and Order

Adopted: August 15, 1979.
Released: August 22, 1979.

In the matter of amendment of § 73.606(b), *Table of Assignments, Television Broadcast Stations*. (St. Louis, Missouri), Docket No. 20902, RM-2642.¹

1. On July 9, 1979, under delegated authority, the Chief, Broadcast Bureau, adopted a *Report and Order* in the above proceeding, in response to a petition filed by Double Helix Corporation ("Double Helix"), requesting the assignment of UHF television Channel *46 to St. Louis, Missouri, for noncommercial educational television use.

2. St. Louis is presently served by five commercial television stations operating on Channels 2, 4, 5, 11 and 30. It is also served by one noncommercial educational station operating on Channel *9. In addition, two competing applications were pending on Channel *40, the only vacant educational TV channel assigned to St. Louis. One was filed by Double Helix Corporation and the other was filed by St. Louis Regional Educational and Public Television Commission ("St. Louis Regional"), licensee of an educational station on TV Channel *9. Double Helix proposed assigning Channel 46 so that both proposed operations could be accommodated.

3. In the *Report and Order* Channel *46 was assigned to St. Louis on the basis of the showing of need for an additional noncommercial assignment in that city and the fact that an applicant was ready to provide that service. Since then, St. Louis Regional has asked for

¹ See 44 FR 44184, July 27, 1979.

¹ See 44 FR 42693, July 20, 1979.

dismissal of its application. This means that the remaining applicant for Channel *40, Double Helix, can be accommodated on this channel. As a consequence there is no longer a need for the assignment of an additional channel (Channel *46) to St. Louis. We will therefore rescind the *Report and Order* making this assignment.

4. It is ordered, That the *Report and Order* adopted on July 9, 1979, in Docket No. 20902 assigning Channel *46 to St. Louis, Missouri, is rescinded.

5. Accordingly, it is further ordered, That the petition filed by Double Helix Corporation for the assignment of Channel *46 to St. Louis, Missouri, is denied.

6. Authority for this action is contained in Sections 4(i), 5(d)(1) and 303(r) of the Communications Act of 1934, as amended, and §§ 1.108 and 0.281 of the Commission's rules.

7. It is further ordered, that this proceeding is terminated.

Federal Communications Commission.
Richard J. Shiben,
Chief, Broadcast Bureau.

[FR Doc. 79-26628 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

[47 CFR Part 73]

[BC Docket No. 79-212; RM-3295]

FM Broadcast Stations in Manhattan, Kans.; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rule making.

SUMMARY: Action taken herein proposes the assignment of a second Class A channel to Manhattan, Kansas, in response to a petition filed by Richard H. Kaldor and Timothy A. Hawks. Petitioners state the proposed channel could bring a needed additional aural service to the community.

DATES: Comments must be filed on or before October 15, 1979, and reply comments must be filed on or before November 5, 1979.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Notice of proposed rule making

Adopted: August 15, 1979.
Released: August 22, 1979.

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Manhattan,

Kansas), BC Docket No. 79-212, RM-3295.

1. *Petitioner, Proposal, Comments.* (a) A petition for rulemaking¹ was filed on December 12, 1978, by Richard H. Kaldor and Timothy A. Hawks ("petitioners"), proposing the assignment of Channel 280A to Manhattan, Kansas, as its second Class A FM assignment. Supporting comments were filed by Taylor Communications, Inc., licensee of Station KCLY(FM), Clay Center, Kansas.

(b) The channel can be assigned without affecting any existing FM assignments in the Table.

2. *Community Data*—(a) *Location.* Manhattan, in Riley County, is located in northwest Kansas, approximately 60 kilometers (101) miles west of Kansas City, Kansas.

(b) *Population.* Manhattan—27,575; Riley County—56,788.²

(c) *Local Aural Broadcast Service.* Manhattan presently receives local service from daytime-only AM Station KMAN, and FM Station KMKF (Channel 269A).

3. *Economic Data.* Petitioners indicate that, according to the Riley County Assessors Office, Manhattan's population has increased from 26,087 in 1970 to 30,047 in 1976, and continues to increase steadily. Petitioners claim that Manhattan is one of the fastest growing retail trade areas in the State of Kansas. Petitioners note that the major employers are McCall Pattern Company, followed by Farm Bureau, Inc., Steel & Pipe Company and Guerdon Industries. Petitioners have submitted detailed economic and demographic information with respect to Manhattan in an effort to demonstrate the need for a second FM assignment. Also, letters from local citizens have been submitted in support of the proposed assignment.

4. *Preclusion Study:* Preclusion would occur on the co-channel only, since the use of all six pertinent adjacent channels is precluded by existing FM assignments. Two Kansas communities with populations greater than 1,000 are in the co-channel precluded area: Clay Center (pop. 4,963) and Osage City (pop. 2,600). Clay Center has an FM assignment and petitioners state an alternate channel is available for assignment to Osage City. Therefore, preclusion is not an impediment to the proposed assignment.

5. Comments are invited on the proposal to amend the FM Table of Assignments (§ 73.202(b) of the

¹ Public Notice of the petition was given on January 3, 1979, Report No. 1157.

² Population figures are taken from the 1970 U.S. Census.

Commission's rules) with regard to the community of Manhattan, Kansas, as follows:

City	Channel No.	
	Present	Proposed
Manhattan, Kansas.....	269A	269A, 280A

6. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

7. Interested parties may file comments on or before October 15, 1979, and reply comments on or before November 5, 1979.

8. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission.

Federal Communications Commission.
Richard J. Shiben,
Chief, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 79-26629 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

[47 CFR Part 73]

[BC Docket No. 79-211; RM-3278]

FM Broadcast Station in Bentonville, Ark.; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rule making.

SUMMARY: Action taken herein proposes the assignment of a Class A FM channel to Bentonville, Arkansas, in response to a petition filed by JEM Broadcasting Company. The proposed channel could be used to provide a first full-time local aural broadcast service to the community.

DATES: Comments must be filed on or before October 15, 1979, and reply

comments must be filed on or before November 5, 1979.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Adopted: August 15, 1979.

Released: August 22, 1979.

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations. (Bentonville, Arkansas), BC Docket No. 79-211, RM-3278.

1. A petition for rule making¹ was filed by JEM Broadcasting Company ("petitioner"), permittee of daytime-only AM Station KJEM, Bentonville, Arkansas, proposing the assignment of Channel 252A to Bentonville, Arkansas, as that community's first FM assignment.

2. Another petition² was filed by Robert R. Estes ("Estes"), requesting the same channel (252A) for assignment to Springdale, Arkansas. Channel 252A cannot be assigned to both Springdale and Bentonville because of spacing requirements. Estes has amended his petition to specify Channel 237A for Springdale in lieu of Channel 252A, thus eliminating the conflict. Since the conflict has been resolved, we will proceed with proposing Channel 252A for Bentonville. The Estes petition will be considered separately at a later date.

3. Bentonville (pop. 5,508), seat of Benton County (pop. 50,476),³ is located in northwest Arkansas, approximately 245 kilometers (152 miles) northwest of Little Rock. It is served locally by daytime-only AM Station KJEM.

4. Petitioner claims that Bentonville's population has increased more than 50% between 1960-1970. According to the Northwest Arkansas Population Projections, Bentonville should reach a population of 8,900 by 1980. Petitioner states that the raising of poultry and dairy production are major factors in the area's economy. In support of its proposal, petitioner has submitted detailed population and demographic data with respect to Bentonville in an effort to demonstrate a need for a first FM assignment in the community.

5. In view of the fact that the proposed FM channel assignment would provide for a first full-time aural broadcast service to Bentonville, the Commission believes it appropriate to propose

¹ Public Notice of the petition was given on December 18, 1978, Report No. 1135.

² Public Notice of the petition was given on May 4, 1979, Report No. 1176.

³ Population figures are taken from the 1970 U.S. Census.

amending the FM Table of Assignments, § 73.202(b) of the Commission's rules, with regard to Bentonville, Arkansas, as follows:

City	Channel No.	
	Present	Proposed
Bentonville, Arkansas		252A

6. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

7. Interested parties may file comments on or before October 15, 1979, and reply comments on or before November 5, 1979.

8. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission.

Federal Communications Commission.
Richard J. Shiben,
Chief, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM Table of Assignments, Section 73.202(b) of the Commission's rules and regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, NW., Washington, D.C.

[FR Doc. 79-28631 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

[47 CFR Part 73]

[Docket No. 20735]

Changes in the Rules relating to Noncommercial Educational FM Broadcast Stations

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: Action taken herein extends the time for filing comments and reply comments indefinitely in a proceeding involving changes in the rules relating to noncommercial educational FM broadcast stations. Additional time will be needed so that the parties can respond to a Report being prepared by the Commission's staff.

DATES: Time for filing comments and reply comments extended indefinitely.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Gregory DePriest, Broadcast Bureau, (202) 632-6303.

SUPPLEMENTARY INFORMATION:

Order Extending Time for Filing Comments and Reply Comments

Adopted: August 17, 1979.

Released: August 20, 1979.

In the matter of changes in the rules relating to Noncommercial Educational FM Broadcast Stations, Docket No. 20735.¹

1. On June 7, 1978, the Commission adopted a *Further Notice of Proposed Rule Making*, 43 FR 27682, in the above-captioned proceeding. The dates for filing comments and reply comments are presently October 15, and November 30, 1979, respectively.

2. In an *Order* released April 27, 1979, the Commission extended the time to the present filing dates in order to provide an opportunity for parties to comment on a Report being prepared by the Office of Chief Scientist pertaining to Channel 6 interference considerations. However, there has been a delay in the issuance of the Report. Therefore, on the Commission's own motion, the filing dates in this proceeding will be extended indefinitely. Upon completion of the Report, new dates will be set.

3. Accordingly, it is ordered, That the dates for filing comments and reply comments in Docket No. 20735 are extended indefinitely.

4. This action is taken pursuant to authority contained in Sections 4(i), 5(d)(1) and 303(r) of the Communications Act of 1934, as amended, and § 0.281 of the Commission's rules.

Federal Communications Commission
Richard J. Shiben,
Chief, Broadcast Bureau.

[FR Doc. 79-28633 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

¹ See 44 FR 26772, May 7, 1979.

Notices

Federal Register

Vol. 44, No. 168

Tuesday, August 28, 1979

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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Agency Organization and Personnel; Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of a meeting of the Committee on Agency Organization and Personnel of the Administrative Conference of the United States, to be held at 10:00 a.m., Wednesday, September 12, 1979, in the library of the Administrative Conference, Suite 500, 2120 L Street, N.W., Washington, D.C.

The Committee will meet to discuss reports and possibly proposed recommendations from Professor Michael Cardozo on experience under the Federal Advisory Committee Act and from Professor Thomas Morgan on post-employment restrictions on former Federal employees.

Attendance is open to the interested public, but limited to the space available. Persons wishing to attend should notify this office at least two days in advance. Members of the public may be permitted to present oral statements, if deemed appropriate by the Committee Chairman. Members of the public may also file a written statement with the Committee before, during or after the meeting.

For further information concerning this meeting contact Richard K. Berg (202-254-7020). Minutes of the meeting will be available upon request.

Richard K. Berg,
Executive Secretary.

August 21, 1979.

[FR Doc. 79-26700 Filed 8-27-79; 8:45 am]

BILLING CODE 6110-01-M

Committee on Rulemaking and Public Information; Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of a meeting of the Committee on Rulemaking and Public Information of the Administrative

Conference of the United States, to be held in the Library of the Conference, 2120 L Street, N.W., Suite 500, Washington, D.C. This meeting will be held at 2:00 p.m. on September 12, 1979.

The purpose of this meeting is to discuss a draft report and proposed recommendations concerning the administration of the Federal Trade Commission's program for compensating public participants in Magnuson-Moss trade regulation rulemakings.

Attendance is open to the interested public, but limited to the space available. Persons wishing to attend should notify this office at least two days in advance of the meeting. The Committee Chairman, if he deems it appropriate, may permit members of the public to present oral statements at the meeting; any member of the public may file a written statement with the Committee before, during or after the meeting.

For further information, contact Stephen L. Babcock (202-254-7020). Minutes of the meeting will be available on request.

Richard K. Berg,
Executive Secretary.

August 21, 1979.

[FR Doc. 79-26699 Filed 8-27-79; 8:45 am]

BILLING CODE 6110-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

Implementation of NEPA Procedures

AGENCY: Animal and Plant Health Inspection Service.

ACTION: This notice publishes the final "APHIS Guidelines Concerning Implementation of NEPA Procedures."

SUMMARY: The "APHIS Guidelines Concerning Implementation of NEPA Procedures" was written to comply with the regulations of the Council on Environmental Quality (CEQ). The CEQ NEPA Regulations (40 CFR 1500-1508) were published in the Federal Register on November 29, 1978, (43 FR 55978-56007) to implement the procedural provisions of the National Environmental Policy Act (NEPA). The purpose of this notice is to publish in final form the procedures APHIS will use to implement the provisions of NEPA.

FOR FURTHER INFORMATION CONTACT: N. E. Bedessem, Office of the Administrator, APHIS, USDA (202-447-2290).

EFFECTIVE DATE: August 28, 1979.

SUPPLEMENTARY INFORMATION: On November 13, 1974, APHIS published "Guidelines for the Preparation of Environmental Impact Statements" in the Federal Register (39 FR 40048). Recently published regulations of CEQ (43 FR 55978-56007, November 29, 1978) and final regulations of the Department of Agriculture (USDA) (44 FR 44802-44803, July 30, 1979) require USDA agencies to adopt implementation procedures for NEPA. APHIS published a proposed "APHIS Guidelines Concerning Implementation of NEPA Procedures," on July 3, 1979 (44 FR 38945-38949), and asked the public to comment by July 24, 1979.

This final APHIS issuance outlines only those Agency-specific actions needed for compliance with the NEPA process and must be read in conjunction with the CEQ NEPA Regulations and the USDA regulations.

This notice makes the final guidelines available to the public. The procedures to be used by APHIS decisionmakers should lead to decisions in which environmental concerns are fully reviewed and which ensure timely public involvement in the NEPA process. The issuance designates major decision points for Agency actions affecting the environment which are not categorically excluded by CEQ or USDA regulations. It provides procedures for Agency preparation of the EIS and supplemental statements, and includes procedures for use in emergency situations. It outlines a plan for public involvement in the decisionmaking process. It provides a comprehensive list of reference sources for use in preparing EIS's. The new "APHIS Guidelines Concerning Implementation of NEPA Procedures" supersedes the previous publication, "Guidelines for the Preparation of Environmental Impact Statements," published in November of 1974.

ALTERNATIVES CONSIDERED: In developing the new procedures, there was only one alternative available to APHIS since compliance with NEPA is required of all Federal agencies. That one alternative was to require more than was needed to comply with NEPA, CEQ NEPA Regulations, and USDA regulations. This was rejected on the

grounds that the added expense would not justify the added benefits. Compliance with the letter and spirit of NEPA as envisioned in the "APHIS Guidelines" will result in appropriate measures being taken by APHIS officials to protect against unwarranted adverse environmental impact.

PUBLIC COMMENT AND GOVERNMENT REVIEW: No public comments on the proposed "APHIS Guidelines" have been received. Several changes have been made to the proposal as a result of internal USDA review and external review by the Office of Environmental Review of the Environmental Protection Agency. The changes make the "APHIS Guidelines" more specific and are outlined below:

1. A new sentence, "APHIS officials will assure that all alternatives considered are addressed in the documents and that all alternatives in the documents are considered by the decisionmakers," has been added to Section III, "Agency Decisionmaking Procedures." This change complies with section 1505.1(e) of the CEQ NEPA Regulations which requires that the alternatives considered by the decisionmaker and the alternatives addressed in the environmental documents coincide.

2. Also in Section III, "Agency Decisionmaking Procedures," two editorial changes were made to the identification of the first decision point. In order to make it consistent with the rest of the "APHIS Guidelines," the term "programs" was changed to "plans, projects and programs" and the qualifier "environmental" was added to "adverse effects."

3. Two sentences were added to section IV B, "Preparation of EIS for APHIS actions," paragraph 3, to address an omission in the July 3 proposal. There are in APHIS ongoing projects and programs which, because of their age and unchanging nature, have never been formally reviewed under NEPA requirements. The new sentence articulates the goal that all APHIS projects and programs be the subject of an environmental assessment at least every five years.

4. A new paragraph was added to section IV B, "Preparation of EIS for APHIS Actions" and was designated paragraph 4. The new paragraph lists the criteria to be considered by APHIS officials in making and environmental assessment. The addition is designed to more clearly comply with Section 1507.2 (b)(3) of the CEQ NEPA regulations.

5. Section IV C, "Tiering", was changed by deleting the phrase, "when appropriate," which was not definitive, and adding, "as specified in CEQ NEPA Regulations. (1502.20, 1508.28)." the intent of the proposal was to take advantage of the tiering process as permitted in the CEQ NEPA Regulations and this change makes that clear without repeating the words of the CEQ issuance.

6. A new sentence was added to Section VII, "Public Involvement," in paragraph B to make more specific the kinds of contact the Agency intends to make in soliciting public participation.

7. A new paragraph B has been added to Section VIII, "Responsibilities." The old paragraph B has been relettered and becomes paragraph C. The new paragraph addresses the responsibility of the work groups established to review all environmental assessments prepared by APHIS officials, make recommendations concerning the need for an EIS, monitor the programs for which EIS's have been prepared to assure mitigating measures are being followed, and to call attention to those ongoing projects and programs which need environmental assessments. This addition makes more specific the Agency's compliance with Section 3100.34 of the final USDA regulations and addresses the problem of those ongoing actions which need review for NEPA compliance.

8. Editorial changes were made to Section IX, "Reference Sources for EIS Preparation," items C and G to list the most recent or more accurate titles.

9. Corrections were made to appendix I, "Processing EIS Initiated and Prepared by APHIS." The first reduced the number of copies of a "Finding of No Significant Impact" that need to be sent to EPA from five to one, as requested by EPA. The second corrected a mistake in footnote 3 which would have permitted a Record of Decision to be published before the completion of the 30-day waiting period required by Section 1506.10 (b)(2) of the NEPA Regulations.

APHIS Guidelines Concerning Implementation of NEPA Procedures

I. Purpose

These procedures comply with the Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (NEPA) (43 FR 55978-56007, 40 CFR Parts 1500-1508) and applicable Departmental regulations (7 CFR 3100). The procedures outline those Agency-specific actions needed for compliance with the NEPA process. These procedures include requirements, guidance, and references for developing environmental impact statements (EIS's) and also designate responsible officials as required by the CEQ NEPA Regulations. Unless otherwise identified, all parenthetical numerical references are to the CEQ NEPA Regulations.

II. Terminology

Terms used in these APHIS procedures will have the same meaning as in the CEQ NEPA Regulations. (1508.1-1508.28)

III. Agency Decisionmaking Procedures

APHIS officials shall ensure that proposals for new or changes to old projects, plans, and programs not categorically excluded from the NEPA process under the Department's regulations (7 CFR 3100) have designated major decision points. All

environmental documents will accompany proposals as they are reviewed by appropriate APHIS decisionmakers at each of the decision points. APHIS officials will assure that all alternatives considered are addressed in the documents and that all alternatives addressed in the documents are considered by the decisionmakers.

Those decision points are:

1. When proposals for new changes to old projects, plans, and programs are being considered which may cause significant adverse environmental effects;
2. Upon completion of assessments;
3. At the finding of no significant impact;
4. Before preparation of an EIS is begun;
5. Upon completion of a draft EIS;
6. Upon evaluation of comments and completion of final EIS.

The decisionmaking process will not be concluded until a record of decision is prepared and made available to the public. (1502.2)

All environmental documents, including supplements, will be made part of the Administration Actions File (APHIS Directive 131.2), which is the APHIS formal administrative record. This file will be available for public evaluation of the alternatives considered. Appendix I is a flow chart which graphically portrays the decisionmaking process.

IV. EIS Preparation

A. Requirement. The NEPA requires an EIS with every proposal for legislation or other major Federal action which significantly affects the quality of the human environment. Executive Order 12114, January 4, 1979, extends these requirements to environmental effects abroad of major Federal actions.

B. Preparation of EIS for APHIS Actions.

1. APHIS will use no categorical exclusions from the NEPA process other than those listed in the USDA regulations (7 CFR 3100.22). (1508.4)

2. Because APHIS projects, plans and programs do not lend themselves to the kind of classification that would be necessary to designate categories of actions for which EIS's will always be prepared, no such designations will be made. (1507.3)

3. APHIS officials will make an environmental assessment for legislative proposals originating in APHIS, for each proposed new action and for each significant change to ongoing projects, plans and programs. The assessment will be the basis for the Agency's determination to prepare an EIS or to publish a finding of no significant impact. In addition, APHIS officials will schedule for environmental assessments those ongoing projects or programs

which, because of their age and unchanging nature, have not been reviewed for environmental impact in the past five years. It is the Agency goal that every project or program be reviewed for environmental impact at least every five years.

4. The following criteria will be considered by APHIS officials in making the environmental assessment:

- a. Degree of environmental disturbance; both onsite and offsite should be recognized.
- b. Irreversible effects on basic resources; short-term and long-term commitments.
- c. Cumulative effects of many small actions.
- d. Chain reactions or secondary effects of interrelated activities.
- e. National, state, and local importance.
- f. Uniqueness or rareness of resources being affected.
- g. Scope of anticipated public involvement and controversy anticipated.
- h. Interaction with other Federal projects and actions of the private sector.

C. *Tiering*. A broad EIS would be prepared for repetitive program action as specified in CEQ NEPA Regulations. (1502.20, 1508.28)

D. Supplemental Statements.

1. APHIS officials will prepare supplements to an EIS if the program for which it was prepared and approved undergoes significant changes. (7 CFR 3100.28)

2. Supplemental EIS's, when required, will be prepared according to CEQ NEPA Regulations. (1502.9(c))

V. Format

APHIS officials will follow the format recommended in the CEQ NEPA Regulations (1502.10). The cover sheet will conform to the format in Appendix II (1502.11).

VI. Emergency Procedures

Where circumstances require immediate action to prevent spread of exotic or domestic animal or plant diseases or pests, and that action has significant environmental impact, the provisions of section 1506.11 of the CEQ NEPA Regulations will take effect. APHIS officials will notify the Department's Office of Environmental Quality Activities in consulting with CEQ about alternate arrangements.

VII. Public Involvement

A. APHIS officials shall inform and involve the public when (1506.6):

1. substantive changes in programs have significant adverse effects on the human environment;
2. they intend to prepare an EIS and request participation in the scoping process; (1501.7)
3. a draft EIS, final EIS, or finding of no significant impact is available; and

4. the record of decision is available. (1505.2, 1506.1)

B. APHIS officials will maintain distribution lists of interested persons (e.g., Federal, State, and local agencies, interested industry representatives, national and local organizations, and private citizens, etc.). The lists will be amended as additional interested persons are identified. Mailings to those on the distribution list will be made early and at critical stages in the NEPA process where public input is appropriate (7 CFR 3100.29). In addition, APHIS will make timely use of direct verbal contact, meetings, printed materials, news media, public notices and hearings, and any other appropriate means of increasing public participation in evaluating the environmental impact of agency actions.

C. Whenever APHIS officials inform the public in compliance with paragraph A of this section, a specific address where additional material and information may be obtained will be published in whatever informational media is used. General inquiries concerning APHIS environmental activities may be addressed to the Administrator, Animal and Plant Health Inspection Service, USDA, Washington, D.C. 20250.

VIII. Responsibilities

A. The Deputy Administrators are responsible for preparation of EIS's within their respective functional areas.

B. Interdisciplinary work groups have been established in APHIS to review all environmental assessments prepared by APHIS officials. These work groups will make recommendations to the Deputy Administrators concerning the requirements for EIS's. The groups are also responsible for monitoring programs which have been the subject of an EIS to assure that environmental safeguards and planned mitigating factors are followed. In addition, each of these groups will bring to the attention of the appropriate APHIS official any project or program which has not been formally reviewed for environmental impact during the previous five years.

C. APHIS officials conducting field operations are responsible for reporting any unusual environmental conditions to their respective regional directors. If necessary, regional directors will obtain guidance from the responsible APHIS staff officer. Except for emergency situations, the field official should report the unusual condition before taking any action.

IX. Reference Sources for EIS Preparation

Actions taken under these supplemental procedures are subject to the provisions of applicable laws and authorities. The following authorities, directives, and regulations have been published and are the principal reference sources for preparing and processing EIS's:

A. Section 102(2), National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321-4347).

B. Executive Order 11514, dated March 5, 1979, as amended by Executive Order 11541, dated July 1, 1970, and as further amended by Executive Order 11991, dated May 24, 1977.

C. Executive Order 12088, October 13, 1978, Federal Compliance with Pollution Control Standards.

D. Environmental Protection Agency Regulations on the Preparation of Environmental Impact Statements (40 CFR 6).

E. CEQ Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR 1500-1508).

F. Clean Air Act (42 U.S.C. 1857 *et seq.*).

G. Clean Water Act (33 U.S.C. 1251 *et seq.*).

H. Solid Waste Disposal Act of 1976 (42 U.S.C. 3251 *et seq.*).

I. Noise Control Act of 1972 (42 U.S.C. 4901 *et seq.*).

J. Federal Insecticide, Fungicide, and Rodenticide Act as amended by the Federal Environmental Pesticide Control Act of 1972 (7 U.S.C. 135 *et seq.*).

K. Secretary's Memorandum No. 1662, Supplement 8, June 28, 1976.

L. Secretary's Memorandum No. 1695, May 24, 1970, and Supplements.

M. Safe Drinking Act (42 U.S.C. 300f).

N. National Historic Preservation Act (16 U.S.C. 470t).

O. Executive Order 12044, "Improving Government Regulations"; Secretary's Memorandum No. 1955.

P. Endangered Species Act of 1973, as amended (16 U.S.C. 1531-1543).

Q. Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions," January 4, 1979.

This notice has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this notice should not be classified "significant" under those criteria. A Final Impact Analysis has been prepared and is available from the Office of the Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Done at Washington, D.C., this 22nd day of August 1979.

James O. Lee, Jr.,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 79-25996 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-34-M

Office of Safety and Health Management

Occupational Safety and Health Program

AGENCY: Department of Agriculture, Office of Safety and Health Management.

ACTION: Solicitation of public comment.

SUMMARY: This document seeks public comment on the Department of Agriculture's proposed Occupational Safety and Health Program.

DATES: Comments must be received by close of business October 1, 1979.

ADDRESS: Comments should be sent to: U.S. Department of Agriculture, Office of Safety and Health Management, Room 48-W, 14th and Independence Avenue, S.W., Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Julius C. Jimeno, Director, OSHM, U.S. Department of Agriculture, 14th and Independence Avenue, S.W., Washington, D.C. 20250, telephone: 202-447-8247.

SUPPLEMENTARY INFORMATION: The proposed Occupational Safety and Health Program responds to the requirements of Section 19 of the Occupational Safety and Health Act of 1970, Executive Order 11807, and 29 CFR Part 1960. A number of resource documents were reviewed prior to developing this proposed program. This resource material included: (1) Evaluations of the safety and health program conducted by the Office of Federal Agency Safety and Health Programs, Occupational Safety and Health Administration; (2) safety and health audits performed by the General Accounting Office; (3) an evaluation performed by a USDA task force appointed by the Assistant Secretary for Administration; (4) comments made by the House of Representatives Subcommittee on Health and Safety; and (5) a draft proposed new Executive Order on occupational safety and health sent by OMB to agencies for review.

A task force was established to provide guidance in developing this proposed program. The task force was composed of USDA safety and health specialists, representatives of employees, and high level management officials. Prior to finalizing this program,

it is believed that although the policies are internal in nature, comment from the private sector will be beneficial. Following public comment, the final program will be codified in Title 13 of the USDA Administrative Regulations and read as follows:

Title 13—Occupational Safety and Health Management

Chapter 1—Occupational Safety and Health

Section 1—General

11. *Purpose.* This Title contains the Occupational Safety and Health Program of the U.S. Department of Agriculture (USDA).

12. *Authority.* The authority for the USDA occupational safety and health program is contained in Section 19 of the Occupational Safety and Health Act of 1970, Executive Order 11807, and 29 CFR Part 1960.

13. *Occupational Safety and Health Act of 1970.* Section 19 of the Act contains special provisions to assure safe and healthful working conditions for Federal employees. Pursuant to Section 19, it is the responsibility of the Agency Head to establish and maintain an effective and comprehensive occupational safety and health program which is consistent with the safety and health standards promulgated by the Occupational Safety and Health Administration (OSHA) pursuant to Section 6 of the Act.

14. *Executive Order 11807.* Section 2 of Executive Order 11807 defines the responsibilities and outlines the duties of the Agency Head for Federal occupational safety and health programs, including observation of "guidelines" published by the Secretary of Labor.

15. *29 CFR Part 1960.* 29 CFR Part 1960 is the "guidelines" of the Secretary of Labor and contains the safety and health provisions which the Agency Head is expected to observe in establishing and maintaining occupational safety and health programs for Federal employees.

16. *Designated Safety and Health Official.* The Secretary of Agriculture has delegated the authority of the USDA occupational safety and health program to the Assistant Secretary for Administration (7 CFR 2.25.f) who in turn has delegated the authority for the occupational safety and health program to the Director, Office of Safety and Health Management (7 CFR 2.76). The Assistant Secretary reserved the authority to exercise final judgments in all safety and health matters, including individual cases, that involve the jurisdiction of more than one General Officer in USDA.

17. *U.S. Department of Agriculture Occupational Safety and Health Committee.* The U.S. Department of Agriculture Occupational Safety and Health Committee is established to advise the Assistant Secretary for Administration in carrying out the responsibilities of this Title.

A. The committee consists of 12 members appointed by the Secretary and includes 6 representatives of the Program Assistant Secretaries and 6 employee representatives who are full-time employees of USDA.

B. The Assistant Secretary, or a designee, serves as the Chairperson of the committee

and prescribes rules for the conduct of business as are necessary and appropriate.

C. The Director, Office of Safety and Health Management, serves as Secretariat of the committee.

18. *Explanation for use of terms agency and agency head.* Use of the term Agency Head in this section refers to the Head of an Executive Department, as defined in 5 U.S.C. 101. Use of the term Agency Head beyond section 1 of this chapter refers to the head of USDA Agencies and staff offices.

Section 2—Office of Safety and Health Management (OSHM) Responsibilities in Occupational Safety and Health Program Management

21. *Establishment of the Office of Safety and Health Management (OSHM).* Secretary's Memorandum 1940 dated March 27, 1978, established OSHM as a staff office reporting to the Assistant Secretary for Administration. The establishment of OSHM resulted in the transfer of the functions of the Safety Manager, Medical Officer, and Health Units from the Office of Personnel to OSHM.

22. *Authority.* OSHM is authorized to: A. Adopt or develop, after consultation with the Secretary of Labor, occupational safety and health standards necessary to comply with Section 19 of the OSH Act of 1970, Executive Order 11807, and 29 CFR Part 1960.

B. Grant waivers, after consultation with the Secretary of Labor, to USDA agencies for alternate safety and health standards which provide equal or greater protection to USDA employees.

C. Inspect and evaluate, without advance notice to operating units, any installation where USDA employees perform official duties to determine the status of any reported, alleged, or suspected unsafe/unhealthful working conditions and issue reports which include conclusions and recommendations for action.

D. Evaluate reported acts of discrimination or reprisal which result from an employee's participation in the activities of the Department's or Agency's safety and health program and issue reports which include conclusions and recommendations for action.

23. *Responsibilities.* OSHM provides Department-wide leadership and coordination of occupational safety and health programs for USDA by:

A. Assuring that representatives of USDA employees are consulted or negotiated with as appropriate in the activities of USDA occupational safety and health programs, including but not limited to:

1. Development of safety and health policies.

2. Development of safety and health standards.

3. Inspections and evaluations of installations.

4. Membership on safety and health committees.

B. Promulgating Department-wide policies for the uniform development and implementation of occupational safety and health programs.

C. Promulgating or adopting, in consultation with the Secretary of Labor, occupational safety and health standards

which ensure that USDA employees are provided safe and healthful working conditions.

D. Evaluating the occupational safety and health programs of USDA agencies to determine compliance with Department policies and standards and issue reports which include conclusions and recommendations for action.

E. Coordinating the delivery of specialized technical resources to Department agencies to resolve complex safety and health problems.

F. Coordinating the development and/or conduct of human resources development activities for Agency Heads, safety and health specialists/managers, and collateral duty safety and health personnel.

G. Coordinating the development of safety and health program and procedure manuals for managers, supervisors, and employees.

H. Coordinating the development and/or conduct of safety and health training programs and materials for managers, supervisors, and employees.

I. Developing and maintaining a Safety and Health Management Information System (SHMIS) for gathering, analyzing, and disseminating information and data on the causes and extent of job-related injuries, illnesses, and property damage incidents.

J. Coordinating implementation of Department-wide promotional programs generated by OSHA or developed by OSHM.

K. Providing Department-wide liaison of safety and health activities with the Department of Labor, Department of Health, Education and Welfare, Environmental Protection Agency, Department of Commerce, Department of Transportation, Office of Personnel Management, General Services Administration, and safety and health components of state and local governments and universities.

L. Reporting serious incidents as defined in para. 36B.4 to the Secretary of Labor.

Section 3—Agency Responsibilities in Occupational Safety and Health Management

31. *Purpose.* This section describes the responsibilities of Agency Officials in the establishment and implementation of occupational safety and health programs.

32. *Responsibilities of agency personnel in establishing and implementing occupational safety and health programs.* All managers and supervisors are to be assigned responsibilities in the establishment and implementation of occupational safety and health programs. Each manager and supervisor is to have safety and health responsibilities considered in his/her annual performance appraisal.

A. Agency Heads are to ensure that the requirements of this Title are implemented in agency program activities and design safety and health programs specifically to reduce the human, financial and productivity losses due to job-related injury, illness, and property damage incidents. To ensure the exercise of this responsibility, each Agency Head shall designate an Agency Safety and Health Manager with appropriate subordinate staffing to develop and manage these programs (see paragraph 34).

B. Safety and Health Managers are to develop and implement programs which are consistent with the requirements of this Title.

C. Management and supervisory officials are to be evaluated for their effectiveness in providing employees safe and healthful working conditions under their jurisdiction. Managers and supervisors are not to subject an employee to restraint, interference, coercion, discrimination, or reprisal by virtue of employee's participation in the safety and health program.

D. Employees are to conduct their job assignments in a safe and healthful manner and observe all Department and agency safety and health policies and regulations. Employees are to report any suspected unsafe/unhealthful working conditions to their supervisor for corrective action.

33. *Organization of the safety and health function.* Agency Heads are to ensure that the safety and health of their employees are a fundamental part of all program decisions. To ensure proper exercise of this responsibility, Agency Heads are to organize the safety and health function as a staff entity which has direct access to all top level agency officials. Within 60 days of final publication of this Title, Agency Heads are to submit the Director, OSHM, the organizational plan for placement of the safety and health functions at Headquarters and field locations. The plan is to identify delegations of authority for the Agency safety and health manager, assignment of functions to the safety and health staff, and the Agency organizational chart, identifying the safety and health functions from Headquarters to the field level. The submission must include the rationale and justification for the organization plan.

34. *Staffing for safety and health.* Agency Heads are to provide appropriate Headquarters and field staffing to effectively develop, implement, and evaluate their occupational safety and health programs.

A. Agencies with 1,500 or more employees are to employ a full-time qualified safety and health professional to manage the agency safety and health program. By "qualified" it is meant that he/she meets the Office of Personnel Management's qualification requirements of the Safety and Health Management series (GS-018), Safety Engineer series (GS-803), or Industrial Hygienist series (GS-690). In addition, agencies are to employ additional safety and health specialists based on the agency's mission; size; potential exposure to hazardous conditions; injury, illness, property damage experience; and workers' compensation costs.

B. Agencies with less than 1,500 employees may assign the safety and health program responsibilities to an employee on a collateral duty basis. The employee's annual performance appraisal must document the amount of time spent in safety and health duties, and the employee shall meet either the Office of Personnel Management's requirements for the Safety and Health Management series (GS-018), Safety Engineer series (GS-803), or Industrial Hygienist (GS-690) series or be provided the training in order to qualify the individual for their safety and health management responsibilities within 1 year of the appointment.

35. *Consultation with representatives of employees.* Agency Heads are to consult or negotiate as appropriate with employees and representatives of employees and provide for employee participation in the operation of the agency safety and health program.

36. *Minimum requirements for development of agency safety and health programs.* Agency safety and health programs shall be action oriented and geared to the reduction of human, financial, and productivity losses due to job-related injuries, illnesses, and property damage incidents.

A. Investigation of Injury, Illness, and Property Damage Incidents.

1. All job-related injury, illness, and property damage incidents are to be thoroughly investigated by the agency to identify causes and initiate corrective action.

2. Boards of inquiry are to be established by the agency to identify the causes of all serious incidents (see para. 36B.4 for definition of serious incidents) and to recommend corrective actions to prevent similar occurrences. The number of members and makeup of the board is to be determined by the Agency Head. A report of the findings of the board is to be sent to the Director, OSHM, within 15 days of the adjournment of the board.

3. OSHM is to be provided with a copy of the Agency's written plan for determining the expertise and depth of investigation for all types of injury, illness, and property damage occurrences.

B. Reporting of Injury, Illness, and Property Damage Incidents.

1. The AD-278, "Supervisor's Report of Accident," is to be used for the collection and summarization of information for injury, illness, and property damage incidents.

2. Agencies are to establish review and routing procedures to ensure that information collected on the AD-278 is accurate and that responsible management officials and field safety and health committees review and initiate corrective action to prevent similar occurrences. Completed AD-278's are to be sent to the processing center within 15 calendar days of the incident. Copies of the completed form are to be retained by the originating office for a period of at least 5 years beyond the calendar year of occurrence.

3. AD-278's are completed whenever: (1) a "Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation" (CA-1) is completed; (2) a "Federal Employee's Notice of Occupational Disease and Claim for Compensation" (CA-2) is completed; or (3) \$100 of property damage results from official activities of the agency. This includes accidental damage to property resulting from fires, materials handling, etc., even though no injury or illness occurred.

4. Serious incidents are to be reported immediately by telephone or telegraph to OSHM whenever there is: (1) an employee fatality; (2) hospitalization of five or more employees; and/or (3) \$100,000 or more property damage (Government or private). A followup written report shall be forwarded to OSHM within 24 hours of notice and shall include: (1) date of accident; (2) names of persons involved; (3) location of accident; (4) extent of injury or illness; (5) brief narrative

explaining how it happened; (6) type of investigation being conducted; (7) corrective actions taken; and (8) amount of property damaged. Agencies are also to report serious incidents involving non-Federal employees in the performance of agency official duties.

C. Data Analysis. Agencies are to regularly analyze data produced by the Safety and Health Management Information System (SHMIS) in order to:

1. Establish necessary management initiatives to reduce or eliminate the causes of injury, illness, or property damage incidents;
2. Determine the need for onsite safety and health inspections;
3. Establish training priorities; and
4. Allocate human and financial resources for safety and health program.

D. Safety and Health Committees.

1. Agencies are to establish a safety and health committee at the Headquarters level and include representation of employees. The committee is to advise the Agency Head in carrying out his/her responsibilities and review and evaluate the effectiveness of the agency safety and health activities. The chairperson of the committee is to submit minutes of its meetings to the Agency Head and the Director, OSHM.

2. Agencies are to establish field safety and health committees and include representation from management and employees. The field committees review safety and health inspection reports; report of findings for serious incidents; injury, illness, and property damage statistics; and safety and health management activities. The committees are to recommend preventive activities such as, but not limited to, the following:

- a. Discussing safety and health information at staff meetings and developing training activities.
- b. Developing awareness programs to reduce high injury, illness, and property damage losses.
- c. Developing safety and health policy recommendations and evaluating effectiveness of operating policies.

3. Existing interagency committees at the state and local levels (e.g. state administrative or county administrative committees) should be utilized to address safety and health issues where this approach is most practical (e.g. for collocated offices).

E. Safety and Health Promotion.

1. Agencies are to establish a variety of methods of promoting safety and health awareness to all employees. These programs ensure that employees are aware of (a) the extent and causes of occupational injury, illnesses, and property damage incidents which are occurring in their work units, (b) procedures for requesting workplace inspections and reporting suspected safety and health hazards, (c) procedures for employee involvement in activities of agency safety and health programs, and (d) agency and Department procedures for conducting inspections and reporting/investigating injury, illness, and property damage incidents.

2. Agencies that develop safety and health awards programs are to have these programs approved by the Office of Personnel as required by Department Personnel Manual Chapter 451.

3. Agencies are to post and keep posted a notice informing employees of the protections and obligations provided for in the OSHA Act of 1970, Executive Order 11807, as well as the Department and agency safety and health programs. Posters supplied by the Department of Labor may be used to accomplish this requirement. The poster is to identify, by name and title, the agency's designated safety and health official and the safety and health coordinator for that unit.

F. Safety and Health Training.

1. Managers, supervisors, and employees are to be provided education and training activities which ensure that every employee:

- a. Can demonstrate an understanding of the operation and requirements of the Department and agency's safety and health programs.
- b. Possess the skills necessary to carry out his/her responsibilities in effective management of agencies safety and health programs.

2. Collateral duty personnel and employee representatives are to be provided specialized education and training activities which ensure that they possess the skills to manage or participate in the following activities:

- a. Organizing and participating in safety and health committees.
- b. Scheduling, conducting, and documenting safety and health inspections.
- c. Conducting investigations and documenting causes of injury, illness, and property damage incidents.
- d. Developing safety and health information materials to keep employees aware of safety and health problems in their job activities.
- e. Initiating corrective action for identified safety and health hazards.
- f. Utilizing community resources for safety and health program activities.

G. Safety and Health Inspections.

1. Agencies are to conduct annual safety and health inspections of all its facilities and equipment. The frequency, depth of inspection, and technical expertise required for inspections of facilities and equipment is to be determined by the nature of the operation; potential and incidence of injury/illness; equipment and machinery used; and the potential exposure to toxic substances.

2. Agencies are to develop and submit to OSHM within 60 days of final publication of this Title a Safety and Health Inspection Plan which includes the following features:

- a. Criteria used to determine the frequency and scheduling of inspections (announced and unannounced).
- b. Technical competence and/or training of individuals who conduct inspections of high hazard operations.
- c. Participation of representatives of employees in inspection activities.
- d. Abatement procedures used to initiate corrective action in (i) agency-owned facilities, (ii) GSA-managed buildings, (iii) leased buildings and facilities, and (iv) private industry facilities.
- e. Method of documenting the results of safety and health inspections.
- f. Employees' rights to request inspection of unsafe and unhealthy working conditions.

g. Review and approval procedures of all new space and renovation projects prior to acquisition or occupancy.

h. Means to notify employees of identified safety and health hazards in their workplace.

i. Evacuating employees from facilities where imminent dangers are identified.

H. Safety and Health Standards.

1. The Department of Labor's occupational safety and health standards, as promulgated under Section 6 of the OSH Act, are the U.S. Department of Agriculture standards. These standards are published in Title 29, Chapter XVII, Parts 1910 (Occupational Safety and Health Standards); 1925 (Safety and Health Standards for Federal Service Contracts); 1926 (Safety and Health Regulations for Construction); and 1928 (Safety and Health Standards for Agriculture).

2. Agencies may request to adopt an alternate standard that provides equal or greater protection than the applicable OSHA standard. A request for a waiver from the applicable OSHA standard is to be made in writing to the Director, OSHM. The request is to include a justification for the waiver along with the agency's proposed plan to provide safety and health protection to employees that equals or exceeds the OSHA standard. The Director, OSHM, in consultation with OSHA officials, will determine if the proposed waiver provides an acceptable level of safety and health for employees.

3. Special work situations within agencies may be outside the scope of existing or future OSHA standards. In these cases, Agency Heads will develop specific agency-wide standards which are consistent with the OSH Act requirements. Proposed standards are to be submitted to the Director, OSHM, for concurrence prior to adoption by the agency. The Director, OSHM, in consultation with OSHA officials, will determine if an adequate level of safety and health for employees is provided by the standard. Whenever an approved supplemental standard is applicable to more than one agency, it will be considered for approval as a Department-wide standard.

4. Agencies that identify conflicts in application of safety and health standards are to submit a description of these conflicts to the Director, OSHM, for interpretation and resolution.

5. Agencies may adopt such emergency standards as necessary for the safety and health of employees. The Director, OSHM, shall be notified immediately of the adoption of that standard. Emergency standards adopted by OSHA or OSHM on the same subject shall replace the agency emergency standard.

I. Field Federal Safety and Health Councils.

1. Agencies are to encourage all field safety and health specialists and collateral duty safety and health officers to support the activities of their local Field Federal Safety and Health Council.

2. Agencies are to provide representatives of agency employees the opportunity to participate in the activities of the Field Federal Safety and Health Council.

37. Responsibilities of agency heads in evaluating the effectiveness of their occupational safety and health programs. Agency Heads are to evaluate the

effectiveness of their occupational safety and health programs in field locations. Agency Heads are to submit a written report of each field evaluation to OSHM within 30 days of the evaluation visit.

38. *Responsibilities of agency heads in reporting the status of their occupational safety and health programs.* Agency Heads are to report to the Director, OSHM, by February 1 of each year the status of the agency's development and implementation of each requirement in Section 3, Chapter 1, Title 13, of the USDA Administrative Regulations.

Julius C. Jimeno,

Director, Office of Safety and Health Management.

[FR Doc. 79-26761 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-72-M

Rural Electrification Administration

Cajun Electric Power Cooperative, Inc.; New Roads, La.; Proposed Loan Guarantee

Under the authority of Pub. L. 93-32 (87 Stat. 65) and in conformance with applicable agency policies and procedures as set forth in REA Bulletin 20-22 (Guarantee of Loans for Bulk Power Supply Facilities), notice is hereby given that the Administrator of REA will consider providing a guarantee supported by the full faith and credit of the United States of America for a loan in the amount of \$452,000,000 to Cajun Electric Power Cooperative, Inc., of New Roads, Louisiana. These loan funds will be used to finance the construction of a 540 MW coal-fired steam electric generating unit.

Legally organized lending agencies capable of making, holding, and servicing the loan proposed to be guaranteed may obtain information on the proposed project, including engineering and economic feasibility studies and proposed schedule for the advances to the borrower of guaranteed loan funds from Mr. James R. Smith, Manager, Cajun Electric Power Cooperative, Inc., P. O. Box 578, New Roads, Louisiana 70760.

In order to be considered, proposals must be submitted (on or before September 27, 1979) to Mr. Smith. The right is reserved to give such consideration and make such evaluation or other disposition of all proposals received as Cajun and REA deem appropriate. Prospective lenders are advised that the guaranteed financing for this project is available from the Federal Financing Bank under a standing agreement with the Rural Electrification Administration.

Copies of REA Bulletin 20-22 are available from the Director, Information Services Division, Rural Electrification

Administration, Washington, D. C. 20250.

Dated at Washington, D.C., this 20 day of August, 1979.

Robert W. Feragen,

Administrator, Rural Electrification Administration.

[FR Doc. 79-26667 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-15-M

Science and Education Administration

Committee of Nine; Meeting

In accordance with the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), the Science and Education Administration, Cooperative Research, announces the following meeting:

Name: Committee of Nine.

Dates: September 11 and 12, 1979.

Time: 8:30 a.m., both days.

Place: Conference Room, Baileys Harbor Yacht Club, Baileys Harbor, Wisconsin.

Type of Meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person listed below.

Purpose: To evaluate and recommend proposals for cooperative research on problems that concern agriculture in two or more States, and to make recommendations for allocation of regional research funds appropriated by Congress under the Hatch Act for research at the State agricultural experiment stations.

Contact Person, for Agenda and More Information: Dr. Estel H. Cobb, Recording Secretary, U.S. Department of Agriculture, Science and Education Administration, Cooperative Research, Washington, D.C. 20250, telephone: 202/447-4329.

Done at Washington, D.C., this 23rd day of August, 1979.

John D. Sullivan,

Acting Deputy Director for Cooperative Research.

[FR Doc. 79-26666 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-22-M

Soil Conservation Service

Construction Area 1 of Upper Tri-County Watershed, Arkansas; Intent Not To Prepare an Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for Construction Area 1 of the Upper Tri-County Watershed

Project in Sharp, Lawrence, and Independence Counties, Arkansas.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. M. J. Spears, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project concerns a plan to reduce flooding and provide for watershed protection within Construction Area 1 of the Upper Tri-County Watershed. This construction area encompasses a 16,077-acre subwatershed of the 95,894-acre Upper Tri-County Watershed. Planned works of improvement include three floodwater retarding structures and technical assistance for accelerated application of land treatment measures. The Upper Tri-County Watershed project was approved for operations on August 27, 1969.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment is on file and may be reviewed by interested parties at the Soil Conservation Service, 5029 Federal Building, 700 West Capitol, Little Rock, Arkansas. All inquiries should be addressed to M. J. Spears, State Conservationist, Soil Conservation Service, P.O. Box 2323, Little Rock, Arkansas 72203; 501-378-5445. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication (September 27, 1979).

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program—Public Law 83-566, 16 U.S.C. 1001-1008.)

Joseph W. Haas,

Assistant Administrator for Water Resources, Soil Conservation Service.

[FR Doc. 79-26701 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-16-M

Buffalo Creek Watershed, Ohio; Intent Not To File an Environmental Impact Statement for Deauthorization of Federal Funding

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of

1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the deauthorization of Federal funding of the Buffalo Creek Watershed, Guernsey and Noble Counties, Ohio.

The environmental assessment of this action indicates that deauthorization of Federal funding of the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Clifton A. Maguire, Acting State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this action.

Project deauthorization involves not constructing any of the structural measures which included three reservoirs, one with multipurpose uses, and 8.7 miles of channel work. The municipal water supply included in dam 1 is not crucial since the village of Sarahsville has piped water in from another source. Three hundred acres of cropland and 29 acres of woodland will not be disrupted by project construction. Two thousand and thirty-four acres of flood plain and about 400 individuals will not receive the benefits of reduced flooding. The estimated project costs would have exceeded benefits.

The notice of intent not to file an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Clifton A. Maguire, Acting State Conservationist, Soil Conservation Service, 200 North High Street, Columbus, Ohio 43215, telephone number 614-469-6932. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until 60 days after the date of this publication in the **Federal Register** (October 29, 1979).

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program—Public Law 83-566, 16 U.S.C. 1001-1008.)

Dated: August 21, 1979.

Joseph W. Haas,
*Assistant Administrator for Water Resources,
Soil Conservation Service.*

[FR Doc. 79-26702 Filed 8-27-79; 8:45 am]

BILLING CODE 3410-16-M

CIVIL AERONAUTICS BOARD

[Docket 34242]

Florida Airlines, Inc. Fitness Investigation; Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that the hearing in the above-entitled proceeding presently scheduled to be held on September 18, 1979, is hereby postponed to September 20, 1979, at 10:00 a.m. (local time) in Room 1003, Hearing Room D, Universal Building North, 1875 Connecticut Avenue NW., Washington, D.C., before the undersigned Administrative Law Judge.

For details of the issues involved in this proceeding, interested persons are referred to the Prehearing Conference Report, served on July 26, 1979, and other documents which are in the docket of this proceeding on file in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., August 22, 1979.

William H. Dapper,
Administrative Law Judge.

[FR Doc. 79-26731 Filed 8-27-79; 8:45 am]

BILLING CODE 6320-01-M

[Docket 34242]

Florida Airlines, Inc.; Fitness Investigation, Reassignment of Proceeding

This proceeding has been reassigned from Administrative Law Judge Richard J. Murphy to Administrative Law Judge William H. Dapper. Future communications should be addressed to Judge Dapper.

Dated at Washington, D.C., August 22, 1979.

Nahum Litt,
Chief Administrative Law Judge.

[FR Doc. 79-26732 Filed 8-27-79; 8:45 am]

BILLING CODE 6320-01-M

COMMISSION ON CIVIL RIGHTS

Minnesota Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a factfinding meeting of the

Minnesota Advisory Committee (SAC) of the Commission originally scheduled for September 20-21, 1979 has been changed, (FR Doc. 79-22532) on page 42750.

The meeting now will be held on September 27-28, 1979, beginning at 8:30 am and will end at 9:00 pm on September 27, 1979, and beginning at 8:30 am and will end at 5:00 pm on September 28, 1979, at the Minneapolis Main Post Office, 1st Avenue and Marquette, Minneapolis, Minnesota 55401.

Dated at Washington, D.C., August 23, 1979.

John I. Binkley,
Advisory Committee Management Officer.

[FR Doc. 79-26675 Filed 8-27-79; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

Bureau of the Census

Annual Surveys in Manufacturing Area; Correction

In FR Doc. 79-22677, at page 43032, appearing in the issue of Monday, July 23, 1979, correct pages 43032 and 43033, to read as follows:

Annual surveys proposed to be initiated or continued for the year 1979.

As Appeared

Major Group 22—TEXTILE MILL PRODUCTS
Broadwoven good finished
Narrow fabrics
Yarn Production

Should Read

Major Group 22—TEXTILE MILL PRODUCTS
Broadwoven goods finished
Narrow fabrics
Yarn production
Knit fabric production

Survey representing annual counterparts of monthly and quarterly surveys.

As Appeared

Major Group 22—TEXTILE MILL PRODUCTS
Finishing plant report—broadwoven fabrics
Consumption of wool and other fibers, and production of tops and noils
Carpet and rugs
Knit fabric production

Should Read

Major Group 22—TEXTILE MILL PRODUCTS
Broadwoven fabric (gray)
Consumption of wool and other fibers, and production of tops and noils
Carpet and rugs

As Appeared

Major Group 32—STONE, CLAY, AND GLASS
Glass containers

Refractories
Clay construction products

Should Read

Major Group 32—STONE, CLAY, AND GLASS
Glass containers
Refractories
Clay construction products
Flat glass

As Appeared

Major Group 36—ELECTRICAL MACHINERY, EQUIPMENT AND SUPPLIES
Fluorescent lamp ballasts

Should Read

Major Group 36—ELECTRICAL MACHINERY, EQUIPMENT AND SUPPLIES
Fluorescent lamp ballasts
Electric lamps

Dated: August 23, 1979.

Vincent P. Barabba,

Director, Bureau of the Census.

[FR Doc. 79-28736 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-07-M

Industry and Trade Administration

NYS Department of Health, et al.; Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, Bureau of Trade Regulation, U.S. Department of Commerce, Washington, D.C. 20230, on or before September 17, 1979.

Regulations (15 CFR 301.9) issued under the cited Act prescribe the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 A.M. and 5:00 P.M., Monday through Friday, in Room 735 at 666-11th Street N.W., Washington, D.C.

Docket number: 79-00349. Applicant: NYS Department of Health, Division of Laboratories and Research, Empire State Plaza, Albany, NY 12201. Article: MS 5074/DS55 Gas Chromatographic/Mass Spectrometer Data System and Accessories. Manufacturer: Kratos Inc., United Kingdom. Intended use of article: The article is intended to be used in a variety of projects ranging from research

and development of new methods for health related compound identification to the application of some of these methods in identifying eminent biological and environmental agents threatening the health of many residents in New York State. The capabilities of the article will support research in:

1. Developing new methods of organic extraction and concentrations in the presence of interferences such as PCB.
2. Toxicologic and metabolic studies of ingestion of various tetrachlorodioxin isomers (22 isomers of varying toxicity) by mammals.
3. Identification of other dioxin isomers with one to eight chlorines, which are now overlooked.
4. Development of new mass spectrometry techniques to increase the sensitivity and specificity of the MS5074. These will include negative ion chemical ionization, and secondary ion decomposition.
5. Detection of tetrachlorodibenzofuran which has tentatively been identified in fish in the Hudson River.
6. Analysis of N-alkyl nitrosamines in vaginal fluids using both capillary column chromatography and high resolving power.
7. Metastable ion analysis of polynucleararomatics.
8. Computer acquisition of metastable spectra and matrix identification mixtures.
9. Peptide sequencing.

Application received by Commissioner of Customs: July 13, 1979.

Docket number: 79-00350. Applicant: Southern Illinois University—Edwardsville, Edwardsville, IL 62026. Article: JNM/FX-90Q(II) High Resolution Fourier Transformation Multi-Nuclear Magnetic Resonance Spectrometer System and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article will be used in studies entitled:

1. The Structure of Metal—Chelating Glycopeptide Antibiotics (^1H , ^{13}C , ^{55}Mn)
2. The Role of Metal Ions in the Structure and Function of Plant Lectins, (^1H , ^{13}C , ^{15}N , ^{19}F , ^{31}P).
3. The Chemistry of Natural Bithienyl Acetylenes. (^1H , ^{13}C).
4. The Chemistry of Strained-Ring Heterocycles (^1H , ^{13}C , ^{19}F , ^{15}N , ^{17}O).
5. Interpretation of Host-Guest Interactions in Macrocyclic O and N Bridged Compounds (^1H , ^{13}C , ^{23}Na , ^7Li , ^{17}O , ^{15}N) which will require the determination of the molecular structure or conformational states of synthetic and natural organic molecules, metal sites of metallopolymers, and metal complexing materials will be sought from NMR data. In addition, the projects intend to seek information on the dynamics of conformational interchange processes, metal-ligand exchange rates, and metal-protein interactions, and some thermodynamic and structural information will be obtained in the course of the experimentation.

Application received by Commissioner of Customs: July 13, 1979.

Docket number: 79-00351. Applicant: University of North Dakota School of Medicine, Department of Anatomy, Grand Forks, North Dakota 58202. Article: Electron Microscope, Model JEM 100S and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The foreign article will be used for studying the ultrastructure of biological specimens to include, in part: (1) developing retina and choroid (ocular tissues), (2) brain (development, trace element deficiencies and retrograde degeneration), (3) subarachnoid space, (4) cardiac muscle, (5) tissues within regenerating limbs, (6) reproductive tract, (7) connective tissues and (8) biopsies of pathological tissues. Some experiments to be conducted involve the ultrastructural characterization of these biological specimens in normal health, under experimental conditions and during disease. The foreign article will also be used in training 12 to 16 graduate students in the basic medical sciences in the techniques of conventional transmission electron microscopy. Application received by Commissioner of Customs: July 13, 1979.

Docket number: 79-00354. Applicant: New Mexico Institute of Mining and Technology, Campus Station, Socorro, NM 87801. Article: TH 600 Fluid Inclusion Heating Stage and Control Unit. Manufacturer: Linkam Scientific Instruments, United Kingdom. Intended use of article: The foreign article will be used for microscopic study of fluid inclusions which may yield the temperature of the mineral depositing fluids, the pressure (or depth) at which deposition occurred and some knowledge of the chemistry of the depositing fluids. Fluid inclusion studies will also be used to study hydrothermal ore deposits and metamorphic rocks to determine temperature and pressure during metamorphism. The foreign article will also be used for the education of graduate students in ore deposits in their thesis research. Application received by Commissioner of Customs: July 13, 1979.

Docket number: 79-00355. Applicant: University of Texas Medical Branch, UMB 9-12970, Galveston, TX 77550. Article: LKB 2088 Ultratome V Ultramicrotome and Accessories. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The foreign article is intended to be used for the following:

- (1) Studies on *pathologic human tissues* where it is expected that *softer tissues* (such as renal or striated muscle) as well as *harder tissues* (such as collagen-rich tendon or epidermis) will be encountered frequently.
- (2) Studies on *normal and pathologic animal tissues* which include, for example,

experimental identification, localization, and modification of the surface charge present in the capillary loops of rat kidney glomeruli, and

(3) Studies on *host-parasite interfaces* which include, for example, the progressive (in time) examination of schistosome egg maturation in liver tissue of host animals. Host animals bearing infections of known age will be periodically sacrificed and areas of suspected parasite infestation located, dissected, and prepared for various assays, including electron microscopic examination.

The objectives are to contribute to basic knowledge of cell and tissue ultrastructure in normal and pathologic tissues. One objective is to reveal what, if any, diagnostic correlates exist between light and electron microscopic examination of pathologic tissues. Moreover, the study of host-parasite interactions will reveal at the ultrastructural level morphological alterations in cellular and subcellular components as a result of parasite infestation. The objective pursued in the course of these investigations is to understand early pathological alterations in tissues (as induced in animal models) and to correlate these changes with clinical alterations seen in human pathologic tissues. By understanding early alterations we may begin to formulate preventative treatments in human diseases. The foreign article will also be used in the residency training program offered by the Pathology Department and in the graduate training program of the School of Biomedical Sciences wherein the residents and graduate students will be taught techniques of electron microscopy. Application received by Commissioner of Customs: July 13, 1979.

Docket number: 79-00356. Applicant: Johns Hopkins University, Charles and 34th Streets, Baltimore, MD. 21218. Article: Electron Microscope, Model JEM-100CX (Standard Side Entry Type) and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The foreign article will be used in studies of the structures of naturally occurring cells, tissues, cell organelles, macromolecules, macromolecular assemblies, and viruses which are isolated by cell fractionation and biochemical purification to relate the molecular architecture of biological specimens to their function. The foreign article will also be used for education in a course entitled "Optical Methods in Biology" and in students' thesis research. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00357. Applicant: The Johns Hopkins University, The Good Samaritan Hospital, Section of Orthopaedics, Charles and 31st Streets, Baltimore, Md. 21218. Article:

Microtome, Model 1140 and Accessories. Manufacturer: Waldemar Jung GmbH, West Germany. Intended use of article: The foreign article will be used in research to study cellular detail and micro vasculature of bone altered by experimentally produced ischemia on dog models. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00358. Applicant: Hospital for Joint Diseases—Orthopaedic Institute, 301 East 17th Street, New York, New York 10003. Article: Electron Microscope, Model JEM-100CX (Standard Side Entry Type) and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The foreign article is intended to be used to study human cells and tissues of skeletomuscular diseases including soft tissue, cartilage, bone and other related tissues such as blood cells and bone marrow. Ultrastructural studies of benign and neoplastic conditions of the skeletomuscular system from both human and animal specimens are included. Investigation of the morphological characteristics of the musculoskeletal tissues in different diseases of humans at the ultrastructural level, as well as comparative studies of normal tissue, will be undertaken. The foreign article will also be used in education to train pathology residents, fellows, and medical students in tissue evaluation in Pathology. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00359. Applicant: The Research Foundation of SUNY, Upstate Medical Center, 117 Monroe Street, Syracuse, NY 13210. Article: Cryogenic Probe. Manufacturer: Louis Rochon, France. Intended use of article: The article is intended to be used to explore systems of the brain that are related to the temporal lobe with animals trained on tasks that are used as measures of memory and that are sensitive to temporal lobe injury. An independent variable will be the different brain structures in which reversible lesions are placed by localized cooling. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00360. Applicant: The University of Texas Health Science Center at San Antonio, Department of Anatomy, 7703 Floyd Curl Drive, San Antonio, Texas 78284. Article: Cryoultramicrotomy System, Complete; Consisting of Ultramicrotome, LKB 2088 Ultratome V, CryoKit, LKB 14800-1, Cryotools, LKB 14860-1. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to study all kinds of tissue and

cells of interest to individual investigators. The morphology and elemental content and elemental distribution of the natural substances in the tissues will also be studied. Experiments will be conducted to prepare tissue and preserve its natural morphology and elemental content in order to subsequently be able to investigate the tissue using the technique of electron probe X-ray microanalysis. In addition, the article will be used as a teaching tool for specimen preparation in a graduate course (Anatomy 60385, X-ray Microanalysis, 3 semester hours credit). Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00361. Applicant: University of Florida, College of Pharmacy, Box J-4, J. Hillis Miller Health Center, Gainesville, FL 32610. Article: JASCO Model MCD-1B electromagnet with power supply and Accessories. Manufacturer: JASCO, Japan. Intended use of article: The foreign article is intended to be used in two main areas (a) development of the magnetic circular dichroism technique as an analytical tool and (b) to understand drug macromolecule interactions. A variety of drugs alone and in conjunction with albumin, nucleic acid and other macromolecules will be examined. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00362. Applicant: University of California—Lawrence Livermore Laboratory, P.O. Box 5012, Livermore, CA 94550. Article: Imacon Model 790 Streaking and Framing Camera with extra large S-20 Photocathode and Accessories. Manufacturer: John Hadland, United Kingdom. Intended use of article: The article is intended to be used for interferometric measurements of free surface velocity of shocked surfaces, fast multiframe photography of rapid events studied in surface fluff ejection, and high-speed intensified flash X-ray diagnostics. Experiments will be conducted to measure the thermodynamic properties of materials under shock-loading conditions, and to measure very high time resolution velocity histories and surface qualities under high magnification. In addition, the article will be used to understand more fully the thermodynamic properties of matter at high pressure and temperature. Application received by Commissioner of Customs: July 27, 1979.

Docket number: 79-00363. Applicant: University of Delaware, Evans Hall, Room 229, Newark, Delaware 19711. Article: Electron Microscope, Model EM 400 HTG and Accessories.

Manufacturer: Philips Electronics Instruments NVD, The Netherlands. Intended use of article: The article is intended to be used for studies of a wide variety of metals, ceramics, polymers and marine organisms. All of the experiments to be conducted can be classified into one or more of the following types:

- (1) Production of images and analyses of the internal or surface defect structure of metals, ceramics, and polymers.
- (2) Normal and micro electron diffraction analyses of the constituents of metallic alloys, ceramics and polymers.
- (3) Examination and photographic recording of tissue sections from marine organisms, both normal and experimentally altered.
- (4) Microanalysis of constituents of metallic alloys, ceramics, polymers, and shells from marine organisms.

The article will also be used for educational purposes in the courses Metallurgy 302 Material Science for Engineers, Metallurgy 401 Structure of Materials, and Metallurgy 801 Diffraction of Radiation by Matter. Application received by Commissioner of Customs: July 27, 1979.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26886 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

University of Houston; Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 79-00216. Applicant: University of Houston, 4800 Calhoun, Houston, TX 77004. Article: 12kW RU-200 Constant Potential Rotating Anode X-Ray Generator and Accessories. Manufacturer: Rigaku Corp., Japan. Intended use of article: the article is intended to be used for the study of atomic arrangements in metals, semiconductors and insulators in order to understand the relation of structure to properties. The article provides a very high intensity source of x-rays incident upon weakly scattering materials. The article will also be used for individual

graduate instruction in x-ray methods. Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides a high power (12 kilowatts) high intensity source. The National Bureau of Standards advises in its memorandum dated July 24, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26887 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

DHEW/NIH—National Cancer Institute; Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5:00 p.m. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 79-00217. Applicant: Dept. of Health, Education, and Welfare—National Institutes of Health, National Cancer Institute, Division of Cancer Biology and Diagnosis, Building 31, Room 3A-05, Bethesda, Maryland 20014. Article: Accessories for Small Animal Irradiator consisting of Gammacell-40 Sample Cavity Collimator, Set of 3 Attenuators and Sample Drawer Tray. Manufacturer: Atomic Energy of Canada Ltd., Canada. Intended use of article: the article is intended to be used for investigation of immunologic functions of various types from the administration of relatively low doses (200-300 rads) which permits the

transplantation of foreign neoplasms to lethal doses in the 800-900 rad range followed by the transplantation of hematopoietic cells. Since the hematopoietic system is relatively sensitive to ionizing irradiation, animals may be rendered deficient in certain types of cells by exposure to lethal irradiation and replacement of only the desired hematopoietic cell types, e.g., immunologists study various functions of the immune systems by producing T-cell or B-cell different animals. Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The application relates to accessories for an instrument that had been previously imported for the use of the applicant institution. The article is being furnished by the manufacturer which produced the instrument with which the article is intended to be used and is pertinent to the applicant's purposes. The National Bureau of Standards (NBS) advises in its memorandum dated July 26, 1979 that it knows of no domestic instrument of equivalent scientific value to the article for its intended uses. The Department of Commerce knows of no other similar accessories being manufactured in the United States, which are interchangeable with or can be readily adapted to the instrument with which the foreign article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26888 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

Louisiana State University; Application for Duty Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket No. 79-00050. Applicant: Louisiana State University, Institute for Environmental Studies, 42 Atkinson Hall, Baton Rouge, LA 70803. Article:

Triaxial Equipment, Oedometer with swelling attachment, Electric unconfined apparatus, and Lab. Penetrometer. Manufacturer: Geonor, Norway. Intended use of article: The foreign article is intended to be used in the investigation of geotechnical parameters such as density, residual stress and stress history, existence of discontinuities, temperature, time etc. requiring drained or undrained triaxial, direct shear, and consolidation tests for in situ methods evaluation on borings, standard penetration, core penetration, vane shear and pressuremeter to investigate the utility of Gulf Coast Salt Domes for the storage or disposal of radioactive wastes.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides a combination of swell potential capability, self-recording, penetrometer capability and slow testing speeds (from 2 to 6 hours per strain rate test and up to 8 hours per shearing test). The National Bureau of Standards advises in its memorandum dated June 15, 1979 that (1) combination of the capabilities of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26689 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket No.: 79-00223. Applicant: National Radio Astronomy Observatory, Associated Universities, Inc., 2010 N. Forbes Blvd., Suite 100, Tucson, AZ 85705. Article: Repair of Klystron Model VRB2113A30 and Accessories. Manufacturer: Varian Associates of Canada Ltd., Canada. Intended use of article: The article is intended to be used as a phase-locked local oscillator in a millimeter wave radio astronomy receiver. The receiver is used in conjunction with a microwave antenna to measure the intensity, polarization, frequency and direction of cosmic radiation.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides a frequency in the range between 80-110 gigahertz. The National Bureau of Standards (NBS) advises in its memorandum dated July 25, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26690 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket No. 79-00162. Applicant: National Aeronautics and Space Administration, Langley Research Center, Mail Stop 267, Hampton, Virginia 23655. Article: Air to Water Cross Flow Heat Exchanger. Manufacturer: GEA Luftkühlgesellschaft Happel GmbH and Co., West Germany. Intended use of article: The article is intended to be used in the national Transonic Facility (NTF) for the study of High Reynolds Number Aerodynamic phenomena as related to defense and commercial aircraft.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides a low turbulence level of 2.6 percent in existing gas (dry air or nitrogen) using its elliptically shaped tubes. The National Bureau of Standards advises in its memorandum dated July 11, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-26691 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-25-M

National Radio Astronomy Observatory—Tucson; Application for Duty Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

National Aeronautics and Space Administration; Application for Duty Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

National Oceanic and Atmospheric Administration; Modification of Marine Mammals Permit

Notice is hereby given that, pursuant to the provisions of Sections 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Public Display Permit No. 227 issued to Mystic Marinelife Aquarium on March 28, 1978, is modified in the following manner:

Section B is modified by deleting Section B-8 and substituting therefor the following: "8. This Permit is valid with respect to the taking authorized herein until December 31, 1981."

This modification is effective on the date of publication of this Notice in the Federal Register.

The permit, as modified, and documentation pertaining to the modification is available for review in the following offices:

Assistant Administrator for Fisheries,
National Marine Fisheries Service, 3300
Whitehaven Street, NW., Washington, D.C.;
Regional Director, National Marine Fisheries
Service, Northeast Region, Federal
Building, 14 Elm Street, Gloucester,
Massachusetts 01930;

Regional Director, National Marine Fisheries
Service, Northwest Region, 1700 Westlake
Avenue North, Seattle, Washington 98109;
and

Regional Director, National Marine Fisheries
Service, Alaska Region, P.O. Box 1668,
Juneau, Alaska 99802.

Dated: August 21, 1979.

Winfred H. Meibohm,

Associate Director, National Marine
Fisheries Service.

[FR Doc. 79-20692 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-22-M

Correction of Notice of Public Meeting

AGENCY: National Marine Fisheries
Service, NOAA.

SUMMARY: The Federal Register notices of August 17, 1979, found on pages 48313-48314, announcing public meetings on the Mollusk Fishery Management Plan and Deep-Water Reef Fishes Fishery Management Plan should be amended to reflect that they are being conducted as "scoping meetings" under NEPA and satisfy the Notice of Intent to Prepare Environmental Impact Statements. Work plans, as indicated, will be prepared as a result of the scoping meeting.

EFFECTIVE DATE: This correction is effective August 23, 1979.

FOR FURTHER INFORMATION CONTACT:
Caribbean Fishery Management
Council, Suite 1108, Banco de Ponce
Building, Hato Rey, Puerto Rico 00918,
Telephone: (809) 753-4926.

Signed at Washington, D.C., this 23rd day
of August 1979.

Winfred H. Meibohm,

Executive Director, National Marine
Fisheries Service.

[FR Doc. 79-26734 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council's Groundfish Advisory Subpanel; Amended Meeting Notice

AGENCY: National Marine Fisheries
Service, NOAA.

SUMMARY: The Pacific Fishery
Management Council, established by
Section 302 of the Fishery Conservation
and Management Act of 1976 (Public
Law 94-265), has established a
Groundfish Advisory Subpanel (AP)
which has changed its meeting location
(FR Vol. 44, No. 163, dated August 21,
1979).

ADDRESS: The AP will meet at the
Cosmopolitan Motor Hotel, 1030 N.E.
Union, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT:
Pacific Fishery Management Council,
526 S.W. Mill Street, Second Floor,
Portland, Oregon 97201, Telephone: (503)
221-6352.

Dated: August 22, 1979.

Winfred H. Meibohm,

Executive Director, National Marine
Fisheries Service.

[FR Doc. 79-26733 Filed 8-27-79; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF DEFENSE

Department of the Army

Chief of Engineers Environmental Advisory Board; Open Meeting

Pursuant to Section 10(a)(2) of the
Federal Advisory Committee Act (Pub.
L. 92-463), notice is hereby given that
the next meeting of the Environmental
Advisory Board (EAB) of the Chief of
Engineers will be held September 19-20,
1979 in the Commonwealth Room,
(Center) of the Olde Colony Motor
Lodge at the corner of North
Washington and First Streets,
Alexandria, Virginia 22313. All 19-20
September sessions of the meeting are
open to the public. Time and subjects of
each session follow:

P.M. Session, 19 September

1330-1350 hours—Opening remarks.
1350-1420 hours—Review of corps plan
formulation process.
1420-1435 hours—Discussion.
1435-1535 hours—The integration of
environmental considerations in the plan
formulation and decisionmaking process.
1550-1630 hours—Discussion.
1630-1645 hours—Summary of discussion.
1645 hours—Meeting adjourned.

A.M. Session, 20 September

0830 hours—Meeting reconvenes.
0830-1130 hours—Previous day's discussion
continued.

P.M. Session

1300-1500 hours—Workshop to draft
conclusions and recommendations.
1515-1600 hours—Workshop to scope future
meetings
1600 hours—Meeting adjourns.

Seating in the meeting room is limited
to approximately 20 persons. Written
statements, to be made part of the
minutes, may be submitted prior to, or
up to 10 days following, the meeting.
Persons planning to attend or desiring
further information should contact LTC
George F. Boone, Assistant Director of
Civil Works, Environmental Programs,
Office of the Chief of Engineers,
telephone 202 272-0103.

By authority of the Secretary of the Army.

Dated: August 22, 1979.

George A. Bailey,

Colonel, U.S. Army, Director, Administrative
Management, TAGCEN.

[FR Doc. 79-26643 Filed 8-27-79; 8:45 am]

BILLING CODE 3710-08-M

Coastal Engineering Research Board; Open Meeting

Pursuant to section 10(a) (2) of the
Federal Advisory Committee Act (Pub.
L. 92-463), notice is hereby given of a
meeting of the Coastal Engineering
Research Board to be held on 25-27
September 1979.

The meeting will be held in the
President's Room, University Towers
Hotel, 4507 Brooklyn, NE., Seattle,
Washington, from 0800 hours to 1630
hours on 25 September 1979 and from
0800 hours to 1200 hours on 27
September 1979. The entire day of 26
September will be devoted to an aerial
inspection of various projects in the
North Pacific Division.

The 25 September session will be
devoted to a report on action items from
previous meeting; Status Report on the
Field Research Facility, Duck, N.C.;
Wave Data Collection Program on the
West Coast; Navigation Channel Design;
the Danish Hydraulic Institute
Agreement; presentations on projects in
the North Pacific Division; and North
Pacific Division Research Needs.

The 27 September session will be
devoted to CERB discussion of the field
inspection trip; CERC's FY 80, 81, and 82
Budget; the Field Monitoring Program;
the West Coast Ecological Program;
Status of Civil Works; and CERB
recommendations.

Participation by the public is
scheduled for 0810 to 0840 hours on 27
September. The meeting will be open to
the public subject to the following
limitations:

a. As the seating capacity of the
conference room is limited, it is desired

that advance notice of intent to attend be provided. This will assure adequate and appropriate arrangements for all attendants.

b. Written statements, to be made a part of the minutes, may be submitted prior to, or up to 30 days following the meeting, but oral participation by the public is limited because of the time schedule. Inquiries may be addressed to Colonel Ted E. Bishop, Executive Secretary, U.S. Army Coastal Engineering Research Board, Kingman Building, Fort Belvoir, Virginia 22060, telephone (202) 325-7000.

By Authority of the Secretary of the Army.

Dated: August 23, 1979.

George A. Bailey,

Colonel, U.S. Army, Director, Administrative Management, TAGCEN.

[FR Doc. 79-26644 Filed 8-27-79; 8:45 am]

BILLING CODE 3710-08-M

Military Traffic Management Command

Military Personal Property Symposium; Open Meeting

Announcement is made of a meeting of the Military Personal Property Symposium. This meeting will be held on 27 September 1979 at the Ramada Inn, I-395 and Seminary Road East, Alexandria, VA, and will convene at 0900 hours and adjourn at approximately 1500 hours.

PROPOSED AGENDA: The purpose of the Symposium is to provide an open discussion and free exchange of ideas with the public on procedural changes to the Personal Property Traffic Management Regulation (DOD 4500.34-R), and the handling of other matters of mutual interest relating to the movement and/or storage of household goods and unaccompanied baggage, as well as proposed changes and innovations in the Department of Defense Personal Property Movement and Storage Program.

All interested persons desiring to submit topics to be discussed should submit them in writing to the Commander, Military Traffic Management Command, ATTN: MT-PPM, Washington, DC 20315. Topics to be discussed should be received on or before 20 September 1979.

Dated: August 23, 1979.

John J. Durant,

Colonel, GS, Director of Personal Property.

[FR Doc. 79-26642 Filed 8-27-79; 8:45 am]

BILLING CODE 3710-08-M

Corps of Engineers

Intent to Prepare a Draft Environmental Impact Statement (DEIS) for Proposed Flood Control and Related Water Resource Problems as Part of the Sacramento-San Joaquin Delta Investigation in Alameda, Contra Costa, Sacramento, San Joaquin, Solano, and Yolo Counties, California.

AGENCY: U.S. Army Corps of Engineers, Department of Defense.

ACTION: Notice of Intent to prepare a draft environmental impact statement (DEIS).

SUMMARY: 1. *Proposed Action.*—At the request of the State of California and in response to resolutions of the Congress of the United States, the Corps of Engineers and the California Department of Water Resources are jointly investigating the feasibility of providing flood control, recreation facilities, and water quality improvement in the Sacramento-San Joaquin River Delta.

2. *Alternatives.*—Alternatives being considered include: no action, non-structural measures, and structural measures. The structural measures consist of: Rehabilitation of individual island levees, construction of master levees (polders), construction of downstream barriers, and construction of upstream dams. Each structural measure is being further evaluated at three levels of flood protection and two levels of levee freeboard. Three levels of recreation development are being evaluated for each flood control plan.

3. *Scoping of the DEIS.*—All interested parties are being invited to participate in a public meeting and scoping conference to be held at 7:30 p.m. on August 30, 1979 in the South Hall, Civic Memorial Auditorium, Civic Center, Fremont and Center Streets, Stockton, California. The purpose of the meeting is to present the alternatives under investigation and to identify significant environmental concerns to be presented in detail in the environmental impact statement and less significant issues to be presented in less detail.

4. *Estimated Date of DEIS.*—A DEIS is expected to be circulated for public review in August 1980.

ADDRESS: Questions about the proposed action and DEIS can be answered by Mr. Ray Williams, Planning Engineer, Sacramento District, Corps of Engineers, 650 Capitol Mall, Sacramento, CA 95814, telephone (916) 440-3429 (FTS-448-3429).

Dated: August 16, 1979.

Paul F. Kavanaugh,

Colonel, CE District Engineer.

[FR Doc. 79-26686 Filed 8-27-79; 8:45 am]

BILLING CODE 3710-GH-M

Office of the Secretary

Per Diem, Travel and Transportation Allowance Committee

AGENCY: Per Diem, Travel and Transportation Allowance Committee, DoD.

ACTION: Publication of Changes in Per Diem Rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 88. This bulletin lists changes in per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Canal Zone, and possessions of the United States. Bulletin Number 88 is being published in the Federal Register to assure that travelers are paid per diem at the most current rates.

EFFECTIVE DATE: August 21, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick W. Weiser, 325-9330.

SUPPLEMENTARY INFORMATION: This document gives notice of changes in per diem rates prescribed by the Per Diem, Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. Distribution of Civilian Per Diem Bulletins by mail was discontinued effective June 1, 1979. Per Diem Bulletins published periodically in the Federal Register now constitute the only notification of changes in per diem rates to agencies and establishments outside the Department of Defense.

The text of the Bulletin follows:

Civilian Personnel Per Diem Bulletin Number 88

To the Heads of Executive Departments and Establishments

SUBJECT: Table of Maximum Per Diem Rates in Lieu of Subsistence for United States Government Civilian Officers and Employees for Official Travel in Alaska, Hawaii, the Commonwealth of Puerto Rico, the Canal Zone, and Possessions of the United States

1. This bulletin is issued in accordance with Memorandum for Heads of Executive Departments and Establishments from the Deputy Secretary of Defense dated August 17, 1966, SUBJECT: Executive Order 11294, August 4, 1966, "Delegating Certain Authority of the President to Establish

Maximum Per Diem Rates for Government Civilian Personnel in Travel Status" in which this Committee is directed to exercise the authority of the President (5 U.S.C. 5702(a)(2)) delegated to the Secretary of Defense for Alaska, Hawaii, the Commonwealth of Puerto Rico, the Canal Zone, and possessions of the United States. When appropriate and in accordance with regulations issued by competent authority, lesser rates may be prescribed.

2. The maximum per diem rates shown in the following table are continued from the preceding Bulletin Number 87 except in the case identified by an asterisk which rate is effective on the date of this Bulletin. The date of this Bulletin shall be the date the last signature is affixed hereto.

3. Each Department or Establishment subject to these rates shall take appropriate action to disseminate the contents of this Bulletin to the appropriate headquarters and field agencies affected thereby.

4. The maximum per diem rates referred to in this Bulletin are:

Locality	Maximum rate
Alaska:	
Adak ¹	\$9.65
Anchorage	62.00
Annette	61.00
Barrow	94.00
Bethel	84.00
College	60.00
Cordova	76.00
Deadhorse	110.00
Delta Junction	59.00
* Dillingham	83.00
Dutch Harbor	82.00
Eielson AFB	60.00
Elmendorf	62.00
Fairbanks	60.00
Ft. Greely	59.00
Ft. Richardson	62.00
Ft. Wainwright	60.00
Galena	52.00
Juneau	60.00
Ketchikan	61.00
King Salmon	62.00
Kodiak	68.00
Kotzebue	91.00
Murphy Dome	60.00
Noatak	91.00
Nome	90.00
Noorvik	91.00
Petersburg	61.00
Shemya AFB ¹	11.00
Shungnak	91.00
Sitka-Mt. Edgecombe	61.00
Skagway	61.00
Spruce Cape	68.00
Tanana	90.00
Valdez	70.00
Wainwright	79.00
Wrangell	61.00
Other	62.00
American Samoa	54.00
Canal Zone	50.00
Guam, M.I.	54.00
Hawaii:	
Hawaii	59.00
Kauai	55.00
Mau	54.00
Molokai	54.00
Oahu	70.00
Other	54.00
Johnston Atoll	15.00
Midway Islands ¹	9.65

Locality	Maximum rate
Puerto Rico:	
Aguadilla (Incl. CG Air Station Borinquen)	60.00
Bayamon:	
12-16-5-15	66.00
5-16-12-15	52.00
Dorado	54.00
Fajardo:	
12-16-5-15	66.00
5-16-12-15	52.00
Ft. Buchanan (Incl. GSA Service Center, Guaynabo):	
12-16-5-15	66.00
5-16-12-15	52.00
Mayaguez	60.00
Ponce (Incl. Ft. Allen NCS)	58.00
Roosevelt Roads:	
12-16-5-15	66.00
5-16-12-15	52.00
Sabana Seca:	
12-16-5-15	66.00
5-16-12-15	52.00
San Juan (Incl. San Juan Coast Guard Units):	
12-16-5-15	66.00
5-16-12-15	52.00
Other	52.00
Virgin Islands of U.S.:	
12-1-4-30	66.00
5-1-11-30	54.00
Wake Island ¹	17.00
Other Localities	15.00

¹ Commercial facilities are not available. This per diem rate covers charges for meals in available facilities plus an additional allowance for incidental expenses and will be increased by the amount paid for Government quarters by the traveler.

² Commercial facilities are not available. Only Government-owned and contractor operated quarters and mess are available at this locality. This per diem rate is the amount necessary to defray the cost of lodging, meal, and incidental expenses.

Dated: August 23, 1979.

H. E. Lofdahl,
Director, Correspondence & Directives,
Washington Headquarters Services,
Department of Defense.

[FR Doc. 79-26711 Filed 8-27-79; 8:45 am]

BILLING CODE 3810-70-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

Receipt of Petitions for Temporary Public Interest Exemptions for Use of Natural Gas by Existing Powerplants Under the Powerplant and Industrial Fuel Use Act of 1978 and Proposed Order Granting the Petitions for Temporary Exemptions

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of Petitions and Proposed Orders.

SUMMARY: A number of petitions have been received and filed with the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) for temporary public interest exemptions for the use of natural gas as a primary energy source. Such exemptions are authorized by Section 311(e) of the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 et seq., November 9, 1978, (FUA or the Act). The owners/operators of the powerplants have provided the following information.

Petitioner's name/generating station	Unit identification	Maximum quantity of oil displaced (thousands of barrels)/type of oil displaced (distillate/residual)	Maximum Quantity of coal displaced (tons)
City of Tallahassee:			
(Purdum)	GT-1	8 Distillate	0
	GT-2		
(Hopkins)	GT-1	9 Distillate	0
	GT-2		
Louisiana Power & Light:			
(Sterlington)	CC-7	4 Distillate	0
Mississippi Power Co:			
(Sweat)	CT-A	22 Distillate	0
(Watson)	CT-A	22 Distillate	0
Omaha Public Power District:			
(Sarpy County)	CT-1	98 Distillate	0
	CT-2		
(Jones Street)	#11	64 Distillate	0
	#12		
Power Authority of the State of New York:			
(Astoria)	#6	650 Residual	0
San Diego Gas & Electric Company:			
(Encina)	#1	4,343 Residual	0
	#2		
	#3		
	#4		
	CT-1	5 Residual	0
(El Cajon)	CT-1	7 Distillate	0
(Miramar)	GT-1A-01	21 Distillate	0
	GT-1B-02		
(Silver Gate)	#1	233 Distillate	0
	#2		
	#3		
	#4		
San Diego Gas & Electric Company:			
(Kearny)	GT-1A-01	53 Distillate	0
	GT-2A-02		
	GT-2B-03		
	GT-2C-04		
	GT-2D-05		
	GT-3A-06		
	GT-3B-07		
	GT-3C-08		
	GT-3D-09		

Petitioner's name/generating station	Unit identification	Maximum quantity of oil displaced (thousands of barrels)/type of oil displaced (distillate/residual)		Maximum Quantity of coal displaced (tons)
(South Bay).....	#1	5,444	Residual	0
	#2			
	#3			
	#4			
(Station B).....	#21	83	Distillate	0
	#23			
	#24			
	#25			
	#26			
	#27			
	#28			
	#31			
	#32			
	#33			
South Carolina Public Service Authority:				
(Myrtle Beach).....	#2	6	Distillate	0
Illinois Power Company:				
(Stallings).....	GT-1	35	Distillate	0
	GT-2			
	GT-3			
	GT-4			
(Oglesby).....	GT-1	25	Distillate	0
	GT-2			
	GT-3			
	GT-4			
Lafayette Utilities System:				
(Doc Bonin).....	#1	1,103	Distillate	0
	#2			
(Rodemacher).....	#1	101	Distillate	0
	#2			
	#3			
	#4			
Los Angeles Department of Water and Power:				
(Scattergood).....	#1	186	Residual	0
	#2			
(Haynes).....	#1	35	Residual	0
	#2			
	#3			
	#4			
	#5			
	#6			
Iowa Public Service Company:				
(Kirk).....	#1	31	Distillate	0
	#2			
	#4			
	#5			
	#6			
(Maynard).....	#12	4	Distillate	0
(Electriform).....	#1	93	Distillate	0
	#2			
	#3			
(Parr).....	CT-1	76	Distillate	0
	CT-2			
Georgia Power Co:				
(McManus).....	CT-3A	165	Distillate	0
	CT-3B			
	CT-3C			
City of Grand Island:				
(Burdick).....	CT-1	1	Distillate	0
Applied Energy, Inc:				
(North Island).....	CT-2	124	Distillate	0
Shelby Municipal Electric:				
(Shelby Municipal).....	#1	336	Distillate	0
	#2			
	#3			
	#4			
Springfield Municipal Utilities:				
(Springfield Municipal).....	#1	.05	Distillate	0
	#4			
	#5			
Carolina Power & Light Company:				
(H.B. Robinson).....	#1	43	Distillate	0
	CT-1			
Cambridge Electric Light Company:				
(Kendall Square).....	#1	268	Residual	0
	#2			
	#3			
(Blackstone Street).....	#1	131	Residual	0
	#3			
	#4			
Arizona Electric Power Company:				
(Apache).....	CT-1	294	Distillate	0
	CT-2			
	CT-3			
Detroit Edison Company:				
(Clemens Creek).....	#8	28	Distillate	0
	#9			
	#10			
	#12			
	#13			
	#14			
(Beacon).....	#1	17	Distillate	0
	#2			
(St. Clair).....	CT-11	19	Distillate	0

FUA became effective on May 8, 1979. FUA prohibits the use of natural gas as a primary energy source in certain existing powerplants and also authorizes an exemptions procedure in regard to that and other prohibitions.

ERA intends to issue proposed orders which would grant temporary public interest exemptions to all of the petitioners enumerated above. These proposed orders would grant a temporary exemption from the prohibition against natural gas use, contained in Section 301(a)(2) and (3) of FUA, to the subject powerplants. Those proposed orders to grant temporary public interest exemptions are issued under the authority of Section 311(e) of FUA and 10 CFR 508, published by ERA on April 9, 1979, (44 FR 21230).

ERA is publishing this notice of petitions filed and its proposed order to grant these exemptions, to invite interested persons to submit written comments pursuant to the requirements of FUA. In addition, any interested person may request that a public hearing be convened in regard to these petitions under the provisions of Section 701(d) of FUA.

DATES: Written comments relating to these petitions and the proposed order are due on or before October 10, 1979. Requests for a public hearing are also due on or before October 10, 1979.

ADDRESSES: Requests for a public hearing and/or 10 copies of written comments shall be submitted to: Department of Energy, Case Control Unit, Box 4629, Room 2313, 2000 M Street, NW., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

William L. Webb (Office of Public Information), Economic Regulatory Administration, Department of Energy, Room B-110, 2000 M Street, NW., Washington, D.C. 20461, (202) 634-2170.
Elmer Lee (Office of Fuels Conversion), Economic Regulatory Administration, Department of Energy, Room 7219-F, 2000 M Street, NW., Washington, D.C. 20461, (202) 254-5436.

Robert L. Davies (Office of Fuels Conversion), Economic Regulatory Administration, Department of Energy, Room 3128, 2000 M Street, NW., Washington, D.C. 20461, (202) 254-7442.

James H. Heffernan (Office of General Counsel), Department of Energy, Room 7134, 12th & Pennsylvania Avenue, NW., Washington, D.C. 20461, (202) 633-8820.

SUPPLEMENTARY INFORMATION: On April 9, 1979, ERA issued a final rule implementing the authority granted to DOE by Section 311(e) of FUA. This final rule, set forth in 10 CFR Part 508, establishes the policy ERA has adopted in implementing its authority under

Section 311(e) of FUA and the eligibility criteria, which petitioners for the temporary exemption must demonstrate. This temporary exemption will allow certain existing electric powerplants to use natural gas as a primary energy source in excess of the amounts which are mandated by Section 301(a)(2) and (3) of FUA.

The use of natural gas, permitted under these temporary exemptions, will allow existing electric powerplants to displace distillate and residual fuel oils as their primary energy source.

This expanded use of natural gas in these powerplants will be a significant step toward reducing our short term oil consumption and will help the United States in meeting its goals to reduce its demand for imported oil, protect the Nation from the effects of any oil

shortages, and will serve to cushion the impact of increasing world oil prices.

The above listed owners/operators have filed petitions with ERA to request a temporary public interest exemption for their existing electric powerplants. ERA has reviewed their petitions and has found that the powerplants meet the eligibility criteria established in Part 508.2 of the final rule (44 FR 21230).

ERA, intends in its proposed order, to grant temporary public interest exemptions for the above listed powerplants.

This is not the final notice of petitions and proposed orders under the special rule. ERA will continue to comply with the requirements of Section 701(c) of FUA and will publish further notices as petitions are received.

Issued in Washington, D.C. on August 21, 1979.

Robert L. Davies,

Acting Assistant Administrator, Office of Fuels Conversion, Economic Regulatory Administration.

[FR Doc. 79-26672 Filed 8-27-79; 8:45 am]

BILLING CODE 6450-01-M

Proposed Order Granting Special Temporary Public Interest Exemptions

The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby sets forth its Order proposing to grant a special temporary public interest exemption from the prohibitions of Section 301(a)(2) and (3) of the Powerplant and Industrial Fuel Use Act of 1978 (FUA or the Act), 42 U.S.C. 8301 *et seq.*, pursuant to Section 311(e) of FUA, 10 CFR 501.68, and 10 CFR 508, to the following powerplant(s):

Case control number	Petitioner's name	Generating station	Unit ident.	Location
52875-0688-21-41, 52875-0688-22-41	City of Tallahassee	Purdom	GT-1 GT-2	St. Marks, Florida
52875-0689-21-41, 52875-0689-22-41		Hopkins	GT-1 GT-2	Tallahassee, Florida
51894-1404-57-41	Louisiana Power & Light	Sterlington	CC-7	Sterlington, Louisiana
51888-2048-21-41	Mississippi Power Company	Sweatt	CT-A	Meridian, Mississippi
51888-2049-21-41		Watson	CT-A	Gulfport, Mississippi
52172-2292-21-41, 52172-2292-22-41	Omaha Public Power District	Sarpy County	CT-1 CT-2	Omaha, Nebraska
52172-2290-11-41, 52172-2290-12-41		Jones Street	#11 #12	Omaha, Nebraska
52375-9098-06-41	Power Authority of the State of New York	Astoria	#6	Astoria, New York
52570-0302-01-41, 52570-0302-02-41, 52570-0302-03-41, 52570-0302-04-41, 52570-0302-21-41	San Diego Gas & Electric Company	Encina	#1 #2 #3 #4 CT-1	Carlsbad, California
52570-0301-21-41		El Cajon	CT-1A	El Cajon, California
52570-0305-21-41, 52570-0305-22-41		Miramar	GT-1A-01 GT-1B-02	San Diego, California
52570-0309-01-41, 52570-0309-02-41, 52570-0309-03-41, 52570-0309-04-41		Silver Gate	#1 #2 #3 #4	San Diego, California
52570-0303-21-41, 52570-0303-22-41, 52570-0303-23-41, 52570-0303-24-41, 52570-0303-25-41, 52570-0303-26-41, 52570-0303-27-41, 52570-0303-28-41, 52570-0303-29-41		Kearny	GT-1A-01 GT-2A-02 GT-2B-03 GT-2C-04 GT-2D-05 GT-3A-06 GT-3B-07 GT-3C-08 GT-3D-09	San Diego, California
52570-0310-01-41, 52570-0310-02-41, 52570-0310-03-41, 52570-0310-04-41		South Bay	#1 #2 #3 #4	Chula Vista, California
52570-0311-01-41, 52570-0311-03-41, 52570-0311-04-41, 52570-0311-05-41, 52570-0311-06-41, 52570-0311-07-41, 52570-0311-08-41, 52570-0311-11-41, 52570-0311-12-41, 52570-0311-13-41		Station B	#21 #23 #24 #25 #26 #27 #28 #31 #32 #33	San Diego, California
52693-3320-02-41	South Carolina Public Service Authority	Myrtle Beach	#2	Myrtle Beach, South Carolina
52385-0895-21-41, 52385-0895-22-41, 52385-0895-23-41, 52385-0895-24-41	Illinois Power Company	Stallings	GT-1 GT-2 GT-3 GT-4	Stallings, Illinois
52385-0894-21-41, 52385-0894-22-41, 52385-0894-23-41, 52385-0894-24-41		Oglesby	GT-1 GT-2 GT-3 GT-4	Oglesby, Illinois
51549-1443-01-41, 51549-1443-02-41	Lafayette Utilities System	Doc Bonin	#1 #2	Lafayette, Louisiana

Case control number	Petitioner's name	Generating station	Unit ident.	Location
51549-1445-01-41, 51549-1445-02-41, 51549-1445-03-41, 51549-1445-04-41.		Rodemacher	#1 #2 #3 #4	Lafayette, Louisiana
51691-0404-01-41, 51691-0404-02-41	Los Angeles Department of Water & Power	Scattergood	#1 #2	Playa Del Rey, California
51691-0400-01-41, 51691-0400-02-41, 51692-0400-03-41, 51691-0400-04-41, 51691-0400-05-41, 51691-0400-06-41.		Haynes	#1 #2 #3 #4 #5 #6	Long Beach, California
51408-1095-01-41, 51408-1095-02-41, 51408-1095-04-41, 51408-1095-05-41, 51408-1095-06-41.	Iowa Public Service Company	Kirk	#1 #2 #3 #4 #5 #6	Sioux City, Iowa
51408-1096-12-41		Maynard	#12	Waterloo, Iowa
51408-6063-01-41, 51408-6063-02-41, 51408-6063-03-41		Electriform	#1 #2 #3	Waterloo, Iowa
51408-9066-21-41, 51408-9066-22-41		Parr	CT-1 CT-2	Charles City, Iowa
51100-0713-21-41, 51100-0713-22-41, 51100-0713-23-41	Georgia Power Company	McManus	CT-3A CT-3B CT-3C	Brunswick, Georgia
51150-2241-21-41	City of Grand Island	Burdick	CT-1	Grand Island, Nebraska
51007-9090-22-41	Applied Energy, Incorporated	North Island	GT-2	San Diego, California
52637-2493-01-41, 52637-2493-02-41, 52637-2493-03-41, 52637-2493-04-41.	Shelby Municipal Electric	Shelby Municipal	#1 #2 #3 #4	Shelby, Ohio
67008-9089-01-41, 67008-9089-04-41, 67008-9089-05-41	Springfield Municipal Utilities	Springfield Municipal	#1 #4 #5	Springfield, Colorado
50441-9063-01-41, 50441-9063-21-41	Carolina Power & Light Company	H. B. Robinson	#1 CT-1	Hartsville, South Carolina
50412-1595-01-41, 50412-1595-02-41, 50412-1595-03-41	Cambridge Electric Light Company	Kendall Square	#1 #2 #3 #4	Cambridge, Massachusetts
50412-1594-01-41, 50412-1594-03-41, 50412-1594-04-41		Blackstone Street	#1 #3 #4	Cambridge, Massachusetts
50099-0161-51-41, 50099-0161-22-41, 50099-0161-23-41	Arizona Electric Power	Apache	CC-1 CT-2 CT-3	Cochise County, Ariz.
50782-1726-08-41, 50782-1726-09-41, 50782-1726-10-41, 50782-1726-12-41, 50782-1726-13-41, 50782-1726-14-41.	Detroit Edison	Conners Creek	#8 #9 #10 #12 #13 #14	Detroit, Michigan
50782-1724-01-41, 50782-1724-02-41		Beacon	#1 #2	Detroit, Michigan
50782-1743-31-41		St. Clair	CT-11	East China Township, Mich.

I. The above listed powerplants are prohibited by Section 301(a)(2) of FUA from using natural gas as a primary energy source, or are prohibited from using natural gas as a primary energy source in excess of the average base year proportions allowed in Section 301(a)(3) of the Act.

II. *Eligibility.* The existing powerplants listed above have submitted petitions to ERA for a Special Temporary Public Interest Exemption and have asserted that:

(a) Each existing powerplant is:
(1) Prohibited on May 8, 1979 from using natural gas as a primary energy source by

Section 301(a)(2) of FUA, or

(2) Prohibited from using natural gas in excess of the average base year proportions allowed in Section 301(a)(3) of FUA.

(b) The proposed use of natural gas as a primary energy source, to the extent that such use would be prohibited by Section 301(a)(2) or (3) of FUA:

- (1) Will displace consumption of middle distillate or residual fuel oil; and
- (2) Will not displace the use of coal or any other alternate fuel in any facility of the owner/operator utility system, including the powerplant for which the exemption was submitted.

III. Rationale. To the extent that the near-term choice of fuels for certain existing powerplants is limited to petroleum or natural gas, the use of natural gas is preferred over petroleum. The expanded use of natural gas in these powerplants will be a significant step toward reducing our short-term oil consumption. This increased use of natural gas will help the United States meet its commitment to reduce its demand for imported petroleum products, protect the Nation from the effects of any oil shortages, and will cushion the impact of increasing world oil prices, which have had a detrimental effect on the Nation's balance of payments and domestic inflation rate.

To the extent that this increased use of natural gas will accomplish these goals, it will reduce the importation of petroleum and further the goal of national energy self-sufficiency. This is in keeping with purposes of FUA and is in the public interest.

Since the increased use of natural gas is in keeping with the purposes of FUA and is in the public interest, and since the petitioners have demonstrated that they have met the eligibility criteria established in Section 508.2 of the Special Rule (April 9, 1979, 44 FR 21230), ERA proposes to grant the exemptions.

IV. Duration. ERA proposes to grant these temporary public interest exemptions generally for a period of two years and may extend them from one to three additional years. Certain petitioners have requested that they be granted exemptions for a period of greater than two years but less than five

years, the maximum period allowed under FUA, and to the extent that these requests are in the public interest ERA will consider them.

These proposed exemptions are subject to termination by ERA, upon six months written notice, if ERA determines such termination to be in the public interest.

V. Terms and Conditions. Pursuant to the authority of Section 314 of FUA and 10 CFR 508.6, ERA will require the order recipient upon issuance of a final order to: (1) Complete a Form ERA 316 (Temporary Public Interest Exemption for Use of Natural Gas by Existing Powerplants Form), (2) report the actual monthly volumes of natural gas used in each exempted powerplant and the estimated number of barrels of each type of fuel oil displaced during the exemption period, (3) submit a system-wide fuel conservation plan to include the two-year period covered by the temporary exemption, and (4) submit annually to ERA a report on progress achieved in implementing the system-wide fuel conservation plan.

Issued in Washington, D.C., on August 21, 1979.

Robert L. Davies,

Acting Assistant Administrator, Office of Fuels Conversion, Economic Regulatory Administration.

[FR Doc. 79-26670 Filed 8-27-79; 8:45 am]

BILLING CODE 6450-01-M

Office of Energy Research

Price of Americium-241

AGENCY: Department of Energy;

ACTION: Additional Information on Price Increase for Americium-241.

A notice effecting a price increase for Americium-241 was published in the

Federal Register on July 26, 1979 (44 FR 43806). One comment was received in response to the proposed price increase notice published on May 16, 1979 (44 FR 28707), suggesting that the price increase be instituted in increments over a 2-year period. This comment was rejected because to adopt such a proposal would not be consistent with the Department of Energy policy of full recovery of costs.

FOR FURTHER INFORMATION CONTACT:

Dr. John L. Burnett, Division of Nuclear Sciences, ER-14, Office of Basic Energy Sciences, U.S. Department of Energy, Washington, DC 20545, MS J-309, (301) 353-3613.

Issued in Washington, DC., August 20, 1979.

Charles E. Cathey,

Director, Division of Budgets and Program Coordination, Office of Energy Research.

[FR Doc. 79-26671 Filed 8-27-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. ECAO-CD-78-2; FRL 1306-2]

Air Quality Criteria Document for Oxides of Nitrogen; Extension of Comment Period for Second External Review Draft

The deadline for receipt of comments on the second external review draft, announced in 44 FR 40559 (July 11, 1979), is extended from August 31 to September 30, 1979.

Dated: August 23, 1979.

Steven R. Reznick,

Acting Assistant Administrator for Research and Development.

[FR Doc. 79-26754 Filed 8-27-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 1189]

Petitions for Reconsideration of Actions in Rulemaking Proceedings Filed

August 20, 1979.

Docket or RM No.	Rule No.	Subject	Date received
21211	73.202(b)	Amendment of Section 73.202(b), Table of Assignments, FM Broadcast Stations. (Knoxville, Clinton, Sweetwater, Cleveland, LaFollette and Oneida, Tennessee). (Filed by Grover C. Cooper and Richard J. Bordorff, Attorneys for Clinton Broadcasters, Inc., (WYSH-FM).	Aug. 8, 1979.

Note.—Oppositions to petitions for reconsideration must be filed within 15 days after publication of this Public Notice in the Federal Register. Replies to an opposition must be filed within 10 days after time for filing oppositions has expired.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 79-28640 Filed 8-27-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreements Filed

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of each of the agreements and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10423; or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before September 17, 1979. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreement No. T-3775-2, T-2885-13, T-2884-10, T-3553-2 and T-2880-17.

Filing Party: Mr. John C. Barnett, Assistant Chief, Leases & Operating Agreements Division, The Port Authority of NY and NJ, One World Trade Center, New York, New York 10048.

Summary: The above agreements, between the Port Authority of NY and NJ and respective lessees, viz: Farrell Lines, Inc. (T-3775-2), Universal Maritime Service Corp. (T-2885-13 and T-2884-10), International Terminal Operating Co., Inc. (T-3553-2), and John W. McGrath Corporation (T-2880-17), amend the basic lease agreements by

providing for an increase in the rate per revenue ton payable by the lessees under a minimum-maximum rental formula. Each of the agreements also changes the definition of "revenue ton" with respect to certain specifically enumerated types of cargo.

Agreement No. T-3738-1.

Filing Party: H. H. Wittren, Manager, Waterfront Real Estate, Port of Seattle, P.O. Box 1209, Seattle, Washington, 98111.

Summary: Agreement T-3738-1, between the Port of Seattle (Port) and Hapag-Lloyd AG, Hamburg, Bremen (HL), modifies the parties' basic agreement which provides for the Port's lease to HL of certain premises at Terminal 18, Seattle, Washington, together with the preferential use of ships' berth and pier apron, two Port-owned container cranes and eight straddle carriers. The purpose of the modification is to amend paragraph 45(a) of the basic agreement, "use of Premises," to include Evergreen Line vessels in addition to the lines already permitted to use the facilities.

Agreement No. T-3844.

Filing Party: H. H. Wittren, Manager, Waterfront Real Estate, Port of Seattle, P.O. Box 1209, Seattle, Washington 98111.

Summary: Agreement No. T-3844, between the Port of Seattle (Port) and Associated Transportations, Inc. (Associated) provides for the month-to-month lease of 56,882 square feet of warehouse space and an office trailer at Terminal 106-W in the Port of Seattle for use in container freight station activities. As compensation, Associated will pay the monthly rental of \$9,251.12, plus any applicable taxes. By Order of the Federal Maritime Commission.

Dated: August 22, 1979.

Francis C. Harney,
Secretary.

[FR Doc. 79-26606 Filed 8-28-79; 9:35 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Bank Holding Companies; Proposed De Novo Nonbank Activities

The bank holding companies listed 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 section 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 each application, 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 interest,

or unsound banking practices." Any comment on an application 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.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings 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 September 17, 1979.

A. Federal Reserve Bank of Boston, 33 Pearl Street, Boston, Massachusetts 02106:

Old Stone Corporation, Providence, Rhode Island (consumer finance and credit-related insurance activities; Florida); to engage *de novo*, through its indirect subsidiary, UniCredit Corporation; in the origination, acquisition and servicing of consumer finance installment contracts; and in connection with extensions of credit by UniCredit, making available to borrowers credit-related life insurance. These activities will be conducted from an office in Miami, Florida, serving Dade and Broward Counties.

B. Federal Reserve Bank of Richmond, 701 East Byrd Street, Richmond, Virginia 23261:

Union Trust Bancorp., Baltimore, Maryland (consumer finance and insurance activities; North Carolina); to engage, through its subsidiary Landmark Financial Services, Inc., in making personal installment loans; purchasing sales finance contracts executed in connection with the sale of personal, family or household goods and services; acting as agent in the sale of credit life and credit accident and health insurance directly related to its extensions of credit; acting as agent in the sale of insurance protecting collateral held against the extensions of credit; and making second mortgage loans secured in whole or part by mortgage or other lien on real estate. These activities would be conducted from offices in Winston-Salem, North Carolina, serving the City of Winston-Salem and its adjacent environs.

C. Federal Reserve Bank of San Francisco, 400 Sansome Street, San Francisco, California 94120:

1. Orbanco, Inc., Portland, Oregon (finance company, loan servicing, personal property leasing, and insurance activities; Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia); to engage, through its subsidiary, Northwest Acceptance Corporation, in making or acquiring loans or other extensions of credit such as would be made or acquired by a commercial finance company; servicing loans or participations in loans and other extensions of credit; leasing personal property in accordance with the Board's Regulation Y; and acting as broker or agent for the sale of life insurance in connection with such extensions of credit. The loans and other extensions of credit will be secured by machinery and equipment, inventory, accounts receivable, or other assets. The proposed activities would be conducted from an office in Lake Success, New York, serving Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia.

2. First Hawaiian, Inc., Honolulu, Hawaii (insurance activities; Hawaii): to engage, through its subsidiary Hawaii Thrift and Loan, Inc., in selling as agent or broker, property damage and liability insurance directly related to extensions of credit by Hawaii Thrift and Loan. This activity will be conducted from the offices of Hawaii Thrift and Loan, located in: Honolulu, Haleiwa, Kahala, Keeaumoku, Moiliili, Kailua, Waipahu and Kaneohe, serving the island of Oahu; Lihue, serving the island of Kauai; Kahului, serving the island of Maui; and Hilo, serving the island of Hawaii.

D. Other Federal Reserve Banks: None.

Board of Governors of the Federal Reserve System, August 17, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26715 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Blackburn Bancshares, Inc.; Formation of Bank Holding Company

Blackburn Bancshares, Inc., Blackburn, Missouri, has 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 a bank holding company by acquiring 80 per cent or more of the voting shares (less directors' qualifying shares) of Blackburn Bank, Blackburn, Missouri.

The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 17, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 16, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26706 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Capital Bancshares, Inc.; Formation of Bank Holding Company

Capital Bancshares, Inc., Baton Rouge, Louisiana, has 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 a bank holding company by acquiring 80 percent or more of the voting shares of Capital Bank & Trust Company, Baton Rouge, Louisiana. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 17, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 16, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26707 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Clover Bottom Estates, Inc.; Formation of Bank Holding Company

Clover Bottom Estates, Inc., Hendersonville, Tennessee, has 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 a bank holding company by acquiring 80 per cent of the voting shares of Bank of Hendersonville, Hendersonville, Tennessee. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than September 20, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 20, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26705 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Corpus Christi Bankshares, Inc.; Formation of Bank Holding Company

Corpus Christi Bankshares, Corpus Christi, Texas, has 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 a bank holding company by acquiring 80 per cent or more of the voting shares of First State Bank of Corpus Christi, Corpus Christi, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 17, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing

the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 16, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26709 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Farmers Bancshares, Inc.; Formation of Bank Holding Company

Farmers Bancshares, Inc., Douglas, Georgia, has 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 a bank holding company by acquiring 80 per cent or more of the voting shares of The Farmers State Bank, Caldwell, Georgia. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 17, 1979. Any comment on an application that requests a hearing must include a statement or why a written presentation would not suffice in lieu of a hearing. Identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 17, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26704 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Federal Open Market Committee; Domestic Policy Directive of July 11, 1979

In accordance with § 271.5 of its rules regarding availability of information, there is set forth below the Committee's Domestic Policy Directive issued at its meeting held on July 11, 1979.¹

The information reviewed at this meeting suggests that real output of goods and services declined somewhat in the second quarter, as slackening in demands was intensified by reduced supplies and sharply higher prices of motor fuels. During the quarter, the dollar value of retail sales

declined, and in real terms, sales in June were substantially below those of last December. Growth in nonfarm payroll employment slowed during the quarter to a pace considerably below that in the preceding six months, but the unemployment rate in June, at 5.6 percent, was somewhat lower than earlier in the year. Industrial production recovered in May, after having declined in April in large part because of a work stoppage. Over the first half of this year, broad measures of prices increased at a much faster pace than during 1978, although producer prices of foods declined in the second quarter. The rise in the index of average hourly earnings has slowed in recent months.

Downward pressure on the dollar in foreign exchange markets emerged in mid-June after several months of strength, and since then the trade-weighted value of the dollar against major foreign currencies has declined about 3 percent. The U.S. trade deficit for April and May combined widened somewhat from the first-quarter rate.

M-1 expanded sharply in June, after having increased little in May, and M-2 and M-3 also grew rapidly. Inflows of interest-bearing deposits included in M-2 grew rapidly in June, as net flows into money market certificates at commercial banks expanded further and savings deposits increased for the first time since last September. At nonbank thrift institutions, inflows of deposits picked up from the sharply reduced pace in May. On a quarterly average basis, M-1 grew at an annual rate of about 7½ percent in the second quarter, compared with a decline at a rate of about 2 percent in the first quarter; M-2 and M-3 grew at rates of about 8½ percent and 7½ percent respectively in the second quarter, compared with rates of about 1½ percent and 4½ percent in the first quarter. Market interest rates in general have declined substantially over the past several weeks, but mortgage interest rates have risen further.

Taking account of past and prospective developments in employment, unemployment, production, investment, real income, productivity, international trade and payments, and prices, it is the policy of the Federal Open Market Committee to foster monetary and financial conditions that will resist inflationary pressures while encouraging moderate economic expansion and contributing to a sustainable pattern of international transactions. The Committee agreed that these objectives would be furthered by growth of M-1, M-2, and M-3 from the fourth quarter of 1978 to the fourth quarter of 1979 within ranges of 1½ to 4½ percent, 5 to 8 percent, and 6 to 9 percent respectively, the same ranges that had been established in February. Having established the range for M-1 in February on the assumption that expansion of ATS and NOW accounts would dampen growth by about 3 percentage points over the year, the Committee also agreed that actual growth in M-1 might vary in relation to its range to the extent of any deviation from that estimate. The associated range for bank credit is 7½ to 10½ percent. The Committee anticipates that for the period from the fourth quarter of 1979 to the fourth quarter of 1980, growth may be

within the same ranges, depending upon emerging economic conditions and appropriate adjustments that may be required by legislation or judicial developments affecting interest-bearing transactions accounts. These ranges will be reconsidered at any time as conditions warrant.

In the short run, the Committee seeks to achieve bank reserve and money market conditions that are broadly consistent with the longer-run ranges for monetary aggregates cited above, while giving due regard to the program for supporting the foreign exchange value of the dollar and to developing conditions in domestic financial markets. Early in the period before the next regular meeting, System open market operations are to be directed at maintaining the weekly average federal funds rate at about the current level. Subsequently, operations shall be directed at maintaining the weekly average federal funds rate within the range of 9½ to 10½ percent. In deciding on the specific objective for the federal funds rate the Manager shall be guided mainly by the relationship between the latest estimates of annual rates of growth in the July-August period of M-1 and M-2 and the following ranges of tolerance: 2½ to 6½ percent for M-1 and 6½ to 10½ percent for M-2. If, with approximately equal weight given to M-1 and M-2, their rates of growth appear to be close to or beyond the upper or lower limits of the indicated ranges, the objective for the funds rate is to be raised or lowered in an orderly fashion within its range.

If the rates of growth in the aggregates appear to be above the upper limit or below the lower limit of the indicated ranges at a time when the objective for the funds rate has already been moved to the corresponding limit of its range, the Manager will promptly notify the Chairman, who will then decide whether the situation calls for supplementary instructions from the Committee.

Note: On July 27, the Committee modified the domestic policy directive adopted at its meeting on July 11, 1979, by raising the upper limit of the intermeeting range for the federal funds rate to 10½ percent and by instructing the Manager to aim for a weekly average rate within a range of 10½ to 10¾ percent, depending on subsequent projections of growth of M-1 and M-2 over the July-August period, on conditions in foreign exchange markets, and on the current Treasury financing.

By order of the Federal Open Market Committee, August 17, 1979.

Murray Altmann,
Secretary.

[FR Doc. 79-26716 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

First American Bancshares, Inc.; Formation of Bank Holding Company

First American Bancshares, Inc., Baytown, Texas, has 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 a bank holding company by acquiring 100 percent of the voting shares (less

¹The Record of Policy Actions of the Committee for the meeting of July 11, 1979, is filed as part of the original document. Copies are available on request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

directors' qualifying shares) of the successor by merger to First American Bank & Trust of Baytown, Baytown, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 20, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 20, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26706 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

First Antlers Bancshares, Inc.; Formation of Bank Holding Company

First Antlers Bancshares, Inc., Antlers, Oklahoma, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares (less directors' qualifying shares) of The First National Bank at Antlers, Antlers, Oklahoma. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

First Antlers Bancshares, Inc., Antlers, Oklahoma, has also 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* through its indirect subsidiary, First Antlers Insurance Agency, Inc., Antlers, Oklahoma. First Antlers Insurance Agency, Inc., is a wholly-owned subsidiary of First Antlers Business Trust, Antlers, Oklahoma which is a wholly-owned subsidiary of Applicant.

Applicant states that the proposed subsidiary would engage in the sale of credit life and accident and health insurance in connection with extensions of credit by Bank. These activities would be performed from offices of Applicant's subsidiary in Antlers, Oklahoma, and the geographic area to be served is the same as that area to be served by Bank which is approximated

by Pushmataha County, Oklahoma. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

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 Dallas.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 21, 1979.

Board of Governors of the Federal Reserve System, August 21, 1979.

Edward T. Mulrenin,

Assistant Secretary of the board.

[FR Doc. 79-26721 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

First Waukegan Corporation; Formation of Bank Holding Company

First Waukegan Corporation, Chicago, Illinois, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of The First National Bank of Waukegan, Waukegan, Illinois. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 20, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation

would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 20, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26722 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

GAB Company; Formation of Bank Holding Company

T1GAB Company, Dallas, Texas, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Grand Avenue Bank, Dallas, Texas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 21, 1979. 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 facts that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26723 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Landmark Bancshares Corp.; Acquisition of Bank

Landmark Bancshares Corporation, Clayton, Missouri, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 90 percent or more of the voting shares of Ladue Bank and Trust Company, Ladue, Missouri. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of St. Louis. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve

System, Washington, D.C. 20551, to be received not later than September 17, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 16, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26710 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Lone Rock Investments, Inc.; Formation of Bank Holding Company

Lone Rock Investments, Inc., Lone Rock, Wisconsin, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 99.4 per cent or more of the voting shares of State Bank of Lone Rock, Lone Rock, Wisconsin. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 20, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 20, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26724 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Pender State Corp.; Formation of Bank Holding Company

Pender State Corporation; Pender, Nebraska, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Pender State Bank, Pender, Nebraska. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received not later than September 21, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26725 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Port City Bancshares, Inc.; Formation of Bank Holding Company

Port City Bankshares, Inc., Houston, Texas, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 100 percent, less directors' qualifying shares, of the voting shares of Port City State Bank, Houston, Texas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 21, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26726 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Rocky Mountain Bancorporation; Formation of Bank Holding Company

Rocky Mountain Bancorporation, Salt Lake City, Utah, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C.

§ 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares (less directors' qualifying shares) of Rocky Mountain State Bank-East Millcreek, Salt Lake City, Utah, and of Rocky Mountain State Bank of Bountiful, Bountiful, Utah. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than September 21, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26727 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Security Bancshares of Montana, Inc.; Acquisition of Bank

Security Bancshares of Montana, Inc., Billings, Montana, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire 100 percent of the voting shares (less directors' qualifying shares) of Pioneer Bank, Billings, Montana. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the board of governors or at the Federal Reserve bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than September 21, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-20728 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Bank Holding Companies; Proposed De Novo Nonbank Activities

The bank holding companies listed 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 section 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 each application, 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 interest, or unsound banking practices." Any comment on an application 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.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings 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 September 21, 1979.

A. Federal Reserve Bank of San Francisco, 400 Sansome Street, San Francisco, California 94120:

First Hawaiian, Inc., Honolulu, Hawaii (industrial loan and insurance activities; Hawaii): to engage, through a *de novo* office of its subsidiary, Hawaii Thrift and Loan, Incorporated, in operating an industrial loan company as authorized by Hawaii law, with activities including lending money upon individual credit, or the pledge or mortgage of real or personal property,

and issuing and selling certificates for the payment of money at any time; and selling, as agent or broker, property, casualty, life, accident and health insurance, directly related to extensions of credit by Hawaii Thrift and Loan, Incorporated. These activities will be conducted from an office to be located in Pearl City, Hawaii, serving the towns of Pearl City and Aiea on the island of Oahu, Hawaii.

B. Other Federal Reserve Banks: None.

Board of Governors of the Federal Reserve System, August 21, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-20717 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Citicorp; Proposed Acquisition of Citishare Corp.

Citicorp, New York, New York, 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 acquire voting shares of Citishare Corporation, New York, New York.

Applicant states that the proposed subsidiary would:

1. Provide data processing for the internal operations of applicant and its subsidiaries;

2. Engage in developing, assembling, storing, processing, and distributing financial, economic and banking data, such as selected income statement and balance sheet items, economic time-series, securities prices, and foreign exchange rates;

3. Engage in computer "time sharing" activities, which involve providing customers with access to data of the type listed in (2) above and packaged financial systems via computer terminals in the customers' offices. According to Applicant, such packaged financial systems would permit customers to obtain the benefit of its financial information systems and financial analysis expertise with respect to such applications as financial modeling, loan analysis, accounting and bookkeeping, budget and profitability analysis, portfolio recordkeeping and analysis, foreign exchange exposure, general ledger, and bond analysis;

4. Provide packaged financial systems for installation at a customer's site and packaged systems for installation at other financial institutions;

5. Make available to others excess computer processing capacity as may from time to time be available, on the condition that the only involvement by

Citishare is furnishing the facility and necessary operating personnel, and perform other incidental activities necessary to carry on the permissible activities in this area, as specified by the Board in its interpretation on data processing activities in 12 CFR § 225.123.

Applicant states that these activities have been specified by the Board, in section 225.4(a)(8) of Regulation Y (12 CFR § 225.4(a)(8)), as being permissible for bank holding companies as activities "so closely related to banking or managing or controlling banks as to be a proper incident thereto," within the meaning of section 4(c)(8) of the Bank Holding Company Act, or, in a Board interpretation (12 CFR § 225.123(e)), as incidental activities necessary to carry on such activities. These activities would be performed from offices of applicant's subsidiaries in New York, New York, and the geographic areas to be served are the continental United States, Puerto Rico, and various cities in Australia, Canada, England, France, and Mexico.

Interested persons may express their views on the question of whether the proposed activities are "so closely related to banking or managing or controlling banks as to be a proper incident thereto," or are incidental to "closely related" activities.

Interested persons may also express their views on the question of 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 these questions 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 New York.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 21, 1979.

Board of Governors of the Federal Reserve System, August 21, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26718 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Community Bancorporation, Inc.; Formation of Bank Holding Company

Community Bancorporation, Inc., Bristow, Oklahoma, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent of the voting shares (less directors' qualifying shares) of Community Bank, Bristow, Oklahoma. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

Community Bancorporation, Inc., Bristow, Oklahoma, has also 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 acquire 100 percent of the voting shares of Community Business Trust, Bristow, Oklahoma, which will own 100 percent of Community Insurance Agency, Inc., Bristow, Oklahoma.

Applicant states that the proposed subsidiary would engage *de novo* in the activities of selling credit life insurance and credit accident and health insurance. These activities would be performed from offices of Applicant's subsidiary in Bristow, Oklahoma serving the Bristow area. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

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 Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 20, 1979.

Board of Governors of the Federal Reserve System, August 21, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26719 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Farmer City Agency, Inc.; Acquisition of Additional Shares of Bank

Farmer City Agency, Inc., Farmer City, Illinois, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire additional voting shares of Farmer City State Bank, Farmer City, Illinois, thereby increasing Farmer City Agency, Inc.'s ownership from 40.75 percent to 50.05 percent of the voting shares of Farmer City State Bank. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than September 21, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, August 21, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26720 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

Turon Banc Shares, Inc.; Formation of Bank Holding Company

Turon Banc Shares, Inc., Turon, Kansas, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding

company by acquiring 94 per cent of the voting shares (less directors' qualifying shares) of The Turon State Bank, Turon, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

Turon Banc Shares, Inc., Turon, Kansas, has also 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*, as agent or broker, in the sale of credit life and credit accident and health insurance that is directly related to extensions of credit by Bank. These activities would be performed from offices of Applicant's subsidiary in Turon, Kansas, and the geographic areas to be served are Turon, Kansas, and surrounding areas. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

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 Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 20, 1979.

Board of Governors of the Federal Reserve System, August 20, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-26729 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

UBT Bancorp, Inc.; Formation of Bank Holding Company

UBT Bancorp, Inc., Bartlesville, Oklahoma, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent, or more, less directors' qualifying shares of the voting shares of Union Bank & Trust ("Bank"), Bartlesville, Oklahoma. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

UBT Bancorp, Inc., Bartlesville, Oklahoma, has also 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 acquire indirectly voting shares of UBT Insurance Agency, Inc.

Applicant states that the proposed subsidiary would engage in the activities of selling credit life and credit accident and health insurance directly related to extensions of credit of Bank. These activities would be performed from offices of Applicant's subsidiary in Bartlesville, Oklahoma, and the geographic areas to be served are the cities of Bartlesville and Dewey in Oklahoma. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

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 Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve

System, Washington, D.C. 20551, not later than September 21, 1979.

Board of Governors of the Federal Reserve System, August 22, 1979.

Edward T. Mulrenin,
Assistant Secretary of the Board.

[FR Doc. 79-26730 Filed 8-27-79; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

[E-79-3]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent, in conjunction with the Administrator of General Services, the consumer interests of the executive agencies of the Federal Government in proceedings before the New Jersey Board of Public Utilities involving an energy adjustment clause and the establishment of a new energy adjustment factor.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in me by the Federal Property and Administrative Service Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the New Jersey Board of Public Utilities involving the application of the Jersey Central Power and Light Company for an establishment of a new energy adjustment factor. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: August 16, 1979.

R. G. Freeman III,
Administrator of General Services.

[FR Doc. 79-26638 Filed 8-27-79; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**Center for Disease Control****Mine Health Research Advisory Committee; Meeting****Correction**

In FR Doc. 79-25959, published at page 49012, on Tuesday, August 21, 1979, the following corrections should be made:

1. On page 49012, in the eleventh line, "Place: Conference Room C . . ." should be corrected to read "Place: Conference Room G . . .";

2. On page 49013, in the first column, the File Line after the signature, [FR Doc. 79-25969 . . .] should be corrected to read [FR Doc. 79-25959 . . .].

BILLING CODE 1505-01-M

Office of Education**Graduate and Professional Opportunities Program; Closing Date for Transmittal of Applications for Fiscal Year 1980**

Applications are invited for new projects under the Graduate and Professional Opportunities Program.

Authority for this program is contained in Title IX Parts A and B of the Higher Education Act of 1965, as amended.

[20 U.S.C. 1134 et seq.]

This program issues awards to individual institutions of higher education or to combinations of those institutions.

The purpose of the awards is to develop training programs at institutions of higher education by providing fellowships for graduate and professional study to members of groups, particularly minorities and women, that have traditionally been underrepresented among recipients of graduate and professional degrees.

Closing Date for Transmittal of Applications: An application for a grant must be mailed or hand delivered by October 17, 1979.

Applications Delivered by Mail: An application sent by mail must be addressed to the U.S. Office of Education, Application Control Center, Attention: 13.580, Washington, D.C. 20202.

An applicant must show proof of mailing consisting of one of the following:

(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 proof of mailing acceptable to the U.S. Commissioner of Education.

If an application is sent through the U.S. Postal Service, the Commissioner does not accept either of the following as proof of mailing: (1) a private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

An applicant should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

An applicant is encouraged to use registered or at least first class mail. Each late applicant will be notified that its application will not be considered.

Applications Delivered by Hand: An application that is hand delivered must be taken to the U.S. Office of Education, Application Control Center, Room 5673, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C.

The Application Control Center will accept a hand delivered application between 8 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 closing date.

Program Information: Preference will be given to training programs that speak directly to those academic or professional studies of high national priority in which minorities and women are most particularly underrepresented (except those, such as medicine, which receive substantial funding under other Federal programs). Generally, no fewer than three to five new fellowships will be allocated to each approved program; institutions may receive support in a total of no more than five such program areas. In instances where only one academic or professional area is approved for support, this area should have the capacity to accept no fewer than 5 fellowships. Institutional grant awards under Part A are intended to be used in conjunction with fellowship awards to augment or provide special services in such related fields as recruitment, orientation programs before or during the academic year, and efforts at retention which include a variety of supportive services.

Subject to the availability of funds, requests for the renewal of fellowship support to those continuing Fellows in good academic standing are not subject to the competitive process and will, therefore, be automatically granted.

Available Funds: A budget request of \$15.0 million was made to continue this

program during 1980-1981. If appropriated, this amount would provide support for those individuals in good standing to continue their studies and for approximately 925 new fellowships at some 125 institutions. Of the total amount, about \$1.5 million would be used to support institutional grants at 55 institutions of higher education where evidence indicates strong ties with the fellowship program, especially in such areas as recruitment and retention. A smaller appropriated amount would reduce these estimates proportionately.

These estimates, however, do not bind the U.S. Office of Education to a specific number of grants or to the amount of any grant unless that amount is otherwise specified by statute or regulations.

Application Forms: Application forms and program information packages are available and may be obtained by writing to the Graduate Training Branch, U.S. Office of Education (Room 3060, Regional Office Building 3), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

Applications must be prepared and submitted in accordance with the regulations, instructions, and forms included in the program information packages. The Commissioner strongly urges that the narrative portion of the application not exceed 40 pages in length. The Commissioner further urges that applicants not submit information that is not requested.

Special Procedures: An application for an institutional grant shall provide assurance that the institution has notified the appropriate State Commissioner (established or designated under Section 1202 of the Higher Education Act of 1965, as amended) and that the State Commission has been given the opportunity to offer recommendations on the application to the institution and to the Commissioner.

Applicable Regulations: Regulations applicable to this program include the following:

(a) Regulations governing the Graduate and Professional Opportunities Program (45 CFR Part 179); and

(b) General Provisions Regulations for Office of Education Programs (45 CFR Parts 100 and 100a).

Note.—The proposed Education Division General Administrative Regulations (EDGAR) were published in the Federal Register on May 4, 1979 (44 FR 26298). When EDGAR becomes effective, it will supersede the General Provisions Regulations for Office of Education Programs.

If EDGAR takes effect before grants are made under this program, those grants will be subject to the following provision of EDGAR:

Subpart A (General); Subpart E (What Conditions Must be Met by a Grantee?);

Subpart F (What Are the Administrative Responsibilities of a Grantee?);

Subpart G (What Procedures Does the Education Division Use to Get Compliance?).

Applicants should note that an amendment to §§ 179.50(a) and 179.51 is contemplated. A notice of the proposed change will be published in the Federal Register soon.

Further Information: For further information contact Dr. Donald N. Bigelow, Bureau of Higher and Continuing Education, U.S. Office of Education, (Room 3060, Regional Office Building 3) 400 Maryland Avenue, S.W., Washington, D.C. 20202. Telephone: (202) 245-2347.

(20 U.S.C. 1134 et seq.)

(Catalog of Federal Domestic Assistance Number 13.580 Graduate Professional Opportunities Program)

Dated: August 23, 1979.

John Ellis,

Executive Deputy Commissioner for Educational Programs.

[FR Doc. 79-26741 Filed 8-27-79; 845 am]

BILLING CODE 4110-02-M

Food and Drug Administration

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by Robert O. Bartz, District Director, New Orleans District Office, New Orleans, LA.

DATE: The meeting will be held at 1:30 p.m., Thursday, September 13, 1979.

ADDRESS: The meeting will be held at the Arkansas State Department of Health, 4815 W. Markham St., 4th floor conference room, Little Rock, AR 72201.

FOR FURTHER INFORMATION CONTACT: Francis G. Brysson, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 4298 Elysian Fields Ave., New Orleans, LA 70122, 504-589-2420.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local

consumers and FDA's New Orleans District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 17, 1979.
William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26500 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by Robert O. Bartz, District Director, New Orleans District Office, New Orleans, LA.

DATE: The meeting will be held at 1:30 p.m., Thursday, September 20, 1979.

ADDRESS: The meeting will be held at the Food and Drug Administration, 4298 Elysian Fields Ave., New Orleans, LA 70122.

FOR FURTHER INFORMATION CONTACT: Louise W. Arnolite or Francis G. Brysson, Consumer Affairs Officers, Food and Drug Administration, Department of Health, Education, and Welfare, 4298 Elysian Fields Ave., New Orleans, LA 70122, 504-589-2420.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's New Orleans District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 17, 1978.
William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26499 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: This document announces a forthcoming consumer exchange meeting to be chaired by Abraham I. Kleks, District Director, Los Angeles Office, Los Angeles, CA.

DATE: The meeting will be held at 9 a.m., Monday, September 10, 1979.

ADDRESS: The meeting will be held at the Los Angeles District Office,

Conference Rm., 1521 W. Pico Blvd., Los Angeles, CA 90015.

FOR FURTHER INFORMATION CONTACT: Gordon L. Scott, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 1521 W. Pico Blvd., Los Angeles, CA 90015, 213-688-4395.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA Los Angeles District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 17, 1979.
William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26497 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by LeRoy Gomez, District Director, Denver District Office, Denver, CO.

DATE: The meeting will be held at 9:30 a.m., Thursday, September 20, 1979.

ADDRESS: The meeting will be held at the Federal Bldg., Rm. 239 (2d floor conference room), 19th and Stout Sts., Denver, CO 80202.

FOR FURTHER INFORMATION CONTACT: Kathy Brunner, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 500 U.S. Customhouse, Denver, CO 80202, 303-827-4915.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Denver District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 17, 1979.
William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26510 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by Kenneth A. Hansen, District Director, Seattle District Office, Seattle, WA.

DATE: The meeting will be held 1:30 p.m. to 4 p.m., Tuesday, September 18, 1979.

ADDRESS: The meeting will be held at the Seattle Center, Conference Rm. B, 305 Harrison St., Seattle, WA 98109.

FOR FURTHER INFORMATION CONTACT: Susan J. Hutchcroft, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 909 1st Ave., Seattle, WA 98174, 206-442-5258.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Seattle District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 17, 1978.
William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26498 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

Isocarboxazid; Drugs for Human Use; Drug Efficacy Study Implementation; Permission for Drugs to Remain on the Market; Amendment

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: This notice amends the previously published conditions for marketing isocarboxazid, a drug used in the treatment of depression.

DATE: Protocols due on or before September 27, 1979. Studies must be completed by August 28, 1981.

ADDRESS: Communications in response to this notice should be identified with the NDA number (if any) and the following in a box in the upper portion of the cover letter: "PARAGRAPH XIV DRUG—CATEGORY XX 'ISOCARBOXAZID,'" and directed to the attention of the appropriate office name below.

Abbreviated new drug applications: Division of Generic Drug Monographs (HFD-530), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Requests for opinion of the applicability of this notice to a specific drug product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

All other submissions required by this notice: Division of Neuropharmacological Drug Products, Psychopharmacology Unit (HFD-120), Rm. 10B-40, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: A notice published in the Federal Register of July 14, 1978 (43 FR 30351) specified the conditions under which isocarboxazid and tranlycypromine sulfate may remain on the market pending completion and review of clinical studies to determine effectiveness in the treatment of depression. Among the conditions for marketing was that each manufacturer label its product as "probably effective for severe reactive or endogenous depression in hospitalized or closely supervised patients who have not responded to other antidepressant therapy." Inadvertently, the notice failed to state the correct labeling requirement for isocarboxazid; the notice is now being amended to include that labeling. The July 14, 1978 notice is not otherwise changed by this amendment except that the time limits for submitting protocols and for completing studies on isocarboxazid are extended:

Accordingly, section A. of the July 14, 1978 notice as it pertains to isocarboxazid is amended to read as follows:

A. Requirements for Products now Subjects of Approved NDA's

Proceedings to withdraw approval of any NDA that has a "deemed approved" status on August 28, 1979, will not be initiated provided that:

1. The drug is labeled as probably effective for the treatment of depressed patients who are refractory to tricyclic antidepressants or electroconvulsive therapy and depressed patients in whom tricyclic antidepressants are contraindicated.

2. On or before September 27, 1979, any applicant who intends to conduct clinical studies of effectiveness has submitted protocols to the Division of Neuropharmacological Drug Products, Psychopharmacology Unit (HFD-120) for at least two adequate and well-

controlled studies by independent investigators or a multiclinic study in which the data of at least three investigators can be evaluated independently, to determine whether or not the product is effective. The Bureau of Drugs will review the submitted protocols within a 30-day period and will provide the applicant notice of approval or comments.

3. Within 60 days after receipt of the Bureau's approval or comments on the protocol, studies are in progress and the applicant so notifies the Division of Neuropharmacological Drug Products in writing.

4. At 6-month intervals after studies have begun, the applicant submits a progress report stating the number of patients and investigators in the studies, the number of studies completed, and the number continuing.

5. By August 28, 1981, the applicant submits data on the completed studies to the Division of Neuropharmacological Drug Products. If the studies are completed before the time, the applicant submits the results within 30 days after their completion.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701, 52 Stat. 1052-1053), as amended, 1055-1056, as amended (21 U.S.C. 355, 371) the Administrative Procedure Act (5 U.S.C. 553, 554), and under authority delegated to the Commissioner (21 CFR 5.1).

Dated August 22, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-20652 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79N-0252; DESI 8173]

Monobenzene Topical Ointment; Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: This notice states the conditions for marketing monobenzene topical ointment for the indication for which it is not regarded as effective and offers an opportunity for a hearing concerning other indications reclassified to lacking substantial evidence of effectiveness. The drug is used for depigmentation in extensive vitiligo.

DATES: Hearing requests due on or before September 27, 1979, supplements to new drug applications and data in support of hearing requests due on or before October 29, 1979.

ADDRESSES: Communications in response to this notice should be identified with the reference number DESI 8173, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number); Division of Anti-Infective Drug Products (HFA-140), Rm. 12B-45, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto (identify as such); Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for hearing (identify with docket number appearing in the heading of this notice); Hearing Clerk, Food and Drug Administration (HFD-305), Rm. 4-65.

Requests for the report of the National Academy of Sciences-National Research Council: Public Records and Documents Center (HFI-35), Rm. 12A-12.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

John H. Hazard, Jr., Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 8173), published in the Federal Register of September 18, 1970 (35 FR 14629), the Food and Drug Administration (FDA) announced that monobenzene is possibly effective for its recommended use in the treatment of severe freckling, hyperpigmentation from photosensitization following the use of certain perfumes, melasma of pregnancy, and hyperpigmentation following skin inflammation, and for final depigmentation in disseminated vitiligo.

Subsequently, in a notice published in the Federal Register of July 11, 1973 (38 FR 18477), monobenzene topical preparations were temporarily exempted (as Category XIII) from the time limits established for completing certain phases of the Drug Efficacy Study Implementation (DESI) program. The exemption was granted because no alternative depigmenting agents are available. Benoquin Lotion and Ointment were permitted to remain on

the market pending completion of scientific studies. After the sponsor informed FDA that studies were not being conducted on Benoquin Lotion, the agency revoked the exemption for that product in a notice published in the Federal Register of March 21, 1975 (40 FR 12829) and withdraw approval of the application September 15, 1975 (40 FR 42590), leaving only the following product exempted in Category XIII:

NDA 8-173; Benoquin Ointment containing 20 percent monobenzone; Elder Pharmaceuticals, 705 East Mulberry St., P.O. Box 31, Bryan, OH 43506.

Two clinical studies submitted by Elder support the effectiveness of Benoquin Ointment in extensive vitiligo. Accordingly the September 18, 1970 notice is amended to read as follows with respect to Benoquin Ointment.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the product specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to the product named above. It may also be applicable, under 21 CFR 310.6, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above.).

A. Effectiveness classification. The Food and Drug Administration has reviewed all available evidence and concludes that the drug product is effective for the indication in the labeling conditions below. The drug product now lacks substantial evidence of effectiveness for all other indications.

B. Conditions for approval and marketing. The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. Form of drug. The drug product is in ointment form suitable for topical administration

2. Labeling conditions. a. The label bears the statement, "Caution: Federal

law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indication is as follows:

For depigmentation in extensive vitiligo.

3. Marketing status. a. Marketing of such drug products that are now the subject of an approved or effective new drug application may be continued provided that, on or before October 29, 1979, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide full updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) containing full information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H must be obtained before marketing such product. Marketing before approval of an abbreviated new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

C. Notice of opportunity for hearing. On the basis of all the information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111(a)(5), that demonstrates the effectiveness of the drug for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice.

Notice is given to the holder of the new drug application and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application and all amendments and supplements thereto providing for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice on the ground that new information before him with respect to the drug

product, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug product will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application supplemented, in accord with this notice, to delete the claims lacking substantial evidence of effectiveness.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6) e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962 or for any other reason.

In accordance with section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant and all other persons who manufacture or distribute a drug product which is identical, related, or similar to the drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug product named above and of all identical, related, or similar drug products.

An applicant or any other person subject to this notice under 21 CFR 310.6 who decides to seek a hearing shall file (1) on or before September 27, 1979, a written notice of appearance and request for hearing, and (2) on or before October 29, 1979, the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or

denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other persons subject to this notice under 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes and election by the person not to make use of the opportunity for a hearing concerning the action proposed with respect to the product and constitutes a waiver of any contentions concerning the legal status of any such drug product. Any such drug product labeled for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analysis in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice must be filed in quintuplicate. Such submissions, except for information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053 as amended (21 U.S.C. 355)), and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: August 14, 1979.

Jerome A. Halperin,
Acting Director, Bureau of Drugs.

[FR Doc. 79-26651 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79N-0252; DESI 8173]

Monobenzene Topical Ointment; Drugs for Human Use; Drug Efficacy Study Implementation; Revocation of Exemption

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice revokes the temporary exemption for continued marketing of monobenzene topical ointment. The exemption is no longer needed because the question of the drug's effectiveness has been resolved. The drug has now been found to be effective. Under the exemption, the drug was allowed to remain on the market for continued study beyond the time limit scheduled for implementation of the Drug Efficacy Study.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT:

John H. Hazard, Jr., Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice appearing elsewhere in this issue of the Federal Register, the Food and Drug Administration is reclassifying one of the possibly effective indications for monobenzene topical ointment described below to be effective and the remaining indications to lacking substantial evidence of effectiveness. This product has been allowed to remain on the market beyond the time limit established for implementing the Drug Efficacy Study (DESI) on the condition that the manufacturer undertake additional clinical studies to determine the product's effectiveness. The temporary exemption to permit continued marketing as exempt Category XIII was announced in a notice published in the Federal Register July 11, 1973 (38 FR 18477).

The agency has reviewed data that the manufacturer submitted for the ointment form of monobenzene, and the question of the product's effectiveness has now been resolved. Therefore, the temporary exemption granted by the July 11, 1973 notice, as it pertains to the following product in the Drug Efficacy Study is hereby revoked.

NDA 8-173; Benoquin Ointment containing 20 percent monobenzene; Elder Pharmaceuticals, 705 East Mulberry St., P.O. Box 31, Bryan, OH 43506.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053 as amended (21 U.S.C. 352, 355)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

Dated: August 22, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26650 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79N-0322]

Safety of Certain Food Ingredients; Opportunity for Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity for public hearing on the safety of vitamin A, vitamin A acetate, and vitamin A palmitate to determine if they are generally recognized as safe (GRAS) or subject to a prior sanction. This action accords with procedures of a comprehensive safety review that the agency is conducting. Interested persons are invited to give their views on the safety of these substances.

DATE: Requests to make oral presentations at the public hearing must be received by or postmarked on or before September 27, 1979.

ADDRESSES: Written requests to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014, and to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 26, 1973 (38 FR 20053), FDA issued a notice advising the public that an opportunity would be provided for oral presentation of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (the Select Committee), about the safety of ingredients used in food to determine if they are GRAS or subject to a prior

sanction. The agency now announces that the Select Committee is prepared to conduct a public hearing on the following categories of food ingredients: vitamin A, vitamin A acetate, and vitamin A palmitate for direct food use. The public hearing will provide an opportunity, before the Select Committee reaches its final conclusions, for any interested person(s) to present scientific data, information, and views on the safety of these substances, in addition to those previously submitted in writing under notices published in the *Federal Register* of July 26, 1973 (38 FR 20051, 20053), April 17, 1974 (39 FR 13798), and March 28, 1978 (43 FR 12941).

The Select Committee has reviewed all the available data and information on the categories of food ingredients listed above and has reached one of the five following tentative conclusions on the status of each:

1. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future. (This finding does not apply to the substances covered by this notice.)

2. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard.

3. Although no evidence in the available information demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist

requiring that additional studies be conducted. (This finding does not apply to the substances covered by this notice.)

4. The evidence is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced. (This finding does not apply to the substances covered by this notice.)

5. The information available is not sufficient to make a tentative conclusion. (This finding does not apply to the substances covered by this notice.)

The following table lists each ingredient, the Select Committee's tentative conclusion (keyed to the five types of conclusions listed above), and the available information on which the Select Committee based its conclusions:

Substance	Select Committee tentative conclusion	Scientific literature review (order No.; price code; price)*	Animal study report (order No.; price code; price)*	Other information (order No.; price code; price)*
Vitamin A	2	PB-241-949/AS (vitamin A).....	Mutagenicity evaluation of FDA 75-79 vitamin A acetate crystals submitted by Litton Bionetics, Inc. (PB-278-479/AS; A03; \$4.50).	1. Wade, M. J. 1977. Review of the recent literature on the health aspects of vitamin A, vitamin A acetate and vitamin A palmitate as food ingredients. (PB-275-754/AS; A03; \$4.50.)
Vitamin A Acetate	2	A-99; \$27.75.....		2. Human intake data taken from "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe (GRAS)," available from the National Technical Information Service, PB-Nos. 221-921 through 221-949; —.
Vitamin A Palmitate	2			3. Letters January 16, February 2, and March 7, 1979, from K. R. Fulton, National Research Council, Washington, DC.

Reports in the table with "PB" Prefixes may be obtained from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

In addition to the information contained in the documents listed in the table above, the Select Committee supplemented, where appropriate, its reviews with specific information from specialized sources as announced in a previous hearing opportunity notice published in the *Federal Register* of September 23, 1974 (39 FR 34218).

The Select Committee's tentative report on vitamin A, vitamin A acetate, and vitamin A palmitate is available for review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-56, 5600 Fishers Lane, Rockville, MD 20857, and also at the Public Information Office, Food and Drug Administration, Rm. 3807, 200 C St. SW., Washington, DC 20204. In addition, all reports and documents used by the Select Committee to review the

ingredients are available for review at the office of the Hearing Clerk.

To schedule the public hearing, the Select Committee must be informed of the number of persons who wish to attend and the time requested to give their views. Accordingly, any interested person who wishes to appear at the public hearing to make an oral presentation should inform the Select Committee in writing addressed to The Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014. A copy of each request will be sent to the Hearing Clerk (address above) and all requests will be placed on public display in that office. Any such request must be received by or postmarked on or before September 27, 1979, must state the substance(s) on which an opportunity to present oral views is requested, and must state how much time is requested for the presentation. Requests should specify the docket number found in

brackets in the heading of this notice. As soon as possible after the request deadline, a notice announcing the date, time, place, and scheduled presentations for any public hearing that may be requested will be published in the *Federal Register*.

The purpose of the public hearing is to receive data, information, and views not previously available to the Select Committee about the substances listed above. Information already contained in the scientific literature reviews and in the tentative Select Committee report shall not be duplicated, although views on the interpretation of this material may be presented.

Depending on the number of requests for opportunity to make oral presentations, the Select Committee may reduce the time requested for any presentation. Because of time limitations, individuals and organizations with common interests are urged to consolidate their presentations.

Any interested person may, in lieu of an oral presentation, submit written views, which will be considered by the Select Committee. Three copies of such written views identified with the docket number found in brackets in the heading of this notice, are to be addressed to the Select Committee at the address noted above, and must be received by or postmarked not later than 10 days before the scheduled date of the hearing. A copy of any written views is to be sent to the Hearing Clerk, Food and Drug Administration, and will be placed on public display in that office.

A public hearing will be presided over by a member of the Select Committee. Hearings will be transcribed by a reporting service, and a transcript of such hearing may be purchased directly from the reporting service and will be placed on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

Dated: August 22, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26649 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79N-0269]

Safety of Iron and Iron Salts; Opportunity for Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity for public hearing on the safety of iron and iron salts to determine whether they are generally recognized as safe (GRAS) or subject to a prior sanction. This action is in accordance with procedures of a comprehensive safety review that the agency is conducting. Interested persons are invited to give their views on the safety of these substances.

DATE: Requests to make oral presentations at the public hearing must be received by or postmarked on or before September 27, 1979.

ADDRESS: Written requests to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014, and to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 26, 1973 (38 FR 20053), FDA issued a notice advising the public that an opportunity would be provided for oral presentation of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (hereinafter, the Select Committee), about the safety of ingredients used in food to determine whether they are GRAS or subject to a prior sanction.

FDA now gives notice that the Select Committee is prepared to conduct a public hearing on the following categories of food ingredients: Reduced iron, electrolytic iron, carbonyl iron, ferric citrate, ferric phosphate, ferric pyrophosphate, ferrous fumarate, ferrous carbonate, ferrous ascorbate, ferrous citrate, ferrous gluconate, ferrous lactate, ferric ammonium citrate, iron peptonate, iron polyvinyl pyrrolidone, sodium ferric EDTA, sodium ferricitropyrrophosphate, and sodium ferric pyrophosphate for direct food use; ferrous sulfate and ferric oxide for direct food use and for use in paper and paperboard products; elemental iron, ferric chloride, ferric sulfate, iron caprylate, iron linoleate, iron tallate, and oxides of iron for use in paper and paperboard products; and iron naphthenate for use as a drier in coatings. The public hearing will provide an opportunity, before the Select Committee reaches its final conclusions,

for any interested person(s) to present scientific data, information, and views on the safety of these substances, in addition to those previously submitted in writing under notices published in the Federal Register of July 26, 1973 (38 FR 20051, 20053), April 17, 1974 (39 FR 13798), and March 28, 1978 (43 FR 12941).

The Select Committee has reviewed all the available data and information on the categories of food ingredients listed above and has reached one of the five following tentative conclusions on the status of each:

1. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.

2. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard.

3. Although no evidence in the available information demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. (This finding does not apply to the substances covered by this notice.)

4. The evidence is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced. (This finding does not apply to the substances covered by this notice.)

5. The information available is not sufficient to make a tentative conclusion.

The following table lists each ingredient, the Select Committee's tentative conclusion (keyed to the five types of conclusions listed above), and the available information on which the Select Committee based its conclusions:

Substance	Select Committee tentative conclusion	Scientific literature review (order No.; price code; price)*	Animal study report (order No.; price code; price)*	Other information (order No.; price code; price)*
Iron and iron salts.....		BP-221-236; A06; \$6.50.....		
Direct food ingredient:				
Reduced iron.....	2		a. Mutagenic evaluation of compound 00299-296 (ferrous gluconate) by Litton Bionetics, Inc., under FDA contract. PB-245-477/AS; A03; \$4.50.	a. Letter dated January 29, 1976, from E. Coleman, FDA, Washington, DC
Electrolytic iron.....	2			
Carbonyl iron.....	2			
Ferrous sulfate.....	2			
Ferric citrate.....	2			
Ferric phosphate.....	2			
Ferric pyrophosphate.....	2			
Ferrous fumarate.....	2			
Ferrous carbonate.....	2			
Ferrous ascorbate.....	5		b. Teratologic evaluation of FDA 71-64 (ferrous sulfate) in mice and rats by Food and Drug Research Laboratories, Inc., under FDA contract. PB-245-532/AS; A03; \$4.50.	b. Letter dated January 6, 1976, from G. W. Irving, Jr., FASEB, Bethesda, MD

Substance	Select Committee tentative conclusion	Scientific literature review (order No.; price code; price)*	Animal study report (order No.; price code; price)*	Other information (order No.; price code; price)*
Ferrous citrate.....	5		c. Mutagenic evaluation of compound FDA 71-84 (ferrous sulfate) by Litton Bionetics, Inc., under FDA contract. PB-245-435/AS; A03; \$4.50.	c. Memorandum dated September 13, 1978 by H. C. Chinn, FASEB, Bethesda, MD
Ferrous gluconate.....	5			
Ferrous lactate.....	5			
Ferric ammonium citrate.....	5			
Ferric oxide.....	5			
Iron peptonate.....	5			
Iron polyvinyl pyrrolidone.....	5			
Sodium ferric EDTA.....	5			
Sodium ferricitropyrophosphate.....	5			
Sodium ferric pyrophosphate.....	5			
Paper and paperboard materials:				
Elemental iron.....	1		d. Mutagenic evaluation of compound FDA 73-84 010045860 (ferric orthophosphate) by Litton Bionetics, Inc., under FDA contract. PB-245-514/AS; A03; \$4.50.	d. Letter dated December 19, 1974, from E. Tweedy, General Mills Chemical Inc., Minneapolis, MN
Ferrous sulfate.....	1			
Ferric chloride.....	1			
Ferric oxide.....	1			
Ferric sulfate.....	1		e. Mutagenic evaluation of compound FDA 75-36 (ferric pyrophosphate) by Litton Bionetics, Inc., under FDA contract. PB-257-876/AS; A03; \$4.50.	e. Human intake data taken from "A comprehensive survey of industry on the use of food chemicals generally recognized as safe (GRAS)," available from the National Technical Information Service, PB-221-920 (set); E-99; \$173.00.
Iron caprylate.....	1			
Iron linoleate.....	1			
Iron laurate.....	1			
Oxides of iron.....	1			
Drier in can coatings:				
Iron naphthenate.....	5		f. Mutagenic evaluation of compound FDA 73-82 (sodium ferric pyrophosphate) by Litton Bionetics, Inc., under FDA contract. PB-245-495/AS; A03; \$4.50. g. Teratologic evaluation of FDA 73-82 (ferric sodium pyrophosphate) in mice and rats by Food and Drug Research Laboratories, Inc., under FDA contract. PB-245-524/AS; A03; \$4.50.	f. Committee on GRAS List Survey Phase III. Estimating distribution of daily intakes of certain GRAS substances. g. Letter dated March 12, 1976, from E. Coleman, FDA, Washington, DC h. International Nutritional Anemia Consultative Group. 1977. Guidelines for the eradication of iron deficiency anemia. i. Letter dated October 26, 1976, from R. W. Harkins, Grocery Manufacturers of America, Inc., Washington, DC j. Motzok, I. M. D. Pennell and M. I. Davies. 1973. Factors affecting the biological availability of iron from foodgrade supplements. k. Evaluation of the health aspects of acid, sodium citrate, citric, ammonium citrate, triethyl citrate, isopropyl citrate and stearyl citrate as food ingredients (SCOGS-84). Submitted to FDA by FASEB. PB-280-954/AS; A03; \$4.50. l. Evaluation of the health aspects of sodium, potassium, magnesium and zinc gluconates as food ingredients (SCOGS-78). Submitted to FDA by FASEB. PB-288-675/AS; A02; \$4.00 m. Oster, I. I. 1976. Technical progress report on continuation of contract FDA 223-74-2107. n. Verrett, M. J. 1973. Investigations of the toxic and teratogenic effects of GRAS substances to the developing chicken embryo: ferrous gluconate. FDA in-house investigation. o. Evaluation of the health aspects of lactic acid and calcium lactate, as food ingredients (SCOGS-116). Submitted to FDA by FASEB. PB-283-713/AS; A03; \$4.50. p. Alterman, E. 1978. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryo: ferrous lactate. FDA in-house investigation. q. Verrett, M. J. 1973. Investigation of the toxic and teratogenic effects of GRAS substances to developing embryo (ferrous sulfate). FDA in-house investigation. r. Verrett, M. J. 1977. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryo: ferric pyrophosphate. s. Evaluation of the health aspects of coconut oil, peanut oil, and oleic acid as they may migrate to food from packaging materials, and linoleic acid as a food ingredient (SCOGS-85). Submitted to FDA by FASEB. PB-274-475/AS; A02; \$4.00. t. Evaluation of the health aspects of caprylic acid as a food ingredient (SCOGS-29). Submitted to FDA by FASEB. PB-254-530/AS; A02; \$4.00. u. Hercules (Inc.) N.D. Pale rosin (gum, wood and tall oil); summary of toxicological investigations.

Reports in the table with "PB" prefixes may be obtained from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

In addition to the information contained in the documents listed in the table above, the Select Committee supplemented its reviews, where appropriate, with specific information from specialized sources as announced in a previous hearing opportunity notice published in the *Federal Register* of September 23, 1974 (39 FR 34218).

The Select Committee's tentative report on ingredients that are the subject of this notice of opportunity for a hearing is available for review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-56, 5600 Fishers Lane, Rockville, MD 20857, and also at the Public Information Office, Food and Drug Administration, Rm. 3807, 200 C St. SW., Washington, DC 20204. In addition, all reports and documents used by the Select Committee to review the ingredients are available for review at the office of the Hearing Clerk.

To schedule the public hearing, the Select Committee must be informed of the number of persons who wish to attend and the amount of time requested to give their views. Accordingly, any interested person who wishes to appear at the public hearing to make an oral presentation should inform the Select Committee in writing addressed to: The Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814. A copy of each such request will be sent to the Hearing Clerk, address noted above, and all requests shall be placed on public display in that office. Any such request must be received by or postmarked on or before September 27, 1979, shall state the substance(s) on which an opportunity to present oral views is requested, and shall state how much time is requested for the presentation. Requests shall specify the docket number found in brackets on the heading of this notice. As soon as possible after the request deadline, a notice announcing the date, time, place, and scheduled presentations for any public hearing that may be requested will be published in the *Federal Register*.

The purpose of the public hearing is to receive data, information, and views not previously available to the Select Committee about the substances listed above. Information already contained in the scientific literature reviews and in the tentative Select Committee report shall not be duplicated, although views on the interpretation of this material may be presented.

Depending on the number of requests for opportunity to make oral presentations, the Select Committee may reduce the time requested for any presentation. Because of time limitations, individuals and organizations with common interests are urged to consolidate their presentations. Any interested person may, in lieu of an oral presentation, submit written views, which shall be considered by the Select Committee. Three copies of such written views identified with the docket number found in brackets in the heading of this notice shall be addressed to the Select Committee at the address noted above, and must be received by or postmarked not later than 10 days before the scheduled date of the hearing. A copy of any written views shall be sent to the Hearing Clerk, Food and Drug Administration, and shall be placed on public display in that office.

A public hearing will be presided over by a member of the Select Committee. Hearings will be transcribed by a reporting service, and a transcript of each hearing may be purchased directly from the reporting service and will be placed on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

Dated: August 22, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29646 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[M 44302-M 44303]

Montana; Right-of-Way Applications for Pipeline

August 20, 1979.

Notice is hereby given that pursuant

to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), Continental Pipe Line Company has filed two (2) applications for rights-of-way for a 3-inch crude oil pipeline to hook up Manning and May S&L 23-24 and Juniper 12-X oil wells across 0.12 miles of public land in Musselshell County:

Principal Meridian, Montana
T. 8 N., R. 24 E., Sec. 1, Lot 5.
T. 9 N., R. 25 E., Sec. 34, NE¼SW¼.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the applications should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, Drawer 1160, Lewistown, Montana 59457.

Roland F. Lee,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-26685 Filed 8-27-79; 8:45 am]
BILLING CODE 4310-84-M

Bureau of Reclamation

[INT FES 79-35]

Proposed Enlargement of Bumping Lake, Yakima Project, Washington; Availability of Final Environmental Statement

Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a final environmental statement for the Enlargement of Bumping Lake, Yakima Project, Washington.

The environmental statement concerns replacing the existing Bumping Lake Dam with a larger structure and creating an enlarged Bumping Lake with an active capacity of 458,000 acre-feet for the purpose of providing (a) improved streamflows and new passage and hatchery facilities for enhancement of resident and anadromous fish resources, (b) supplemental water supplies for irrigated lands, (c) flexibility in the Yakima Project storage system to strengthen flood control operations, (d) opportunity to develop recreational potential of the Bumping Lake area in a manner compatible with adjacent

natural values, and (e) modification of the spillway gates in Tieton Dam to improve winter operation for flood control.

Copies are available for inspection at the following locations:

Office of Environmental Affairs, Department of the Interior, Bureau of Reclamation, Room 7622, Washington, DC 20240, Telephone (202) 343-4991.

Division of Management Support, General Services, Denver Federal Center, E&R Center, Library Section, Code 950, Denver, CO 80225, Telephone (303) 234-3019.

Office of the Regional Director, Bureau of Reclamation, 550 West Fort Street, Box 043, Boise, ID 83724, Telephone (208) 384-1208.

Yakima Project Office, Bureau of Reclamation, 1917 Marsh Road, Box 1377, Yakima, WA 98901, Telephone (509) 575-5848.

Single copies of the final environmental statement may be obtained on request to the Commissioner of Reclamation or the Regional Director. Copies will also be available for inspection in libraries in south-central Washington. Please refer to the statement number above.

Dated: August 23, 1979.

Larry E. Meierotto,

Assistant Secretary of the Interior.

[FR Doc. 79-26682 Filed 8-27-79; 8:45 am]

BILLING CODE 4310-09-M

Heritage Conservation and Recreation Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before August 17, 1979. Pursuant to § 60.13 of 36 CFR Part 60, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments or a request for additional time to prepare comments should be submitted by September 7, 1979.

Charles A. Herrington,

Acting Keeper of the National Register.

ALASKA

Sitka Division

Sitka, Sitka Pioneers' Home, Katlian Ave. and Lincoln St.

CALIFORNIA

Shasta County

Whiskeytown vicinity, Lower Clear Creek Archeological District.

CONNECTICUT

Hartford County

Plainville vicinity, New Haven District Campground, Off CT 177.

Tolland County

Mansfield Center vicinity, Spring Hill Historic District, 928-989 Storrs Rd., 3 East Rd., 3 and 4 Beebe Lane.

DELAWARE

New Castle County

Christiana, Lewden, John, House, 107 E. Main St.

Christiana, Public School No. 111-C, DE 7

Sussex County

Georgetown vicinity, Pepper, Carlton David, Farm, SR 469.

INDIANA

DeKalb County

Garrett, Mountz House, 507 E. Houston St.

St. Joseph County

Misawaka, Kamm and Schellinger Brewery, 100 Center St.

Vanderburgh County

Evansville, Alhambra Theatre, 50 Adams Ave.

Evansville, Greyhound Bus Terminal, 102 N.W. 3rd St.

Evansville, McCurdy Building (Sears, Roebuck and Company Building, 101 N.W. 4th St.

KENTUCKY

Fayette County

Lexington, Central Christian Church, 207 E. Short St.

Lexington vicinity, Rogers, Joseph Hale, House, E of Lexington on Bryan Station Pike

Jefferson County

Louisville, Crescent Hill Reservoir, Reservoir Ave.

Laurel County

London, Bennett, Sue, Memorial School Building, College St.

MAINE

Androscoggin County

Lisbon vicinity, Cushman Tavern, NE of Lisbon on ME 9.

Kennebec County

Sidney vicinity, Powers House, Off ME 104.

Lincoln County

Medomak vicinity, Weston, Daniel, Homestead, W of Medomak On ME 32.

Waldoboro vicinity, Ludwig, Godfrey, House, N of Waldoboro On ME 32.

Penobscot County

Bangor, Hamlin, Hannibal, House, 15 5th St.

Piscataquis County

Guilford, Hudson, H., Law Office, Hudson Ave.

York County

North Berwick, Hurd, Mary R., House, Elm St.

Maryland

Allegany County

Cumberland, Canada Hose Company, 400-402 N. Mechanic St.

Baltimore (independent city)

Public School No. 25 (Capt. Henry Fleete School), S. Bond St.

Public School No. 37 (Patrick Henry School) E. Biddle St. and N. Patterson Park Ave.

Public School No. 99 (Columbus School) E. North Ave. and N. Washington St.

Public School No. 109 (Broadway School) N. Broadway and Ashland Ave.

School No. 111 (Francis Ellen Harper School) N. Carrollton Ave. and Riggs Rd.

Baltimore County

Reisterstown, Reisterstown Historic District, U.S. 140 and MD 30.

Washington County

Beaver Creek vicinity, Doub's Mill Historic District, SW of Beaver Creek on Beaver Creek Rd.

Hagerstown, South Prospect Street Historic District, 18-278 S. Prospect St.

Massachusetts

Essex County

Beverly, Beverly Depot, Park St.

Middlesex County

Newton, Winslow-Haskell Mansion, 53 Vista Ave.

Suffolk County

Boston, Commonwealth Pier Five, 165 Northern Ave.

Nebraska

Nineteenth Century Terrace Houses Thematic Resources. Reference—see individual listings under Lancaster County.

Lancaster County

Lincoln, Baldwin Terrace (Nineteenth Century Terrace Houses Thematic Resources) S. 12th St. and K St.

Lincoln, Barr Terrace (Nineteenth Century Terrace Houses Thematic Resources) S. 11th St. and H St.

Lincoln, Helmer-Winnett-White Flats (Nineteenth Century Terrace Houses Thematic Resources) 1022-1028 K St.

Lincoln, Lyman Terrace (Nineteenth Century Terrace Houses Thematic Resources) 1111-1119 H St.

New Hampshire

Hillsborough County

Manchester, Zimmerman House, 223 Heather St.

New Jersey

Morris County

Fayson Lakes, Fredericks House, 6 Duchess Dr.

New York**Montgomery County**

Fort Plain, Fort Plain Conservation Area.

NORTH CAROLINA**Caswell County**

Yanceyville vicinity, Poteat House, N of Yanceyville on NC 62.

Greene County

Snow Hill, St. Barnabas Episcopal Church, SE. 4th St., and St. Barnabas Rd.

Martin County

Williamston, Biggs, Asa, House and Site, 100 E. Church St.

Vance County

Kittrell vicinity, Crudup, Josiah, House, S of Kittrell on U.S. 1.

OREGON**Coos County**

Bandon vicinity, Philpott Site (35 CS 1).

Hood River County

Hood River vicinity, Columbia Gorge Hotel, W. of Hood River at 9000 Westcliffe Dr.

Marion County

St. Paul, St. Paul Roman Catholic Church, Off OR 219.

PENNSYLVANIA**Bucks County**

Erwinna, Stover Mill, PA 32.

Centre County

Philipsburg, Rowland Theatre, Front St.

Lancaster County

Lancaster, Germania Turnverein Building, 33-35 N. Market St.

Lancaster, Hager Building, 25 W. King St.
Lancaster, Sprenger Brewery, 125-131 E. King St.

Lancaster, Steinman Hardware Store, 26-28 W. King St.

Lancaster, Yeates, Jasper, House, 24-46 S. Queen St.

TEXAS**Guadalupe County**

Seguin, Saffold Dam, Off TX 123.

San Patricio County

San Patricio vicinity, McGloin, James, Homestead, NW of San Patricio (boundary increase).

Shackelford County

Fort Griffin vicinity, Fort Griffin Brazos River Bridge, NE of Fort Griffin.

Tarrant County

Fort Worth, Eddleman-McFarland House, 1110 Penn St.

Wise County

Chico, Brown, J.T., Hotel, E. Decatur St.

UTAH**Cache County**

Wellsville, Howell-Theurer House, 30 S. 100 East.

Juab County

Nephi, Booth, Edwin Robert, House, 94 W. 300 South St.

VIRGIN ISLANDS**St. John Island**

Cruz Bay, Keating's Inn, (7-6-76) (proposed move).

VIRGINIA**Fairfax County**

Great Falls vicinity, Patowmack Canal Historic District, E of Great Falls within Great Falls Park (also in Montgomery County, MD).

Hopewell (independent city)**City Point Historic District.**

[FR Doc. 79-26391 Filed 8-27-79; 8:46 am]

BILLING CODE 4310-03-M

DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No. 79-13]

Thomas W. Moore, Jr., M.D.; Bronx, New York: Hearing

Notice is hereby given that on June 18, 1979, the Drug Enforcement Administration, Department of Justice, issued to Thomas W. Moore, Jr., M.D., Bronx, New York, an Order to Show Cause as to why the Drug Enforcement Administration should not deny Respondent's application for registration under the Controlled Substances Act, executed on or about February 16, 1979.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m., on Tuesday, September 18, 1979, in the Hearing Room, Room 1210, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C.

Dated: August 21 1979.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

[FR Doc. 79-26735 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-09-M

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****Advisory Committee on Construction Safety and Health Subgroup on Health Standards; Cancellation of Meeting**

The meeting of the subgroup on Health Standards of the Advisory

Committee on Construction Safety & Health scheduled for August 29 and 30, 1979 in Washington, D.C., is hereby cancelled. Notice of this meeting was published on August 10, 1979 (44 FR 156). The meeting will be rescheduled at a later date. Details will be published in the Federal Register.

Signed at Washington, D.C. this 23rd day of August, 1979.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 79-26780 Filed 8-27-79; 8:36 am]

BILLING CODE 4510-26-M

NUCLEAR REGULATORY COMMISSION**Privacy Act of 1974; New System of Records**

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notification of proposed new system of records.

SUMMARY: The NRC is proposing to establish a new system of records, subject to the Privacy Act. The purpose of the system is to enable the agency to maintain document control for all documents originated by and received by the NRC and to serve as an information source for these documents. The system will incorporate existing system NRC-26. Upon publication of the new system, existing system NRC-26 will be deleted.

COMMENT DATE: Comments are due on or before September 27, 1979.

ADDRESS: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Ellen Whitlow, FOIA/PA Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492-8133.

SUPPLEMENTARY INFORMATION: The new system is identified as Document Control System. It will consist of correspondence and related documents originated by or received by the NRC.

A new system report was filed with the President of the Senate, the Speaker of the House and the Office of Management and Budget on August 20, 1979. The Prefatory Statement containing General Routine Uses applicable to the NRC's systems of records was published at 42 FR 49082, 9/26/77.

All interested persons who desire to submit written comments or suggestions for consideration in connection with the

proposed new system of records should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing & Service Branch, by September 27, 1979. Copies of comments received will be available for inspection and copying at the Commission's Public Document Room, 1717 H Street NW., Washington, DC.

Dated at Bethesda, MD, this 13th day of August 1979.

For the Nuclear Regulatory Commission,
Lee V. Gossick,
Executive Director for Operations.

NRC-29

SYSTEM NAME:

Document Control System—NRC.
Pursuant to 5 U.S.C. 552a(k), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f). This exemption rule is contained in section 9.95 of the NRC regulation (10 CFR 9.95).

SYSTEM LOCATION:

Primary system—
Record Facilities Branch, Office of Administration, NRC, 7920 Norfolk Avenue, Bethesda, Maryland.
Duplicate System—duplicate systems exist, in whole or in part, at the locations listed in Addendum I, Parts 1 and 2, the NRC Local Public Document Rooms (LPDR's) and at the TERA Advanced Services Corporation, 7101 Wisconsin Avenue, Suite 1400, Bethesda, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC staff, contractors, and sub-contractors licensees, Congressional offices, and other correspondents with the NRC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents both received by and originated by the NRC.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

- a. 44 U.S.C. 3101;
- b. Sec. 201, Energy Reorganization Act of 1974, 42 U.S.C. 5841.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

- a. To refer, where appropriate, inquiries to Federal agencies or persons for their reply or action;
- b. To provide information to persons or agencies requesting this information, including provision of Daily Accession Lists in the NRC and Local Public Document Rooms.

c. To prepare a monthly "Title List of Documents Made Publicly Available", and

d. For any of the routine uses specified in the Prefatory Statement.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on microfiche, disks, tapes, and paper in file folders. Classified documents are maintained in locked safes; proprietary and sensitive safeguards documents are maintained in secured facilities.

RETRIEVABILITY:

Accessed by name (author or recipient), corporate source, title of document, subject matter, or other identifying document or control number.

SAFEGUARDS:

Access to and use of these records are limited to those persons whose official duties required such access. Information not exempt from disclosure under the Freedom of Information Act (FOIA) will be publicly available in the PDR and LPDR's.

RETENTION AND DISPOSAL:

Retained and destroyed in accordance with approved records disposal schedules for the various types of records involved.

SYSTEM MANAGER(S) AND ADDRESSES:

Director, Division of Technical Information and Document Control, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

NOTIFICATION PROCEDURE:

Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

RECORD ACCESS PROCEDURES:

Same as "Notification procedure". Information which is classified or otherwise exempt from public disclosure under the FOIA and will not be disclosed.

CONTESTING RECORD PROCEDURES:

Same as "Notification procedure."

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the correspondence to and from the NRC, contractors, and NRC employees.

SYSTEMS OF RECORDS EXEMPT FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a(k), the Commission has exempted portions of this system of records from 5 U.S.C.

552a(c)(3), (d), (e)(1), (e)(4) (G), (H), (I), and (f). This exemption rule is contained in section 9.95 of the NRC regulation (10 CFR 9.95).

[FR Doc. 79-26596 Filed 8-27-79; 8:45 am]
BILLING CODE 7590-01-M

[Docket No. PRM-140-1]

Public Citizen Litigation Group Critical Mass Energy Project; Filing of Petition for Rule Making

Notice is hereby given that representatives of the Public Citizen Litigation Group and the Critical Mass Energy Project, by petition dated July 24, 1979, have requested that the Nuclear Regulatory Commission (NRC) find, pursuant to the procedures and criteria in the NRC's regulation's (Subpart E of 10 CFR Part 140), that the nuclear accident commencing on March 28, 1979 at the Three Mile Island, Unit 2 nuclear power plant constitutes an "extraordinary nuclear occurrence" (ENO). The petition also requested that the NRC amend Subpart E of 10 CFR Part 140 to make less stringent the criteria used by the Commission for determination of whether or not an ENO has occurred.

The Commission intends to treat the first part of the petition as a response to its July 23, 1979, Federal Register notice (44 FR 43128) announcing its decision to initiate "the making of a determination as to whether or not the recent accident at Three Mile Island constitutes an extraordinary nuclear occurrence" and inviting interested persons to submit to the Commission on or before August 22, 1979 "any information in their possession relevant to this determination."

The Commission intends to treat the second part of the petition as being a petition for rule making filed in accordance with 10 CFR 2.802 of the Commission's regulations. This part of the petition states, in relevant part, as follows:

Whether or not the Commission finds that the criteria currently set out in its regulations indicate that the accident at Three Mile Island was an extraordinary nuclear occurrence, petitioners request that the Commission alter or amend those criteria to bring them more into line with the clear intent of Congress on this matter.

Under these criteria, there is no question that the accident at Three Mile Island is of the size and type Congress was led to believe would be considered an extraordinary nuclear occurrence. However, from the inception of the concept of an extraordinary nuclear occurrence, the Commission also contemplated criteria establishing an accident of much smaller proportions than Three Mile Island as an extraordinary nuclear occurrence.

Inasmuch as the Commission has the power and discretion to make the definition of an extraordinary nuclear occurrence responsive to the circumstances and needs of the public, and inasmuch as accidents of far smaller size could be designated extraordinary nuclear occurrences in conformity with the legislative intent of the Price-Anderson Act as amended, it is appropriate and necessary that the criteria for the determination of an extraordinary nuclear occurrence be revised, altered or amended so as to respond effectively to those circumstances and demonstrated needs. In order that the assurances to the public and to Congress not prove to be empty promises, petitioners urge the Commission to alter or amend its criteria for an extraordinary occurrence through appropriate rulemaking procedures, whether or not the current criteria are satisfied by the accident at Three Mile Island.

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

All persons who desire to submit written comments or suggestions concerning the petition for rule making should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 Attention: Docketing and Service Branch by October 29, 1979.

FOR FURTHER INFORMATION CONTACT: Joseph M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: 301-492-7211.

Dated at Washington, DC this 22nd day of August, 1979.

For the Nuclear Regulatory Commission.
Samuel J. Chilk,
Secretary of the Commission.

[FR Doc. 79-26676 Filed 8-27-79; 8:45 am]

BILLING CODE 7590-01-M

POSTAL RATE COMMISSION

[Docket No. MC79-4]

Mail Classification Schedule— Merchandise Return Service, 1979; U.S. Postal Service Filing of Request for Recommended Decision on Establishing a Special Service for Merchandise Return

August 22, 1979.

Notice is hereby given that on August 13, 1979, the United States Postal

Service ("Postal Service"), pursuant to section 3623 of the Postal Reorganization Act (39 U.S.C. 3623), filed a request with the Postal Rate Commission for a recommended decision on establishing a special service for merchandise return. This filing has been assigned Docket No. MC79-4.

The Postal Service states that its request contains such information and data which explain the nature, scope, significance and impact of the proposed special service for merchandise return. Further, the Postal Service states that this proposed service would answer the need of businesses to permit customers to return merchandise without prepaying the postage. The proposed service is to be available to mailers of all classes;¹ however, the Postal Service anticipates that the special service will be used primarily for single piece third-class, special rate fourth-class and parcel post mail.

The merchandise return service would utilize a two-part label printed by the business shipper.² If the customer recipient wishes to return merchandise that has been shipped, the customer would notify the shipper who would then send the customer the two-part label. The customer would re-wrap the parcel and take it to the post office. An employee at the post office would compute the postage, writing it on both parts of the label; that employee would separate the parts of the label, affixing the top portion to the parcel and putting the bottom portion in the first-class mailstream. When the bottom portion arrived at the destination post office, the amount due for each shipper would be computed and the trust-fund account adjusted. The merchandise-return labels, together with the appropriate billing forms, would be put in an envelope for delivery to the shipper.

Hearings will be held on the proposal submitted by the Postal Service in Docket No. MC79-4. Any person desiring to be heard with reference thereto and to become a party to the proceeding, or to participate as a party in any hearing thereon, should file a petition for leave to intervene. Petitions for leave to intervene must be filed with the Secretary, Postal Rate Commission, Washington, D.C. 20268 on or before September 11, 1979, and must be in

accordance with § 20 of the Commission's rules of practice (39 CFR 3001.20). We direct specific attention to § 20(b) which provides that petitions for leave to intervene shall affirmatively state whether or not petitioner requests a hearing or, in lieu thereof, a conference; and further, whether or not the petitioner intends to participate actively in the hearing.³ Alternatively, persons seeking limited participation, but who do not wish to become parties may, on or before September 11, 1979, file a written request for leave to be heard as a "limited participator," pursuant to § 19a of the Commission's rules of practice (39 CFR 3001.19a). In addition, persons wishing to express their views informally, and not desiring to become a party or limited participant, may file comments pursuant to § 19b of the Commission's rules, 39 CFR 3001.19b.

At the same time as it filed its Proposal, the Postal Service, under Commission rule 64(h)(3), filed a motion for "waiver of rule 64(e), of rule 64(h)(2)(i) insofar as it incorporates rules 54(f) (2), (3) and 54(j) (5), (6), and of rule 64(d) (ii), (iii)." The Postal Service says that rule 64(h)(2)(i) insofar as it incorporates rules 54(f) (2), (3) and 54(j) (5), (6), and rule 64(d) (ii)-(iii) should be waived because the Postal Service's rates and fees and the cost-revenue relationship would not be significantly affected. The Postal Service further argues that waiver should be granted because no accurate volume forecast of the proposed service can be projected. Finally, the Postal Service says rule 64(e) should be waived because no interclass changes are contemplated. Parties who wish to address the Postal Service's motion should file their answers by September 11, 1979.

The request of the Postal Service for a recommended decision on establishing a special service for merchandise return and the motion for waiver of certain filing provisions of the rules of practice and procedure are on file with the Commission and are available for public inspection during regular business hours.

³ In this regard, parties who intend to participate actively in this proceeding are encouraged informally and promptly to inform the Postal Service of desired preliminary clarifications of the Postal Service's presentation wherever the participant believes such clarification will expedite this proceeding.

¹ The specific additions to the mail classification schedule are set out, in legislative format, in Attachment A to the Postal Service's Request.

² The service would be available to all shippers. The Postal Service predicts that only businesses would incur the expenses involved.

Further, the Commission designates Stephen L. Sharfman, Assistant General Counsel, Litigation, as the Officer of the Commission in Docket No. MC79-4.

David F. Harris,
Secretary.

[FR Doc. 79-26653 Filed 8-27-79; 8:45 am]

BILLING CODE 7715-01-M

PRESIDENTIAL COMMISSION ON WORLD HUNGER

Meeting

The eighth meeting of the Presidential Commission on World Hunger will be held on Friday, September 7, 1979, in Room 2010 of the New Executive Office Building, 726 Jackson Place, N.W., Washington, D.C. The meeting will begin at 9:30 a.m. and conclude at approximately 4:30 p.m.

The agenda for the meeting will include discussion of draft portions of the Commission's Report.

The meeting will be open to observation by the public to the extent space is available. Reservations are required and requests should be addressed to Presidential Commission on World Hunger, 734 Jackson Place, N.W., Washington, D.C. 20006. Reservations will be honored on the basis of the earliest postmarks of requests.

Donald B. Harper,
Administrative Officer, Presidential Commission on World Hunger.

[FR Doc. 79-26654 Filed 8-27-79; 8:45 am]

BILLING CODE 6820-97-M

SMALL BUSINESS ADMINISTRATION

Region I Advisory Council Meeting; Public Meeting

The Small Business Administration Region I Advisory Council, located in the geographical area of Concord, New Hampshire, will hold a public meeting at 10:00 a.m., Wednesday, September 19, 1979, in the conference room #404 on the fourth floor of the Concord Federal Building, 55 Pleasant Street, Concord, New Hampshire, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Bert Teague, District Director, U.S. Small Business Administration, 55 Pleasant Street, Concord, New Hampshire, 03301 (603) 224-5588.

Dated: August 21, 1979.

K Drew,
Deputy Advocate for Advisory Councils.

[FR Doc. 79-26751 Filed 8-27-79; 8:45 am]

BILLING CODE 8025-01-M

Region I Advisory Council Meeting; Public Meeting

The Small Business Administration Region I Advisory Council, located in the geographical area of Providence, Rhode Island, will hold a public meeting at 12:00 noon, Monday, October 15, 1979, at the Governor Dyer's Buffet House, Providence, Rhode Island, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Charles J. Fogarty, District Director, U.S. Small Business Administration, 57 Eddy Street, Providence, Rhode Island 02903—(401) 528-4580.

Dated: August 21, 1979.

K Drew,
Deputy Advocate for Advisory Councils.

[FR Doc. 79-26749 Filed 8-27-79; 8:45 am]

BILLING CODE 8025-01-M

Region IV Advisory Council Meeting; Public Meeting

The Small Business Administration Region IV Advisory Council, located in the geographical area of Charlotte, North Carolina, will hold a public meeting at 2:00 p.m., Wednesday, September 19, 1979, and Thursday, September 20, 1979, at Fairfield Harbour, New Bern, North Carolina, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call George W. Marschall, District Director, U.S. Small Business Administration, 230 South Tryon Street, Suite 700, Charlotte, North Carolina 28202—(704) 371-6561.

Dated: August 21, 1979.

K Drew,
Deputy Advocate for Advisory Councils.

[FR Doc. 79-26747 Filed 8-27-79; 8:45 am]

BILLING CODE 8025-01-M

Region IV Advisory Council Meeting; Public Meeting

The Small Business Administration Region IV Advisory Council, located in the geographical area of Jackson, Mississippi, will hold a public meeting

at 9:00 a.m., Friday, September 28, 1979, at Howard Johnson Motor Lodge, Tom Bailey Drive, Meridian, Mississippi, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Ardis Jones, District Director, U.S. Small Business Administration, Suite 322 Federal Building, 100 West Capitol Street, Jackson, Mississippi 39201—(601) 969-4363.

Dated: August 21, 1979.

K Drew,

Deputy Advocate for Advisory Councils.

[FR Doc. 79-26748 Filed 8-27-79; 8-45 am]

BILLING CODE 8025-01-M

Region IX Advisory Council Meeting; Public Meeting

The Small Business Administration Region IX Advisory Council, located in the geographical area of San Diego, California, will hold a public meeting at 11:30 a.m., through 2:30 p.m., Thursday, September 27, 1979, at the Little America Westgate Hotel, San Diego, California, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Robert B. Strauss, District Director, U.S. Small Business Administration, 880 Front Street, Suite 4-S-33, San Diego, California 92188—(714) 895-5430.

Dated: August 21, 1979.

K Drew,

Deputy Advocate for Advisory Councils.

[FR Doc. 79-26750 Filed 8-27-79; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF STATE

Office of the Secretary

[CM-8/219]

Study Group 1 of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT); Meeting

The Department of State announces that Study Group 1 of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT) will meet on September 19, 1979 at 9:30 a.m. in Room A-110 (Annex) of the Federal Communications Commission, 1229 20th Street, NW., Washington, D.C. This Study Group deals with U.S. Government regulatory aspects of international telegraph and telephone operations and tariffs.

The Study Group will discuss international telecommunications questions relating to telegraph, telex, new record services, data transmission and leased channel services in order to develop U.S. positions to be taken at international CCITT meetings.

Members of the general public may attend the meeting and join in the discussion subject to instructions of the Chairman. Admittance of public members will be limited to the seating available.

Requests for further information should be directed to Richard H. Howarth, State Department, Washington, D.C. 20520, telephone (202) 632-1007.

Richard H. Howarth,
Chairman, U.S. CCITT National Committee.
August 17, 1979.

[FR Doc. 79-26683 Filed 8-27-79; 8:45 am]

BILLING CODE 4710-07-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 79-6]

Commerce in Explosives; List of Explosive Materials

Pursuant to the provisions of section 841(d) of Title 18, United States Code, and 27 CFR 181.23, the Director, Bureau of Alcohol, Tobacco, and Firearms, must publish and revise at least annually in the Federal Register a list of explosives determined to be within the coverage of 18 U.S.C. Chapter 40, Importation, Manufacture, Distribution and Storage of Explosive Materials. This Chapter covers not only explosives, but also blasting agents and detonators, all of which are defined as explosive materials in section 841(c) of Title 18, United States Code.

Accordingly, the following is the 1979 List of Explosive Materials subject to regulation under 18 U.S.C. Chapter 40, which includes both the list of explosives (including detonators) required to be published in the Federal Register and blasting agents. The list is intended to also include any and all mixtures containing any of the materials in the list. Materials constituting blasting agents are marked by an asterisk. While the list is comprehensive, it is not all inclusive. The fact that an explosive material may not be on the list does not mean that it is not within the coverage of the law if it otherwise meets the statutory definitions in Section 841 of Title 18, United States Code. Explosive materials are listed alphabetically by their

common names followed by chemical names and synonyms in brackets. This revised list supersedes the List of Explosive Materials dated July 27, 1978 (43 FR 32492).

List of Explosive Materials

A

Acetylides of heavy metals.
Aluminum containing polymeric propellant.
Aluminum ophorite explosive.
Amatex.
Amatol.
Ammonal.
Ammonium nitrate explosive mixtures (cap sensitive).
*Ammonium nitrate explosive mixtures (non cap sensitive).
Aromatic nitro-compound explosive mixtures.
Ammonium Perchlorate having particle size less than 15 microns.
Ammonium perchlorate composite propellant.
Ammonium picrate [picrate of ammonia, Explosive D].
Ammonium salt lattice with isomorphously substituted inorganic salts.
*ANFO [ammonium nitrate-fuel oil].

B

Baratol.
Baronol.
BEAF [1, 2-bis (2, 2-difluoro-2-nitroacetoxyethane)].
Black powder.
Black powder based explosive mixtures.
*Blasting agents, nitro-carbo-nitrates, including non cap sensitive slurry and water-gel explosives.
Blasting caps.
Blasting gelatin.
Blasting powder.
BTNEC [bis (trinitroethyl) carbonate].
BTNEN [bis (trinitroethyl) nitramine].
BTTN [1,2,4 butanetriol trinitrate].
Butyl tetryl.

C

Calcium nitrate explosive mixture.
Cellulose hexanitrate explosive mixture.
Chlorate explosive mixtures.
Composition A and variations.
Composition B and variations.
Composition C and variations.
Copper acetylide.
Cyanuric triazide.
Cyclotrimethylenetrinitramine [RDX].
Cyclotetramethylenetetranitramine [HMX].
Cyclotol.

D

DATB [diaminotrinitrobenzene].
DDNP [diazodinitrophenol].
DEGDN [diethyleneglycol dinitrate].
Detonating cord.
Detonators.
Dimethylol dimethyl methane dinitrate composition.
Dinitroethyleneurea.
Dinitroglycerine [glycerol dinitrate].
Dinitrophenol.
Dinitrophenolates.
Dinitrophenyl hydrazine.
Dinitroresorcinol.
Dinitrotoluene-sodium nitrate explosive mixtures.

DIPAM.

Dipicryl sulfone.
Dipicrylamine.
DNBP [dinitropentano nitrile].
DNPA [2, 2-dinitropropyl acrylate].
Dynamite.

E

EDNA.
Ednatol.
EDNP [ethyl 4, 4-dinitropentanoate].
Erythritol tetranitrate explosives.
Esters of nitro-substituted alcohols.
EDGN [ethylene glycol dinitrate].
Ethyl-tetryl.
Explosive conitrates.
Explosive gelatins.
Explosive mixtures containing oxygen releasing inorganic salts and hydrocarbons.
Explosive mixtures containing oxygen releasing inorganic salts and nitro bodies.
Explosive mixtures containing oxygen releasing inorganic salts and water insoluble fuels.
Explosive mixtures containing oxygen releasing inorganic salts and water soluble fuels.
Explosive mixtures containing sensitized nitromethane.
Explosive mixtures containing tetranitromethane (nitro form).
Explosive nitro compounds of aromatic hydrocarbons.
Explosive organic nitrate mixtures.
Explosive liquids.
Explosive powders.

F

Fulminate of mercury.
Fulminate of silver.
Fulminating gold.
Fulminating mercury.
Fulminating platinum.
Fulminating silver.
Gelatinized nitrocellulose.
Gem-dinitro aliphatic explosive mixtures.
Guanyl nitrosamino guanyl tetrazene.
Guanyl nitrosamino guanylidene hydrazine.
Guncotton.

H

Heavy metal azides.
Hexanite.
Hexanitrodiphenylamine.
Hexanitrostilbene.
Hexogen or octogene and a nitrated H-methylaniline.
Hexolites.
HMX [cyclo-1, 3, 5, 7-tetramethylene-2, 4, 6, 8-tetranitramine; Octogen].
Hydrazinium nitrate/hydrazine/aluminum explosive system.
Hydrazoic acid.

I

Igniter cord.
Igniters.

K

KDNBF [potassium dinitrobenzo-furoxane].

L

Lead azide.
Lead mannite.
Lead mononitroresorcinol.
Lead picrate.
Lead salts, explosive.

Lead styphnate [styphnate of lead, lead trinitroresorcinol].
Liquid nitrated polyol and trimethylolethane.
Liquid oxygen explosives.

M

Magnesium ophorite explosives.
Mannitol hexanitrate.
MDNP [methyl 4, 4-dinitropentanoate].
Mercuric fulminate.
Mercury oxalate.
Mercury tartrate.
Minol-2 [40% TNT, 40% ammonium nitrate, 20% aluminum].
Mononitrotoluene-nitroglycer in mixture.
Monopropellants.

N

NIBTN [nitroisobutametrial trinitrate].
Nitrate sensitized with gelled nitroparaffin.
Nitrated carbohydrate explosive.
Nitrated glucoside explosive.
Nitrated polyhydric alcohol explosives.
Nitrates of soda explosive mixtures.
Nitric acid and a nitro aromatic compound explosive.
Nitric acid and carboxylic fuel explosive.
Nitric acid explosive mixtures.
Nitro aromatic explosive mixtures.
Nitro compounds of furane explosive mixtures.
Nitrocellulose explosive.
Nitroderivative of urea explosive mixture.
Nitrogelatin explosive.
Nitrogen trichloride.
Nitrogen tri-iodide.
Nitroglycerine [NG, RNG, nitro, glyceryl trinitrate, trinitroglycerine].
Nitroglycide.
Nitroglycol [ethylene glycol dinitrate, EGDN].
Nitroguanidine explosives.
Nitroparaffins and ammonium nitrate mixtures.
Nitronium perchlorate propellant mixtures.
Nitrostarch.
Nitro-substituted carboxylic acids.
Nitrourea.

O

Octogen [HMX].
Octol [75 percent HMX, 25 percent TNT].
Organic amine nitrates.
Organ nitramines.

P

PBX [RDX and Plasticizer].
Pellet powder.
Penthrinite composition.
Pentolite.
Perchlorate explosive mixtures.
Peroxide based explosive mixtures.
PETN [nitropentraerythrite, pentaerythrite tetranitrate, pentaerythritol tetranitrate].
Picramic acid and its salts.
Picramide.
Picrate of potassium explosive mixtures.
Picratol.
Picric acid (explosive grade).
Picryl chloride.
Picryl fluoride.
PLX [95 percent nitromethane, 5 percent ethylenediamine].
Polynitro aliphatic compounds.
Polyolpolynitrate-nitrocellulose explosive gels.
Potassium chlorate and lead sulfocyanate explosive.

Potassium nitrate explosive mixtures.
Potassium nitroaminotetrazole.

R

RDX [cyclonite, hexogen, T4, cyclo-1,3,5-trimethylene-2,4,6-trinitramine; hexahydro-1,3,5-trinitro-S-triazine].

S

Safety fuse.
Salts of organic amino sulfonic acid explosive mixture.
Silver acetylide.
Silver azide.
Silver fulminate.
Silver oxalate explosive mixtures.
Silver styphnate.
Silver tartrate explosive mixtures.
Silver tetrazene.
Slurried explosive mixtures of water, inorganic oxidizing salt, gelling agent, fuel and sensitizer (cap sensitive).
Smokeless powder.
Sodamol.
Sodium amatol.
Sodium dinitro-ortho-cresolate.
Sodium nitrate-potassium nitrate explosive mixture.
Sodium picramate.
Squibs.
Styphnic acid.

T

Tacot [tetranitro-2,3,5,6-dibenzo-1,3a,4,6a-tetrazapentalene].
TATB [Triaminotrinitrobenzene].
TEGDN [triethylene glycol dinitrate].
Tetrazene [tetracene, tetrazine, 1(5-tetrazolyl)-4-guanyl tetrazene hydrate].
Tetranitrocarbazole.
Tetryl [2,4,6 tetranitro-N-methylaniline].
Tetrytol.
Thickened inorganic oxidizer salt slurried explosive mixture.
TMETN (trimethylolethane trinitrate).
TNEF [trinitroethyl formal].
TNEOC [trinitroethyl orthocarbonate].
TNEOF [trinitroethyl orthoformate].
TNT [trinitrotoluene, trotyl, trilit, triton].
Torpex.
Tridite.
Trimethylol ethyl methane trinitrate composition.
Trimethylolethane trinitrate-nitrocellulose.
Trimonite.
Trinitroanisole.
Trinitrobenzene.
Trinitrobenzoic acid.
Trinitrocresol.
Trinitro-meta-cresol.
Trinitronaphthalene.
Trinitrophenetol.
Trinitrophenol.
Trinitroresorcinol.
Trinitroresorcinol.
Tritonal.

U

Urea nitrate.

W

Water bearing explosives having salts of oxidizing acids and nitrogen bases, sulfates, or sulfamates (cap sensitive).

X

Xanthomonas hydrophilic colloid explosive mixture.

Signed: July 11, 1979.

J. R. Dickerson,
Director.

[FR Doc. 79-28655 Filed 8-27-79; 8:45 am]

BILLING CODE 4810-31

Customs Service

Malleable Pipe Fittings of Iron From Japan; Receipt of Countervailing Duty Petition and Initiation of Investigation

AGENCY: United States Customs Service, Treasury Department.

ACTION: Initiation of Countervailing Duty Investigation.

SUMMARY: This notice is to advise the public that a satisfactory petition has been received and that a countervailing duty investigation has been initiated to determine if benefits which constitute the payment of a bounty or grant within the meaning of the countervailing duty law are conferred by the Government of Japan upon the manufacture, production or exportation of malleable pipe fittings of iron. A preliminary determination will be made no later than December 28, 1979, and a final determination in accordance with section 102(a)(2) of the Trade Agreements Act of 1979, will be made no later than March 17, 1980.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Stephen Nyschot, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229, telephone (202) 566-5492.

SUPPLEMENTARY INFORMATION: A petition in satisfactory form was received on June 28, 1979, on behalf of the American Pipe Fittings Associates alleging that benefits conferred by the Government of Japan upon the manufacture, production or exportation of malleable pipe fittings of iron from Japan constitute the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930 as amended (19 U.S.C. 1303).

The products covered by this investigation are malleable pipe fittings of iron used as fittings and junctions in water, steam and gas piping systems. These products are classified under item no. 610.7400, TSUSA, as cast iron fittings, malleable, advanced in condition by operations or processes subsequent to the casting process.

The petitioner alleges that financial assistance for small and medium sized enterprises under legislation enacted February 14, 1978 entitled "Law Concerning Temporary Measures for Medium and Small Enterprises Related to Steep Revaluation of Yen Rates" (High Yen Measures Law) constitutes

bounties or grants. Under this law, qualified enterprises have access to low interest loans for the stabilization of business and for the establishment of facilities required for a change of business, liberalized repayment terms for loans used for modernization, liberalized terms for government sponsored credit guarantees and extended carry forward and carry back periods for net losses when computing taxable corporate income.

Other programs which petitioner alleges constitute bounties or grants are:

(1) Access to a special credit fund sponsored by the government of Japan for the disposition of idle facilities in depressed industries.

(2) Tax deferral on part of previous year's export earnings and current year deduction of all outlays for new market development under the Overseas Market and Development Reserve Program (OMDR).

(3) Export promotion assistance through overseas market research, introductory advertising, foreign credit investigations and overseas trade fairs by the Japan External Trade Organization (JETRO).

(4) Loans granted on concessionary terms by the Japan Development Bank (JDB).

The high yen measures and the tax deferral aspects of OMDR listed above have been found to constitute a bounty or grant in prior investigations.

The alleged bounty concerning Government of Japan guarantees of repayment of certain loans to depressed industries has not been the subject of prior countervailing duty determinations. It is currently under investigation in the case of *Valves and Parts Thereof from Japan*, 44 FR 18780 (1979). While this program on its face is not export oriented, its effect could be to provide bounties or grants and therefore will be investigated with respect to the malleable pipe fitting industry.

The assistance rendered by JETRO is general in nature and not oriented towards the export promotion of specific products. Treasury has, in past determinations, concluded that this program results in the payment or bestowal of a bounty or grant on the grounds that these activities, at least indirectly, defray costs which would otherwise be incurred by the exporters involved and to that extent may subsidize the industry under consideration. However, information has been presented indicating that JETRO has altered its activities to include the promotion of imports into Japan. The changed nature of JETRO's overall mission, particularly its activities relating to import assistance

and promotion, has led Treasury to reconsider whether JETRO expenditures are countervailable. Pending resolution of this question, this program will be included in the investigation, and the Treasury invites public comment as to the appropriate resolution of this issue.

Preferential financing by the JDB (No. 4) was found to constitute a bounty or grant in *Certain Consumer Electronic Products from Japan*, 41 FR 1298 (1976), although in that case its effect was found to be *de minimis* in size.

Each of these programs will, therefore, be investigated in the proceedings hereby initiated.

Pursuant to section 303(a)(4) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)(4)), the Secretary of the Treasury is required to issue a preliminary determination as to whether or not any bounty or grant is being paid or bestowed within the meaning of the statute within 6 months of receipt, in satisfactory form, of a petition alleging the payment or bestowal of a bounty or grant. Under section 102(a)(2) of the Trade Agreements Act of 1979, a final determination will be made within 75 days of the coming into force of the law on January 1, 1980.

Therefore, a preliminary determination regarding this petition will be made no later than December 28, 1979, as to whether or not the alleged payments or bestowals conferred by the Government of Japan upon the manufacture, production, or exportation of the merchandise described above constitute a bounty or grant within the meaning of section 303, Tariff Act of 1930, as amended. A final determination will be made no later than March 17, 1980.

This notice is published pursuant to section 303(a)(3) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)(3)), and § 159.47(c) of the Customs Regulations (19 CFR 159.47(c)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order No. 101-5, May 16, 1979, the provisions of Treasury Department Order No. 165, revised, November 2, 1954, and § 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the initiation of a countervailing duty investigation by the Commissioner of Customs, are hereby waived.

David R. Brennan,

Acting General Counsel of the Treasury.

August 21, 1979.

[FR Doc. 79-28681 Filed 8-27-79; 8:45 am]

BILLING CODE 4810-22-M

Office of the Secretary

[Supplement to Department Circular Public Debt Series—No. 19-79]

Series W-1981 Notes; Interest Rate

August 23, 1979.

The Secretary announced on August 22, 1979, that the interest rate on the notes designated Series W-1981, described in Department Circular—Public Debt Series—No. 19-79, dated August 15, 1979, will be 9% percent. Interest on the notes will be payable at the rate of 9% percent per annum.

Paul H. Taylor,

Fiscal Assistant Secretary.

[FR Doc. 79-26703 Filed 8-27-79; 8:45 am]

BILLING CODE 4810-40-M

Office of Revenue Sharing**Final Date of Adjustments; Demands for Entitlement Period Nine**

AGENCY: Office of Revenue Sharing, Department of the Treasury.

ACTION: Data Notice.

SUMMARY: This notice announces that allocation payments to State and local governments for Entitlement Period Nine (October 1, 1977—September 30, 1978) of general revenue sharing will be final unless a demand for adjustment has been received by September 30, 1979.

FOR FURTHER INFORMATION CONTACT:

Matthew Butler, Manager, Data and Demography Division, Office of Revenue Sharing, 2401 E Street, N.W., Washington, D.C. 20226, telephone 202-634-5166.

SUPPLEMENTARY INFORMATION: Section 102(b) of the State and Local Fiscal Assistance Amendments of 1976(e)(2) of the State and Local Fiscal Assistance Amendments of 1976 (Pub. L. 94-488; 90 Stat. 2347; 31 U.S.C. 1221) provides that for entitlement periods beginning after December 31, 1976, no adjustment shall be made in a government's payments for an entitlement period unless a demand for adjustment has been made by the recipient government or the Secretary of the Treasury within one year after the end of that entitlement period. A demand by the Director or the Deputy Director of the Office of Revenue Sharing will be treated as a demand for adjustment by the Treasury.

An entry in the *Federal Register* of April 20, 1977 (42 FR 20525) originally gave notice that the Office of Revenue Sharing will honor adjustment demands for Entitlement Period Nine received from a government or the Secretary of the Treasury by September 30, 1979. Thus, this notice finalizes the

Entitlement Period Nine allocations to recipient governments for which demands for adjustment are not pending with the Office of Revenue Sharing on September 30, 1979. A demand accompanied by adequate supporting documentation pending at the close of business on the September 30, 1979 deadline will be researched and a written decision on the data challenge will be rendered. Any resulting adjustment to a government's allocation due to a pending adjustment will be made by the Office of Revenue Sharing.

Dated: August 22, 1979.

Bernadine Denning,

Director, Office of Revenue Sharing.

[FR Doc. 79-26835 Filed 8-27-79; 8:45 am]

BILLING CODE 4810-28-M

VETERANS ADMINISTRATION**Voluntary Service National Advisory Committee; Meeting**

The Veterans Administration gives notice that the annual meeting of the Veterans Administration Voluntary Service National Advisory Committee, composed of representatives of 45 national voluntary organizations, will be held at the Ramada Inn Rosslyn, 1900 North Fort Myer Drive, Arlington, Va., October 24-26, 1979.

Registration of the conferees and preliminary meetings on procedural matters will be held beginning at 8:30 a.m. on October 24, 1979. The meeting will officially convene with a Plenary Session at 9 a.m., October 25, in the Rosslyn Room A and B of the hotel and will conclude at noon on October 26, 1979.

The purposes of the meeting are to instruct committee members and officials of their organizations in obligations they have accepted for volunteer recruitment, communications and program interpretation, and to seek the advice of the committee in further developing volunteer participation in the care and treatment of veteran patients throughout the Agency's nationwide medical program.

Dated: August 20, 1979.

By direction of the Administrator:

John J. Leffler,

Associate Deputy Administrator.

[FR Doc. 79-26873 Filed 8-27-79; 8:45 am]

BILLING CODE 8320-01-M

INTERSTATE COMMERCE COMMISSION

[Notice No. 125]

Assignment of Hearings

August 22, 1979

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 138882 (Sub-180F), Wiley Sanders Truck Lines, Inc., MC-138882 (Sub-183F), Wiley Sanders Truck Lines, Inc., now assigned for hearing on September 11, 1979 (2 days), in Room 13216-C, 450 Golden Gate Avenue, San Francisco, CA.

MC 145633F, Walter B. Maki, DBA Maki International & Company, now assigned for hearing on October 15, 1979 (1 week), at Miami, Florida in a hearing room to be later designated.

MC 31389 (Sub-271F), McLean Trucking Company, now assigned for hearing on October 15, 1979 (1 week), at Chicago, IL, in a hearing room to be later designated.

MC 129537 (Sub-24F), Reeves Transportation Co., now assigned for hearing on October 15, 1979 (1 week), at Montgomery, AL, in a hearing room to be later designated.

MC 138100 (Sub-2F), Mellow Truck Express, Inc., now being assigned for hearing on November 27, 1979 (2 days), at Portland, OR in a hearing room to be designated later.

MC 146231 F, Seaton Smithson Flegel and Jerry Dean Flegel, DBA S. S. Flegel Trucking, now being assigned for hearing on November 29, 1979 (2 days), at Portland, OR in a hearing room to be designated later.

MC 83835 (Sub-153F), Wales Transportation, Inc., now being assigned for hearing on December 3, 1979 (1 week), at Portland, OR in a hearing room to be designated later.

MC 103926 (Sub-86F), W.T. Mayfield Sons Trucking Company, a Corporation, now being assigned for hearing on October 15, 1979 (1 day), at Atlanta, GA in a hearing room to be designated later.

MC 146102 F, Tamway Corporation, now being assigned for hearing on October 17, 1979 (1 day), at Atlanta, GA in a hearing room to be designated later.

MC 116254 (Sub-250F), Chem-Haulers, Inc., now being assigned for hearing on October 18, 1979 (1 day), at Atlanta, GA in a hearing room to be designated later.

MC 41404 (Sub-156F), Argo-Collier Truck Lines, Corporation, now being assigned for hearing on October 19, 1979 (1 day), at

Atlanta, GA in a hearing room to be designated later.

MC 730 (Sub-428), Pacific Intermountain Express Co., a Nevada Corporation, now being assigned for hearing on October 16, 1979 (9 days), at Hawthorne, CA will be held at the Cockatoo Inn, 4334 West Imperial Highway, Hawthorne, CA.

MC-C-10300 Fogarty Van Lines, Inc.—Investigation and Revocation of Certificates, now assigned for hearing on September 10, 1979 at Atlanta, GA will be held in Conference Room No. 556, 275 Peachtree Street.

MC 144041 (Sub-19F), Downs Transportation Co., Inc., now assigned for hearing on September 5, 1979, Atlanta, GA will be held in Conference Room No. 556, 275 Peachtree Street.

MC-F-12184, Nebraska-Iowa Xpress, Inc.—Control Chappell Freight Lines, Inc., now assigned for hearing on September 6, 1979 at Denver, CO is postponed indefinitely.

AB-102 (Sub-8F), Missouri-Kansas-Texas Railroad Company Abandonment at Burkburnett, TX and Altus, OK in Wichita County, TX and Cotton, Tillman, and Jackson Counties, OK now assigned for hearing on September 6, 1979 at Wichita Falls, TX, will be held at the City Hall, City Council Chambers, 1300-6th Street.

MC 115904 (Sub-130F), Grover Trucking Co., now assigned September 11, 1979 at Salt Lake City, UT is cancelled and transferred to Modified Procedure.

MC 46829 (Sub-12F), Allard Express, Inc., now being assigned for hearing on November 27, 1979 (2 weeks) at Chicago, IL, location of hearing room will be designated later.

MC 116254 (Sub-224F), Chem-Haulers, Inc., now assigned for hearing September 11, 1979 at Nashville, TN is cancelled and transferred to Modified Procedure.

MC 141804 (Sub-161F), Western Express, Division of Interstate Rental, Inc. A Nevada Corporation, now assigned for hearing on September 17, 1979 at Los Angeles, CA will be held in Room No. 8544, Federal Bldg. 300 N. Los Angeles St, Los Angeles, CA.

MC 141804 (Sub-162F), Western Express, Division of Interstate Rental, Inc., now assigned for hearing on September 18, 1979 at Los Angeles, CA will be held in Room No. 8544, Federal Bldg. 300 N. Los Angeles St, Los Angeles, CA.

MC 134501 (Sub-34F), Incorporated Carriers, Ltd., now assigned for hearing on September 19, 1979 at Los Angeles, CA will be held in Room No. 8544, Federal Bldg. 300 N. Los Angeles St, Los Angeles, CA.

MC 103490 (Sub-75F), Provan Transport Corp., transferred to Modified Procedure.

MC 115641 (Sub-655F), Colonial Refrigerated Transportation, Inc., now assigned September 17, 1979 (5 days), at Los Angeles, CA is canceled and reassigned to September 17, 1979 (2 days) at Los Angeles, CA, in Room 203, U.S. County Court House, 111 North Hill Street and September 19, 1979 (3 days) at the Monterey Civic Center, Fisherman's Wharf, Monterey, Calif.

MC 127840 (Sub-84F), Montgomery Tank Lines, Inc., now being assigned for continued hearing on October 16, 1979 (4

days) at Chicago, IL, location of hearing room will be by subsequent notice.

AB-6 (Sub-60F), Burlington Northern, Inc. Abandonment near St. Joseph, MO, and Humeston, IA, in Buchanan, Andrew, DeKalb, Gentry and Harrison Counties, MO and Decatur and Wayne Counties, IA, now being assigned for hearing on October 15, 1979 (1 week) at Chicago, IL location of hearing room will be by subsequent notice.

MC 117786 (Sub-48F), Riley Whittle, Inc., transfer to Modified Procedure.

Agatha L. Mergenovich,
Secretary.

[FR Doc. 79-26663 Filed 8-27-79; 8:45 am]
BILLING CODE 7035-01

[Finance Docket No. 28934 F]

Chicago and North Western Transportation Company Construction of a Line of Railroad in Niobrara and Gosheen Counties, WY and Sioux and Scotts Bluff Counties, NE

AGENCY: Interstate Commerce Commission, Office of Policy and Analysis, Energy and Environment Branch.

ACTION: Notice that in considering the above-entitled application for approval of a planned rail construction project, the Interstate Commerce Commission's Energy and Environment Branch will entertain any comments made at public hearings recently scheduled by the Federal Railroad Administration.

SUMMARY: The Federal Railroad Administration's (FRA) Office of Federal Assistance recently announced that it would hold two public hearings to receive oral comments on the draft environmental impact statement prepared jointly by FRA, the ICC and other agencies with respect to the Chicago and North Western Transportation Company's proposed Coal Line Project. These hearings will be held at Niobrara County High School Auditorium, Lusk, Wyoming on August 28, 1979 at 8:00 p.m. and at Gering High School Auditorium, Gering, Nebraska on August 28, 1979 at 7:00 p.m. Comments will be received from persons who indicate to FRA by August 27, 1979 an intention to testify. The purpose of this notice is to indicate that the Commission's Energy and Environment Branch will give consideration to any comments made at these hearings to the extent that they bear on the application for approval of construction now pending before the Commission.

FOR FURTHER INFORMATION CONTACT: Steve Botts, Energy and Environment Branch, Interstate Commerce Commission, 12th and Constitution

Avenue, Washington, DC 20423, Tel. (202) 275-7917.

[FR Doc. 79-26661 Filed 8-27-79; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB 7 (Sub No. 86 F)]

Stanley Hillman, Trustee of the Property of Chicago, Milwaukee, St. Paul and Pacific Railroad Company—Abandonment—Portions of Pacific Coast Extension in Montana, Idaho, Washington, and Oregon

AGENCY: Interstate Commerce Commission, Office of Policy and Analysis, Energy and Environment Branch.

ACTION: Notice of intent to prepare an environmental impact statement in the above-entitled proceeding.

SUMMARY: The Commission's Energy and Environment Branch (Branch) intends to prepare an environmental impact statement (EIS) with respect to the action contemplated in the above-entitled proceeding. Although, in light of the expedited procedure adopted by the Commission, no formal scoping meeting has been held, a proposed outline for the Draft Environmental Impact Statement (DEIS) is set forth as an appendix. Comments on the proposed outline are invited.

COMMENTS AND DATES: Written comments should be submitted to the Energy and Environment Branch (Room 5377), Interstate Commerce Commission, 12th and Constitution Ave., NW., Washington, DC, 20423 on or before September 21, 1979.

FOR FURTHER INFORMATION CONTACT: Paul S. Mushovic, telephone nos. 202-275-7916 or 202-347-5298.

Agatha L. Mergenovich,
Secretary.

Appendix—Preliminary Outline

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- ii. Summary (ICC Responsibility).
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 - 1.1 Introduction—General Background.
 - 1.11 General Description Entire MILW System.
 - 1.12 Reason for Action.
 - 1.121 General Update—Status in Court.
 - 1.123 BN Inclusion.
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 - 1.2 Description of Action—Miles City West.
 - 1.21 History of Pacific Coast Extension.
 - 1.22 Rationale for Development of Regional & Sub-Regional Analysis.¹

¹ The environmental description and analysis will be broken down into four major regions. Sub-regional analyses will be conducted where applicable. The four regions include: Miles City to

Footnotes continued on next page

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- 1.222 Plummer Jct. to Garcia.
- 1.223 Butte to Spokane.
- 1.224 Miles City to Newcomb.
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- 2.1 Introduction to Types of Alternatives Available.
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(FR Doc. 79-26652 Filed 8-27-79; 8:45 am)

BILLING CODE 7035-01-M

Permanent Authority Decisions Applications; Decision-Notice

The following applications, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's Rules of Practice (49 CFR 1100.247).

These rules provide, among other things, that a petition for intervention, either in support of or in opposition to the granting of an application, must be filed with the Commission within 30 days after the date notice of the application is published in the *Federal Register*. Protests (such as were allowed to filings prior to March 1, 1979) will be rejected. A petition for intervention without leave must comply with Rule 247(k) which requires petitioner to demonstrate that it (1) holds operating authority permitting performance of any of the service which the applicant seeks authority to perform, (2) has the necessary equipment and facilities for performing that service, and (3) has performed service within the scope of the application either (a) for those supporting the application, or, (b) where the service is not limited to the facilities of particular shippers, from and to, or between, any of the involved points.

Persons unable to intervene under Rule 247(k) may file a petition for leave to intervene under Rule 247(l) setting forth the specific grounds upon which it is made, including a detailed statement of petitioner's interest, the particular facts, matters, and things relied upon, including the extent, if any, to which petitioner (a) has solicited the traffic or business of those supporting the application, or, (b) where the identity of those supporting the application is not included in the published application notice, has solicited traffic or business identical to any part of that sought by applicant within the affected marketplace the extent to which petitioner's interest will be represented by other parties, the extent to which petitioner's participation may reasonably be expected to assist in the development of a sound record, and the extent to which participation by the petitioner would broaden the issues or delay the proceeding.

Petitions not in reasonable compliance with the requirements of the rules may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

Section 247(f) provides, in part, that an applicant which does not intend to timely prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal. If an applicant has introduced rates as an issue it is noted. Upon request, an applicant must provide a copy of the tentative rate schedule to any protestant.

Footnotes continued from last page
Newcomb Mt., Butte to Spokane, WA.; Plummer Jct., ID., to Garcia, ID.; and lines west of Cedar Falls, WA.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administrative acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the transportation policy of 49 U.S.C. 10101. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In those proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a petitioner, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. 10101 subject to the right of the Commission, which is expressly reserved, to impose such terms, conditions or limitations as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. 10930(a) [formerly section 210 of the Interstate Commerce Act].

In the absence of legally sufficient petitions for intervention, filed within 30 days of publication of this decision-notice (September 26, 1979) (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of the decision-notice. To the extent that

the authority sought below may duplicate an applicant's other authority, such duplication shall be construed as conferring only a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

[Volume No. 111]

Decided: June 29, 1979.

By the Commission, Review Board Number 1, Members Carleton, Joyce and Jones.

MC 25869 (Sub-150F), filed March 23, 1979. Applicant: NOLTE BROS. TRUCK LINE, INC., 6217 Gilmore Avenue, Omaha, NE 68107. Representative: Irwin Schwartz, P.O. Box 7184 South Omaha Sta., Omaha, NE 68107. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, in tank vehicles, and those requiring special equipment), from the facilities of Montgomery Ward and Company, at or near Chicago, IL, to Kansas City, MO, Albuquerque, NM, and points in IA, restricted to the transportation of traffic destined to the facilities of Montgomery Ward and Company. (Hearing site: Chicago, IL, or Omaha, NE.)

MC 78118 (Sub-43F), filed March 28, 1979. Applicant: W. H. JOHNS, INC., 35 Witmer Road, Lancaster, PA 17602. Representative: Christian V. Graf, 407 North Front Street, Harrisburg, PA 17101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *iron and steel articles*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between Downingtown and Coatesville, PA, on the one hand, and, on the other, points in MD, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Washington, D.C.)

MC 78118 (Sub-44F), filed April 3, 1979. Applicant: W. H. JOHNS, INC., 35 Witmer Road, Lancaster, PA 17602. Representative: Christian V. Graf, 407 North Front St., Harrisburg, PA 17101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *thermal blankets, undergarments, and cotton underwear*, from Tamaqua, Tower City,

Williamstown, Phoenixville, Gilbertsville, and Hometown, PA, to points in NJ, DE, PA, MD, VA, NC, SC, OH, and DC; and (2) *thread, yarn, elastic, and polyethylene bags*, in the reverse direction, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Washington, DC, or, Harrisburg, PA.)

MC 108119 (Sub-134F), filed April 4, 1979. Applicant: E. L. MURPHY TRUCKING COMPANY, a corporation, P.O. Box 43010, St. Paul, MN 55164. Representative: Andrew R. Clark, 1000 First National Bank Building, Minneapolis, MN 55402. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *vehicle wheel alignment equipment*, between Englewood, CO, on the one hand, and, on the other, points in the United States (except AK and HI); and (2) *parts and attachments* for the commodities in (1) above, from Englewood, CO, to points in the United States (except AK and HI). (Hearing site: Denver, CO, or Minneapolis, MN.)

MC 113528 (Sub-39F), filed April 3, 1979. Applicant: MERCURY FREIGHT LINES, INC., P.O. Box 1247, Mobile, AL 36601. Representative: Joy Stephenson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles* (except those which because of size or weight require the use of special equipment), from points in Georgetown County, SC, to points in GA, KY, NC, MS, TN, and those in AL on and north of U.S. Hwy 278. (Hearing site: Columbia, SC, or Birmingham, AL.)

MC 113678 (Sub-787F), filed March 28, 1979. Applicant: CURTIS, INC., 4810 Pontiac Street, Commerce City, CO 80022. Representative: Roger M. Shaner (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *foodstuffs* (except commodities in bulk), and (2) *meats, meat products, meat byproducts, and articles distributed by meat-packing houses*, except foodstuffs and commodities in bulk, from points in CO, to points in the United States (except AK, HI, and CO). (Hearing site: Denver, CO.)

Note.—By this application applicant seeks, in part, to consolidate its existing certificates, and, in part, to convert present joint-line service to single-line service. Not a "substitution" application under Ex Parte MC-109.

MC 117439 (Sub-2F), filed March 28, 1979. Applicant: BULK TRANSPORT,

INC., 550 Florida Boulevard, P.O. Box 1429, Baton Rouge, LA 70821. Representative: Edward A. Winter, 235 Rosewood Drive, Metairie, LA 70005. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *dry fertilizer*, from the facilities of Monsanto Company, at or near Luling, LA, to points in AL, GA, and MS. (Hearing site: Baton Rouge or New Orleans, LA.)

MC 118959 (Sub-207F), filed March 28, 1979. Applicant: JERRY LIPPS, INC., 130 South Frederick Street, Cape Girardeau, MO 63701. Representative: Donald B. Levine, 39 South LaSalle Street, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *such merchandise* as is dealt in or used by grocery and food business houses, between the facilities of Ralston Purina Company, at or near Clinton and Davenport, IA, on the one hand, and, on the other, points in IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, and WI. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 118959 (Sub-208F), Filed March 28, 1979. Applicant: JERRY LIPPS, INC., 130 South Frederick Street, Cape Girardeau, MO 63701. Representative: Donald B. Levine, 39 South LaSalle Street, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *canned and preserved foodstuffs*, from the facilities of Heinz USA, at or near Muscatine and Iowa City, IA, to points in KS, MO, and IL, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Washington, DC, or Pittsburgh, PA.)

MC 119789 (Sub-564F), Filed March 27, 1979. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *candy and chewing gum* (1) from Holland, MI, to Dallas, TX, Kansas City, MO, San Jose, CA, Milwaukie, OR, Atlanta, GA, Charlotte, NC, Jacksonville, FL, Baltimore, MD, and North Bergen, NJ and (2) between Holland, MI, and Canajoharie, NY. (Hearing site: New York, NY.)

MC 119789 (Sub-565F), Filed April 3, 1979. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr.

(same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *such commodities* as are dealt in by grocery stores, drug stores, and hardware stores (except commodities in bulk), and (2) *materials and supplies* used in the manufacture of the commodities in (1) above, (except commodities in bulk), between the facilities of Boyle-Midway, at or near (a) Atlanta, GA, and (b) Dallas, TX (Hearing site: New York, NY.)

MC 119789 (Sub-601F), Filed April 3, 1979. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *electrical capacitors and parts for electrical capacitors*, from Pickens, SC, to points in NE. (Hearing site: Greenville, SC.)

MC 125708 (Sub-160F), filed March 27, 1979. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., 425 West 152d Street, East Chicago, IN 46312. Representative: Anthony C. Vance, 1307 Dolley Madison Boulevard, McLean, VA 22101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *fertilizer and fertilizer materials*, between points in IL, IN, MO, KY, and TN. (Hearing site: St. Louis, MO.)

MC 127579 (Sub-19F), filed April 4, 1979. Applicant: HAULMARK TRANSFER, INC., 1100 North Macon Street, Baltimore, MD 21205. Representative: Glenn M. Heagerty (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *books*, between points in CT, MD, NJ, NY, and PA, on the one hand, and, on the other, points in AZ, CA, CO, CT, ID, MD, MT, NJ, NY, NV, NM, OR, PA, UT, TX, WA, and WY. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 133689 (Sub-266F), filed April 2, 1979. Applicant: OVERLAND EXPRESS, INC., 719 First Street, Southwest, New Brighton, MN 55112. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, packing-house products, and commodities used by packing houses*, as described in Appendix I to the report in *Descriptions in Motor Carrier*

Certificates, 61 M.C.C. 209 and 768 (except commodities in bulk), between the facilities of Lauridsen Foods Inc., at or near Britt, IA, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, AR, and LA, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: St. Paul, MN.)

MC 134319 (Sub-9F), filed April 3, 1979. Applicant: BRAAFADT TRANSPORT CO., a corporation, 301 North Broadway, P.O. Box 1065, Dimmitt, TX 79027. Representative: John C. Sims, P.O. Box 10236, Lubbock, TX 79408. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *anhydrous ammonia*, in tank vehicles, from the facilities of NAPCO Pipeline, at or near Mocane, OK, to points in KS, TX, and CO. (Hearing site: Amarillo or Lubbock, TX.)

MC 136818 (Sub-69F), filed March 30, 1979. Applicant: SWIFT TRANSPORTATION CO., INC., 335 West Elwood Road, P.O. Box 3902, Phoenix, AZ 85030. Representative: Donald E. Fernaays, 4040 East McDowell Road, suite 320, Phoenix, AZ 85008. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *charcoal, charcoal briquets, fireplace logs, wood chips, and lighter fluid* (except in bulk, in tank vehicles), (1) from Branson, MO, to points in AR, LA, MS, TN, IN, IL, OH, TX, OK, KY, NE, IA, WV, PA, NM, AL, CO, CA, KS, UT, and NV, (2) from Pachuta, MS, to points in TX, AK, TN, KY, VA, WV, NC, SC, LA, and FL, (3) from Waupaca, WI, to points in OH, MI, IL, and IN, (4) from Dickinson, ND, to points in MN, ND, SD, IA, NE, MO, AK, LA, TX, OK, KS, MT, ID, WA, OR, WY, CA, NV, AZ, CO, and NM, (5) from White City, OR, to points in CA, AZ, NV, WA, ID, MT, UT, and WY, and (6) from Ocala, FL, to points in GA, AL, NC, SC, TN, KY, and LA. (Hearing site: Phoenix, AZ.)

Note.—Dual operations may be involved.

MC 138109 (Sub-11F), filed March 28, 1979. Applicant: RAY J. FORNEY, INC., P.O. Box 207, Ashton, IL 61006. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 866 11th Street NW., Washington, DC 20001. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *salt and salt products, pepper, and food seasoning compounds*, (except commodities in bulk) and (2) *materials, equipment, and supplies* used in the manufacture, sale, and

distribution of the commodities in (1) above, (except commodities in bulk), between the facilities of Morton Salt Company, Division of Morton-Norwich Incorporated, at or near Newark, CA, on the one hand, and, on the other, points in the United States (except AK and HI), under a continuing contract(s) with Morton Salt Company, Division of Morton-Norwich, of Chicago, IL. Incorporated. (Hearing site: Chicago, IL.)

MC 138109 (Sub-12F), filed March 28, 1979. Applicant: RAY J. FORNEY, INC., P.O. Box 207, Ashton, IL 61006. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *salt and salt products*, *pepper*, and *food seasoning compounds*, (except commodities in bulk) and (2) *materials, equipment, and supplies* used in the manufacture, sale, and distribution of the commodities in (1) above, (except commodities in bulk), between the facilities of Morton Salt Company, Division of Morton-Norwich Incorporated, at or near Manistee, MI, on the one hand, and, on the other, points in the United States (except AK and HI), under a continuing contract(s) with Morton Salt Company, division of Morton-Norwich, of Chicago, IL. Incorporated. (Hearing site: Chicago, IL.)

MC 138109 (Sub-13F), filed March 26, 1979. Applicant: RAY J. FORNEY, INC., P.O. Box 207, Ashton, IL 61006. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *salt and salt products*, *pepper*, and *food seasoning compounds*, (except commodities in bulk) and (2) *materials, equipment, and supplies* used in the manufacture, sale, and distribution of the commodities in (1) above, (except commodities in bulk), between the facilities of Morton Salt Company, Division of Morton-Norwich Incorporated, at or near Fairport Harbor, OH, on the one hand, and, on the other, points in the United States (except AK and HI), under a continuing contract(s) with Morton Salt Company, Division of Morton-Norwich, of Chicago, IL. Incorporated. (Hearing site: Chicago, IL.)

MC 140829 (Sub-212F), filed April 3, 1979. Applicant: CARGO, INC., P.O. Box 206, Sioux City, IA 51102. Representative: William J. Hanlon, 55 Madison Avenue, Morristown, NJ 07960. To operate as a *common carrier*, by motor vehicle, in interstate or foreign

commerce, over irregular routes, transporting *chemicals* (except in bulk, in tank vehicles), from the facilities of Athea Laboratories Incorporated, at or near Milwaukee, WI, to points in CT, IA, KS, MA, MO, NE, NH, NJ, NY, OK, PA, RI, TX and VT, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 142508 (Sub-59F), filed March 19, 1979. Applicant: NATIONAL TRANSPORTATION, INC., P.O. Box 37465, 10810 South Street, Omaha, NE 68137. Representative: Lanny N. Fauss, P.O. Box 37096, Omaha, NE 68137. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs and materials, equipment, and supplies* used in the manufacture, distribution and sale of foodstuffs (except commodities in bulk), between the facilities of Ocean Spray Cranberries, Inc., at or near (a) Montgomery, AL, (b) Yuba City and Stockton, CA, (c) Chicago, IL, (d) Bordentown, Burlington, and Morristown, NJ, (e) Middleboro, MA, (f) North East, PA, (g) Sulphur Springs, TX, (h) Markham, WA, (i) Kenosha, WI, (j) Eau Claire, MI, and (k) Clackamas, OR, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Boston, MA, or Washington, DC.)

MC 142508 (Sub-70F), filed April 4, 1979. Applicant: NATIONAL TRANSPORTATION, INC., P.O. Box 37465, 10810 South Street, Omaha, NE 68137. Representative: Lanny N. Fauss, P.O. Box 37096, Omaha, NE 68137. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *breeding and batter*, from the facilities of Modern Maid Food Products, Inc., at (a) Evansville, IN, and (b) Los Angeles, CA, to points in CA, LA, MA, NJ, NY, TX, OH, PA, and WI. (Hearing site: New York, NY, or Washington, DC.)

MC 143059 (Sub-72F), filed March 29, 1979. Applicant: MERCER TRANSPORTATION CO., a corporation, 12th and Main Streets, P.O. Box 35610, Louisville, KY 40232. Representative: James L. Stone (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *steel bars*, from the facilities of North Star Steel Co., at or near Wilton, IA, to points in the United

States (except AK and HI), restricted to transportation of traffic originating at the named origin. (Hearing site: Louisville, KY, or Washington, DC.)

MC 144119 (Sub-2F), filed April 3, 1979. Applicant: HANSEN CONSOLIDATORS, INC. 16121 Canary Street, La Mirada, CA 90638. Representative: Miles L. Kavaller, 315 South Beverly Drive, Suite 315, Beverly Hills, CA 90212. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such plastic articles* as are dealt in by grocery, drug, and variety stores, and (2) *hair care products*, (except commodities in bulk), from the facilities of (a) Wilson Manufacturing Corporation and (b) Hugh H. Wilson Company, at Sunbury, PA, to La Mirada, CA, and Carrollton, TX. (Hearing site: Los Angeles, CA, or Harrisburg, PA.)

MC 146948 (Sub-1F), filed March 30, 1979. Applicant: ROBERT L. MAHER AND LOWELL R. JOSLIN, a partnership, d.b.a. HEALTH FOOD CARRIERS, 147 North 10th Avenue, Upland, CA 91786. Representative: Milton W. Flack, 4311 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in by health food stores, (except commodities in bulk), from points in the United States (except AK and HI), to (a) the facilities of Landstrom Distributors, at or near South San Francisco, CA, (b) the facilities of Collegedale Distributors, at or near Chattanooga and Ooltewah, TN, (c) the facilities of Keene Distributors, at Keene, TX, and (d) the facilities of Dairy Distributors, at or near City of Industry, CA, under continuing contract(s) in (a) above with Landstrom Distributors, or South San Francisco, CA, in (b) above with Collegedale Distributors, of Collegedale, TN, in (c) above with Keene Distributors, of Keene, TX, and in (d) above with Dairy Distributors, of City of Industry, CA. (Hearing site: Los Angeles, CA.)

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Decided: July 12, 1979.

By the Commission, Review Board Number 2, Members Boyle, Eaton and Liberman, Member Liberman not participating.

MC 200 (Sub-341F), filed March 22, 1979. Applicant: RISS INTERNATIONAL CORPORATION, a Delaware corporation, 903 Grand Ave., Kansas City, MO 64106. Representative: Ivan E. Moody (same address as applicant). To operate as a *common carrier*, by motor

vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *gypsum* (except in bulk, in tank vehicles), (2) *building materials* (except commodities in bulk, in tank vehicles), and (3) *materials, equipment, and supplies* used in the manufacture, installation, and distribution of the commodities in (1) and (2) above, (except commodities in bulk, in tank vehicles), between the facilities of Georgia-Pacific Corporation, at or near (a) Akron and Buchanan, NY, (b) Milford, VA, and (c) Wilmington, DE, on the one hand, and, on the other, points in CT, DE, MA, MD, ME, MI, NC, NH, NJ, NY, OH, PA, RI, TN, VA, VT, WV, and DC. (Hearing site: Kansas City, MO.)

MC 720 (Sub-65F), filed April 2, 1979. Applicant: BIRD TRUCKING COMPANY, INC., P.O. Box 227, Waupun, WI 53983. Representative: Tom Westerman (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *paper and paper products* (except commodities in bulk), between the facilities used by Scott Paper Company, at or near Marinette, Oconto Falls, Green Bay, and Fond du Lac, WI, on the one hand, and, on the other, points in AR, IA, IL, IN, KS, MI, MN, MO, NE, and OH, restricted to the transportation of traffic originating at and destined to the above-named points. (Hearing site: Milwaukee, WI, or Chicago, IL.)

MC 720 (Sub-66F), filed April 2, 1979. Applicant: BIRD TRUCKING COMPANY, INC., P.O. Box 227, Waupun, WI 53983. Representative: Tom Westerman (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in or used by drugstores, hospitals, discount and variety stores, and grocery and food business houses (except commodities in bulk), from Bedford Park, IL, to Milwaukee, WI, restricted to the transportation of traffic originating at the facilities of Bristol-Myers, Inc., at Bedford Park, IL. (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 2900 (Sub-366F), filed March 30, 1979. Applicant: RYDER TRUCK LINES, INC., 2050 Kings Road, P.O. Box 2408, Jacksonville, FL 32203. Representative: S. E. Somers, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as

defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Acme Tube, Inc., at Mansfield, LA, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Shreveport, LA, or Jacksonville, FL.)

MC 13651 (Sub-17F), filed March 12, 1979. Applicant: PEOPLES TRANSFER, INC., 1430 West 11th St., Long Beach, CA 90813. Representative: Edward J. Hegarty, 100 Bush St., San Francisco, CA 94104. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in or used by (i) grocery and food business houses, and (ii) discount and variety houses, between points in CA, on the one hand, and, on the other, points in AZ, NV, OR, and WA, restricted to the transportation of traffic originating at or destined to the facilities of (a) Amstar Corp., (b) The Kingsford Company, (c) Patterson Frozen Foods, (d) The Procter & Gamble Distributing Company and (e) United Grocers, Ltd. (Hearing site: San Francisco or Sacramento, CA.)

MC 29910 (Sub-211F), filed April 2, 1979. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 South 11th St., Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of MTD Products, Inc., at or near Brownsville, TN, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 29910 (Sub-213F), filed April 2, 1979. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 South 11th St., Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Avenue, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Continental Warehouse of MO, Inc., at New Madrid

and Lilbourn, MO, as intermediate or off-route points in connection with the carrier's otherwise authorized regular-route operations between St. Louis, MO and Memphis, TN. (Hearing site: St. Louis, MO, or Memphis, TN.)

MC 35320 (Sub-245F), filed April 2, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas, (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts for ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of the Osceola Shoe Company, Inc., at or near Manial and Osceola, AR, as off-route points in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-254F), filed March 30, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas, (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts for ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Jockey International, Inc., at or near Belzoni, MS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-283F), filed March 30, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas, (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts for ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Cutter-Hammer, Inc., at or near Bowling Green, KY, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Nashville, TN, or Washington, DC.)

MC 41240 (Sub-20F), filed March 30, 1979. Applicant: NELSON TRUCKING SERVICE, INC., Mediapolis, IA 52637. Representative: Kenneth F. Dudley, P.O. Box 279, 611 Church Street, Ottumwa, IA 52501. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *adhesives, building materials, gypsum, and gypsum products* (except commodities in bulk), and (2) *materials and supplies* used in the manufacture, installation, and distribution of the commodities named in (1) above (except commodities in bulk), between the facilities of the United States Gypsum Company, at or near Mediapolis, IA, on the one hand, and, on the other, points in IL, IN, MN, MO, and WI. (Hearing site: Chicago, IL.)

MC 47171 (Sub-125F), filed March 26, 1979. Applicant: COOPER MOTOR LINES, INC., P.O. Box 2820, Greenville, SC 29602. Representative: Harris G. Andrews, (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *electric storage batteries, spent batteries, and materials and supplies* used in the manufacture and distribution of electric storage batteries (except commodities in bulk), (1) from Selma, AL, to Framingham, MA, and Fleetwood, PA; and (2) from Framingham, MA, to Reading, PA. (Hearing site: Washington, DC.)

MC 52921 (Sub-35F), filed March 29, 1979. Applicant: RED BALL, INC., P.O. Box 520, Sapulpa, OK 74066. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *glass*, from Sapulpa, OK, to points in AZ, CA, ID, MT, NV, OR, UT, WA, and WY; and (2) *equipment, materials, and supplies* used in the manufacture and distribution of glass (except commodities in bulk, and those requiring the use of special equipment), in the reverse direction. (Hearing site: Tulsa, OK.)

MC 67450 (Sub-83F), filed April 2, 1979. Applicant: PETERLIN CARTAGE CO., a corporation, 9651 S. Ewing Avenue, Chicago, IL 60617. Representative: Joseph Winter, 29 South LaSalle Street, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *grain products*, in bulk, from Milwaukee, WI, to points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 88380 (Sub-35F), filed April 2, 1979. Applicant: REB TRANSPORTATION, INC., P.O. Box 4309, Fort Worth, TX 76106. Representative: Clint Oldham, 1108 Continental Life Building, Fort Worth, TX 76102. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1)(a) *iron and steel articles*, and (b) *pipe*, from Conroe, TX, to points in the United States (including AK, but excluding HI); and (2) *materials, equipment, and supplies* used in the manufacture or distribution of the commodities named in (1) above, in the reverse direction. (Hearing site: Dallas or Houston, TX.)

MC 95490 (Sub-47F), filed April 4, 1979. Applicant: UNION CARTAGE COMPANY, INC., 9A Southwest Cutoff, Worcester, MA 01604. Representative: Edward J. Kiley, 1730 M Street, N.W., Suite 501, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *glass containers and plastic containers*, from Bridgeton, Yardville, and Millville, NJ, to Boston Methuen, Lawrence, Amesbury, and Ayer, MA, and Providence, RI. (Hearing site: Boston, MA, or Washington, DC.)

MC 95540 (Sub-1099F), filed April 2, 1979. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, FL 33802. Representative: Benjy W. Fincher (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *tea and tea dust*, from Houston, TX, Seattle, WA, and San Francisco and Los Angeles, CA, to Denver, CO. (Hearing site: Denver, CO, or Washington, DC.)

MC 110191 (Sub-33F), filed April 3, 1979. Applicant: TURNER'S EXPRESS, INCORPORATED, 1300 Shelton Avenue, Norfolk, VA 23502. Representative: D. L. Turner, P.O. Box 1006, Norfolk, VA 23501. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving Williamsburg, VA, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Norfolk, VA.)

MC 110420 (Sub-805F), filed March 28, 1979. Applicant: QUALITY CARRIERS, INC., P.O. Box 186, Pleasant Prairie, WI 53158. Representative: John R. Sims, Jr.,

915 Pennsylvania Bldg., 425 13th St., NW., Washington, DC 20004. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *plastics, plastic articles, and synthetic resins*, in bulk, in tank vehicles, from the facilities of E. I. DuPont de Nemours & Co., at Seneca, IL, to points in AL, AR, CT, DE, FL, GA, IA, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NJ, NY, OH, OK, PA, RI, SC, TN, TX, VA, WI, and WV. (Hearing site: Chicago, IL, or Washington, DC.)

MC 110420 (Sub-810F), filed March 30, 1979. Applicant: QUALITY CARRIERS, INC., P.O. Box 186, Pleasant Prairie, WI 53158. Representative: John R. Sims, Jr., 915 Pennsylvania Bldg., 425 13th St., NW., Washington, DC 20004. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *petroleum and petroleum products*, in bulk, in tank vehicles, from Chicago, IL, to points in DE, IN, IA, KY, MD, MA, MI, MN, MO, NE, NJ, NY, OH, PA, and WI. (Hearing site: Chicago, IL, or Washington, DC.)

MC 111231 (Sub-200F), filed March 29, 1979. Applicant: JONES TRUCK LINES, INC., 610 East Emma Avenue, Springdale, AR 72764. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood, Fort Smith AR 72902. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *asphalt building materials, and insulation materials*, and (2) *materials and supplies* used in the installation of the commodities named in (1) above, between the facilities of GAF Corporation, at or near Dallas, TX, on the one hand, and, on the other, points in AL, AR, CO, GA, KS, LA, MO, MS, NM, and OK. (Hearing site: Dallas, TX.)

MC 111320 (Sub-72F), filed March 22, 1979. Applicant: KEEN TRANSPORT, INC., 2001 Barlow Road, Hudson, OH 44236. Representative: Michael Spurlock, 275 East State St., Columbus, OH 43215. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *construction equipment and earth-moving equipment*, and (2) *parts* for the commodities named in (1) above, from the facilities used by Fiat-Allis Construction Machinery, Inc., at or near Portsmouth, VA, to points in CT, DE, IL, IN, KY, MA, MD, ME, MO, NH, NJ, NY, OH, PA, RI, VT, and WI. (Hearing site: Columbus, OH.)

MC 111401 (Sub-558F), filed April 4, 1979. Applicant: GROENDYKE TRANSPORT, INC., P.O. Box 632, 2510 Rock Island Blvd., Enid, OK 73701.

Representative: Victor R. Comstock (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *chemicals*, in bulk, in tank vehicles, from Colwich, KS, to points in CO, NM, OK, TX, and WY. (Hearing site: Kansas City, KS, or Dallas, TX.)

MC 112520 (Sub-364F), filed March 16, 1979. Applicant: MCKENZIE TANK LINES, INC., P.O. Box 1200, Tallahassee, FL 32302. Representative: Thomas F. Panebianco (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *source and special radioactive materials*, from the facilities of International Minerals and Chemical Corporation, and New Wales Chemicals, Inc., at New Wales, FL, to points in the United States (except AK and HI). Condition: Any certificate issued in this proceeding shall be limited in point of time to a period expiring 5 years from the date of issuance. (Hearing site: Atlanta, GA, or Tampa, FL.)

MC 114211 (Sub-403F), filed March 15, 1979. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Adelor J. Warren (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *irrigation systems*, (2) *parts* for irrigation systems, (3) *solar energy systems and fuel burning heating appliances*, and (4) *parts and accessories* used in the installation, operation, and maintenance of the commodities in (1), (2), and (3) above, (5)(a) *pipe and poles*, and (b) *materials, equipments, and supplies* used in the installation and maintenance of pipe and poles, (6) *iron and steel articles*, and (7) *materials, equipment, and supplies* used in the manufacture of the commodities in (1), (2), (3), (4), 5(a), 5(b), and (6) above, between the facilities of Valmont Industries, Inc., at or near Valley, NE, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Omaha or Lincoln, NE.)

MC 115331 (Sub-492F), filed March 27, 1979. Applicant: TRUCK TRANSPORT INCORPORATED, 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: J.R. Ferris, 230 St. Clair Avenue, East St. Louis, IL 62201. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *non-alcoholic*

beverages, in containers, from St. Louis, MO, to points in GA and WI; and (2) *materials and supplies* used in the production and distribution of the commodities named in (1) above, (except commodities in bulk), from points in AL, AR, GA, IL, IN, IA, KS, KY, NE, MS, LA, OH, OK, PA, TN, TX, and WI, to St. Louis, MO. (Hearing site: St. Louis, MO.)

MC 115730 (Sub-70F), filed March 29, 1979. Applicant: THE MICKOW CORP., P.O. Box 1774, 531 S. W. Sixth St., Des Moines, IA 50306. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles*, from the facilities of Nucor Steel Co., at Jewett, TX, to points in CO, IA, IL, IN, KS, MI, MN, MO, NE, OH, and WI. (Hearing site: Dallas, TX, or Washington, DC.)

MC 115730 (Sub-8F), filed March 29, 1979. Applicant: THE MICKOW CORP., 531 S. W. Sixth St., P.O. Box 1774, Des Moines, IA 50306. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles*, from the facilities of North Star Steel Company, at Newport, MN, to points in the United States (except AK and HI); and (2) *materials, equipment, and supplies* used in the manufacture of iron and steel articles, (except commodities in bulk), in the reverse direction. (Hearing site: St. Paul, MN, or Chicago, IL.)

MC 117940 (Sub-324F), filed April 2, 1979. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, MN 55359. Representative: Allan L. Timmerman, 5300 Highway 12, Maple Plain, MN 55359. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in by book stores, between points in NJ, on the one hand, and, on the other, the facilities of B. Dalton Bookseller, at points in CA. (Hearing site: Minneapolis or St. Paul, MN.)

MC 117940 (Sub-325F), filed April 2, 1979. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, MN 55359. Representative: Allan L. Timmerman, 5300 Highway 12, Maple Plain, MN 55359. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel tubing* (except commodities requiring special equipment), from the

facilities of Markin Tubing, Inc., at or near Pearl Creek, NY, to Canton, SD and Galesburg, IL, restricted to the transportation of traffic originating at the named origin facilities and destined to the named destinations. (Hearing site: Buffalo, NY.)

MC 117940 (Sub-326F), filed April 2, 1979. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, MN 55359. Representative: Allan L. Timmerman, 5300 Highway 12, Maple Plain, MN 55359. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in by retail department stores (except foodstuffs, commodities in bulk, and household goods as defined by the Commission), from points in IL, MA, MO, NJ, NY, and PA, to the facilities of Nordstrom's Inc., at points in CA and OR, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Seattle, WA.)

MC 119630 (Sub-21F), filed March 26, 1979. Applicant: VAN TASSEL, INC., 5th and Grand, Pittsburg, KS 66762. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1)(a) *plastic pipe, vinyl plastic siding, extruded plastic products, and fittings*, and (b) *accessories* for the commodities in (1)(a) above, from the facilities of Vinylplex, Inc., at or near Pasadena, TX, to points in the United States (except AK and HI); and (2) *materials, equipment, and supplies* used in the manufacture of the commodities named in (1) (a) and (b) above, between the facilities of Vinylplex, Inc., at or near (a) Pasadena, TX, and (b) Pittsburg, KS. (Hearing site: Kansas City, MO.)

Note.—Dual operations may be involved.

MC 119641 (Sub-164F), filed March 30, 1979. Applicant: RINGLE EXPRESS, INC., 450 E. Ninth St., Fowler, IN 47944. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles*, from the facilities of Wheeling-Pittsburgh Steel Corporation, at (a) Canfield, Martins Ferry, Mingo Junction, Steubenville, and Yorkville, OH, (b) Allenport and Monessen, PA, and (c) Beechbottom, Benwood, Follansbee, and Wheeling, WV, to points in IL, IN, MI,

and WI. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 119641 (Sub-165F), filed March 30, 1979. Applicant: RINGLE EXPRESS, INC., 450 E. Ninth St., Fowler, IN 47944. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *lumber, lumber products, lumber mill products, forest products, and wood products*, from Holly Hill and Walterboro, SC, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 119641 (Sub-166F), filed April 2, 1979. Applicant: RINGLE EXPRESS, INC., 450 E. Ninth St., Fowler, IN 47944. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *composition board* and (2) *materials, supplies, and accessories* used in the installation of composition board, from the facilities of Abitibi Corporation, at (a) Blountstown, FL, and (b) Roaring River (Wilkes County), NC, to points in IL, IN, IA, KY, MI, MN, MO, NE, NY, ND, OH, PA, SD, and WI. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 119741 (Sub-155F), filed March 30, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *scrap metal*, from the facilities of Webster, City Iron and Metal Co., Inc., at Webster City, IA, to Chicago, IL, and St. Louis, MO, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Fort Dodge, IA.)

MC 119741 (Sub-156F), filed March 30, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *bakery goods* (except frozen), (1) from the facilities of Interbake Foods Inc., at Richmond, VA, to points in AR, CO, IL, IA, KS, MN, MO, NE, ND, OK, SD, TX, and WI; and (2) from the facilities of Interbake Foods

Inc., at North Sioux City, SD, to points in AR, CT, DE, IL, IN, IA, KY, MD, MA, MI, MO, NJ, NY, OH, PA, RI, VA, WV, and DC, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Richmond, VA.)

MC 119741 (Sub-165F), filed April 2, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *bakery goods* (except frozen), from the facilities of Interbake Foods Inc., at Battle Creek, MI, to points in AR, CO, LA, MN, ND, SD, TX, and WI, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Battle Creek, MI.)

MC 124951 (Sub-41F), filed April 2, 1979. Applicant: WATHEN TRANSPORT, INC., P.O. Box 237, Henderson, KY 42420. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *malt beverages*, in containers, and empty *malt beverage containers*, (1) between the facilities of Olympia Brewing Company, at St. Paul, MN, on the one hand, and, on the other, Owensboro, KY, and (2) between the facilities of G. Heileman Brewing Company, at Evansville, IN, on the one hand, and, on the other, Bowling Green, KY. (Hearing site: Evansville, IN, or Louisville, KY.)

MC 127840 (Sub-94F), filed April 2, 1979. Applicant: MONTGOMERY TANK LINES, INC., 17550 Fritz Drive, P.O. Box 382, Lansing, IL 60438. Representative: William H. Towle, 180 North LaSalle Street, Chicago, IL 60601. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *chemicals*, in bulk, in tank vehicles, from Meredosia, IL, to points in AR and TX. (Hearing site: New York, NY.)

MC 129401 (Sub-14F), filed March 6, 1979. Applicant: DOUGLAS & BESS, INC., Box 238, Statesville, NC 28677. Representative: Charles Ephraim, Suite 600, 1250 Connecticut Ave., NW., Washington, DC 20036. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *feed and feed ingredients* (except commodities in bulk), from Decatur, IL, to points in NC,

under continuing contract(s) with A. E. Staley Manufacturing Company, of Decatur, IL. (Hearing site: Charlotte, NC.)

MC 133591 (Sub-66F), filed April 2, 1979. Applicant: WAYNE DANIEL TRUCK, INC., Post Office Box 303, Mount Vernon, MO 65712. Representative: Charles A. Daniel (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in or used by grocery and feed business houses, (1) between the facilities of Ralston Purina Co., at or near Sparks, NV, on the one hand and on the other, points in CA, OR, and WA, and (2) between the facilities of Ralston Purina Co., at or near (a) San Diego, CA, and (b) Flagstaff, AZ, on the one hand, and, on the other, Memphis, TN, and points in AR, CO, KS, LA, MN, MO, NE, ND, OK, SD, and TX. (Hearing site: St. Louis or Kansas City, MO.)

Note.—Dual operations may be involved.

MC 134131 (Sub-8F), filed April 2, 1979. Applicant: R & S TRANSIT, INC., 1323 W. Locust, Springfield, MO 65803. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *drugs, toilet preparations, and shampoos*, (except commodities in bulk), from the facilities of Bristol-Myers Products Inc., at or near St. Louis, MO, to La Mirada and Oakland, CA, and Portland, OR. (Hearing site: St. Louis or Kansas City, MO.)

Note.—The purpose of this application is to substitute single-line for joint-line operations.

MC 134300 (Sub-38F), filed April 2, 1979. Applicant: TRIPLE R EXPRESS, INC., 498 First St., NW., New Brighton, MN 55112. Representative: Samuel Rubenstein, 301 North Fifth St., Minneapolis, MN 55403. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), between the facilities of Lauridsen Foods, Inc., at or near Britt, IA, on the one hand, and, on the other, points in CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT, and DC, restricted to the transportation of traffic originating at the named origin facilities and destined

to the indicated destinations. (Hearing site: Minneapolis or St. Paul, MN.)

MC 134501 (Sub-48F), filed March 30, 1979. Applicant: INCORPORATED CARRIERS, LTD., P.O. Box 3128, Irving, TX 75061. Representative: T. M. Brown, P.O. Box 1540, Edmond, OK 73034. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce over irregular routes, transporting *new furniture*, from Vernon, AL, to those points in TX south and east of a line beginning at the TX-AR State line and extending along U.S. Hwy 67 to Dallas, TX, then along Interstate Hwy 35E to Waco, TX, then along U.S. Hwy 81 to junction U.S. Hwy 84, then along U.S. Hwy 84 to junction U.S. Hwy 67, then along U.S. Hwy 67 to junction U.S. Hwy 290, then along U.S. Hwy 290 to junction U.S. Hwy 80, and then along U.S. Hwy 80 to the TX-MN State line, points in TN (except Shelby County), and points in ME, VT, NH, CT, MA, RI, NY, PA, VA, DE, MD, NJ, WV, NC, SC, GA, FL, LA, MS, KY, OH, IN, MI, IL, MO, and DC. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 134921 (Sub-4F), filed March 29, 1979. Applicant: MID AMERICA TRANSPORT, INC., P.O. Drawer 370, Madisonville, KY 42431. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce over irregular routes, transporting *material, equipment, and supplies*, used in the manufacture, sale, and distribution of non-alcoholic beverages, from points in AL, AR, IL, IN, KY, MI, MS, MO, OH, and TN, to Madisonville, KY, under continuing contract(s) with Mid America Canning Corporation, of Madisonville, KY. (Hearing site: Evansville, IN, or Louisville, KY.)

MC 136511 (Sub-34F), filed March 30, 1979. Applicant: VIRGINIA APPALACHIAN LUMBER CORPORATION, 9640 Timberlake Rd., Lynchburg, VA 24502. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce over irregular routes, transporting *foodstuffs* (except in bulk), from Kent City, MI, to points in the United States (except AK and HI). (Hearing site: Richmond, VA, or Washington, DC.)

MC 136511 (Sub-35F), filed March 30, 1979. Applicant: VIRGINIA APPALACHIAN LUMBER CORPORATION, 9640 Timberlake Rd., Lynchburg, VA 24502. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC. To operate as a

common carrier, by motor vehicle, in interstate or foreign commerce over irregular routes, transporting *frozen prepared foods*, from the facilities of Banquet Foods Corporation, at or near Carrollton, Marshall, Macon, and Moberly, MO, to points in AL, GA, KY, NC, SC, TN, VA, and WV. (Hearing site: St. Louis, Mo.)

MC 140460 (Sub-7F), filed April 2, 1979. Applicant: COAST REFRIGERATED TRUCKING CO., INC., P.O. Box 188, Holly Ridge, NC 28445. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Spring, MD 20910. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *bananas*, from Hampton, Portsmouth, and Norfolk, VA, to points in IL, IN, IA, KY, MI, NE, NY, OH, PA, WV, and WI, restricted to the transportation of traffic having a prior movement by water. (Hearing site: Washington, DC.)

Note.— Dual operations may be involved.

MC 140601 (Sub-12F), filed March 29, 1979. Applicant: BILLY FRANK, d.b.a., FRANK BROS., 349 Abbott Avenue, Hillsboro, TX 76645. Representative: Charles E. Munson, 500 West Sixteenth Street, P.O. Box 1945, Austin, TX 78767. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1)(a) *plastic pipe, vinyl plastic siding, extruded plastic products, and fittings*, and (b) *accessories* for the commodities named in (1)(a) above, from the facilities of Vinylplex, Inc. at or near Pasadena, TX, to points in the United States (except AK and HI) and (2) *materials, equipment, and supplies* used in the manufacture of the commodities named in (1)(a) and (b) above, between the facilities of Vinylplex, Inc., at or near (a) Pittsburg, KS, and (b) Pasadena, TX, under continuing contract(s) with Vinylplex, Inc., of Pittsburg, KS. (Hearing site: Dallas, TX.)

MC 141921 (Sub-54F), filed April 2, 1979. Applicant: SAV-ON TRANSPORTATION, INC., 143 Frontage Road, Manchester, NH 03108. Representative: John A. Sykas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products, and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), (1) from Fremont, NE, to Baltimore, MD,

and points in NY and (2) from Newark, NJ, Mount Airy, MD, Philadelphia, PA, Wilmington, DE, and Boston, MA, to points in PA and KY. (Hearing site: Boston, MA, or Concord, NH)

Note.— Dual operations may be involved.

MC 143210 (Sub-15F), filed April 2, 1979. Applicant: H. O. WOLDING, INC., Box 56, Nelsonville, WI 54458. Representative: Wayne W. Wilson, 150 E. Gilman Street, Madison, WI 53703. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are manufactured, used or dealt in by manufacturers, converters, and printers of paper and paper products (except commodities in bulk), from points in Portage and Wood Counties, WI, to points in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY. (Hearing site: Madison or Stevens Point, WI)

MC 143031 (Sub-14F), filed March 28, 1979. Applicant: LLOYD PAUL MURPHY, JAMES EDWARD MURPHY, TIMOTHY PAUL MURPHY, AND ERNEST STEWART MURPHY, MURPHY AND SONS, a Partnership, Route 2, Box 139, Spring City, TN 37381. Representative: Stan Guthrie, Suite 500, Dome Building, 736 Georgia Avenue, Chattanooga, TN 37402. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *stainless steel sinks, and materials, and supplies* used in the manufacture of stainless steel sinks, (a) from the facilities of Dayton Products, Inc., at Dayton, TN, to points in IL, and to Dayton Ogden Corporation, at Ogden, UT, and (b) from the facilities of Elkay Manufacturing Company, at Chicago, IL, and the facilities of Dayton Ogden Corporation, at Ogden, UT, to the facilities of Dayton Products, Inc., at Dayton, TN; (2) *materials, equipment, and supplies* used in the manufacture of stainless steel sinks, from the facilities of Mortell Corporation, at Griffin, GA, and the facilities of International Chemical Corporation, at Philadelphia, PA, to the facilities of Dayton Products, Inc., at Dayton, TN; and (3) *garbage disposal units*, from the facilities of Elkay Disposal Corporation, at Chatsworth, CA, to the facilities of Dayton Products, Inc., at Dayton, TN, under continuing contract(s) in (1), (2), and (3) above with Dayton Products, Inc., of Dayton, TN. (Hearing site: Nashville or Chattanooga, TN.)

MC 143110 (Sub-7F), filed March 29, 1979. Applicant: K&B EXPRESS INC., P.O. Box 841, Union City, NJ 07083. Representative: Stuart R. Mandel, 315 S. Beverly Drive, Suite 315, Beverly Hills, CA 90212. To operate as a *contract*

carrier, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *agricultural fertilizers, and agricultural chemicals* (except commodities in bulk); and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk), between points in AL, AR, CA, FL, GA, LA, MD, MS, NC, NJ, NY, OK, PA, SC, TN, TX, VA, and WV, under continuing contract(s) with Helena Chemicals Company, of Memphis, TN. (Hearing site: New York, NY.)

MC 144051 (Sub-7F), filed March 29, 1979. Applicant: ALFORD-LOGSTON, INC., 1714 Tabor, Houston, TX 77009. Representative: Michael Connelly, Esperson Buildings, Houston, TX 77002. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *home care products*, between Memphis, TN, and points in MS, under continuing contract(s) with Stanley Home Products, Inc., of Easthampton, MA. (Hearing site: Houston or Fort Worth, TX.)

MC 145390 (Sub-1F), filed April 2, 1979. Applicant: WILLIAM SMITH, d.b.a. ALCOTT TRUCKING, 59 Alcott Road, Mahwah, NJ 07430. Representative: Joseph R. Siegelbaum, Seventeen Academy St., Newark, NJ 07102. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *malt beverages and empty containers* used in the distribution of malt beverages, from Newark, NJ and Cranston, RI, to Malone and Plattsburgh, NY, under continuing contract(s) with (1) Lapans & Sons, of Plattsburgh, NY, and (2) Malone Beverages, Inc., of Malone, NY. (Hearing site: New York, NY.)

MC 145441 (Sub-30F), filed March 26, 1979. Applicant: A.C.B. TRUCKING, INC., P.O. Box 5130, North Little Rock, AR 72119. Representative: E. Lewis Coffey (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *rubber articles, plastic articles, and housewares*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above, between Wooster, OH, on the one hand, and, on the other, points in AZ, AR, CA, CO, FL, GA, ID, KS, LA, NV, NM, OK, OR, SC, TX, UT, and WA. (Hearing site: Columbus, OH, or Little Rock, AR.)

Note.—Dual operations may be involved.

MC 145481 (Sub-8F), filed March 26, 1979. Applicant: COYOTE TRUCK LINE, INC., P.O. Box 756, Thomasville, NC 27360. Representative: John T. Wirth, 717 17th St., Suite 2600, Denver, CO 80202. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *drugs, cosmetics, plastic articles, weed killing compounds, and animal and poultry feed supplements* (except commodities in bulk), and (2) *materials, supplies, and equipment* used in the manufacture, and distribution of the commodities named in (1) above, (except commodities in bulk), (a) between the facilities use by Eli Lilly & Co., at or near (a) Roanoke, VA, and (b) West Helena, AR, on the one hand, and, on the other points in CA and IN, and (b) between the facilities of Eli Lilly & Co., at or near Indianapolis, Lafayette, and Clinton, IN, on the one hand, and, on the other, Atlanta, GA, Raleigh, NC, Memphis, TN, and Norfolk, VA. (Hearing site: Indianapolis, IN.)

Note.—Dual operations may be involved.

MC 145701 (Sub-2F), filed March 28, 1979. Applicant: D. C. TRANSPORT, INC., 916 South Riverside Ave., St. Clair, MI 48079. Representative: James J. Sheehan (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *salt and salt products*, (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, and (3) *restaurant supplies*, in mixed loads with the commodities in (1) above, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Diamond Crystal Salt Company. (Hearing site: Detroit, MI, or Washington, DC.)

MC 145981 (Sub-5F), filed March 30, 1979. Applicant: ACE TRUCKING CO., INC., 1 Hackensack Ave., South Kearny, NJ 07032. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *zinc dust* (except in bulk); and (2) *materials, equipment, and supplies* used in the manufacture and sale of zinc dust (except commodities in bulk), from the facilities of L D L Technology, Inc., at or near Paterson, NJ, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: New York, NY, or Washington, DC.)

Note.—Dual operations may be involved.

MC 146090 (Sub-2F), filed March 5, 1979. Applicant: WESTERN MOTOR EXPRESS, a Corporation, d.b.a. WESTERN TRANSPORT, 7843 Chatfield St., Whittier, CA 90606. Representative: Robert Fuller, Suite 310, Whittier Square, Whittier, CA 90601. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *wrought steel pipe*, the transportation of which because of size of weight requires the use of special equipment, from points in Los Angeles, San Bernardino, and Riverside Counties, CA, to points in AZ. (Hearing site: Los Angeles or San Francisco, CA.)

MC 146140 (Sub-3F), filed April 3, 1979. Applicant: MELVIN SALES COMPANY, a Corporation, 901 North Vermillion, Streator, IL 61364. Representative: Paul J. Maton, Suite 1620, 10 south LaSalle Street, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *silica sand*, in bulk, from points in LaSalle County, IL, to Lawrenceburg, IN. (Hearing site: Chicago, IL.)

MC 146291 (Sub-2F), filed March 26, 1979. Applicant: LARRY WILSON, d.b.a. WILSON TRUCKING CO., P.O. Box 581, Plainview, TX 79072. Representative: Richard Hubbert, P.O. Box 10236, Lubbock, TX 79408. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *farm equipment*, from the facilities of Tye Sales Company, at or near Lockney, TX, to points in the United States (except AK and HI); and (2) *equipment, materials, and supplies* used in the manufacture of farm equipment in the reverse direction. (Hearing site: Lubbock or Dallas, TX.)

MC 146640F, filed April 4, 1979. Applicant: M & S TRUCKING, INC., 1589 East Fifth Avenue, Columbus, OH 44216. Representative: Michael L. Moushey, 275 East State St., Columbus, OH 43215. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *wooden pallets*; and (2) *materials, equipment, and supplies* used in the manufacture of wooden pallets, between the facilities used by B. F. Goodrich Company, at Columbus, OH, on the one hand, and, on the other, points in IN, PA, AL, IL, TX, KS, GA, OK, and KY, under continuing contract(s) with B. F. Goodrich Company, of Akron, OH. (Hearing site: Columbus or Cleveland, OH.)

MC 146860 (Sub-2F), filed April 2, 1979. Applicant: GRANT'S TRUCKING SERVICE, INC., Post Office Box 10158, Goldsboro, NC 27532. Representative: Ralph McDonald, Post Office Box 2246, Raleigh, NC 27602. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *wood residuals*. — from points in NC, to points in VA. (Hearing site: Raleigh, NC.)

MC 146701 (Sub-1F), filed April 2, 1979. Applicant: WEAVER TRUCKING CO., INC., P.O. Box 45, Eton, GA 30724. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *aluminum hydrate* (except in bulk), from Chatsworth, GA, to points in CA, and to those points in the United States in and east of MN, IA, MO, AR, and LA, under continuing contract(s) with North Georgia Minerals and Chemicals, Inc., of Chatsworth, GA. (Hearing site: Atlanta, GA.)

MC 146701 (Sub-2F), filed April 2, 1979. Applicant: WEAVER TRUCKING CO., INC., P.O. Box 45, Eton, GA 30724. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products, and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), in vehicles equipped with mechanical refrigeration, from points in CO, IL, IA, KS, MN, NE, NM, ND, OK, and TX, to points in AL, FL, GA, KY, NC, SC, TN, and VA, under continuing contract(s) with Missouri Valley Foods, Inc., of Omaha, NE. (Hearing site: Atlanta, GA.)

Passenger Authority

MC 143140 (Sub-3F), filed April 2, 1979. Applicant: SEYMOUR BUS LINES, INC., Route #3, Maynardville, TN 37807. Representative: Lewis S. Witherspoon, 88 East Broad St., Columbus, OH 43215. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *passengers and their baggage*, in the same vehicle with passengers, in special round-trip operations, beginning and ending at points in Anderson, Blount, Campbell, Clairborne, Jefferson, Knox, and Union

Counties, TX, and extending to points in the United States (including AK, but excluding HI). Hearing site: Knoxville, TN.)

Note.—Applicant has introduced the issue of rates in support of its application.

Passenger Authority

MC 146941 (Sub-1F), filed March 30, 1979. Applicant: CRAWFORD TRANSIT, INC., 43 National Avenue, Staunton, VA 24401. Representative: Leonard A. Jaskiewicz, 1730 M Street NW., Suite 501, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *passengers and their baggage*, in the same vehicle with passengers, in round-trip charter operations, beginning and ending at Staunton, Waynesboro, Harrisonburg, Lexington, Clifton Forge, Covington, Buena Vista, and Charlottesville, VA, and points in Albemarle, Alleghany, Amherst, Augusta, Bath, Greene, Highland, Nelson, Page, Rockbridge, and Rockingham Counties, VA, and extending to those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Charlottesville, VA.)

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Decided: July 19, 1979.

By the Commission, Review Board Number 3, Members Parker, Fortier, and Hill.

MC 531 (Sub-388F), filed April 6, 1979. Applicant: YOUNGER BROTHERS, INC., 4904 Griggs Road, P.O. Box 14048, Houston, TX 77021. Representative: Wray E. Hughes (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *chemicals*, in bulk, in tank vehicles, from Meredosia, IL, to points in AR and TX. (Hearing site: St. Louis, IL, or Houston, TX.)

MC 531 (Sub-389F), filed April 6, 1979. Applicant: YOUNGER BROTHERS, INC., 4904 Griggs Road, P.O. Box 14048, Houston, TX 77021. Representative: Wray E. Hughes (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *liquid plastics*, in bulk, in tank vehicles, from San Carlos, CA, to Oak Creek, WI. (Hearing site: San Francisco, CA.)

MC 3581 (Sub-23F), filed April 5, 1979. Applicant: THE MOTOR CONVOY, INC., 2175 Parklake Drive, N.E., Suite 107, Atlanta, GA 30345. Representative: Paul M. Daniell, P.O. Box 872, Atlanta, GA 30301. To operate as a *common carrier*, by motor vehicle, in interstate or

foreign commerce, over irregular routes, transporting *automobiles, trucks, and tractors*, in initial and secondary movements, in driveway and truckaway service, from Hapeville, GA, to points in the United States (except AK and HI). (Hearing site: Atlanta, GA, or Detroit, MI.)

MC 19311 (Sub-59F), filed March 30, 1979. Applicant: CENTRAL TRANSPORT, INC., 34200 Mound Road, Sterling Heights, MI 48077. Representative: Elmer J. Maue, Suite 1200, 755 West Big Beaver Rd., Troy, MI 48064. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *voting machines and equipment, materials, and supplies used in the manufacture and distribution of voting machines*, between points in New York, on the one hand, and, on the other, points in IL, IN, and OH; and (2) *new furniture, new household, office and store fixtures, and furnishings, and equipment, materials, and supplies used in the manufacture and distribution of new furniture, new office and store fixtures, and furnishings*, between points in CT, ME, MD, MA, NH, NJ, NY, PA, RI, and VT, on the one hand, and, on the other, points in IL, IN, OH, and WI. (Hearing site: Washington, DC.)

MC 29910 (Sub-212F), filed April 2, 1979. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, Inc., 301 South 11th Street, Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Avenue, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the commission, commodities in bulk, and those requiring special equipment), Between junction U.S. Hwy 30 and Interstate Hwy 79, and Dayton, OH: From junction U.S. Hwy 30 and Interstate Hwy 79, then over Interstate Hwy 79 to junction Interstate Hwy 70, then over Interstate Hwy 70 to junction Interstate Hwy 75, then over Interstate Hwy 75 to Dayton, OH, and return over the same route, serving the termini as points of joinder only, as an alternate route for operating convenience only. (Hearing site: Washington, DC.)

MC 29910 (Sub-214F), filed April 4, 1979. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 South 11th Street, Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Avenue, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, in

interstate or foreign commerce over irregular routes, transporting *aluminum ingots*, from Jones Mills and Gum Springs, AR, to Listerhill, AL. (Hearing site: Little Rock, AR, or Washington, DC.)

MC 35320 (Sub-356F), filed April 4, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Rebel Tires, Inc., at or near Jonesboro, AR, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-257F), filed April 4, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Colonial Corp. of America, at or near (a) Woodbury, Smithville, Manchester, Auburntown, Dunlap, Tracy City, and Sevierville, TN, and (b) Portland and Fountain Run, KY, as off-route points in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN, or Washington, DC.)

MC 35320 (Sub-258F), filed April 4, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Hytrol Conveyor Company, Inc., at or near Jonesboro, AR, as an off-route point in connection with

applicant's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-259F), filed April 5, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), between the facilities of Plan Hold Corp., at or near Irvine, CA, on the one hand, and, on the other, Houston, TX. (Hearing site: Los Angeles, CA, or Washington, DC.)

MC 35320 (Sub-260F), filed April 5, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Lanson Industries, Inc., at or near Cullman, AL, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN, or Washington, DC.)

MC 35320 (Sub-261F), filed April 5, 1979. Applicant: T.I.M.E.-DC, INC., a Delaware Corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), between the facilities of Main Fireplaces, Inc., at or near Santa Rosa, CA, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: San Francisco, CA, or Portland, OR.)

MC 35320 (Sub-263F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas

(same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Union Carbide Corp., at or near Osceola, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-264F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Rockwell International, at or near Texarkana, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Tulsa, OK, or Little Rock, AR.)

MC 35320 (Sub-265F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Brown & Williamson Tobacco Corporation, at or near Macon, GA, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-266F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition,

household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Irvin Industries, at or near Blytheville, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-267F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Proffitt's Inc., at or near Maryville, TN, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Knoxville, TN, or Washington, DC.)

MC 35320 (Sub-268F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of The Hudson Pulp & Paper Company, at or near Pine Bluff, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 35320 (Sub-269F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Cabot Manufacturing Co., Inc., at or near Cabot, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations.

(Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 35320 (Sub-271F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Triangle "PWC", Inc., at or near Sikestown, MO, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-272F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Vantage Products Corp., at or near Conyers, GA, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-273F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Simmons Mfg. Co., Inc., at or near McDonough, GA, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-274F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle,

in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Lear Siegler Inc., at or near Seymour, IN, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Louisville, KY, or Washington, DC.)

MC 35320 (Sub-275F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Central Maloney Transformer, at or near Pine Bluff, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Washington, DC.)

MC 35320 (Sub-276F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Roberts Brothers Tire Service, Inc., at or near Pine Bluff, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Washington, DC.)

MC 35320 (Sub-277F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment),

serving the facilities of William L. Bonnell Company, Inc., at or near Newnan, GA, and Carthage, TN, as off-route points in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-278F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Ben Pearson Archery, Inc., at or near Pine Bluff, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 35320 (Sub-284F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of A. J. King Lumber Company, Inc., at or near Sevierville, TN, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Knoxville, TN, or Washington, DC.)

MC 35320 (Sub-285F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Brown & Root, at or near Ashdown, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 42011 (Sub-46F), filed February 26, 1979. Applicant: D. Q. WISE & CO., INC., P.O. Drawer L, Tulsa, OK 74112. Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *castings, shipping containers, electrical cable, switchboards, transformers, motors, pumps, motor parts, and pump parts*, and (2) *accessories for pumps and motors*, and (3) *equipment, materials and supplies used in the maintenance, operation, repair, manufacture, removal and installation of the commodities named in (1) and (2) above*, between the facilities of Centrilit, Inc., at or near Claremore, OK, on the one hand, and, on the other, points in the United States (including AK, but excluding HI), restricted to the transportation of traffic originating at or destined to the above-named facilities. (Hearing site: Tulsa, OK.)

MC 53841 (Sub-24F), filed April 4, 1979. Applicant: W. H. CHRISTIE & SONS, INC., Box 517, East State St., Knox, PA 16232. Representative: John A. Pillar, 1500 Bank Tower, 307 Fourth Ave., Pittsburgh, PA 15222. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron powder* (except in bulk), from Riverton, NJ, to points in PA and NY. (Hearing site: Pittsburgh, PA, or New York, NY.)

MC 59680 (Sub-225F), filed March 29, 1979. Applicant: STRICKLAND TRANSPORTATION CO., INC., 11353 Reed Hartman Hwy, Cincinnati, OH 45241. Representative: Edward G. Bazelon, 39 South LaSalle Street, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between San Antonio, TX, and Round Rock, TX, over Interstate Hwy 35, as an alternate route for operating convenience only, serving no intermediate points, and serving Round Rock, TX for purposes of joinder only. (Hearing site: Cincinnati, OH, or Washington, DC.)

Note.—Applicant intends to interline at San Antonio, TX, and intends to tack the authority sought herein with other authority held by applicant.

MC 75320 (Sub-210F), filed January 23, 1979. Applicant: CAMPBELL SIXTY-SIX EXPRESS, INC., P.O. Box 807, Springfield, MO 65801. Representative:

Phineas Stevens, 17th Floor, Deposit Guaranty Plaza, P.O. Box 25567, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) between Memphis and Nashville, TN, over Interstate Hwy 40, serving no intermediate points, but serving Jackson and Nashville, TN, for purposes of joinder only, (2) between Birmingham, AL, and Nashville, TN, over Interstate Hwy 65, serving no intermediate points, but serving Nashville, TN, for purposes of joinder only, (3) between Atlanta, GA, and Nashville, TN, from Atlanta, GA, over Interstate Hwy 75 and U.S. Hwy 41 to Chattanooga, TN, then over Interstate Hwy 24 to Nashville, TN, and return over the same route, serving no intermediate points and serving Chattanooga and Nashville, TN, for purposes of joinder only, (4) between Nashville, TN, and Louisville, KY, over Interstate Hwy 65, serving no intermediate points, but serving Nashville for purpose of joinder only, (5) between Louisville, KY and Indianapolis, IN, over Interstate Hwy 65, serving no intermediate points, but serving the function of Interstate Hwy 65 and U.S. Hwy 50 at or near Seymour, IN, for purposes of joinder only, NOTE: Service at Louisville and points within its commercial zone is restricted against the transportation of traffic originating at, destined to or interlined with connecting carriers at Indianapolis and points within its commercial zone. (6) between St. Louis, MO and Cincinnati, OH, over U.S. Hwy 50, serving the junction of U.S. Hwy 50 and Interstate Hwy 65, at or near Seymour, IN, for purposes of joinder only, * (7) between Louisville, KY and Cincinnati, OH, over Interstate Hwy 71, serving no intermediate points.

Note.—Service at Louisville and points within its commercial zone is restricted against the transportation of traffic originating at, destined to or interlined with connecting carriers at Cincinnati and points within its commercial zone.

(8) between Cincinnati and Cleveland, OH, over Interstate Hwy 71, serving no intermediate points, but serving Columbus, OH, for purposes of joinder only, (9) between Chattanooga, TN and Cincinnati, OH, over Interstate Hwy 75, serving no intermediate points, but serving Chattanooga, TN for purpose of

* Applicant holds authority required in Docket No. MC-F-12713.

joinder only, (10) between Tupelo, MS and Jackson, TN, over U.S. Hwy 45, serving no intermediate points, but serving Jackson, TN, for purpose of joinder only, (11) between Indianapolis and Richmond, IN, over Interstate Hwy 70, serving no intermediate points, NOTE: Service at Richmond and points within its commercial zone is restricted against the transportation of traffic originating at, destined to or interlined with connecting carriers at Indianapolis and points within its commercial zone. (12) between Columbus and Zanesville, OH, over Interstate Hwy 70, serving no intermediate points, but serving Zanesville for purpose of joinder only, (13) between Cincinnati, OH and Pittsburgh, PA, over U.S. Hwy 22, serving Zanesville, OH, for purpose of joinder only,* (14) between Indianapolis, IN and Chicago, IL, from Indianapolis, IN over interstate Hwy 65 to junction Interstate Hwy 94, then over Interstate Hwy 94 to Chicago, IL, and return over the same route, serving no intermediate points. (Hearing site: Indianapolis, IN.)

Note.—Service at Indianapolis and points within its commercial zone is restricted against the transportation of traffic originating at, destined to or interlined with connecting carriers at Chicago and points within its commercial zone.

Note.—Applicant indicates intention to tack with existing authority at points in AL, GA, IL, IN, KY, MS, OH, and TN.

MC 83850 (Sub-11F), filed April 2, 1979. Applicant: JOHNSONS TRANSFER, INC., 6951 Norwitch Drive, Philadelphia, PA 19153. Representative: Harold P. Boss, 1100 Seventeenth Street NW., Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, foodstuffs, and those requiring special equipment), between points in CT, DE, ME, MD, MA, NH, NJ, NY, NC, OH, PA, RI, VT, VA, WV, and DC, restricted to the transportation of traffic originating at or destined to the facilities of the United States Gypsum Company. (Hearing site: Washington, DC, or Philadelphia, PA.)

MC 95540 (Sub-1097F), filed April 2, 1979. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, FL 33802. Representative: Benjy W. Fincher (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in by wholesale, and retail department stores

(except those of unusual value, classes A and B explosives, and commodities in bulk), from points in GA, NC, SC, and AL, to points in MN. (Hearing site: Minneapolis, MN, or Washington, DC.)

MC 97310 (Sub-32F), filed April 2, 1979. Applicant: SHARRON MOTOR LINES, INC., P.O. Box 31066, 3730 First Avenue South, Birmingham, AL 35222. Representative: Bruce E. Mitchell, 3390 Peachtree Rd. 5th Floor, Atlanta, GA 30326. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) Between, Memphis, TN, and New Orleans, LA, over U.S. Hwy 61, serving intermediate points in MS on and south of U.S. Hwy 80, and all intermediate points in LA, (2) between Memphis, TN, and Kenner, LA: From Memphis, TN over U.S. Hwy 51 or Interstate Hwy 55 to junction U.S. Hwy 61, at or near Kenner, LA, and return over the same route, serving all intermediate points in MS on and south of U.S. Hwy 80, and all intermediate points in LA, (3) between Memphis, TN, and New Orleans, LA: From Memphis, TN over U.S. Hwy 78 to junction U.S. Hwy 45, then over U.S. Hwy 45 to junction U.S. Hwy 11, then over U.S. Hwy 11 to New Orleans, LA, and return over the same route, serving all intermediate points in MS on and south of U.S. Hwy 80, and all intermediate points in LA, (4) Between Birmingham, AL, and New Orleans, LA: From Birmingham, AL over U.S. Hwy 31 to Montgomery, AL, then over Interstate Hwy 65 to Mobile, AL, then over U.S. Hwy 90 to New Orleans, LA, and return over the same route, serving all intermediate points, (5) Between Meridian, MS, and Mobile, AL, over U.S. Hwy 45, serving all intermediate points, (6) Between Jackson, MS, and Mobile, AL: From Jackson, MS over U.S. Hwy 49 to junction U.S. Hwy 98, then over U.S. Hwy 98 to Mobile, AL, and return over the same route, serving all intermediate points, (7) Between Jackson, MS, and Gulfport, MS, over U.S. Hwy 49, serving all intermediate points, (8) Between Natchez, MS, and Mobile, AL, over U.S. Hwy 98, serving all intermediate points, (9) Between Natchez, MS, and junction U.S. Hwy 84 and U.S. Hwy 45, over U.S. Hwy 84, serving all intermediate points, and (10) Between Baton Rouge, LA, and junction U.S. Hwy 190 and U.S. Hwy 90, over U.S. Hwy 190, serving all intermediate points, service is authorized at all points in MS south of

U.S. Hwy 80 as off-route points in connection with operation over the routes described above. (Hearing site: Birmingham, AL, Jackson, MS, and New Orleans, LA.)

MC 104881 (Sub-7F), filed March 29, 1979. Applicant: GAY TRUCK LINE, INC., Post Office Box 134, Falkner, MS 38629. Representative: John A. Crawford, 17th Floor, Deposit Guaranty Plaza, Post Office Box 22567, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) Between Walnut, MS, and the MS-AL State line, over U.S. Hwy 72, serving all intermediate points, (2) Between the MS-TN State line, and Baldwin, MS: From the MS-TN State line over U.S. Hwy 45 and U.S. Hwy 45 By-pass to Baldwin, MS, and return over the same route, serving all intermediate points, and (3) Between Booneville, MS, and Ripley, MS, over MS Hwy 4, serving all intermediate points, serving points in Alcorn and Prentiss Counties, MS, and the Yellow Creek Port Terminal and Industrial Area in Tishomingo and Alcorn Counties, MS, and the Nuclear Power Plant facilities in Tishomingo County, MS as off-route points in parts (1), (2), and (3). (Hearing site: Memphis, TN, and Corinth, MS.)

MC 106920 (Sub-79F), filed April 4, 1979. Applicant: RIGGS FOOD EXPRESS, INC., P.O. Box 26, New Bremen, OH 45869. Representative: David C. Venable, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs and supplies and equipment* used in the production of foodstuffs, between the facilities of Anderson Clayton Foods, Inc., at Jacksonville, IL, on the one hand, and on the other, points in FL, GA, TN, IN, KY, and MI. (Hearing site: Dallas, TX.)

MC 106920 (Sub-80F), filed April 4, 1979. Applicant: RIGGS FOOD EXPRESS, INC., P.O. Box 26, New Bremen, OH 45869. Representative: E. Stephen Heasley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs* (except in bulk), from Napoleon, OH, to points in IL, IN, MI, MO, NJ, NY, PA,

VA, and WI. (Hearing site: Columbus, OH, or Chicago, IL.)

MC 108831 (Sub-11F), filed March 15, 1979. Applicant: BOB YOUNG TRUCKING, INC., Schoenersville Road at Industrial Drive, Bethlehem, PA 18017. Representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, PA 19102. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *boilers, furnaces, heat transfer units, forgings, castings, weldments, filter presses, material handling and processing equipment*, and *commodities*, the transportation of which because of size of weight require the use of special equipment, from the facilities of The Bethlehem Corporation, in Palmer Township, PA (Northampton County), to points in the United States (except AK, HI, and PA), and (2) *materials and equipment* used in the manufacture of the commodities in (1) above, in the reverse direction. (Hearing site: Philadelphia, PA, or Washington, DC.)

MC 109490 (Sub-10F), filed March 29, 1979. Applicant: HEDING TRUCK SERVICE, INC., P.O. Box 43, Union Center, WI 53962. Representative: Richard A. Westley, 4506 Regent Street, Suite 100, Madison, WI 53705. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *feed and feed ingredients*, from the facilities of Milk Specialties Division of General Host Corporation, at or near Dundee, IL, and Boscobel and New Holstein, WI, to points in the United States (except AK and HI); and (2) (a) *caseinate*, (b) *blends* consisting of soy flour and dairy products, and (c) *commodities* otherwise exempt from economic regulation, when moving in mixed loads with the commodities named above, from the facilities of Elroy Community Dairy, Inc., at or near Elroy, WI, to points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 110380 (Sub-11F), filed March 23, 1979. Applicant: BERSCHENS OF MADISON, INC., 120 West Verona Avenue, Verona, WI 53593. Representative: Rolfe E. Hanson, 121 West Doty Street, Madison, WI 53703. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *plastic pipe, conduit, and materials, supplies, and tools* (except commodities in bulk), used in the installation of plastic pipe and conduit, from points in Dane and Rock Counties, WI, to points in NE, ND, SD, KS, TN, KY,

WV, PA, and MN. (Hearing site: Madison or Milwaukee, WI.)

MC 119641 (Sub-163F), filed March 30, 1979. Applicant: RINGLE EXPRESS, INC., 450 E. Ninth St., Fowler, IN 47944. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *sewerage treatment plants, aerators, lift stations, and accessories* thereof, from the facilities of Clow Corporation, near Richwood, KY, to points in the United States (except AK and HI); and (2) *pipe, fittings, valves, hydrants, and accessories* used in the installation thereof, from the facilities of Clow Corporation, at points in Jefferson and Talladega Counties, AL, and at Columbia, MO, to points in IL, IN, IA, MI, MN, NE, OH, and WI. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 119741 (Sub-164F), filed April 2, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue, NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *food, food products, and food ingredients* (except commodities in bulk, in tank vehicles), from points in CO, KS, and MO, to the facilities of Archer Daniels Midland Company, at Decatur, IL, restricted to the transportation of traffic originating at the named origins and destined to the indicated destination. (Hearing site: Chicago, IL.)

MC 119741 (Sub-166F), filed April 6, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue, NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *animal drugs or medicines, animal feed and supplemental powder*; and (2) *material, equipment, and supplies* used in the conduct of business of (1) above, between the facilities of Salsbury Laboratories, at or near Charles City, IA, on the one hand, and, on the other, points in AR, DE, GA, MD, NJ, and NY, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Mason City, IA.)

MC 121470 (Sub-22F), filed April 4, 1979. Applicant: TANKSLEY TRANSFER COMPANY, a Corporation, 801 Cowan Street, Nashville, TN 37207.

Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *composition board, hardboard, flakeboard, particle board, and lumber mill products*, from Bluegrass Industrial Park, at or near Louisville, KY, and from Sellersburg, IN, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the named points. (Hearing site: Louisville, KY, or Nashville, TN.)

MC 129121 (Sub-4F), filed April 5, 1979. Applicant: GEORGE W. CARMEAN, INC., P.O. Box 129, Georgetown, DE 19947. Representative: J. Michael May, Suite 508, 1447 Peachtree St. NE., Atlanta, GA 30309. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *feed ingredients*, in bulk, from the facilities of International Bakerage, Inc., at Carteret, NJ, to points in DE, MD, NC, and VA, under continuing contract(s) with International Bakerage, of Carteret, NJ. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 135430 (Sub-2F), filed April 4, 1979. Applicant: LEAVITTS FREIGHT SERVICE, INC., 3855 Maroola Road, Springfield, OR 97447. Representative: David C. White, 2400 SW Fourth Ave., Portland, OR 97201. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *laminated wood products, prefabricated wooden timbers, trusses, and beams and lumber*, from points in OR, to points in WA, OR, CA, ID, NV, MT, WY, CO, UT, AZ, and NM; (2) *treated poles, pilings, and posts*, (a) from points in OR and WA, to points in WA, OR, ID, CA, and NV, and (b) from Weed, CA, to points in OR and NV; and (3) *lumber*, from those points in CA in and north of Mendocino, Lake, Yolo, Sacramento, and El Dorado Counties, and points in ID, WA, and OR, to points in OR. (Hearing site: Portland, OR.)

Note.—Condition for issuance of certificate: Coincidental cancellation at applicant's written request of its permits in MC-116474 and subs.

MC 138000 (Sub-46F), filed April 4, 1979. Applicant: ARTHUR H. FULTON, INC., P.O. Box 86, Stephens City, VA 22855. Representative: Edward N. Button, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, MD 21740. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *bakery goods*, from

Richmond, VA, to points in MT.
(Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 138741 (Sub-76F), filed April 6, 1979. Applicant: AMERICAN CENTRAL TRANSPORT, INC., 2005 North Broadway, Joliet, IL 60435. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *plastic pipe and fittings*, from the facilities of Some Industries, Inc., a Division of Robintech, Inc., at or near Rolla, MO, to points in AR, IL, IN, KS, KY, MI, OH, OK, TN, and WI. (Hearing site: Kansas City, MO.)

MC 139960 (Sub-1F), filed April 4, 1979. Applicant: WESTERN PACIFIC TRANSPORT COMPANY, a Corporation, 526 Mission Street, San Francisco, CA 94105. Representative: Stephen T. Rudman (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except classes A and B explosives, commodities in bulk, and used household goods), (1) Between Woodland, CA, and Sacramento, CA, over Interstate Hwy 5, serving all intermediate points, (2) Between San Jose, CA, and Oakland, CA, over CA Hwy 17, serving all intermediate points, (3) Between Salinas, CA, and San Jose, CA, over U.S. Hwy 101, serving all intermediate points, (4) Between Santa Clara, CA, and Oakland, CA: From Santa Clara, CA over U.S. Hwy 101 to junction Interstate Hwy 80 to Oakland, CA, and return over the same route, serving all intermediate points, (5) Between Stockton, CA, and Oakland, CA: From Stockton, CA over Interstate Hwy 5, to junction Interstate Hwy 205, then over Interstate Hwy 205 to junction Interstate Hwy 580, then over U.S. Hwy 580 to Oakland, CA, and return over the same route, serving all intermediate points, (6) Between Oakland, CA, and Sacramento, CA over U.S. Hwy 80, serving all intermediate points, (7) Between Milpitas, CA, and junction Interstate Hwys 80 and 680: From Milpitas, CA over CA Hwy 237 to junction Interstate Hwy 680, then over Interstate Hwy 680 to junction Interstate Hwys 80, and return over the same route, serving junction Interstate Hwy 80 and 680 for purposes of joinder only, and serving all intermediate points and the off-route points of Crockett, Pittsburg, and Antioch, CA, (8) Between Oroville, CA, and Sacramento, CA: From Oroville, CA over CA Hwy 70 to junction CA Hwy 99, then over CA Hwy

99 to Sacramento, CA, and return over the same route, serving all intermediate points and the off-route points of Yuba City, CA and Beale Air Force Base, CA, (9) Between Fresno, CA, and Sacramento, CA, over CA Hwy 99, serving all intermediate points and the off-route points of Lathrop and Escalon, CA, (10) Between Sacramento, CA, and Reno, NV, over Interstate Hwy 80, serving the intermediate points of Auburn and Newcastle, CA, and the off-route points of Rocklin and Sunset-Whitney Ranch, CA, (11) Between Reno, NV, and Salt Lake City, UT, over Interstate Hwy 80 and U.S. Hwy 40, serving no intermediate points, (12) Between Tooele, UT, and Salt Lake City, UT: From Tooele, UT over UT Hwy 36 to junction Interstate Hwy 80, then over Interstate Hwy 80 to Salt Lake City, UT, and return over the same route, serving the intermediate point of Lake Point, UT, and the off-route point of Tooele Army Depot, UT, (13) Between Salt Lake City, UT, and Payson, UT, over Interstate Hwy 15, serving all intermediate points, (14) Between Salt Lake City, UT, and Ontario, OR: From Salt Lake City, UT, over Interstate Hwy 15 to junction Interstate Hwy 80-N (Interstate Hwy 80-N will be redesignated Interstate Hwy 84 on or about May 1, 1980), then over Interstate Hwys 15 and 80-N to Tremonton, UT, then over Interstate Hwy 80-N to Glens Ferry, ID, then over U.S. Hwys 26 and 30 from Glens Ferry, ID, to junction Interstate Hwy 80-N near Hammett, ID, then over Interstate Hwy 80-N to Ontario, OR, and return over the same route, serving all intermediate points, and the off-route points of Rupert, Paul, Burley, Buhl, Twin Falls, Jerome, Mountain Home, and Mountain Home Air Force Base, ID, (15) Between Ogden, UT, and St. Anthony, ID: From Ogden, UT over U.S. Hwy 89 to junction U.S. Hwy 91, then over U.S. Hwys 89 and 91 to Logan, UT, then over U.S. Hwy 91 to junction Interstate Hwy 15, then over Interstate Hwy 15 to Idaho Falls, ID, then from Idaho Falls, ID over U.S. Hwy 191 to St. Anthony, ID, and return over the same route, serving all intermediate points, and Shelley, ID, and the facilities of Basic American Food Company, near Blackfoot, ID, as off-route points, (16) Between Pocatello, ID, and Ogden, UT, over Interstate Hwy 15, serving no intermediate points as an alternate route for operating convenience only, (17) Between Pocatello, ID, and junction Interstate Hwys 86 and 80-N (Interstate Hwy 80-N will be redesignated Interstate Hwy 84 on or about May 1, 1980): From Pocatello, ID over Interstate Hwy 86 to junction U.S. Hwy 30, then over

Interstate Hwy 86 and U.S. Hwy 30 to junction Interstate Hwys 86 and 80-N, and return over the same route, serving no intermediate points, and serving junction Interstate Hwys 86 and 80-N for purposes of joinder only, and serving the off-route point of American Falls, ID, (18) Between Jerome, ID, and Twin Falls, ID: From Jerome, ID, over ID Hwy 79 to junction Interstate Hwy 80-N (Interstate Hwy 80-N will be redesignated Interstate Hwy 84 on or about May 1, 1980), then over Interstate Hwy 80-N to junction U.S. Hwy 93, then over U.S. Hwy 93 to Twin Falls, ID, and return over the same route, serving no intermediate points, (19) Between Twin Falls, ID, and Reno, NV: From Twin Falls, ID, over U.S. Hwy 93 to Wells, NV, then over Interstate Hwy 80 to Reno, NV, and return over the same route, serving no intermediate points as an alternate route for operating convenience only, and (20) Between Caldwell, ID, and Reno, NV: From Caldwell, ID over ID Hwy 55 to junction U.S. Hwy 95, then over U.S. Hwy 95 to junction Interstate Hwy 80, then over Interstate Hwy 80 to Reno, NV, and return over the same route, serving no intermediate points as an alternate route for operating convenience only. (Hearing site: San Francisco, CA, Reno, NV, or Sacramento, CA.)

MC 141450 (Sub-14F), filed April 4, 1979. Applicant: OLIN WOOTEN TRANSPORT CO., INC., P.O. Box 731, Hazlehurst, GA 31539. Representative: Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, FL 32202. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *glass containers*, from Cliffwood, NJ, Warner Robbins, GA, Henryetta, OK, Terre Haute, IN, and Shakopee, MN, to points in TX, KS, NE, NM, IA, WI, MO, IL, AR, LA, MS, AL, FL, GA, SC, TN, KY, NC, VA, WV, OH, IN, MI, PA, DE, MD, NJ, NY, CT, and RI; and (2) *materials and supplies* used in the manufacture and distribution of glass containers, in the reverse direction, under continuing contract(s) with Midland Glass Co., Inc., of Cliffwood, NJ. (Hearing site: Jacksonville, FL, or Atlanta, GA.)

MC 141781 (Sub-17F), filed February 28, 1979. Applicant: LARSON TRANSFER AND STORAGE CO., INC., 10700 Lyndale Ave., South, Minneapolis, MN 55420. Representative: Samuel Rubenstein 301 North Fifth St., Minneapolis, MN 55403. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *metal containers and container ends*, and *materials and supplies* used in the

manufacture and distribution of containers, from Chicago, IL, and Gary, IN, to points in IA, MN, and WI. (Hearing site: Minneapolis or St. Paul, MN.)

Note.—Dual operations may be involved.

MC 141921 (Sub-34F), filed November 27, 1978. Applicant: SAV-ON TRANSPORTATION, INC., 143 Frontage Rd., Manchester, NH 03108. Representative: John A. Sykas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Illini Packers, Inc., at or near Geneseo, IL, to points in CT, ME, MA, NH, VT, RI, and NY, restricted to the transportation of traffic originating at the named facilities and destined to the above-indicated destinations (except traffic moving in foreign commerce). (Hearing site: Concord, NH, or Boston, MA.)

Note.—Dual operations may be involved.

MC 142901 (Sub-6F), filed April 6, 1979. Applicant: TMI TRANSPORT CORP., 050, 3rd Avenue West, Dickinson, ND 58601. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *Skis and storage tanks*, from the facilities of Steffes & Son Manufacturing, Inc., at or near Dickinson, ND, to points in the United States (except AK and HI); and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above, in the reverse direction. (Hearing site: Bismarck, ND.)

Note.—Dual operations may be involved.

MC 142920 (Sub-2F), filed April 4, 1979. Applicant: OLIVER TRUCKING CORP., 2203 W. Oliver Avenue, Indianapolis, IN 46221. Representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, NY 10048. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in or used by manufacturers and distributors of sound, communications, educational, and entertainment materials (except in bulk), (1) between points in CT, NY, NJ, and CA, on the one

hand, and, on the other, points in IN and IL, (2) between points in CT, on the one hand, and, on the other, points in NJ, and (3) between points in CA, on the one hand, and, on the other, points in CT, NY, and NJ, under continuing contract(s) with CBS, Inc., of New York, NY. (Hearing site: New York, NY.)

MC 143500 (Sub-5F), filed April 4, 1979. Applicant: R. B. CARRIERS, INC., P.O. Box 92, Jeffersonville, IN 47130. Representative: James E. Savitz, Suite 145, 4 Professional Drive, Gaithersburg, MD 20760. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *household appliances, parts for household appliances, and cabinets*, between Mansfield and Ontario, OH, Murray, KY, Springfield and Nashville, TN, and Dalton, GA, on the one hand, and, on the other, points in AZ, AR, CA, CO, FL, GA, ID, KY, LA, MO, MT, NV, NM, OH, OK, OR, TN, TX, UT, WA, WI, and WY, under continuing contract(s) with The Tappan Co., of Mansfield, OH. (Hearing site: Louisville, KY.)

MC 144630 (Sub-16F), filed April 4, 1979. Applicant: STOOPS EXPRESS, INC., 2239 Malibu Court, Anderson, IN 46011. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *extruded or injection molder rubber and plastic products*, from the facilities of Entek Corporation of America, at Irving, TX, to points in the United States (except AK and HI), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), in the reverse direction. (Hearing site: Dallas, TX.)

Note.—Dual operations may be involved.

MC 145011 (Sub-3F), filed April 4, 1979. Applicant: R. F. WESTBURY, 1617 Willis Road, Richmond, VA 23224. Representative: Carroll B. Jackson, 1810 Vincennes Road, Richmond, VA 23229. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *fiber yarn, plastic, and plastic products*; and (2) *materials, supplies, and equipment* used in the manufacture, distribution, and storage of the commodities named in (1) above (except commodities in bulk, in tank vehicles), between Bermuda Hundred, VA, on the one hand, and, on the other, points in CA, IL, MI, OK, and TX, under continuing contract(s) with Allied Chemical Corporation, Fibers Division,

of New York, NY. (Hearing site: New York, NY, or Washington, DC.)

MC 145131 (Sub-2F), filed April 3, 1979. Applicant: O. E. PONDER, d.b.a. PONDER FARM SUPPLY, P.O. Box 100, Bremen, AL 35033. Representative: James R. Knight, Griffith Building, P.O. Drawer M, Cullman, AL 35055. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *dry fertilizer*, (1) from Hanceville, AL, to the facilities of Gold Kist Associations, at points in Jackson, Holmes, and Gadsden Counties, FL, and points in GA, and (2) from Tyner, TN, to the facilities of Gold Kist Associations, at points in GA and AL, under continuing contract(s) with Gold Kist, Inc., of Atlanta, GA. (Hearing site: Birmingham, AL.)

MC 145701 (Sub-1F), filed March 29, 1979. Applicant: D.C. TRANSPORT, INC., 916 South Riverside Avenue, St. Clair, MI 48079. Representative: John W. Bryant, 900 Guardian Building, Detroit, MI 48226. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *fabrics, textiles, and urethane foam*; and (2) *laminations* for the commodities named in (1) above, from Cornelius, Greensboro, and Wallace, NC, and Stoughton, MA, to the facilities of Inmont Corporation, at Port Huron, MI. (Hearing site: Detroit, MI.)

MC 145921 (Sub-2F), filed April 4, 1979. Applicant: AIR COURIERS, INC., 9338 Woodson Terrace Industrial Court, Woodson Terrace, MO 63134. Representative: Clyde W. Jenkins (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and articles requiring special equipment), between Lambert Field, St. Louis, MO, O'Hare International Airport, Chicago, IL, and points in Adams, Brown, Schuyler, Pike, Cook, Scott, Morgan, Cass, Mason, Menard, Logan, DeWitt, Macon, Piatt, Champaign, Vermilion, Sangamon, Christian, Moultrie, Douglas, Edgar, Coles, Shelby, Clark, Cumberland, Montgomery, Macoupin, Greene, Calhoun, Jersey, Bond, Madison, Fayette, Effingham, Jasper, Crawford, Clay, Richland, Lawrence, Marion, Clinton, St. Clair, Monroe, Randolph, Washington, Jefferson, Wayne, Edwards, Wabash, Perry, Franklin, Hamilton, White, Jackson, Williamson, Saline, Gallatin, Union, Johnson, Pope, Hardin, Alexander, Pulaski, and Massac

Counties, IL, and Warren, St. Louis, St. Charles, Franklin, Jefferson, Ste. Genevieve, St. Francois, Perry, Iron, Reynolds, Madison, Bollinger, Cape Girardeau, Wayne, Stoddard, Scott, Mississippi, New Madrid, Dunkin, Pemiscot, Butler, Ripley, Carter, Washington, Crawford, Phelps, Maries, Miller, Gasconade, Osage, Cole, Morgan, Moniteau, Callaway, Cooper, Boone, Montgomery, Lincoln, Pike, Audrain, Saline, Howard, Chariton, Macon, Randolph, Shelby, Monroe, Marion, Ralls, Lewis, Jackson, Platte, Clay, Lafayette, and Clark Counties, MO, restricted in all the above to the transportation of traffic having a prior or subsequent movement by air. (Hearing site: St. Louis, MO.)

MC 145950 (Sub-11F), filed April 5, 1979. Applicant: BAYWOOD TRANSPORT, INC., P.O. Box 2611, Waco, TX 76710. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St. NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *canned and preserved foodstuffs*, from the facilities of Heinz USA, at or near Pittsburgh, PA, to points in AR, OK, and TX, restricted to the transportation of traffic originating at the named origin facilities and destined to the indicated destinations. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 146041 (Sub-3F), filed April 4, 1979. Applicant: CAL-TEX, INC., 2300 Harbor Blvd. No. 8, Costa Mesa, CA 92626. Representative: Robert G. Egerton (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *frozen boxed meat*, from the facilities of Landmark Beef Processors, at or near Los Angeles, CA, to points in NC, NJ, SC, and VA. (Hearing site: Los Angeles, CA, or Washington, DC.)

Note.—Dual operations may be involved.

MC 146520 (Sub-1F), filed April 4, 1979. Applicant: QUALITY TRANSPORT, INC., 4404 West Berteau, Chicago, IL 60641. Representative: William J. Boyd, 600 Enterprise Drive, Suite 222, Oak Brook, IL 60521. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C.

209 and 766 (except hides and commodities in bulk), between the facilities of Lauridsen Foods, Inc., at or near Britt, IA, and Armour and Company, at or near Mason City, IA, on the one hand, and, on the other, points in CT, DE, KY, IL, IN, MA, MD, ME, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV, and DC, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Chicago, IL, or Washington, DC.)

Note.—Dual operations may be involved.

MC 146690 (Sub-1F), filed March 29, 1979. Applicant: NORTHEAST TOWING, INC., 7618 Glencoe Street, Philadelphia, PA 19111. Representative: Robert M. Rubin, 600 Penn Square Building, Philadelphia, PA 19107. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *partially completed trucks*, in Truckaway service; (2) *wrecked and disabled trucks and trailers*, in Truckaway service; and (3) *replacement vehicles* for wrecked and disabled trucks and trailers, in Truckaway service, between points in AL, CT, DE, FL, GA, IL, IN, KY, LA, ME, MD, MA, MI, MN, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV, WI, and DC. (Hearing Site: Philadelphia, PA, or Washington, DC.)

MC 146701 (Sub-3F), filed April 4, 1979. Applicant: WEAVER TRUCKING CO., INC., P.O. Box 45, Eton, GA 30724. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *carpeting*, from Eton and Chatsworth, GA, to points in the United States (except AK and HI), under continuing contract(s) with (1) Kimberly Carpet Mills, of Chatsworth, GA, and (2) Diamond Carpet and Rug Mills, Inc., and Lanass Carpet, Co., Inc., both of Eton, GA. (Hearing site: Atlanta, GA.)

MC 146971F, filed April 4, 1979. Applicant: CONTRANS, INC., Arch Street, Erving, MA 01344. Representative: David M. Marshall, 101 State Street, Suite 304, Springfield, MA 01103. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *paper and paper articles, plastic and plastic articles, metal articles*; and (2) *materials and supplies* used in the manufacture of the commodities named in (1) above (except commodities in bulk, in tank vehicles), between the facilities of Erving Paper Mills, and its wholly owned

subsidiaries, Baldwinville Products, Inc., of Baldwinville, MA, Flamingo Products, Incorporated, of Hialeah, FL, Fox Paper Incorporated, of Lockland, OH, Hinsdale Products Company, Inc., of Hinsdale, NH, LaGrange Paper Products Co., of LaGrange, GA, and Sorg Products, Inc., of Ligonier, IN, at or near Brattleboro, VT, Hinsdale, NH, Erving and Baldwinville, MA, Lockland, OH, Ligonier, IN, Hialeah, FL, and LaGrange and Mount Vernon, GA, on the one hand, and, on the other, points in the United States (except AK and HI), under a continuing contract(s) with Erving Paper Mills, or said wholly owned subsidiaries. (Hearing site: Albany, NY, or Boston, MA.)

MC 146890 (Sub-4F), filed March 12, 1979. Applicant: C & E TRANSPORT, INC., C. E. ZUMSTEIN CO., P.O. Box 27, Moore St., Lewisburg, OH 45338. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *chemicals, chemical compounds, antifreeze, plastics, and plastic products* (except commodities in bulk); and (2) *materials, equipment, and supplies* used in the manufacture, distribution, or sale of the commodities named in (1) above (except commodities in bulk), between the facilities of Northern Petrochemical Company, at or near Mankato, MN, Newark, OH, Clinton, MA, Chicago, Morris, and Mapleton, IL, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

MC 146080 (Sub-2F), filed March 30, 1979. Applicant: MCKINLEY MUNCY, JR., CARDINAL BUS LINES, P.O. Box 7831, Huntington, WV 25778. Representative: John M. Friedman, 2930 Putnam Avenue, Hurricane, WV 25526. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *passengers and their baggage, express and newspapers*, in the same vehicle with passengers, between Williamson, WV, and Huntington, WV; From Williamson, WV to Moses Fork Mountain over U.S. Hwy 52, then over WV Hwy 152 to Echo, WV, then over U.S. Hwy 52 to Huntington, WV, and return over the same route, serving all intermediate points. (Hearing site: Charleston, WV.)

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Decided: July 25, 1975.

By the Commission, Review Board Number 1, Members Carleton, Joyce and Jones.

MC 5470 (Sub-186F), filed April 12, 1979. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *coke and coke breeze*, in bulk, in dump vehicles, from Erie, PA, and Toledo, OH, to points in CT, DE, IA, IL, IN, KY, MA, MD, ME, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VA, VT, WI, WV, and DC. (Hearing site: Washington, DC, or Pittsburgh, PA.)

MC 5470 (Sub-189F), filed April 9, 1979. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *bauxite ore*, in bulk, in dump vehicles, from Baltimore, MD, to Gary, IN and Sproul, PA. (Hearing site: Washington, DC, or Philadelphia, PA.)

MC 35320 (Sub-225F), filed March 16, 1979, previously noticed in the Federal Register issue of July 18, 1979, as Sub-226F. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of American Electrical Industries, at or near Sedalia, MO, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Kansas City, MO, or Washington, DC.)

Note.—This republication states the correct Sub-Number.

MC 35320 (Sub-226F), filed March 16, 1979, previously noticed in the Federal Register issue of July 18, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Danver Shoe Company, at or near Blytheville, AR, as an off-route point in connection with

applicant's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

Note.—This republication states the correct Sub-Number.

MC 35320 (Sub-262F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Polyguard Corp., at or near Pryor, OK, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Tulsa, OK, or Dallas, TX.)

MC 35320 (Sub-270F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Medart, Inc., at or near Greenwood, MS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-279F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Don P. Smith Chair Co., Inc., at or near Loudon, TN, as an off-route point in connection with the applicant's otherwise authorized regular-route operations. (Hearing site: Knoxville, TN, or Washington, DC.)

MC 35320 (Sub-280F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate

as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Arvin Automotive, Inc., at or near Columbus and Franklin, IN, as off-route points in connection with the applicant's otherwise authorized regular-route operations. (Hearing site: Louisville, KY, or Washington, DC.)

MC 35320 (Sub-281F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Koehring-Atomaster Division, at or near Bowling Green, KY, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Louisville, KY, or Washington, DC.)

MC 35320 (Sub-282F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Arnold-Sub. Magnetics Electronics, Inc., at or near Sevierville, TN, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN, or Washington, DC.)

MC 35320 (Sub-286F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring

special equipment), serving the facilities of Kagan Dixon Wire Corp., at or near Osceola, AR as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-287F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Bruner Ivory Handle, Inc., at or near Hope, AR, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 35320 (Sub-288F), filed April 6, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Leggs Products, Inc., at or near (a) Rockingham, NC, and (b) Marion and Hartsville, SC, as off-route points in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-289F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Dow Corning Corporation, at or near Elizabethtown, and Carrollton, KY, as off-route points in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Louisville, KY, or Washington, DC.)

MC 35320 (Sub-290F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Tupelo Coffee Company, at or near Tupelo, MS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-291F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Dowell Division of Dow Chemical Co., at or near Wichita Falls, TX, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Tulsa, OK, or Dallas, TX.)

MC 35320 (Sub-292F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Volume Shoe Corporation, at or near Topeka, KS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 35320 (Sub-293F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities*

(except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Aeroquip Gustin-Bacon Division, at or near Lawrence, KS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 35320 (Sub-294F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Borg Textiles, at or near Delavan and Jefferson, WI, as an off-route points in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Milwaukee, WI, or Washington, DC.)

MC 35320 (Sub-296F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Potlatch, point at or near Sikeston, MO, as an off-route Packagins, in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-297F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Fashion Pillows, Inc., at or near Jackson, GA, as an off-route point in

connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 35320 (Sub-295F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Colson Equipment Co., at or near Caruthersville, MO, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN or Washington, DC.)

MC 35320 (Sub-298F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Packer Plastics, Incorporated, at or near Lawrence, KS, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Kansas City, MO or Washington, DC.)

MC 35320 (Sub-299F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Southern Paper Box Company, at or near Benton, AR, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Little Rock, AR, or Tulsa, OK.)

MC 35320 (Sub-300F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas

(same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Essex Group, Inc., at or near Pauline and Ellsworth, KS, as off-route points in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 35320 (Sub-301F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition, parts of ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Facet Enterprises (Campbell Filter Company), at or near Dexter, MO, as an off-route point in connection with the carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN, or Washington, DC.)

MC 35320 (Sub-304F), filed April 10, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition and parts for ammunition, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the facilities of American Sandpaper Company, at or near Rockland, MA on the one hand, and, on the other, points in MS. (Hearing site: Boston, MA, or Washington, DC.)

MC 35320 (Sub-305F), filed April 10, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, ammunition and parts for ammunition, household goods as defined by the Commission, commodities in bulk, and

those requiring special equipment), between the facilities of Olin Corporation, at or near Charleston, TN, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chattanooga, TN, or Washington, DC.)

MC 35320 (Sub-310F), filed April 9, 1979. Applicant: T.I.M.E.-DC, INC., P.O. Box 2550 Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring special equipment, ammunition, and parts of ammunition), serving the facilities of Arvin Industries, Inc., at or near Princeton, KY, as an off-route point in connection with applicant's otherwise authorized regular-route operations. (Hearing site: Louisville, KY, or Washington, DC.)

MC 38481 (Sub-13F), filed April 9, 1979. Applicant: FARRUGGIO'S BRISTOL AND PHILADELPHIA AUTO EXPRESS, INC., 1419 Radcliffe St., Bristol, PA 19007. Representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, PA 19102. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *sponge rubber carpet padding and carpet adhesives*, and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above, between the facilities of General Felt Industries, Inc., at or near Philadelphia, PA, on the one hand, and, on the other, points in DE, MD, NJ, NY, PA, and DC. (Hearing site: Washington, DC, or Philadelphia, PA.)

MC 56270 (Sub-27F), filed April 9, 1979. Applicant: LEICHT TRANSFER & STORAGE CO., a Corporation, 1401-55 State St., P.O. Box 2385, Green Bay, WI 54306. Representative: Dennis L. Sedlacek (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *such commodities* as are dealt in or used by manufacturers and distributors of laminated plastic and wood products (except commodities in bulk), between Oconomowoc, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

MC 61231 (Sub-141F), filed April 9, 1979. Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINES,

INC., P.O. Box 1351, Des Moines, IA 50309. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *insulation and vermiculite products*, and (2) *materials, equipment, and supplies* used in the manufacture, distribution, and installation of the commodities in (1) above, (a) between Commerce City and Pueblo, CO, on the one hand, and, on the other, points in IA, KS, MN, MO, NE, ND, OK, and SD, and (b) between Minneapolis, MN, on the one hand, and, on the other, points in AR, AZ, CO, IN, KS, KY, MO, MT, NM, OH, OK, TX, and WY. (Hearing site: St. Paul, MN, or Denver, CO.)

MC 61231 (Sub-142F), filed April 12, 1979. Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINES, INC., P.O. Box 1351, Des Moines, IA 50305. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles*, from the facilities of Armco, Inc., at Ashland, KY, and Middletown, OH, to points in AR, CO, IA, KS, MN, MO, NE, OK, and TX, restricted to the transportation of traffic originating at the named origins. (Hearing site: Columbus, OH, or Chicago, IL.)

MC 61231 (Sub-143F), filed April 6, 1979. Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINES, INC., P.O. Box 1351, Des Moines, IA 50305. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *steel pipe*, from Springfield, IL, to points in AZ, AR, CO, IN, IA, KS, KY, MI, MN, MO, MT, NE, NM, ND, OH, OK, SD, TX, WI, and WY. (Hearing site: St. Paul, MN, or Chicago, IL.)

MC 80430 (Sub-172F), filed April 6, 1979. Applicant: GATEWAY TRANSPORTATION CO., INC., 455 Park Plaza Drive, La Crosse, WI 54601. Representative: Lem Smith (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Cincinnati, OH, and Evansville,

IN, from Cincinnati, over Interstate Hwy 75 to junction Interstate Hwy 71, then over Interstate Hwy 71 to junction Interstate Hwy 64, then over Interstate Hwy 64 to junction IN Hwy 57, then over IN Hwy 57 to Evansville, and return over the same route, serving no intermediate points as an alternate route for operating convenience only. (Hearing site: Chicago, IL.)

MC 82841 (Sub-250F), filed April 10, 1979. Applicant: HUNT TRANSPORTATION, INC., 10770 "I" St., Omaha, NE 68127. Representative: Donald L. Stern, 610 Xerox Building, 7171 Mercy Road, Omaha, NE 68106. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *pipe, pipe fittings, valves, and hydrants*, from the facilities of Clow Corporation, at or near Columbia, MO, to those points in the United States in and east of CO, MT, NM, and WY. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 93980 (Sub-81F), filed April 9, 1979. Applicant: VANCE TRUCKING COMPANY, INC., P.O. Box 1119, Henderson, NC 27536. Representative: Edward G. Villalon, 1032 Pennsylvania Bldg., Pennsylvania Ave. & 13th St. NW., Washington, DC 20004. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *lumber and composition board*, from points in AL and FL, to those points in the United States in and east of WI, IL, KY, TN, MS, and LA. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 95540 (Sub-1098F), filed April 6, 1979. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, FL 33802. Representative: Benjy W. Fincher (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving those points in TN, within the Chattanooga, TN, commercial zone as off-route points in connection with the carrier's otherwise authorized regular-route authority from and to Chattanooga, TN. (Hearing Site: Chattanooga, TN, or Washington, DC.)

MC 106401 (Sub-68F), filed April 9, 1979. Applicant: JOHNSON MOTOR LINES, INC., P.O. Box 31577, Charlotte, NC 28231. Representative: Roger W. Rash (same address as applicant). To operate as a *common carrier*, by motor

vehicle, in interstate or foreign commerce, over irregular routes, transporting *drugs* (except in bulk), from the facilities of Glenbrook Laboratories, Division of Sterling Drug, Inc., at or near Gulfport, MS, to Dallas, TX. (Hearing site: Gulfport, MS, or Dallas, TX.)

MC 108341 (Sub-143F), filed April 9, 1979. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 26125, Charlotte, NC 28213. Representative: Jack F. Counts (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *zinc, zinc alloy, and zinc products*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), between the facilities of St. Joe Zinc Company, at or near Josephstown, PA, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 109490 (Sub-11F), filed April 9, 1979. Applicant: HEDING TRUCK SERVICE, INC., P.O. Box 43, Union Center, WI 53962. Representative: Richard A. Westley, 4506 Regent St., Suite 100, Madison, WI 53705. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *feed and feed ingredients*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between the facilities of American Feeds & Livestock Co., Inc., at or near Howard Lake, MN, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 109490 (Sub-12F), filed April 12, 1979. Applicant: HEDING TRUCK SERVICE, INC., P.O. Box 43, Union Center, WI 53962. Representative: Richard A. Westley, 4506 Regent St., Suite 100, Madison, WI 53705. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *Dairy products*, from the facilities of Golden Guernsey Dairy, Hiawatha Valley Division, at or near Sparta and Pigeon Falls, WI, to points in the United States (except AK and HI), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of dairy products, in the reverse direction. (Hearing site: Milwaukee, WI, or Chicago, IL.)

MC 110420 (Sub-811F), filed April 6, 1979. Applicant: QUALITY CARRIERS, INC., P.O. Box 186, Pleasant Prairie, WI

53158. Representative: John R. Sims, Jr., 915 Pennsylvania Building, 425 13th Street NW., Washington, D.C. 20004. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *liquid chemicals*, in bulk, between points in Lake County, IN, and Cook, DuPage, Grundy, Kane, Kendall, Lake, McHenry, and Will Counties, IL, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

MC 110420 (Sub-812F), filed April 13, 1979. Applicant: QUALITY CARRIERS, INC., P.O. Box 186, Pleasant Prairie, WI 53158. Representative: John R. Sims, Jr., 915 Pennsylvania Building, 425 13th Street NW., Washington, D.C. 20004. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *liquid chemicals*, in bulk, in tank vehicles, from Lake Charles, LA, to points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

MC 111201 (Sub-41F), filed April 9, 1979. Applicant: J. N. ZELLNER & SON TRANSFER COMPANY, a Corporation, P.O. Box 91247, East Point, GA 30364. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *metal containers and tin plate*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above (except commodities in bulk), between the facilities of Crown Cork and Seal Company, Inc., at or near Atlanta, GA, on the one hand, and, on the other, points in AL, FL, NC, SC, and TN. (Hearing site: Atlanta, GA.)

MC 111401 (Sub-556F), filed April 10, 1979. Applicant: GROENDYKE TRANSPORT, INC., P.O. Box 632, 2510 Rock Island Blvd., Enid, OK 73701. Representative: Victor R. Comstock (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *flour*, in bulk, in tank vehicles, from Enid, OK, to points in IN. (Hearing site: Minneapolis, MN, or Kansas City, KS.)

MC 111401 (Sub-557F), filed April 6, 1979. Applicant: GROENDYKE TRANSPORT, INC., P.O. Box 632, 2510 Rock Island Blvd., Enid, OK 73701. Representative: Victor R. Comstock (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over

irregular routes, transporting (1) *petroleum products*, in bulk, in tank vehicles, from Woodriver, IL, to points in AR, OK, LA, MS, and TX; (2) *petroleum lubricating oil*, in bulk, in tank vehicles, from Good Hope, LA, to Price, UT; and (3) *inedible tallow*, in bulk, in tank vehicles, from Roswell, NM, to Houston, TX. (Hearing site: New Orleans, LA, or Houston, TX.)

MC 115181 (Sub-38F), filed April 9, 1979. Applicant: HAROLD M. FELTY, INC., R. D. #1, Box 148, Pine Grove, PA 17963. Representative: John W. Dry, 541 Penn St., Reading, PA 19601. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *coal*, from points in Schuylkill and Northumberland Counties, PA, to points in Charles, Calvert, and St. Marys Counties, MD, VA, and DC; (2) *coal*, from points in Dauphin, Carbon, and Luzerne Counties, PA, to points in MD, VA, and DC; (3) *cinders*, from points in Schuylkill, Lebanon, Lancaster, Berks, Northumberland, and Snyder Counties, PA, to points in DE, MD, NJ, NY, VA, and DC; (4) *brick and clay products*, from Gonic, NH, to points in DE, MD, NJ, PA, VA, and DC; (5) *brick*, from Perry Township (Berks County), PA, to points in WV; and (6) *brick*, from Wyomissing, PA, to points in MD, ME, NH, RI, VA, VT, WV, and DC. (Hearing site: Reading or Philadelphia, PA.)

MC 115311 (Sub-350F), filed April 9, 1979. Applicant: J. & M. TRANSPORTATION CO., INC., P.O. Box 488, Milledgeville, GA 31061. Representative: K. Edward Wolcott, P.O. Box 872, Atlanta, GA 31061. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *plastic pipe and plastic fittings*, and (2) accessories used in the installation of the commodities in (1) above, from the facilities of Phillips Driscopipe, Inc., at or near Startex, SC, to those points in the United States in and east of MI, IL, KY, TN, AR and LA; and (3) *materials and supplies* used in the manufacture and distribution of the commodities in (1) and (2) above (except commodities in bulk), in the reverse direction. (Hearing site: Atlanta, GA.)

MC 119741 (Sub-168F), filed April 11, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Ave. NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs* (except in bulk, in tank vehicles), from the facilities of

Lloyd J. Harris Pie Co., at Louisville, KY, to points in CO, IA, KS, MN, MO, NE, ND, OK, and SD, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Detroit, MI.)

MC 124170 (Sub-119F), filed April 9, 1979. Applicant: FROSTWAYS, INC., 3000 Chrysler Service Dr., Detroit, MI 48207. Representative: William J. Boyd, 600 Enterprise Dr., Suite 222, Oak Brook, IL 60521. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, packing-house products, and commodities used by packing houses*, as described in Appendix I to the Report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except dairy products, hides, and commodities in bulk), between the facilities of (a) Lauridsen Foods, Inc., at or near Britt, IA, and (b) Armour and Company, at or near Mason City, IA, on the one hand, and, on the other, points in AL, CT, DE, FL, GA, IL, IN, KY, LA, MA, MD, ME, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VA, VT, WV, and DC, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Chicago, IL, or Washington, DC.)

MC 126111 (Sub-10F), filed April 6, 1979. Applicant: SCHAETZEL TRUCKING COMPANY, INC., 520 Sullivan Drive, Fond du Lac, WI 54935. Representative: Richard C. Alexander, 710 N. Plankinton Ave., Milwaukee, WI 53203. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *sweetened condensed milk*, from Fond du Lac, WI, to points in IL and IN, under continuing contract(s) with Galloway-West Company, a division of Borden Company, Inc., of Fond du Lac, WI. (Hearing site: Milwaukee, WI.)

MC 135070 (Sub-44F), filed April 9, 1979. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs*, from (a) Kansas City, MO, and (b) the facilities of Banquet Foods Corporation, at or near Milan, Carrollton, Macon, and Marshall, MO, to points in AR, LA, NM, OK, and TX. Hearing site: Kansas City or St. Louis, MO.)

Note.—Dual operations may be involved.

MC 135410 (Sub-54F), filed April 12, 1979. Applicant: COURTNEY J.

MUNSON, d.b.a. MUNSON TRUCKING, P.O. Box 266, Monmouth, IL 61462. Representative: Stephen H. Loeb, Suite 200, 205 West Touhy Ave., Park Ridge, IL 60068. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Fischer Packing Co., a subsidiary of Wilson Foods Corporation, at Louisville, KY, to points in CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT, VA, and DC, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Dallas, TX, or Kansas City, MO.)

MC 138420 (Sub-35F), filed April 13, 1979. Applicant: CHIZEK ELEVATOR & TRANSPORT, INC., P.O. Box 147, Cleveland, WI 53063. Representative: Wayne W. Wilson, 150 East Gilman St., Madison, WI 53703. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *paper and paper products*, from Ashland, Green Bay, Menasha, Neenah, and Wausau, WI, to points in IN, KY, MI, MN, MO, OH, and those in IL on and south of U.S. Hwy 136, restricted to the transportation of traffic originating at the facilities of American Can Company. (Hearing site: Madison or Neenah, WI.)

MC 139171 (Sub-4F), filed April 6, 1979. Applicant: CONTROLLED DELIVERY SERVICE, INC., P.O. Box 1299, City of Industry, CA 91749. Representative: Patricia M. Schnegg, 707 Wilshire Boulevard, Suite 1800, Los Angeles, CA 90017. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and articles requiring special equipment), between points in CA, UT, and TX, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Wasatch Shippers Association, Inc., of Salt Lake City, UT. (Hearing site: Los Angeles, CA.)

MC 143701 (Sub-8F), filed April 9, 1979. Applicant: HODGES FREIGHT LINES, INC., 5733 Airline Highway OFC 805, Metairie, LA 70003. Representative: Lester C. Arvin, 814 Century Plaza Bldg.,

Wichita, KS 67202. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *prepared animal food and pet supplies*, and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above (except commodities in bulk), between the facilities of Hills Division of Riviana Foods, Inc., at or near (a) Topeka, KS, (b) Commerce City and Hayward, CA, and (c) Miami, FL, on the one hand, and, on the other, points in the United States (except AK, CT, DE, HI, ME, NH, NY, MA, and VT). (Hearing site: Kansas City, MO, or New Orleans, LA.)

MC 145330 (Sub-1F), filed April 9, 1979. Applicant: GILMER ALLISON, d.b.a. ALLISON TRUCKING, Route 3, Box 123A, Lawndale, NC 28090. Representative: W. C. Mauldin, 417 Old Post Rd., Cherryville, NC 28021. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *bone meal, meat meal, fish meal, crab meal, cracker meal, gluten meal, and soybean meal*, between points in GA, MD, NC, SC, and VA. (Hearing site: Charlotte or Raleigh, NC.)

MC 145601 (Sub-2F), filed March 29, 1979. Applicant: MORGAN COUNTY TRUCKING, INC., 1010 East Nutter Street, Martinsville, IN 46151. Representative: Warren C. Moberly, 777 Chamber of Commerce Building, 320 North Meridian Street, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *brick, clay, sewer pipe and fittings, and clay products*, (a) from points in Warren, Tippecanoe, Clinton, Hamilton, Madison, Henry, Rush, Hancock, Marion, Boone, Hendricks, Montgomery, Fountain, Putnam, Parke, Vermillion, Vigo, Clay, Owen, Morgan, Johnson, Shelby, Decatur, Bartholomew, Brown, Monroe, Greene, Sullivan, Knox, Daviess, Martin, Lawrence, Jackson, Jennings, Scott, Washington, Orange, Dubois, Pike, Gibson, Posey, Vanderburgh, Warrick, Spencer, and Crawford Counties, IN, to points in OH, PA, IL, MI, KY, NC, SC, VA, TN, GA, AL, AR, CT, DE, IA, KS, MD, MA, MN, MS, MO, NE, NH, NJ, NY, ND, OK, RI, SD, VT, WV, and WI, and (b) from points in PA, IL, OH, IA, GA, KS, KY, NE, NC, SC, TN, VA, and WV, to the origin points named in (1)(a) above, and (c) from points in AL, KY, MS, TN, and VA, to points in IL; and (2) *sand*, in bags, from Ottawa, IL, to Brazil, IN. (Hearing site: Indianapolis, IN, Chicago, IL, or Washington, DC.)

MC 146631 (Sub-2F), filed April 9, 1979. Applicant: WILLIAM W. BLAUVELT, d.b.a. BILLY B TRUCKING COMPANY, P.O. Box 1304, Oshkosh, WI 54901. Representative: Michael S. Varda, 121 South Pinckney St., Madison, WI 53703. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *paper and paper articles*, from Oshkosh, WI, to points in AZ, CA, NV, OR, and WA, under continuing contract(s) with Hoffmaster Co., Inc., of Oshkosh, WI. (Hearing site: Milwaukee, WI, or Chicago, IL.)

MC 146970 (Sub-1F), filed April 13, 1979. Applicant: J & J GUTIERREZ, INC., Box 336, Elsa, TX 78543. Representative: Thomas F. Sedberry, 801 Vaughn Building, Austin, TX 78701. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *foodstuffs* (except in bulk), from the facilities of Texsun Corporation, in Hidalgo and Cameron Counties, TX, to those points in the United States in and west of NM, CO, WY, and MT (except AK and HI). (Hearing site: McAllen or San Antonio, TX.)

MC 147140F, filed April 10, 1979. Applicant: MARK RENNEN, d.b.a. MT. HOOD TIMBER PRODUCTS, P.O. Box 17370, Portland, OR 97217. Representative: Mark Renner (same address as applicant). To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *wood chips, sawdust, and hog fuel*, from Clatskanie, OR, to Longview, WA; and (2) *lumber*, from Clatskanie, OR, to Kalama, WA, under continuing contract(s) in (1) and (2) above with Beaver Lumber Company of Clatskanie, Inc., of Clatskanie, OR. (Hearing site: Portland, OR.)

Agatha L. Mergenovich,
Secretary.

[FR Doc. 79-20665 Filed 8-27-79; 8:45 am]
BILLING CODE 7035-01-M

[Permanent Authority Decisions Volume No. 116]

Permanent Authority Decisions Applications; Decision-Notice

Decided: July 19, 1979.

The following applications filed on or before February 28, 1979, are governed by Special Rule 247 of the Commission's *Rules of Practice* (49 CFR § 1100.247). For applications filed before March 1, 1979, these rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30 days after the

date notice of the application is published in the Federal Register. Failure to file a protest, within 30 days, will be considered as a waiver of opposition to the application. A protest under these rules should comply with rule 247(e)(3) of the Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (as specifically noted below), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. A protestant should include a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, such request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

On cases filed on or after March 1, 1979, petitions for intervention either with or without leave are appropriate.

Section 247(f) provides, in part, that an applicant which does not intend timely to prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

If applicant has introduced rates as an issue it is noted. Upon request an applicant must provide a copy of the tentative rate schedule to any protestant.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exceptions of those applications involving duly noted

problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the transportation policy of 49 U.S.C. § 10101. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In those proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a protestant, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. § 10101 subject to the right of the Commission, which is expressly reserved, to impose such conditions as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. § 10930(a) [formerly section 210 of the Interstate Commerce Act].

In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 3 Members Parker, Fortier and Hill.

Agatha L. Mergenovich,

Secretary.

MC 112801 (Sub-223F), filed January 30, 1979, previously noticed in the

Federal Register issue of May 9, 1979. Applicant: TRANSPORT SERVICE CO., a Corporation, 2 Salt Creek Lane, Hinsdale, IL 60521. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 686 Eleventh Street NW., Washington, DC 20001. To operate as a common carrier, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting commodities, in bulk, in tank vehicles, (1) between points in IL, IN, IA, KS, KY, MI, MN, MO, NE, OH, TN, and WI, and (2) between points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

Note.—Insofar as the transportation of hazardous materials is authorized the certificate shall expire in 5 years.

Note.—this republication includes WI in part (1).

[FR Doc. 79-20659 Filed 8-27-79; 8:45 am]

BILLING CODE 7035-01-M

[No. 33374 (Sub-1)]

Petition To Vacate Order Prescribing Divisions on Textiles; Notice of Proceeding

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Proceeding.

SUMMARY: A petition was filed by the Catawba Trucking Co., Inc., (Catawba), requesting that the Commission vacate its decision in No. 33374, *Divisions—Textiles, South Carolina to the East*, served March 28, 1963 and amended May 15, 1974. Catawba argues that the decision is obsolete and unduly inhibits its operations and services. The Commission is instituting this proceeding to address this issue and decide whether our prior decision in No. 33374 should be retained, modified or vacated.

DATES: Interested parties are asked to submit a statement of intent to participate 20 days after the date of publication of this notice. Parties should indicate whether they intend to actively participate or whether they merely wish to receive copies of the decision and releases of the Commission. An original and one copy of the statement regarding intent to participate must be filed.

Active participants must serve copies of their statement on all parties on the service list. An original and six copies of written statements must be filed with the Commission.

The filing and service of statements shall be as follows:

(a) Opening statement of facts and arguments by petitioners and any parties supporting petitioners within 40 days from the service date of this order.

(b) 30 days after that date, statement of facts and argument by persons opposing the proposed relief.

(c) Reply by petitioners and any supporting parties 20 days thereafter.

ADDRESSES: Statements and replies should be sent to: Office of Proceedings, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Janice M. Rosenak or Harvey Gobetz, Washington, D.C. 20423 (202-275-7693).

Copies of the decision being issued concurrently with this notice may be obtained by calling: 275-7428.

Issued in Washington, D.C., _____, 1979.

By the Commission, Chairman O'Neal.
Agatha L. Mergenovich,
Secretary.

[FR Doc. 79-26660 Filed 8-27-79; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 29022]

Southwest Forest Industries, Inc., and SWF Gulf Coast, Inc. Control the Atlanta and St. Andrews Bay Railway Co.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts the acquisition of control of the Atlanta & St. Andrews Bay Railway Company by Southwest Forest Industries, Inc., and its wholly owned subsidiary SWF Gulf Coast, Inc., from the requirements of 49 U.S.C. 11343-11347, which requires prior consideration and approval of the transaction by the Commission.

DATE: Effective on August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Michael Erenberg, (202) 275-7545.

SUPPLEMENTARY INFORMATION:

Background

Southwest Forest Industries, Inc. (SWF), SWF Gulf Coast, Inc. (Gulf), and the Atlanta & St. Andrews Bay Railway Co. (Bay Railway), filed a petition for exemption under 49 U.S.C. 10505 on April 17, 1979, requesting that the proposed control of Bay Railway by SWF and Gulf be exempted from the requirements of obtaining prior Commission approval under 49 U.S.C. 11343-11347. We published a notice in the *Federal Register* on May 17, 1979, 44 FR 29816 (1979) requesting comments on the proposed exemption be received on or before 30 days after publication of the notice. Comments were filed in favor and in opposition to the exemption.

The Transaction

SWF, a non carrier engaged in manufacturing and marketing paper, paper products, packaging and building materials, and its wholly owned subsidiary Gulf seek to acquire control of the Bay Railway, a Class III railroad, as the result of a purchase of a paper mill from the International Paper Company (IP). SWF currently controls the Apache Railway Co. (Apache), a Class III railroad, located in Arizona. Apache operates 74.4 miles of main line between Holbrook and McNary, AZ, and also serves Snowflake and Bell, AZ. It connects with the Atchison, Topeka and Santa Fe Railway Company at Holbrook, AZ.

Bay Railway owns and operates approximately 81 miles of main line, 7.16 miles of Branch line, and 50.38 miles of yard and passing track, from Panama City, FL to Dothan, AL with a branch from Campbellton to Graceville, FL. Bay Railway connects with the Louisville and Nashville Railroad at Cottondale and Graceville, FL, and with the Seaboard Coast Line Railroad Company, Central of Georgia Railroad Company Inc., and the Hartford and Slocumb Railroad Company at Dothan, AL. Bay Railway has been a historically profitable railroad, deriving 65 to 75 percent of its operating revenues in the IP paper mill operations at Panama City. It had assets of \$14,240,569 as of December 31, 1978, and gross revenues of \$8,127,406 for 1978 with net income of \$1,785,941.

On March 1, 1979, SWF and Gulf agreed to acquire Bay Railway in conjunction with the acquisition of the paper mill, associated facilities, and 425,000 acres of timberland in Alabama, Florida, and Georgia, from IP. Gulf is accomplishing the purchase with \$150 million in cash plus 350,000 shares of SWF's 9 percent cumulative preferred stock (valued at \$70 million).

The purpose of the transactions is to preserve the paper mill operations in Panama City, FL, which are Bay Railway's sustaining source of freight revenue, and to preserve Bay Railway's existing services for the benefit of paper operations, shippers, and receivers who rely on Bay Railway service.

Parties to the Proceeding

Comments in opposition were filed by J.C. Holden Construction Co., Antoinett Fashions and Florists, A.E. Shipes Garden Shops, Hunts Excavating Service, Helen Ingram, and the Railway Labor Executives' Association. Holden, Antoinett and Hunt's allege no benefit from Gulf and SWF's control of Bay Railway. Shipes and Hunt's both request

a hearing. Shipes explains it can have no knowledge of the future operations without a public hearing. Ingram and RLEA both contend control will harm employees of the Bay Railway.

Thirty-one comments were filed in support of the exemption. These include comments filed by Governors Bob Graham of Florida and Fob James of Alabama, United States Senators Lawton Chiles and Richard (Dick) Stone, United States Congressmen William L. Dickinson and Earl Hutto, the State of Alabama Highway Department, the Florida Department of Transportation, and the State of Florida Public Service Commission. From Panama City, FL support was expressed by Daffin Merchantile Company, Empiregas, Inc. of Panama City, Fillette, Green & Co., Inc., Gulf Asphalt Corporation, North Florida Brick Co., Panama City Port Authority, Panama Machinery and Supply Co., Ryan-Walsh Stevedoring Co., Inc., Sykes Concrete Pipe Co., Sunshine-Jr. Stores, Inc., and Superior Propane Gas Company. From Dothan, AL, support was indicated by the Central Bank of Dothan, N.A., the First Alabama Bank, the Hartford and Slocumb Railroad Company, and Red Fox Fertilizers, Inc. Support was also expressed by Alimenta (U.S.A.) Inc., of Atlanta, GA; Gold Kist, Inc., of Campbellton, FL; Great Southern Paper of Cedar Springs, GA; Pate Stevedore Company of Pensacola, FL; Southern Railway System of Washington, DC; and Sylvachem Corporation of Port St. Jose, FL.

The parties supporting the exemption all make the same general arguments. They point out that the acquisition of the IP paper mill by SWF and Gulf will save approximately 1,000 jobs since IP intended to close the paper mill. Keeping the paper mill open will also preserve approximately 60 percent of Bay Railway's freight revenue. This will result in Bay Railway's viability and existing services being preserved. It is stated that Bay Railway will benefit from its relationship with SWF and Gulf because they are strong companies with the ability to attract financing and management talent.

The supporting parties also point out that we will retain jurisdiction over Bay Railway, that no questions of public interest are raised requiring protracted proceedings, and that Bay Railway will assume no financial obligations. The employees point out that they will not be affected, no environmental impact will ensue, and that no other carriers will be affected or involved. Additionally they argue that this proposed exemption is within the

purpose and intent of the Railroad Revitalization and Regulatory Reform Act of 1976, Pub. L. 94-210.

Statutory Criteria

As pertinent here, 49 U.S.C. 10505 provides that we shall exempt a rail carrier transaction because of its limited scope if we find that application of a provision of 49 U.S.C. Subtitle IV, (1) is not necessary to carry out the national transportation policy, (2) would place an unreasonable burden on a person, class of persons, or interstate and foreign commerce, and (3) serve little or no useful public purpose. We may act under 49 U.S.C. 10505 only after an opportunity for a proceeding. The petition engaged our jurisdiction and the notice and request for comments on the petition for exemption provided the opportunity for a proceeding. We must now determine whether the proposed exemption meets the statutory requirements.

Scope of the transaction. The threshold inquiry is whether the transaction is limited in scope. SWF and Gulf are non-carriers. They own Apache which only operates in Arizona. They are seeking to control Bay Railway which only operates in Florida and Alabama. The tracks of Apache and Bay Railway are geographically distant from each other.

In its petition, and the application filed for authority under 49 U.S.C. 11344, SWF, Gulf, and Bay Railway state that there would be no operational changes resulting from SWF's control of Bay Railway, and that no employees of Bay Railway would be adversely affected. The comments support this. Bay Railway would continue to be used as the railway to originate the shipments from the former IP paper mill.

The record demonstrates that the proposal would not change operations, or affect competitors or employees. We conclude that acquisition of control of Bay Railway by SWF and Gulf, while they control Apache, would constitute a transaction of limited scope.

National Transportation Policy. In order to insure the development, coordination, and preservation of a transportation system that meets the transportation needs of the United States, Congress has declared that it is the policy of the United States Government to provide for the impartial regulation of the modes of transportation subject to 49 U.S.C. Subtitle IV. See 49 U.S.C. 10101. Impartial regulation is achieved through (1) recognizing and preserving inherent advantages of each mode; (2) promoting safe, adequate, economical, and efficient transportation; (3) encouraging sound

economic conditions in transportation, including sound economic conditions among carriers; (4) encouraging the establishment and maintenance of reasonable rates for transportation without unreasonable discrimination or unfair destructive competitive practices; (5) cooperating with each State and official of each state on transportation matters; and (6) encouraging fair wages and working conditions in the transportation industry.

Regulation of SWF's and Gulf's control of Bay Railway is not necessary to carry out the goals of the national transportation policy. The proposed transactions have no effect on any of the policy considerations since the only change involves indirect control of a minor Southeastern rail carrier by a non-carrier corporation which controls another minor Southwestern rail carrier.

Burden. SWF, Gulf, and Bay Railway have filed an application under 49 U.S.C. 11344, complying with the I.C.C. *Railroad Acquisition, Control, Merger, Consolidation Coordination Project, Trackage Rights, and Lease Procedures*, 49 C.F.R. Part 1111 (1978). Although this application has been filed, the proceeding is governed by the time limits of 49 U.S.C. 11345. Since the contract between SWF and IP calls for daily interest payments, the statutory time delays inherent in the processing of the application create an unreasonable burden. Where, as here, there is minimal opposition to, and massive public support of the proposal, and the transaction is of limited scope and minimal national transportation importance, the development of a massive record on which to base a decision would place a grave strain on the applicants and the scarce resources of the Commission. We believe that requiring SWF, Gulf, and Bay Railway to prosecute the application would place an unreasonable burden on them and on interstate and foreign commerce.

Public Purpose. Our function under 49 U.S.C. 11343-11347 is to determine whether a proposed transaction is consistent with the public interest. There is minimal opposition, apparently based on a lack of understanding of the transaction. Additionally, there has been support for the transaction by governmental agencies as well as many shippers who would be affected by the acquisition of the Bay Railway by SWF and Gulf.

The control of Bay Railway by SWF and Gulf is of limited scope and the regulation of it would be both unnecessary and an unreasonable burden. Our review of the application indicates that any further evidence, would be minimal and of little provable

value at best (based on the comments which were received). Therefore, we conclude that our review of this matter would serve little or no useful public purpose.

The Application

SWF, Gulf and Bay Railway filed an application under 49 U.S.C. 11344 concurrently with their petition for exemption. Since we have determined to exempt this transaction from the requirements of 49 U.S.C. 11343-11347, further prosecution of the application filed on April 17, 1979, is not necessary. We shall dismiss the application.

We find: (1) The application of the requirements of 49 U.S.C. 11343-11347 to the control of the Atlanta & St. Andrews Bay Railway Company by Southwest Forest Industries, Inc., and its wholly owned subsidiary, SWF Gulf Coast, Inc., is of a limited scope and (a) is not necessary to carry out the national transportation policy of section 10101(b), would be an unreasonable burden on SWF, Gulf, and Bay Railway, and (c) would serve little or no useful public purpose.

(2) This decision is not a major Federal action significantly affecting energy consumption or quality of the human environment.

It is ordered: (1) The acquisition of control of the Atlanta & St. Andrews Bay Railway Company by Southwest Forest Industries, Inc., and SWF Gulf Coast, Inc., is exempted under 49 U.S.C. 10505 from the requirements of 49 U.S.C. 11343-11347 for the limited purpose of SWF and Gulf obtaining control of Bay Railway.

(2) If SWF and Gulf obtain control of Bay Railway, SWF and Gulf shall, within 60 days of obtaining control submit three copies of a sworn statement confirming, immediately after consummation, the date on which consummation has actually taken place.

(3) The exemption authorized by this decision shall remain in effect for three months following the effective date. Consummation to this exemption must take place during that time.

(4) The application filed on April 17, 1979, under 49 U.S.C. 11344 for SWF and Gulf to acquire control of Bay Railway, is dismissed.

(5) Public notice of our action in this proceeding shall be given to the general public by depositing a copy of this decision 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, for publication therein.

(6) This decision shall be effective August 28, 1979.

Dated: August 21, 1979.

By the Commission. Chairman O'Neal, Vice
Chairman Stafford, Commissioners Gresham,
Clapp, Christian, Trantum and Gaskins.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-26664 Filed 8-27-79; 8:45 am]

BILLING CODE 7035-01-M

Sunshine Act Meetings

Federal Register

Vol. 44, No. 168

Tuesday, August 28, 1979

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL RESERVE SYSTEM, BOARD OF GOVERNORS.

TIME AND DATE: 11:00 a.m., Friday, August 31, 1979.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed purchase, under competitive bidding, of power supply equipment for the Miami Branch of the Federal Reserve Bank of Atlanta.
2. Proposed modifications to the plans for the new building under consideration for the Federal Reserve Bank of San Francisco.
3. Proposed purchases, under competitive bidding, of automation equipment by the Federal Reserve Bank of New York.
4. Proposed disposition of property by a Federal Reserve Bank.
5. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
6. Any agenda 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: August 23, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[S-1682-79 Filed 8-23-79; 4:14 pm]

BILLING CODE 6210-01-M

Registered Federal Trade

Tuesday
August 28, 1979

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Classification of Physical Medicine
Devices; Development of General
Provisions

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 890]

[Docket No. 78N-1182]

Classification of Physical Medicine Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all physical medicine devices. The Medical Device Amendments of 1976 require FDA to classify all medical devices intended for human use into three categories: Class I, general controls; class II, performance standards; and class III, premarket approval. This proposal describes the development of the proposed regulations classifying individual physical medicine devices, which are being published elsewhere in this issue of the *Federal Register*. This document also describes the activities of the Physical Medicine Device Classification Panel, and FDA advisory committee, that makes recommendations to FDA concerning the classification of physical medicine devices.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910 301-427-7238.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls

needed to provide reasonable assurance of their safety and effectiveness. The three categories are: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976 and that is substantially equivalent to a device classified under this scheme is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the medical device regulations (21 CFR Part 807).

Related Regulations

In the *Federal Register* of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the *Federal Register* of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the *Federal Register* of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Physical Medicine Device Classification Panel (the Panel)

was originally chartered on October 15, 1974 as the Panel on Review of Physical Medicine (Physiatry) Devices. On January 28, 1976, FDA filed a report of the Panel's tentative classification recommendations with the office of the Hearing Clerk, Food and Drug Administration, and announced the availability of the report to the public by notice published in the *Federal Register* of June 25, 1976 (41 FR 26245).

On August 9, 1976, the Panel and other preamendment device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to ensure that its recommendations were in accord with the amendments.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of physical medicine devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In November 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk, Food and Drug Administration, and announced its availability to the public by notice published in the *Federal Register* of November 29, 1977 (42 FR 60792). Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual physical medicine device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Physical Medicine Devices

In 1972 FDA surveyed device manufacturers to identify the devices that would require classification regulations. Following this survey, FDA developed a list of physical medicine devices. The Panel supplemented the list, utilizing its members' knowledge of physical medicine devices in use. Devices that were solely for experimental or investigational use or

that were not generally available were not included.

FDA is proposing to establish a new Part 890 in Title 21 of the Code of Federal Regulations. Part 890 will consist of sections identifying each physical medicine device or a generic category of devices with a brief narrative description and stating the classification of those devices. A list of the physical medicine devices appears elsewhere in this preamble.

Individual Physical Medicine Device Classification Regulations

Elsewhere in this issue of the *Federal Register*, the agency is issuing 82 individual proposed regulations to classify each physical medicine device or generic category of devices. The agency is proposing to classify 32 physical medicine devices into class I (general controls), 43 physical medicine devices into class II (performance standards), 2 physical medicine devices into class III (premarket approval), and 5 physical medicine devices into class II for some uses and class III for other uses. The powered finger exerciser was reclassified into class II following a petition for reclassification (under section 513(f) of the act), a notice announcing the reclassification was published in the *Federal Register* of November 11, 1977 (42 FR 58787). The final order will be published later in another issue of the *Federal Register*. The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act.

Published Panel Recommendations

Each published Panel recommendation concerning a physical medicine device includes the information described below.

1. *Identification.* Both the Panel recommendation and proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 890.1 (21 CFR 890.1), any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act and Part 807 of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially

equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act.

Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes that the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into Class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). The Panel recommended that the manufacturers of a few class I devices be exempt from section 510, section 519, and section 520(f) of the act. The agency's policy concerning these exemption recommendations is discussed below in the section "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority (high or low) for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority (high or low) for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory

criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the agency is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied on clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(a)(2) of the act, which requires that a Panel recommendation summarize the data on which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. No. 94-853, 94th Congress, 2d Session (1976)). The agency has determined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preamble to individual physical medicine device regulations. FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's

summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. Risks to health. In identifying the risks to health presented by physical medicine devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified additional risks to health presented by a device. These additional risks are stated in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the Panel classification recommendations and FDA classification regulations do not identify all risks to health presented by physical medicine devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify a physical medicine device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 890 in which the device classification will be codified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of priorities for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities (high or low) of devices recommended for classification into class II or class III, the Panel compared the device with other physical medicine devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device.

The Panel recommended assignment of a high priority only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. At a later date, however, the agency will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the *Federal Register*.

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. Two factors affect the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the panel, regardless of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification, during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions For Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510, registration; section 519, records and reports; and section 520(f), good manufacturing practices.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency has proposed to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation (21 CFR Part 820), published in the *Federal Register* of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations in

accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the Federal Register of July 21, 1978. At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt a device from § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers

adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all such manufacturers are required to comply with the complaint file requirements of § 820.180. All device manufacturers also are 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 GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f) but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of

exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than §§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than §§ 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

At the February 7, 1979 meeting of the Physical Medicine Device Classification Panel, representatives from the American Orthotic and Prosthetic Association (AOPA) requested exemptions from premarket notification (section 510(k) of the act), records and reports (section 519 of the act), and good manufacturing practices (section 520(f) of the act) for 40 orthotic/prosthetic devices. The 40 orthotic/prosthetic devices are included in the proposed regulations published in this issue under the following Hearing Clerk docket numbers: 78N-1194, 78N-1200, 78N-1201, 78N-1203, 78N-1204, 78N-1209, and 78N-1210. The Panel members recommended that FDA accept AOPA's request for these exemptions. This recommendation for exemptions will be considered as part of the comments received on the physical medicine device proposed regulations.

List of Physical Medicine Devices

The following is a list showing the physical medicine devices that FDA is proposing to classify, the section and subpart of Part 890 in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
SUBPART B—PHYSICAL MEDICINE DIAGNOSTIC DEVICES			
890.1100.....	Powered myoelectric biofeedback equipment.....	78N-1183	II
890.1175.....	Electrode cable.....	78N-1184	I
890.1225.....	Chronaximeter.....	78N-1185	II
890.1375.....	Diagnostic electromyograph.....	78N-1186	II
890.1385.....	Diagnostic electromyograph needle electrode.....	78N-1187	II
890.1450.....	Powered reflex hammer.....	78N-1188	II
890.1575.....	Force-measuring platform.....	78N-1189	II
890.1600.....	Intermittent pressure measurement system.....	78N-1190	II
890.1615.....	Miniature pressure transducer.....	78N-1191	II
890.1850.....	Diagnostic muscle stimulator.....	78N-1192	II
890.1925.....	Isokinetic testing and evaluation system.....	78N-1193	II
SUBPART C [RESERVED]			
SUBPART D—PHYSICAL MEDICINE PROSTHETIC DEVICES			
890.3025.....	Prosthetic and orthotic accessories.....	78N-1194	I
890.3075.....	Cane.....	78N-1195	I
890.3100.....	Mechanical chair.....	78N-1196	I

Section	Device	Docket No.	Class
SUBPART D—PHYSICAL MEDICINE PROSTHETIC DEVICES —Continued			
890.3110	Electric positioning chair	78N-1197	II
890.3150	Crutch	78N-1198	I
890.3175	Flotation cushion	78N-1199	I
890.3410	External limb orthotic components	78N-1200	I
890.3420	External limb prosthetic components	78N-1201	I
890.3450	Mechanical hand and foot driving controls	78N-1202	II
890.3475	Limb orthosis	78N-1203	I
890.3490	Truncal orthosis	78N-1204	I
890.3500	External assembled limb prosthesis	78N-1205	II
890.3520	Plinth	78N-1208	I
890.3610	Rigid pneumatic structure orthosis	78N-1207	III
890.3640	Arm sling	78N-1208	I
890.3665	Congenital hip dislocation abduction splint	78N-1209	I
890.3675	Denis Brown splint	78N-1210	I
890.3690	Powered wheeled stretcher	78N-1211	II
890.3700	Nonpowered communication system	78N-1212	I
890.3710	Powered communication system	78N-1213	II
890.3725	Powered environmental control system	78N-1214	II
890.3750	Mechanical table	78N-1215	I
890.3760	Powered table	78N-1216	I
890.3790	Cane, crutch, and walker tips	78N-1217	I
890.3800	Motorized 3-wheeled vehicle	78N-1218	II
890.3825	Mechanical walker	78N-1219	I
890.3850	Mechanical wheelchair	78N-1220	I
890.3860	Powered wheelchair	78N-1221	II
890.3880	Special grade wheelchair	78N-1222	II
890.3890	Stair-climbing wheelchair	78N-1223	III
890.3900	Standup wheelchair	78N-1224	II
890.3910	Wheelchair accessory	78N-1225	I
890.3920	Wheelchair components	78N-1226	I
890.3930	Wheelchair elevator	78N-1227	II
890.3940	Wheelchair platform scale	78N-1228	I
SUBPART E [RESERVED]			
SUBPART F—PHYSICAL MEDICINE THERAPEUTIC DEVICES			
890.5050	Daily activity assist devices	78N-1229	I
890.5100	Immersion hydrobath	78N-1230	II
890.5110	Paraffin bath	78N-1231	II
890.5125	Nonpowered sitz bath	78N-1232	I
890.5150	Powered patient transport	78N-1233	II
890.5160	Air fluidized bed	78N-1234	II
890.5170	Powered flotation therapy bed	78N-1235	II
890.5180	Manual patient rotation bed	78N-1236	I
890.5225	Powered patient rotation bed	78N-1237	II
890.5250	Moist steam cabinet	78N-1238	II
890.5275	Microwave diathermy	78N-1239	II, III
890.5290	Shortwave diathermy	78N-1241	II, III
890.5300	Ultraonic diathermy	78N-1242	II, III
890.5350	Exercise component	78N-1243	I
890.5360	Measuring exercise equipment	78N-1244	I
890.5370	Nonmeasuring exercise equipment	78N-1245	I
890.5380	Powered exercise equipment	78N-1246	II
890.5500	Infrared lamp	78N-1248	II
890.5525	Iontophoresis device	78N-1249	II, III
890.5575	External limb overload warning device	78N-1250	II
890.5650	Powered inflatable tube massager	78N-1251	II
890.5660	Physical therapy muscle relaxer	78N-1252	II
890.5700	Cold pack	78N-1253	I
890.5710	Hot or cold disposable pack	78N-1254	I
890.5720	Water circulating hot or cold pack	78N-1255	II
890.5730	Moist heat pack	78N-1256	I
890.5740	Powered heating pad	78N-1257	II
890.5765	Pressure applying device	78N-1258	I
890.5850	Powered muscle stimulator	78N-1259	II
890.5860	Therapeutic ultrasound and muscle stimulator	78N-1260	II, III
890.5880	Multi-function physical therapy table	78N-1261	II
890.5900	Powered traction equipment	78N-1262	II
890.5925	Traction accessories	78N-1263	I
890.5940	Chilling unit	78N-1264	I
890.5950	Powered heating unit	78N-1265	II
890.5975	Physical therapy pulsator	78N-1266	II

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Physical Medicine Device

Classification Panel and by other panels:

1. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel recommended that the chronaximeter be classified into class II. The devices reviewed by the two Panels are essentially the same. Therefore, the agency is proposing a single regulation

classifying the chronaximeter into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

2. The Neurological Device Classification Panel and the Anesthesiology Device Classification Panels recommended that the electromyograph and electromyograph monitor be classified into class II. The Physical Medicine Device Classification Panel recommended that the diagnostic electromyograph be classified into class II. These devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the diagnostic electromyograph device into class II and is publishing the three Panels' recommendations in the proposal appearing elsewhere in this issue of the **Federal Register**.

3. The General Hospital and Personal Use Device Classification Panel recommended that the wheeled geriatric chair be classified into class I. The Physical Medicine Device Classification Panel recommended that the mechanical chair be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the mechanical chair into class I and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

4. The General Hospital and Personal Use Device Classification Panel recommended that the silicone chair cushion be classified into class I. The Physical Medicine Device Classification Panel recommended that the flotation cushion be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the flotation cushion into class I and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

5. The Gastroenterology Device Classification Panel recommended that the abdominal belt be classified into class II. The Physical Medicine Device Classification Panel recommended that the truncal orthosis be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the truncal orthosis into class I and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

6. The Obstetrics/Gynecological Device Classification Panel

recommended that the manual sitz bath kit (not heated) be classified into class I. The Physical Medicine Device Classification Panel recommended that the nonpowered sitz bath be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the nonpowered sitz bath into class I and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

7. The General Hospital and Personal Use Device Classification Panel recommended that the AC-powered water flotation bed be classified into class II. The Physical Medicine Device Classification Panel recommended that the powered flotation therapy bed be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the powered flotation bed into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

8. The General Hospital and Personal Use Device Classification Panel recommended that the heat lamp (infrared) be classified into class I. The Physical Medicine Device Classification Panel recommended that the infrared lamp be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the infrared lamp into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

9. The General Hospital and Personal Use Device Classification Panel recommended that the chemical hot pack and chemical cold pack be classified into class I. The Physical Medicine Device Classification Panel recommended that disposable hot and cold packs be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the disposable hot or cold pack into class I and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register**.

10. The General and Plastic Surgery Device Classification Panel recommended that the GPS muscle stimulator be classified into class II. The Physical Medicine Device Classification Panel recommended that the powered muscle stimulator be classified into

class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the powered muscle stimulator into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

11. The Anesthesiology Device Classification Panel recommended that the bicycle ergometer and treadmill ergometer be classified into class II. The Physical Medicine Device Classification Panel recommended that powered exercise equipment be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying powered exercise equipment into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

12. The Dental Device Classification Panel recommended that the iontophoretic device be classified into class I. The Ear, Nose, and Throat Device Classification Panel recommended that the iontophoretic anesthetic be classified into class II. The Physical Medicine Device Classification Panel recommended that the iontophoresis device be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the iontophoresis device into class II for its use in the diagnosis of cystic fibrosis, for the acceleration of fluoride in dentistry, and for the local anesthesia of the intact tympanic membrane, and into class III for any other uses. The agency is publishing the three Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

13. The Physical Medicine Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel
Composite surface biopotential electrode	Neurological.
Metallic surface biopotential electrode	Neurological.
Metallic electrode with soft pad covering	Neurological.
Electrode gel	Neurological.
Physical medicine dynamometer	Orthopedic.
Touch discriminator esthesiometer	Neurological.
Two-point discriminator esthesiometer	Neurological.
AC-powered goniometer	Orthopedic.
Mechanical goniometer	Orthopedic.
AC-powered skin resistance meter	Neurological.

Device Classification Panel concurs with the Neurological Device Classification Panel's class II

recommendation for these devices. The recommendation appears in a proposed regulation in the November 28, 1978 Federal Register (43 FR 55650, 55648).

Environmental Impact

FDA has carefully considered the environmental effects of proposed § 890.1 and of the proposed physical medicine device classification regulations and has concluded that an environmental impact statement is not required because the proposed actions will not significantly affect the quality of the human environment. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 U.S.C. 5.1), the Commissioner of Food and Drugs proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 890, Subpart A, to read as follows:

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.

§ 890.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine devices intended for human use.

(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 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a physical medicine device that has two or more types of uses (e.g., use 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.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26260 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1183]

Medical Devices; Classification of Powered Myoelectric Biofeedback Equipment

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered myoelectric biofeedback equipment into class II (performance standards). This proposed classification applies to all powered myoelectric biofeedback equipment whether powered by alternating current (AC) or batteries. The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II if powered by alternating current and classified into class I if battery powered. 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 I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFA-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered myoelectric biofeedback equipment:

1. Identification: Powered myoelectric biofeedback equipment is a device that monitors certain bodily functions (e.g., muscle contraction/relaxation, skin temperature, and electrical resistance of skin) and displays the output of the device to the patient and is used to decrease psychophysiological symptoms and aid in muscle training performance. The device may be powered by alternating current (AC), or it may be battery powered.

2. Recommended classification: The Panel recommends that myoelectric biofeedback equipment that is powered by AC be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel also recommends that devices of this type that are battery powered be classified into class I (general controls), with no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that powered myoelectric biofeedback equipment be classified into class II if AC powered because the Panel believes that a standard is necessary to control electrical current to prevent shock and burns. The device applies an electrical current to the body to measure the intrinsic electrical properties of muscles and nerves, and to measure skin temperature and resistance. The Panel believes that the measurement limitations inherent in this technique should be clearly specified by the manufacturers of the device. The Panel believes that general controls will not provide sufficient control over the electrical characteristics of the AC-powered version of this device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is

sufficient information to establish a standard to provide such assurance.

The Panel believes that general controls would provide reasonable assurance of the safety and effectiveness of battery-powered models of this device because the risks of electrical shock and burns for such a device are minimal. Therefore, the Panel recommends that battery-powered models of this device be classified into class I.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with AC-powered devices; the Panel members' personal knowledge of, and familiarity with, the device; a review of the pertinent literature (Refs. 1 through 4); and information presented during a Panel meeting. The Panel recommends that the device be restricted in use to professionally qualified persons recognized as experienced in the diagnosis, evaluation and/or treatment of the specific condition involved. At the Panel meeting of December 6, 1976, Dr. Kenneth Gaarder, University of Texas (Ref. 1), discussed the "Clinical use of Electromyography (EMG) in Biofeedback." He presented methods and indications of treatment and various other aspects of biofeedback. Dr. Gaarder stated that the procedures are safe with carefully made instruments and that standards could assure the production of high quality instruments.

5. Risks to health: (a) Electrical shock: The patient may receive an electrical shock because the device is electrically powered and connected to the patient by means of electrodes.

(b) Misdiagnosis and inappropriate therapy: Inaccurate measurement function of the device could lead to misdiagnosis and subsequent inappropriate therapy.

Proposed Classification

The Commissioner has reviewed the Panel recommendation on powered myoelectric biofeedback equipment and three studies in the literature, the results of which support the effectiveness and therapeutic value of biofeedback in rehabilitation (Refs. 2, 3, and 4). The Commissioner has concluded that all powered biofeedback equipment, whether battery powered or AC powered, should be subject to performance standards. The Commissioner believes that the battery-powered device, as well as the AC-powered device, presents a risk of electrical shock injuries. Therefore, the Commissioner is proposing that all powered myoelectric biofeedback equipment be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is

sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gaarder, K., "Clinical Use of Electromyography (EMG) in Biofeedback," Unpublished Paper, Attachment A to Summary Minutes of the Second Meeting of the Electrodagnostic Subcommittee of the Physical Medicine Device Classification Panel, December 6, 1976.
2. Canter, A., et al., "A Comparison of EMG Feedback and Progressive Muscle Relaxation Training in Anxiety Neurosis," *British Journal of Psychiatry*, 127:470-477, 1975.
3. Brudny, J., et al., "EMG Feedback Therapy: Review of Treatment of 114 Patients," *Archives of Physical Medicine and Rehabilitation*, 57:55-61, 1977.
4. Cox, D. J., et al., "Differential Effectiveness of Electromyograph Feedback, Verbal Relaxation Instructions, and Medication Placebo with Tension Headaches," *Journal of Consulting and Clinical Psychology*, 43, (6):892-898, 1978.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 by adding new Subpart B and § 890.1100, to read as follows:

Subpart B—Physical Medicine Diagnostic Devices

§ 890.1100 Powered myoelectric biofeedback equipment.

(a) Identification. Powered myoelectric biofeedback equipment is a device that monitors certain bodily functions (e.g., muscle contraction/relaxation, skin temperature, and electrical resistance of skin) and displays the output of the device to the patient and is used to decrease psychophysiological symptoms and aid in muscle training performance. The device may be powered by alternating current (AC), or it may be battery powered.

(b) Classification. Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found

in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26261 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1184]

Medical Devices; Classification of Electrode Cables

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrode cables into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following

recommendation with respect to the classification of electrode cables:

1. Identification: An electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and used to connect an electrode from a patient to a diagnostic machine.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that electrode cables be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that electrode cables be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1175, to read as follows:

§ 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 used to connect an electrode from a patient to a diagnostic machine.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk document number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26262 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1185]

Medical Devices; Classification of Chronaximeters

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying chronaximeters into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the Neurological Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations with

respect to the classification of chronaximeters:

1. Identification: A chronaximeter is a device that measures neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.
2. Recommended classification: Class II (performance standards). The Panels recommend that the establishment of a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panels recommend that the chronaximeter be classified into class II because the device is electrically powered and applies an electric current through the skin. The Panels believe that a performance standard is needed to control electrical leakage current to prevent electrical shock and burns. The chronaximeter provides a measurement function, and the Panels believe that the measurement limitations of this device should be clearly specified by the manufacturers of the device. They also believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device; the Panel members' personal knowledge of, and familiarity with, the device; and a review of the available literature (Refs. 1 and 2). Harris (Ref. 1) describes the procedure to be followed in recording chronaxy, and Parry (Ref. 2) explains the plotting of the strength-duration curve and what the curve represents. The literature supports the need for accuracy of the prognostic and diagnostic data supplied by the chronaximeter.

5. Risks to health: (a) Electrical shock: The patient may receive an electrical shock because the device is electrically powered and connected to the patient by means of electrodes. (b) Burns: Skin burns could result from an excessive direct current component of the output. (c) Misdiagnosis and inappropriate therapy: An inaccurate measurement function could lead to misdiagnosis and subsequent inappropriate therapy.

Proposed Classification

The Commissioner agrees with the recommendations of the Physical Medicine Device Classification Panel and the Neurological Device Classification Panel and is proposing that chronaximeters be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and

effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, R., "Chronaxy," in "Electrodiagnosis and Electromyography," 3d Ed., Edited by Licht, S., Waverly Press, Inc., Baltimore, MD, pp. 218-240, 1971.
2. Parry, C. B. W., "Strength-Duration Curves," in "Electrodiagnosis and Electromyography," 3d Ed., Edited by Licht, S., Waverly Press, Inc., Baltimore, MD, pp. 241-271, 1971.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1225, to read as follows:

§ 890.1225 Chronaximeter.

(a) *Identification.* A chronaximeter is a device that measures 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28283 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1186]

Medical Devices; Classification of Diagnostic Electromyographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic electromyographs into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel, the Neurological Device Classification Panel, and the Anesthesiology Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, the Neurological Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of diagnostic electromyographs:

1. Identification: A diagnostic electromyograph is a device used 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.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Physical Medicine

Device Classification Panel recommends that diagnostic electromyographs be classified into class II because the device is electrically powered, and the Panel believes a performance standard is needed to control leakage of electrical current to prevent electrical shock and burns. Also, because the device applies an electrical current to the body to measure the intrinsic electrical properties of skeletal muscle, the Panel believes that the measurement limitations inherent in this technique should be clearly specified by the manufacturers of the device. The Panel also recommends that the device be restricted to use by a physician trained in diagnostic electromyography. The Neurological Device Classification Panel recommends that the device be classified into class II because the Panel believes that the characteristics of the electric current applied to the body should be controlled to prevent injury. The Panel also believes that the measurement limitations of this device should be controlled to prevent misdiagnosis. The Anesthesiology Device Classification Panel recommends that the device be classified into class II because the Panel believes that a performance standard is needed to control electrical leakage current to prevent electrical shock. The Physical Medicine Device Classification Panel, the Neurological Device Classification Panel, and the Anesthesiology Device Classification Panel believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the potential hazards associated with this device; the Panel members' personal knowledge of, and familiarity with, the device; and a review of the available literature (Refs. 1 and 2). Guld, Rosenfalck, and Willison report that " * * * clinical electromyographers * * * must appreciate that electrodes, amplifiers, and recording apparatus need careful design and maintenance to avoid distortion severe enough to affect experimental results." The authors expand on this topic and report the main sources of error and distortion and the problems of safety and interference in the use of electromyographs (Ref. 1). The Electrodiagnostic Subcommittee of the Physical Medicine Device Classification Panel discussed the problem areas with the use of clinical electrodiagnostic equipment in a presentation by Dr. Joseph Goodgold, Department of Rehabilitation, New York University Medical Center, New York City (Ref. 2). The Subcommittee also discussed some of the general technical requirements of electromyographic equipment in a presentation by Stewart Reiner, Teca Corp., White Plains, New Jersey (Ref. 2). Dr. Goodgold identified the possible problem areas in the clinical use of electrodiagnostic equipment. General concepts for use of the device were presented (Ref. 2). Reiner presented for discussion the technical requirements, standard recommendations,

and specific device problems of the electromyograph (Ref. 2).

5. Risks to health: The Physical Medicine Device Classification Panel, the Neurological Device Classification Panel, and the Anesthesiology Device Classification Panel identified the following risks to health. (a) Electrical shock: The patient may receive an electrical shock because the device is electrically powered and connected to the patient by means of electrodes. (b) Misdiagnosis and inappropriate therapy: Inaccurate measurement function of the device could lead to misdiagnosis and subsequent inappropriate therapy. (c) Local burns and tissue damage: Excessive stimulation current could cause local burns and tissue damage to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendations and is proposing that diagnostic electromyographs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Guld, C., A. Rosenfalck, and R. G. Willison, "Technical Factors in Recording," in *Electrodiagnosis and Electromyography*, 3d Ed., Edited by S. Licht, Waverly Press, Inc., Baltimore, MD, pp. 452-478, 1971.
2. Summary Minutes of the First Meeting of the Electrodiagnostic Subcommittee of the Physical Medicine Device Classification Panel, October 7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 U.S.C. 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1375, to read as follows:

§ 890.1375 Diagnostic electromyograph.

(a) *Identification.* A diagnostic electromyograph is a device used 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26264 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1187]

Medical Devices; Classification of Diagnostic Electromyograph Needle Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic electromyograph needle electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA would issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976. **DATES:** Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of diagnostic electromyograph needle electrodes:

1. Identification: A diagnostic electromyograph needle electrode is a monopolar or bipolar needle that is inserted into muscle or nerve tissue to sense bioelectric signals. The device is used in conjunction with diagnostic electromyography (recording the intrinsic electrical properties of skeletal muscle).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that diagnostic electromyograph needle electrodes be classified into class II because the Panel believes the hazards associated with this device warrant a performance standard. Also, the Panel believes that a performance standard will assure that the performance characteristics of the device are maintained at a satisfactory level. The Panel believes that the materials of which the device is made should be controlled to prevent tip or shaft failure and a loss of insulation. The Panel believes that the materials should allow proper sterilization of the device. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Toxicity: The materials used could produce toxicity. (b) Infection: Infection may result if the device cannot be adequately sterilized. (c) Misdiagnosis: Spontaneous noise generation and/or impedance may cause invalid clinical observations in electromyography. (d) Inappropriate therapy: Loss of needle insulation or tip failure could cause misdiagnosis, resulting in inappropriate therapy.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that diagnostic electromyograph needle

electrodes be classified into class II (performance standards). Two studies on monopolar electromyographic needles were reviewed (Refs. 1 and 2). Mikolich and Waylonis (Ref. 1) studied the durability of teflon-coated needle electrodes over a 2-year period. Their study concluded that the durability of electrode needles varies. It was found, however, that the most common causes of failure of the needle electrode were teflon failure, tip failure, wire pin failure, and electrical artifact and wire bending. Smith and Schulte (Ref. 2) studied the effects of defective insulation of monopolar electrode needles. They concluded that "loss of insulation from a monopolar electrode can appreciably reduce action-potential amplitude." This reduction of action-potential amplitude leaves the tip excessively exposed and may result in altered waveforms leading to misdiagnosis. The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Mikolich, L. M. and G. W. Waylonis, "Durability of Monopolar Teflon-Coated Electromyographic Needles," *Archives of Physical Medicine and Rehabilitation*, 58: 448-451, 1977.
2. Smith, E. M. and H. F. Schulte, "Effects of Defective Insulation of Monopolar Electrodes in Electromyography," *Archives of Physical Medicine and Rehabilitation*, 472-475, July 1965.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1385, to read as follows:

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) *Identification.* A diagnostic electromyograph needle electrode is a monopolar or bipolar needle that is inserted into muscle or nerve tissue to sense bioelectric signals. The device is used in conjunction with diagnostic electromyography (recording the

intrinsic electrical properties of skeletal muscle).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26265 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1188]

Medical Devices; Classification of Powered Reflex Hammers

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered reflex hammers into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical

Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered reflex hammers:

1. Identification: A powered reflex hammer is a motorized device used to elicit and determine controlled deep tendon reflexes.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that powered reflex hammers be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential electrical hazards of shock and burns and to prevent injury to soft tissues. The Panel believes that the measurement limitations of this device should be clearly specified by the manufacturers of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.
5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Bodily injury: Injury to soft tissues could result from excessive power of impact and from excursion. (c) Misdiagnosis: Inaccurate measurement function could lead to misdiagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered reflex hammers be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of

the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1450 to read as follows:

§ 890.1450 Powered reflex hammer.

(a) *Identification.* A powered reflex hammer is a motorized device used to elicit and determine controlled deep tendon reflexes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26286 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1189]

Medical Devices; Classification of Force-Measuring Platforms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying force-measuring platforms into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying

the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of force-measuring platforms:

1. Identification: A force-measuring platform is a device 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.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that force-measuring platforms be classified into class II to require that the performance characteristics be maintained at a satisfactory level. The function of the device is to provide diagnostic data; therefore, the Panel believes the device should provide accurate and replicable measurements. The Panel also recommends that FDA require that the device labeling indicate its diagnostic limitations. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device; a review of the

pertinent literature (Ref. 1); and a presentation by Dr. Thomas P. Andriacchi (Ref. 2). Dr. Andriacchi (Ref. 2) states that the force-measuring platform is useful in gait analysis, postural control studies, and sports activities. However, the device is still used by most physicians as a research tool.

5. Risks to health: Misdiagnosis: Misdiagnosis may result from inaccurate measurement and from the current diagnostic limitations of the device.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that force-measuring platforms be classified into Class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Andriacchi, T. P., J. A. Ogle, and J. O. Gacante, "Walking Speed as a Basis for Normal and Abnormal Gait Measurements," *Journal of Biomechanics*, 10(4) 261-268, 1977.

2. Andriacchi, T. P., "The Use of the Force-Measuring Platform in Gait Analysis," unpublished paper, Attachment A to Summary Minutes of the Fourth Meeting of the Orthotic/Prosthetic Subcommittee of the Physical Medicine Device Classification Panel, October 13, 1977.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1575, to read as follows:

§ 890.1575 Force-measuring platform.

(a) *Identification.* A force-measuring platform is a device 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing

Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26267 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1190]

Medical Devices; Classification of Intermittent Pressure Measurement Systems

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intermittent pressure measurement systems into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that this device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intermittent pressure measurement systems:

1. Identification: An intermittent pressure measurement system is an evaluative device used to measure the actual pressure between the body surface and the supporting media.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intermittent pressure measurement systems be classified into class II because the Panel believes that a standard is necessary to control the electrical properties of this device to avoid the potential hazards of shock and burns. The Panel believes that the measurement limitations of this device should be clearly specified by the manufacturers of the device. The Panel believes that malfunction of the measurement gauge could result in inaccurate determination of the media surface, thereby causing soft tissue injury to the patient. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Electrical shock: Electrical leakage current due to improper grounding or faulty circuitry could result in electrical shock to the patient. (b) Soft tissue injury: An inappropriate surface resulting from inaccurate measurement function could cause skin ulcers.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that intermittent pressure measurement systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1600, to read as follows:

§ 890.1600 Intermittent pressure measurement system.

(a) *Identification.* An intermittent pressure measurement system is an evaluative device used to measure the actual pressure between the body surface and the supporting media.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26288 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 850]

[Docket No. 78N-1191]

Medical Devices; Classification of Miniature Pressure Transducers

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying miniature pressure transducers into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of miniature pressure transducers:

1. *Identification:* A miniature pressure transducer is a device used to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.
2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. *Summary of reasons for recommendation:* The Panel recommends that miniature pressure transducers be classified into class II because the Panel believes that the electrical properties associated with the device should be controlled to avoid a potential shock hazard. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. *Risks to health:* Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that miniature pressure transducers be classified into class II (performance

standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1615, to read as follows:

§ 890.1615 Miniature pressure transducer.

(a) *Identification.* A miniature pressure transducer is a device used to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26289 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1192]

Medical Devices; Classification of Diagnostic Muscle Stimulators

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic muscle stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Physical

Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of diagnostic muscle stimulators:

1. Identification: A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity and is used to diagnose and/or treat motor nerve or sensory neuromuscular disorders and neuromuscular function.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.
3. Summary of reasons for recommendation: The Panel recommends that diagnostic muscle stimulators be classified into class II because the Panel believes that a standard is necessary to control electrical current to prevent shock and burns. The device applies an electrical current to the body to measure the intrinsic properties of muscles. The Panel believes that the measurement limitations inherent in this technique should be clearly specified by the manufacturers of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is

sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device; the Panel members' personal knowledge of, and familiarity with, the device; and a review of the pertinent literature (Ref. 1). Guld, Rosenfalck, and Willison (Ref. 1) describe the procedures used in diagnostic stimulation. The authors stress safety procedures that should be followed in using stimulators. The safety procedures include labeling of controls and sockets, "on-off warning lamp," close proximity of electrodes to localize excessive current flow, and restriction of the use of the device to trained personnel.

5. Risks to health: (a) Electrical shock: The patient may receive an electrical shock because the device is connected to the patient by means of electrodes. Also equipment used with this device might cause a hazardous leakage current that could be dangerous to the patient. (b) Burns: High current density in tissue could, over time, cause burns. (c) Cardiac arrhythmia: Excessive electrical current passing through the heart could cause irregular heartbeat or cardiac arrest. (d) Misdiagnosis: Misdiagnosis may result from inaccurate measurement function.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that diagnostic muscle stimulators be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Guld, C., A. Rosenfalck, and R. G. Willison, "Technical Factors in Recording" in "Electrodiagnosis and Electromyography," 3d. Ed., Edited by S. Licht, Waverly Press, Inc., Baltimore, MD, pp. 452-478, 1978.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1850, to read as follows:

§ 890.1850 Diagnostic muscle stimulator.

(a) *Identification.* A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity and is used to diagnose and/or treat motor nerve or sensory neuromuscular disorders and neuromuscular function.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26270 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1193]

Medical Devices; Classification of Isokinetic Testing and Evaluation Systems

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying isokinetic testing and evaluation systems into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of isokinetic testing and evaluation systems:

1. Identification: An isokinetic testing and evaluation system is a rehabilitative exercise device used to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that isokinetic testing and evaluation systems be classified into class II because the Panel believes that a standard is necessary to control the electrical properties of this device to avoid the potential hazards of shock and burns. The Panel believes that the measurement limitations of this device should be clearly specified by the manufacturers of the device. The Panel also recommends this device be used by trained personnel under the supervision of a physician. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device; the Panel members' personal knowledge of, and familiarity with, the device; and a review of the pertinent literature (Refs. 1, 2, and 3). At the Panel meeting of March 21 through 22, 1976, Ridgeway (Ref. 1) discussed the use of the isokinetic testing and evaluation system and supported the use of this system in rehabilitation, particularly in knee rehabilitation. However, he stressed that "each patient must be individually evaluated" in order to teach an effective exercise regime. Ridgeway reported a "great need for further research into the clinical application * * * of this device, and that the

units presently on the market can and should be improved.

5. Risks to health: (a) Shock and burns: Electrical leakage current due to improper grounding or faulty circuitry could result in electrical shock or burns to the patient. (b) Misdiagnosis: Inaccurate measurement function could lead to misdiagnosis.

Proposed Classification

The Commission agrees with the Panel recommendation and is proposing that isokinetic testing and evaluation systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Ridgeway, R. K., "Presentation of an Isokinetic Knee Rehabilitation Program Using Orthotron Instrumentation," unpublished paper, Appendix C to Summary Minutes of the Seventh Meeting of the Physical Medicine Device Classification Panel, March 21-22, 1976.

2. Savander, G. R., "Use of the Kinetron in the Training of the Below-Knee Amputee," *Physical Therapy*, 52(3), March 1972.

3. Coplin, T. H., "Isokinetic Exercise: Clinical Usage," *Journal of the NATA*, 1971.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.1925 as follows:

§ 890.1925 Isokinetic testing and evaluation system.

(a) *Identification.* An isokinetic testing and evaluation system is a rehabilitative exercise device used to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four

copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26271 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1194]

Medical Devices; Classification of Prosthetic and Orthotic Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prosthetic and orthotic (brace) accessories into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation.

The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prosthetic and orthotic accessories.

1. Identification: A prosthetic and orthotic accessory is a device used 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 limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, or a temporary training splint.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that a prosthetic and orthotic accessory be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that prosthetic and orthotic accessories be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-545 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 890 by adding Subpart C, which is reserved, and adding new Subpart D and § 890.3025, to read as follows:

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 used to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a limb cover, a prosthesis alignment device, a postsurgical prosthesis alignment device, a postsurgical pylon, a

transverse rotator, or a temporary training splint.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 27, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26272 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1195]

Medical Devices; Classification of Canes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying canes into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of canes:

1. Identification: A cane is a device used to provide minimum 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.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a cane be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that canes be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 549-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3075, to read as follows:

§ 890.3075 Cane.

(a) *Identification.* A cane is a device used to provide minimum 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).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26273 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1196]

Medical Devices; Classification of Mechanical Chairs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical chairs into class I (general controls). The FDA is also publishing the recommendations of the Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that this device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of mechanical chairs:

1. Identification: A mechanical chair is a manually operated device 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.

2. Recommended classification: Class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that a mechanical chair be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendations and is proposing that mechanical chairs be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3100, to read as follows:

§ 890.3100 Mechanical chair.

(a) *Identification.* A mechanical chair is a manually operated device 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).

Interested persons may, on or before (October 29, 1979) submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26274 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1197]

Medical Devices; Classification of Electric Positioning Chairs

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electric positioning chairs into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that this device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Johnsie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electric positioning chairs:

1. Identification: An electric positioning chair is a device with a motorized positioning control 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 for therapeutic purposes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that an electric positioning chair be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Electrical shock: Improper grounding or a malfunction of the device may result in an electric shock to the patient or operator. (b) Bodily injury: The lack of an antitipping mechanism or locks on the casters, or a structural failure of the harness belt, could result in bodily injury to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that electric positioning chairs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3110, to read as follows:

§ 890.3110 Electric positioning chair.

(a) Identification. An electric positioning chair is a device with a motorized positioning control 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 for therapeutic purposes.

(b) Classification. Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26275 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]**[Docket No. 78-1198]****Medical Devices; Classification of Crutches**

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying crutches into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Johnsie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of crutches:

1. Identification: A crutch is a device used by disabled persons to provide minimal to moderate weight support while walking.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a crutch be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that crutches be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 53 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner proposes to amend Part

890 in Subpart D by adding new § 890.3150, to read as follows:

§ 890.3150 Crutch.

(a) *Identification.* A crutch is a device used by disabled persons to provide minimal to moderate weight support while walking.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26276 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1199]

Medical Devices; Classification of Flotation Cushions

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying flotation cushions into class I (general controls). The FDA is also publishing the recommendations of The Physical Medicine Device Classification Panel and the General Hospital and Personnel Use Device Classification Panel that this device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305),

Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register, provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of flotation cushions:

1. Identification: A flotation cushion is a device made of plastic filled with water, air, gel, or mud and is used on a seat to lessen the likelihood of skin ulcers.

2. Recommended classification: Class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that a flotation cushion be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendations and is proposing that flotation cushions be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3175, to read as follows:

§ 890.3175 Flotation cushion.

(a) *Identification.* A flotation cushion is a device made of plastic filled with water, air, gel, or mud and is used on a seat to lessen the likelihood of skin ulcers.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26277 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1200]

Medical Devices; Classification of External Limb Orthotic Components

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external limb orthotic (brace) components into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external limb orthotic components:

1. Identification: An external limb orthotic component is a device used 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.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that an external limb orthotic component be classified into class I because it is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.
5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that external limb orthotic components be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposed to amend Part 890 in Subpart D by adding new § 890.3410, to read as follows:

§ 890.3410 External limb orthotic component.

(a) *Identification.* An external limb orthotic component is a device used 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).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28278 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1201]

Medical Devices; Classification of External Limb Prosthetic Components

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external limb prosthetic components into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that this device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of external limb prosthetic components:

1. Identification: An external limb prosthetic component is a device 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.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that an external limb prosthetic component be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.
5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that external limb prosthetic components be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3420, to read as follows:

§ 890.3420 External limb prosthetic component.

(a) *Identification.* An external limb prosthetic component is a device 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).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26279 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1202]

Medical Devices; Classification of Mechanical Automobile Hand and Foot Driving Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical automobile hand and foot driving controls into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA would issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs

proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mechanical automobile hand and foot driving controls:

1. *Identification:* A mechanical automobile hand and foot driving control is a device used to enable persons who have limited use of their arms and legs to drive. This device allows the hand operation of the gas, brake, and clutch pedals or the foot operation of the steering and gear shift.

2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. *Summary of reasons for recommendation:* The Panel recommends that mechanical automobile hand and foot driving controls be classified into class II because the Panel believes that the design and materials of the device must be controlled to assure that there are adequate mechanical safety features to prevent malfunction or breakage of the driving controls and to avoid a potential injury to the driver and the public. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device, and a review of the pertinent literature (Refs. 1 and 2). At the Panel meeting of March 21-22, 1976, Wilfred G. Holsberg, Acting Deputy Director for Prosthetics, Surgical Service, Veterans Administration, discussed the Veterans Administration's standard for hand driving controls (Ref. 1). Mr. Holsberg reported that a driving simulator was used to evaluate the

effectiveness of the various adaptive driving aids, and a computer was used to yield data on patient requirements to operate the device in the laboratory under simulated driving conditions. Mr. Holsberg stated that the VA is "providing eligible veterans with tested and standardized adaptive equipment so they can operate motor vehicles in safety and comfort." Representatives from the American Automobile Association, Department of Transportation, and Sharpe Health School's Handicapped Driver Education (Ref. 2) discussed with the Panel the hazards resulting from faulty devices available for use. The greatest concern is that there may be faulty installation or poor-grade materials used which could result in serious injury. A performance standard to control the parts used in the device would decrease the likelihood of device breakage and accidents.

5. *Risks to health:* (a) *Bodily injury:* Injury to the driver or public could result from a lack of adequate mechanical safety features causing a malfunction in the driving controls.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that mechanical automobile hand and foot driving controls be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Holsberg, W., "White Paper on Adaptive Equipment," Unpublished Paper, Attachment F to Summary Minutes of the Seventh Meeting of the Physical Medicine Device Classification Panel, March 21-22, 1976.

2. Summary Minutes of the Seventh Meeting of the Physical Medicine Device Classification Panel, March 21-22, 1976.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3450, to read as follows:

§ 890.3450 Mechanical automobile hand and foot driving control.

(a) *Identification.* A mechanical automobile hand and foot driving control is a device used to enable persons who have limited use of their

arms or legs to drive. The device allows the hand operation of the gas, brake, and clutch pedals or the foot operation of the steering and gear shift.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28280 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1203]

Medical Devices; Classification of Limb Orthoses

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food Drug Administration (FDA) is issuing for public comment a proposed regulation classifying limb orthoses (braces) into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical

Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of limb orthoses:

1. Identification: A limb orthosis (brace) is a device 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.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a limb orthosis be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that limb orthoses be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3475, to read as follows:

§ 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device 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).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28281 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1204]

Medical Devices; Classification of Truncal Orthoses

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying truncal orthoses (braces for the trunk of the body) into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that this device be classified into class I and the recommendation of the Gastroenterological-Urological Device Classification Panel that abdominal orthoses be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the Gastroenterological-Urological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of truncal orthoses:

1. Identification: A truncal orthosis is a device used to support and/or to immobilize fractures, strains, and sprains of the neck and/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.

2. Recommended classification: The Physical Medicine Device Classification Panel recommends that a truncal orthosis be classified into class I (general controls) and that there be no exemptions. The Gastroenterological-Urological Device Classification Panel recommends that an abdominal orthosis be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel recommends that a truncal orthosis be classified into class I because it is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Gastroenterological-Urological Device Classification Panel recommends that an abdominal orthosis be classified into Class II because the Panel believes that a standard is necessary to control the amount of pressure applied by the device to avoid venous congestion (an increased tendency for thrombosis in veins) and pressure sores. The Panel states, however, that this device is simple in concept and that hazards are very rare or even theoretical. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: None were identified by the Physical Medicine Device Classification Panel. The Gastroenterological-Urological Device Classification Panel identified the following risks to health regarding abdominal orthoses: (a) Possible pulmonary emboli (the sudden blocking of a blood vessel in the lungs so as to obstruct circulation) and pressure sores: Excessive pressure due to abdominal compression could result in possible pulmonary emboli or pressure sores. (b) Contract dermatitis (skin irritation): The materials used in the construction of the device may cause a local skin irritation.

Proposed Classification

The Commissioner agrees with the recommendation of the Physical Medicine Device Classification Panel and is proposing that truncal orthoses be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Commissioner disagrees with the recommendation of the Gastroenterological-Urological Device Classification Panel that abdominal orthoses be classified into class II (performance standards). The Commissioner believes that the hazards associated with the device, as stated by the Gastroenterological-Urological Device Classification Panel, result from improper use and sizing of orthoses. The Panel states that the hazards are rare, and the Commissioner believes that if the device is used in a normal manner and for the purpose recommended, the device presents no undue risks to health.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3490, to read as follows:

§ 890.3490 Truncal orthosis.

(a) *Identification.* A truncal orthosis is a device used to support and/or to immobilize fractures, strains, and sprains of the neck and/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).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28282 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1205]

Medical Devices; Classification of External Assembled Lower Limb Prostheses

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external assembled lower limb prostheses into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. The effect of classifying 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of external assembled lower limb prostheses:

1. Identification: An external assembled lower limb prosthesis 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device by a low priority.

3. Summary of reasons for recommendation: The Panel recommends that external assembled lower limb prostheses be classified into class II because the Panel believes that the structural strength of this device must be controlled to prevent a potential injury to the patient. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazard associated with this device and the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: Bodily injury: Injury from falling could result from breakage of the unit due to inadequate structural strength, particularly of the set screws.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that external assembled lower limb prostheses be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3500, to read as follows:

§ 890.3500 External assembled lower limb prosthesis.

(a) *Identification.* An external assembled lower limb prosthesis 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26263 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR part 890]

[Docket No. 78N-1206]

Medical Devices; Classification of Plinths

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying plinths (a flat padded table or board) into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of plinths:

1. Identification: A plinth is a flat, padded board with legs on which a patient is placed for treatment or examination.

2. Recommended classification: Class I (general controls). The Panel recommends that plinths be exempt from registration, device listing, and premarket notification under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulations under section 520(f) of the act (21 U.S.C. 360(f)).

3. Summary of reasons for recommendation: The Panel recommends that plinths be classified into class I and that manufacturers of this device should not be required to comply with registration, device listing, premarket notification, records and reports, or good manufacturing practice regulations because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that plinths be classified into class I (general controls). The Commissioner believes that general controls are

sufficient to provide reasonable assurance of the safety and effectiveness of the device. In response to the Panel's recommendation that manufacturers of a plinth be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of a plinth, the agency cannot make the required finding. 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 a plinth. 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) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of a plinth be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the *Federal Register* of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and

reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of a plinth be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation 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 GMP regulation, 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 a plinth 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 a plinth 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 GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3520 to read as follows:

§ 890.3520 Plinth.

(a) *Identification.* A plinth is a flat, padded board with legs on which a patient is placed for treatment or examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. The device also is exempt from the good manufacturing practice regulation in

Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28284 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1207]

Medical Devices; Classification of Rigid Pneumatic Structure Orthoses

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rigid pneumatic structure orthoses (whole body braces) into class III (premarket approval). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of rigid pneumatic structure orthoses:

1. Identification: A rigid pneumatic structure orthosis is a device used to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.
2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that the rigid pneumatic structure orthosis be classified into class III because the Panel believes that satisfactory performance of this device has not been demonstrated and, therefore, that it is not possible to establish an adequate performance standard for the device. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus ensure its safety and effectiveness.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the literature concerning the device (Refs. 1 and 2). The literature evaluation did not demonstrate that the device was safe or effective (Ref. 1). The rigid pneumatic structure orthosis was also evaluated as requested by the Veterans' Administration and the Rehabilitation Services Administration, Department of Health, Education, and Welfare (Ref. 2), and did not meet adequate performance standards for safety and effectiveness.
5. Risks to health: (a) Bodily injury: The device could collapse and the patient could fall, resulting in bodily injury, if inflation is lost or the zippers fail. (b) Tissue trauma and/or pressure sores: Tissue trauma and/or pressure sores could result if the support beams overinflate and cause excessive pressure on the skin of the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that rigid pneumatic structure orthoses be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation

and the evaluations of rigid pneumatic structure orthoses (Refs. 1 and 2). The problems found with this device, as stated in the literature, are (1) zipper failure, (2) deflation or overinflation, (3) pressure over bony prominences, causing sores, (4) inability of the patient to climb stairs independently, (5) inability of the patient to move as stated, and (6) difficulty in the patient regaining a standing position after a fall. Future improvements and studies were recommended for rigid pneumatic structure orthoses because a potential exists for their use in early rehabilitation. The Commissioner believes that the device presents a potential unreasonable risk of injury to the patient because satisfactory performance has not been demonstrated. He agrees with the Panel conclusion that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard which would provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Peizer, E., "Special Programs: VA Prosthetics Center Research, Development, and Evaluation Program," *Bulletin of Prosthetics Research*, 10-22: 465-477, Fall, 1974.
2. "Evaluation of the Ortho-Walk Type B Pneumatic Orthosis on Thirty-Seven Paraplegic Patients," Report by the Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education, National Academy of Sciences, Washington, DC, 1976. Supported by the Veterans Administration and the Social Rehabilitation Service, HEW.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3610, to read as follows:

§ 890.3610 Rigid pneumatic structure orthosis.

(a) *Identification.* A rigid pneumatic structure orthosis is a device used to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

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

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk document number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26285 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1208]

Medical Devices; Classification of Arm Slings

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying arm slings into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arm slings:

1. Identification: An arm sling is a device used to immobilize the arm, by means of a fabric band suspended from around the neck.

2. Recommended classification: Class I (general controls). The Panel recommends that an arm sling be exempt from registration, device listing, and premarket notification under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulations under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that an arm sling be classified into class I and that manufacturers of this device not be required to comply with registration, device listing, premarket notification, records and reports, or good manufacturing practice regulations because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that arm slings be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. In response to the Panel's recommendation that manufacturers of an arm sling be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 501 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of an arm

sling, the agency cannot make the required finding. 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 an arm sling. 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) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of an arm sling be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the *Federal Register* of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of an arm sling be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation 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 GMP regulation, 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 an arm sling 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 an arm sling 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 GMP regulation is still appropriate.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3640, to read as follows:

§ 890.3640 Arm sling.

(a) *Identification.* An arm sling is a device used 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 of this chapter. The device also is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the

above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26286 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1209]

Medical Devices; Classification of Congenital Hip Dislocation Abduction Splints

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying congenital hip dislocation abduction splints into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of congenital hip dislocation abduction splints:

1. Identification: A congenital hip dislocation abduction splint is a device used to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a congenital hip dislocation abduction splint be classified into class I because this is a simple device that presents no undue risk to health when used in a normal manner and for the purpose recommended. The Panel recommends that the device be used under the direct supervision of a physician, therapist, or orthotist/prosthetist (makers or fitters of orthotic or prosthetic devices). The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that congenital hip dislocation abduction splints be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.3665, to read as follows:

§ 890.3665 Congenital hip dislocation abduction splint.

(a) Identification. A congenital hip dislocation abduction splint is a device used 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the

above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26287 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1210]

Medical Devices; Classification of Denis Brown Splints

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Denis Brown splints into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Denis Brown splints:

1. Identification: A Denis Brown splint is a device used to immobilize the feet. It is used

on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

2. Recommended Classification: class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Denis Brown splints be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that Denis Brown splints be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3675, to read as follows:

§ 890.3675 Denis Brown splint.

(a) *Identification.* A Denis Brown splint is a device used to immobilize the feet. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28286 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1211]

Medical Devices; Classification of Powered Wheeled Stretchers

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered wheeled stretchers into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to ensure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered wheeled stretchers:

1. Identification: A powered wheeled stretcher is a battery-powered table with wheels that is used by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods of time because of skin ulcers or contractures (muscle contractions).

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The panel recommends that powered wheeled stretchers be classified into class II because the Panel believes that if there is a malfunction of the device, serious harm to the patient could result. The Panel also believes that the electrical properties of the battery must be controlled to avoid the potential hazard of shock or malfunction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Bodily injury: Bodily injury could result from defective controls, battery malfunction, or use of the device on inclined surfaces. (b) Electrical shock: Excessive leakage current or malfunction of the device could result in electric shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered wheeled stretchers be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. Performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3690, to read as follows:

§ 890.3690 Powered wheeled stretcher.

(a) *Identification.* A powered wheeled stretcher is a battery-powered table with wheels that is used 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document.

Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26289 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1212]

Medical Devices; Classification of Nonpowered Communication Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonpowered communication systems into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-27-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides

background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonpowered communication systems:

1. Identification: A nonpowered communication system is a mechanical device used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include the following: an alphabet board, a telephone holder, and a page turner.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a nonpowered communication system be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that nonpowered communication systems be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend part 890 in Subpart D by adding new § 890.3700, to read as follows:

§ 890.3700 Nonpowered communication system.

(a) *Identification.* A nonpowered communication system is a mechanical device used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include the following: An alphabet board, a telephone holder, and a page turner.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing

Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document.

Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26290 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1213]

Medical Devices; Classification of Powered Communication Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered communication systems into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that this device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered communication systems:

1. Identification: A powered communication system is an electrical or battery powered device used to transmit or receive information. It is used by persons unable to use their hands 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that a powered communication system be classified into class II because the Panel believes that the electrical properties of this device must be controlled to avoid the potential hazard of electric shock. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: Electrical shock: Excessive leakage current could result in injury, and a malfunction of the device could result in electric shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered communication systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the

Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3710, to read as follows:

§ 890.3710 Powered communication system.

(a) *Identification.* A powered communication system is an electrical or battery-powered device used to transmit or receive information. It is used by persons unable to use their hands 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28291 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1214]

Medical Devices; Classification of Powered Environmental Control Systems

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered environmental control systems into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered environmental control systems:

1. Identification: A powered environmental control system is an electrical or battery-powered device 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that a powered environmental control system be classified into class II because the Panel believes that the electrical properties of this device must be controlled to avoid the potential hazard of electric shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: Electrical shock: Excessive leakage current could result in injury, and a malfunction of the device could result in electric shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered environmental control systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3725, to read as follows:

§ 890.3725 Powered environmental control system.

(a) *Identification.* A powered environmental control system is an electrical or battery-powered device 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28292 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1215]

Medical Devices; Classification of Mechanical Tables

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical tables into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mechanical tables:

1. *Identification:* A mechanical table is a device 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.

2. *Recommended classification:* Class I (general controls). The Panel recommends that mechanical tables be exempt from registration, device listing, and premarket notification regulations under section 510 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 360), records and reports under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice (GMP) regulations under section 520(f) of the act (21 U.S.C. 360j(f)).

3. *Summary of reasons for recommendation:* The Panel recommends that a mechanical table be classified into class I and that the manufacturers of this device should not be required to comply with registration, device listing, premarket notification, records and reports, or GMP regulations because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device and that a performance standard is not necessary.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. *Risks to health:* None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that mechanical tables be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner disagrees with the Panel recommendation that manufacturers of mechanical tables be exempt from registration, device listing, and premarket notification under section 510 of the act. Under section 510(g)(4) of the act, the Commissioner may exempt a manufacturer from section 510 only upon a finding that compliance with this section is not necessary for the protection of public health. In the case of the mechanical table, the Commissioner cannot make the required finding. To protect the public health, the agency needs to require manufacturers of this device to register and to list their products with FDA, so that the agency is able to identify the firms manufacturing this device and to conduct necessary inspections. Premarket notification by these manufacturers assures that FDA learns of new products, and of significant modifications of existing products, for which premarket approval is required.

The Commissioner disagrees with the Panel's recommendation that manufacturers of a mechanical table be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device

good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

The Commissioner disagrees with the Panel recommendation that manufacturers of the mechanical table be exempt from the good manufacturing practice regulation under section 520(f) of the act. The Commissioner believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of a mechanical table having defects that could harm users.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3750, to read as follows:

§ 890.3750 Mechanical table.

(a) *Identification.* A mechanical table is a device 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26293 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1216]

Medical Devices; Classification of Powered Tables

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered tables into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered tables:

1. *Identification:* A powered table 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.

2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. *Summary of reasons for recommendation:* The Panel recommends that a powered table be classified into class II because the Panel believes that the electrical properties of this device must be controlled to avoid injury. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the potential hazards associated with the electrical properties of the device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. *Risks to health:* Electrical shock: Excessive leakage current could result in injury, and malfunction of the device could result in an electric shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered tables be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3760, to read as follows:

§ 890.3760 Powered table.

(a) *Identification.* A powered table 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26294 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1217]

Medical Devices; Classification of Cane, Crutch, and Walker Tips

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cane, crutch, and walker tips into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305),

Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cane, crutch, and walker tips:

1. Identification: Cane, crutch, and walker tips are rubber accessories applied to the ground end of mobility aids to prevent skidding.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that these devices be classified into class I because they are simple devices that present no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, these devices.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that cane, crutch, and walker tips be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3790, to read as follows:

§ 890.3790 Cane, crutch, and walker tips.

(a) *Identification.* Cane, crutch, and walker tips are rubber accessories applied to the ground end of mobility aids to prevent skidding.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26295 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1218]

Medical Devices; Classification of Motorized Three-Wheeled Vehicles

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying motorized three-wheeled vehicles for outdoor use into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health,

Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of motorized three-wheeled vehicles:

1. Identification: A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device that is used for outside transportation by disabled persons.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.
3. Summary of reasons for recommendation: The Panel recommends that a motorized three-wheeled vehicle be classified into class II because the Panel believes that the design and materials of the device must be controlled to assure that there are adequate mechanical safety features to prevent the patient from falling from the device. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device, on the Panel members' personal knowledge, of and familiarity with, the device, and a review of the pertinent literature (Refs. 1 and 2). Staros and Peizer (Ref. 1) state that good bilateral hand, arm, and shoulder strength and excursion are needed to drive three-wheeled vehicles. The authors report that there have been frequent accidents from the use of these vehicles, caused by excessive speeds and fast turns.
5. Risks to health: Bodily injury: The patient could fall as a result of instability of the vehicle, fast turning, or tipping over of the vehicle while the patient mounts or dismounts. Lack of foot guard rails could cause the patient's feet to become entangled and thus cause injury.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that motorized three-wheeled vehicles be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard

would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Staros, A. and E. Peizer, "VA Prosthetics Center Research Report," *Bulletin of Prosthetics Research*, 10-23:230-235, Spring 1975.
2. Lipskin, R., "Trends in Nonlicensed Mobility Aids," *Bulletin of Prosthetics Research*, 10-22:41-52, Fall 1974.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3800, to read as follows:

§ 890.3800 Motorized three-wheeled vehicle.

(a) *Identification.* a motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device that is used for outside transportation by disabled persons.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26296 Filed 8-22-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1219]

Medical Devices; Classification of Mechanical Walkers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical walkers into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mechanical walkers:

1. Identification: A mechanical walker is a four-legged device used to provide moderate weight support while walking by means of a metal frame. It is used by disabled persons who lack strength, good balance, or endurance.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that a mechanical walker be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's

personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that mechanical walkers be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3825, to read as follows:

§ 890.3825 Mechanical walker.

(a) *Identification.* A mechanical walker is a four-legged device used to provide moderate weight support while walking by means of a metal frame. It is used by disabled persons who lack strength, good balance, or endurance.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26297 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1220]

Medical Devices; Classification of Mechanical Wheelchairs

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical wheelchairs into class I (general controls). The FDA is also publishing the recommendation of

the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mechanical wheelchairs:

1. Identification: A mechanical wheelchair is a manually operated device with wheels used to provide mobility to persons restricted to a sitting position.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that a mechanical wheelchair be classified into class I because this device presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that mechanical wheelchairs be classified into class I (general controls)

with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3850, to read as follows:

§ 890.3850 Mechanical wheelchair.

(a) *Identification.* A mechanical wheelchair is a manually operated device with wheels used to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26298 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1221]

Medical Devices; Classification of Powered Wheelchairs

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered wheelchairs into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA

will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered wheelchairs:

1. Identification: A powered wheelchair is a battery-operated device with wheels used to provide mobility to persons restricted to a sitting position.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that a powered wheelchair be classified into class II because this device is widely used by handicapped persons in numerous public places, both indoors and outdoors. The Panel believes that if the device should malfunction, serious harm to the patient or public could result. The Panel believes that the structural strength of the device must be controlled to prevent the wheelchair from collapsing. The Panel also believes that the control mechanism and power system should be controlled to prevent malfunction and a loss of control of the device and injury to the patient or public. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device and a review of the pertinent literature (Refs. 1 and 2).

5. Risks to health: Bodily injury: Defective controls, battery malfunction, poor structural materials, or use of the device on inclined surfaces could result in bodily injury.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that powered wheelchairs be classified into class II (performance standards). The relevant literature on powered wheelchairs has been reviewed (Refs. 1 and 2). There is a limited amount of literature generated by the Veterans Administration (VA) program evaluating nonlicensed mobility aids. The parameters for a standard to control the hazards associated with the use of this device have been evaluated at the VA Prosthetic Center in New York. The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lipskin, R., "VAPC Program for Electric Wheelchairs and Other Nonlicensed Mobility Aids," *Bulletin of Prosthetics Research*, 10-22:326-336, Fall 1974.

2. Lipskin, R., "Trends in Nonlicensed Mobility Aids," *Bulletin of Prosthetics Research*, 10-22:41-52, Fall 1974.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart B by adding new § 890.3860, to read as follows:

§ 890.3860 Powered wheelchair.

(a) Identification. A powered wheelchair is a battery-operated device with wheels used to provide mobility to persons restricted to a sitting position.

(b) Classification. Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing

Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26296 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1222]

Medical Devices; Classification of Special Grade Wheelchairs

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying special grade wheelchairs into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory

committee, made the following recommendation regarding the classification of special grade wheelchair:

1. Identification: A special grade wheelchair is a device with wheels that provides mobility for those persons restricted to a sitting position and that is designed for long term use to be used in all environments (e.g., for paraplegics, quadriplegics, and amputees).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that a special grade wheelchair be classified into class II because the Panel believes that the design and structural strength of the device must be controlled to assure that there are adequate safety features to prevent the wheelchair from tipping over or collapsing, thus causing injury to the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Bodily injury: Poor structural materials, mechanical breakdown, or instability of the device could result in bodily injury to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that special grade wheelchairs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3880, to read as follows:

§ 890.3880 Special grade wheelchair.

(a) *Identification.* A special grade wheelchair is a device with wheels that provides mobility for those persons

restricted to a sitting position and is designed to be used in all environments for long term uses (e.g., for paraplegics, quadriplegics, and amputees).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26300 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1223]

Medical Devices; Classification of Stair-Climbing Wheelchairs

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stair-climbing wheelchairs into class III (premarket approval). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after date of publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of stair-climbing wheelchairs:

1. Identification: A stair-climbing wheelchair is a mobility assist device used by a disabled person to climb stairs in a sitting position. The device functions by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority because of the large number of potential users and the risk to health involved.

3. Summary of reasons for recommendation: The Panel recommends that stair-climbing wheelchairs be classified into class III because the Panel believes that satisfactory performance of this device has not been demonstrated and, therefore, that it is not possible to establish an adequate performance standard for the device. The design of the device is experimental and data to support its safe and effective use are not available. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the device and on the Panel members' familiarity with stair-climbing wheelchairs and the lack of sufficient data to support the safety and effectiveness of the device. Seybold's article (Ref. 1), describes the device and its use and states that a need for further development, testing, and evaluation of the stair-climbing wheelchair is necessary.

5. Risks to health: Bodily injury: If the device fails the disabled patient could fall and be seriously or fatally injured.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that stair-climbing wheelchairs be classified into class III (premarket approval). The Commissioner believes

that premarket approval is necessary for the device because general controls and performance standards are insufficient to control the risk to health described above and thus to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner believes the device presents a potential unreasonable risk of injury because satisfactory performance has not been demonstrated. The Commissioner also believes that there is not sufficient information to establish a performance standard for this device.

Reference

1. Seybold, James E., "Staircat Awarded R&D Funds by PVA," *Paraplegia News*, p. 40, September 1976.

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3890, to read as follows:

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a mobility assist device used by a disabled person to climb stairs in a sitting position. The device functions 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28301 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1224]

Medical Devices; Classification of Standup Wheelchairs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying standup wheelchairs (that assist a person to stand) into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of standup wheelchairs:

1. Identification: A standup wheelchair is a wheeled mobility-assist device that also operates as an external manually controlled mechanical system that enables a paraplegic to stand by means of an elevating seat.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that

a standup wheelchair be classified into class II because the Panel believes that the design and materials of the device must be controlled to assure that there are adequate mechanical safety features to prevent the patient from falling while arising to the standing position or while in the standing position. The Panel believes that general controls would not provide sufficient control over these over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device, on the Panel members' personal knowledge of, and familiarity with, the device and on a review of the pertinent literature (Refs. 1 and 2). Staros and Peizer (Ref. 1) have identified the following benefits that standup wheelchairs offer: (1) Achieving the upright position early in treatment, (2) prevention of contractures (muscle shortening) and pressure sores, and (3) possible improvements in circulation, urinary drainage, respiration, and other vital functions.

5. Risks to health: Bodily injury: Poor structural materials or instability of the device may cause the patient to fall, resulting in bodily injury.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that standup wheelchairs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Staros, A. and E. Peizer, "Veterans Administration Prosthetics Center Research Report," *Bulletin of Prosthetics Research*, 10-24:185-188, Fall 1975.

2. Lipskin, R., "Trends in Nonlicensed Mobility Aids," *Bulletin of Prosthetics Research*, 10-22:41-52, Fall 1974.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3900, to read as follows:

§ 890.3900 Standup wheelchair.

(a) *Identification.* A standup wheelchair is a wheeled mobility-assist device that also operates as an external manually controlled mechanical system that enables a paraplegic to stand by means of an elevating seat.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26302 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1225]

Medical Devices; Classification of Wheelchair Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying wheelchair accessories into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the devices be classified into class I. The effect of classifying the devices into class I is to require that the devices meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wheelchair accessories:

1. *Identification:* A wheelchair accessory is a device that is sold separately from the wheelchair and is used for 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, blanket and leg rest strap.

2. *Recommended classification:* Class I (general controls). The Panel recommends that wheelchair accessories be exempt from registration, device listing, and premarket notification regulations under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulations under section 520(f) of the act (21 U.S.C. (360)(f)).

3. *Summary of reasons for recommendation:* The Panel recommends that wheelchair accessories be classified into class I and that manufacturers of these devices should not be required to comply with registration, device listing, premarket notification, records and reports, or good manufacturing practice regulations because they are simple devices that pose no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the devices.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, these devices.

5. *Risks to health:* None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that wheelchair accessories be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. In response to the Panel's recommendation that manufacturers of a wheelchair

accessory be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of a wheelchair accessory, the agency cannot make the required finding. 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 a wheelchair accessory. 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) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of a wheelchair accessory be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP

requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of a wheelchair accessory be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation 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 GMP regulation, 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 a wheelchair accessory 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 a wheelchair accessory 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 GMP regulation is still appropriate.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3910, to read as follows:

§ 890.3910 Wheelchair accessory.

(a) *Identification.* A wheelchair accessory is a device that is sold separately from the wheelchair and is used for 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, 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 of this chapter.

The device also is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26303 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1226]

Medical Devices; Classification of Wheelchair Components

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying wheelchair components into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of special grade wheelchair components:

1. *Identification:* A wheelchair component is a device 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.

2. *Recommended classification:* Class I (general controls). The Panel recommends that there be no exemptions.

3. *Summary of reasons for recommendation:* The Panel recommends that wheelchair components be classified into class I because they are simple devices that present no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the devices.

4. *Summary of data of which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, these devices.

5. *Risks to health:* None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that wheelchairs components be classified into class I (general controls), with no exemptions. The Commissioner believes that a general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these 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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3920, to read as follows:

§ 890.3920 Wheelchair component.

(a) *Identification.* A wheelchair component is a device 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).

Interested persons may on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26304 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1227]

Medical Devices; Classification of Wheelchair Elevators

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying wheelchair elevators into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wheelchair elevators:

1. Identification: A wheelchair elevator is a motorized lifting device used by a disabled person to move a wheelchair from one level to another.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that wheelchair elevators be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of bodily injury and strain in case of an electrical malfunction. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: Bodily injury: An electrical malfunction of the device or insufficient protection by the guardrails could result in strain or injury to the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that wheelchair elevators be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and

effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3930, to read as follows:

§ 890.3930 Wheelchair elevator.

(a) *Identification*. A wheelchair elevator is a motorized lift device used by a disabled person to move a wheelchair from one level to another.

(b) *Classification*. Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26305 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1228]

Medical Devices; Classification of Wheelchair Platform Scales

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying wheelchair platform scales into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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.

After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of wheelchair platform scales:

1. Identification: A wheelchair platform scale is a device with a base designed to accommodate a wheelchair and is used to weigh a person who is confined to a wheelchair.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that wheelchair platform scales be classified into class II because the Panel believes that the measurement function of this device should be controlled to lessen the likelihood of misdiagnosis due to inaccurate measurement readings. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on a review of the pertinent literature. Madorsky (Ref. 1) states that significant inaccuracies and inefficiencies in recording weights have occurred due to the varying sizes of wheelchairs, time of day, and different clothing weights. The inconsistencies as stated in the literature and

the possible diagnostic or prognostic use of the weight measured by the scale demands accuracy of the measurement function of the device.

5. Risks to health: Misdiagnosis: Inaccurate information may result if the measurement function is faulty.

Proposed Classification

The Commissioner disagrees with the Panel recommendation that wheelchair platform scales be classified into class II (performance standards). The Commissioner believes that general controls are sufficient to require that the degree of accuracy of a platform scale be described in labeling accompanying the device. Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) requires information under authority of this act to appear on the labeling and that the labeling be prominently placed on the device. Therefore, the Commissioner is proposing that wheelchair platform scales be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Madorsky, A., "Weighing of Wheelchair-Bound Patients," *Archives of Physical Medicine and Rehabilitation*, 57:594, December 1976.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart D by adding new § 890.3940, to read as follows:

§ 890.3940 Wheelchair platform scale.

(a) *Identification:* A wheelchair platform scale is a device with a base designed to accommodate a wheelchair and is used to weigh a person who is confined to a wheelchair.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets

in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26306 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1229]

Medical Devices; Classification of Daily Activity Assist Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying daily activity assist devices into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of daily activity assist devices:

1. Identification: Daily activity assist devices are modified adaptors and utensils (e.g., dressing, grooming, recreational activity, transfer, eating, and homemaking aids) that are used to assist a patient in performing a specific function.

2. Recommended classification: Class I (general controls). The Panel recommends that daily activity assist devices be exempt from registration, device listing, and premarket notification under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360(f)).

3. Summary of reasons for recommendation: The Panel recommends that daily activity assist devices be classified into class I and that manufacturers of these devices not be required to comply with registration, device listing, premarket notification, records and reports, or good manufacturing practice regulations, because they are simple devices that present no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, these devices.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that daily activity assist devices be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. In response to the Panel's recommendation that manufacturers of daily activity assist devices be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of daily activity assist devices, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing these devices 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 daily activity assist devices. The agency does not at this time anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of daily activity assist devices be exempt from records and reports regulations under section 519 of the act. The Records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of daily activity assist devices be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices who does not label or otherwise represent them as sterile be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint

files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of daily activity assist devices, even when they are not labeled or otherwise represented as sterile, 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 daily activity assist devices 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 GMP regulation is still appropriate. A manufacturer of daily activity assist devices that are labeled or otherwise represented as sterile is, in the manufacture of these devices, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 890 by reserving Subpart E and adding new Subpart F and § 890.5050, to read as follows:

Subpart E [Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§ 890.5050 Daily activity assist devices.

(a) *Identification.* Daily activity assist devices are modified adaptors and utensils (e.g., dressing, grooming, recreational activity, transfer, eating, and homemaking aids) that are used to assist a patient to perform a specific function.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. If the devices are not labeled or otherwise represented as sterile, they also are exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26307 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1230]

Medical Devices; Classification of Immersion Hydrobaths

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immersion hydrobaths into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immersion hydrobaths:

1. Identification: An immersion hydrobath (e.g., whirlpool) consists of water agitators and 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that immersion hydrobaths be classified into class II because the Panel believes that a standard is necessary to control the electrical properties of this device to avoid the potential hazards of electrical shock. The Panel believes that the temperature control should be sufficiently accurate to prevent burns, and that the materials and design of the device should enable proper cleaning to prevent infection. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Thermal burns: A faulty temperature control could result in burns. (c) Bodily injury: If the surface of the device is slippery, the patient could sustain bodily injury by falling. (d) Infection: The accumulation of debris in drains and faucets could cause infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immersion hydrobaths be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance

standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide this assurance.

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 him (21 CFR 5.1), the Commissioner of Foods and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5100, to read as follows:

§ 890.5100 Immersion hydrobath.

(a) *Identification.* An immersion hydrobath (e.g., whirlpool) consists of water agitators and 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 standard).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 15, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26308 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1231]

Medical Devices; Classification of Paraffin Baths

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying paraffin baths into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device

Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of paraffin baths:

1. Identification: A paraffin bath is a metal tub to be filled with liquid paraffin (wax) maintained at an elevated temperature in which the appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that paraffin baths be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazards of shock and burns to the operator and/or patient. The Panel believes that the temperature control should be sufficiently accurate to avoid an inappropriate temperature level that may cause burns. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel

members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in patient injury, or a malfunction of the device could result in electrical shock. (b) Burns: Hot wax burns to a patient may result from a faulty temperature control.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that paraffin baths be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide this assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5110, to read as follows:

§ 890.5110 Paraffin bath.

(a) *Identification.* A paraffin bath is a metal tub to be filled with liquid paraffin (wax) maintained at an elevated temperature in which the appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26309 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1232]

Medical Devices; Classification of Nonpowered Sitz Baths

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonpowered sitz baths into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine and the Obstetrical and Gynecological Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of nonpowered sitz baths:

1. Identification: A nonpowered sitz bath is a tub to be filled with water that is used in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

2. Recommended classification: Class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that this device be classified into class I (general controls) because this is a simple device that

presents no risks to health or undue hazards when used in a normal manner for the purpose recommended. The Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that nonpowered sitz baths be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5125, to read as follows:

§ 890.5125 Nonpowered sitz bath.

(a) *Identification.* A nonpowered sitz bath is a tub to be filled with water that is used 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26310 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1233]

Medical Devices; Classification of Powered Patient Transports

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered patient transports into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered patient transports:

1. Identification: A powered patient transport is a motorized device used to assist patient transfers to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that

powered patient transports be classified into class II because the Panel believes that the electrical properties of this device must be controlled to avoid the potential hazard of electrical shock. The Panel also believes that the structural strength of this device should be controlled to prevent a potential injury hazard to the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, and malfunction of the device could result in electrical shock. (b) Bodily injury: Injury could result from the patient falling due to structural failure of the device.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered patient transports be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide this assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5150, to read as follows:

§ 890.5150 Powered patient transport.

(a) *Identification.* A powered patient transport is a motorized device used to assist patient transfers to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26311 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1234]

Medical Devices; Classification of Air-Fluidized Beds

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying air-fluidized beds into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.
DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory

committee, made the following recommendation regarding the classification of air-fluidized beds:

1. Identification: An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small round ceramic objects) to treat decubitus ulcers (bedsores), severe and extensive burns, and aid circulation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that air-fluidized beds be classified into class II because the Panel believes that the electrical properties associated with the device must be controlled to prevent the potential hazard of electrical shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and on the Panel members' personal knowledge of, and familiarity with, the device and a review of the pertinent literature (Refs. 1 through 5). At the Panel meeting of March 18, 1975 (Ref. 1), the Physical Medicine Device Classification Panel recommended that the device be classified into class III (premarket approval) because the Panel at that time believed that there was the possibility of patient infection and that data were insufficient to write an adequate standard for efficacy. However, at the Panel meeting of March 21 through 22, 1976, Sharbaugh (Ref. 2) discussed data on the microbiological aspect of air-fluidized beds. He presented studies in which air-fluidized beds were contaminated with bacteria and fungi. The number of organisms steadily decreased with no fungi or bacteria remaining 24 hours following this initial higher level of contamination. Sharbaugh also stated that the nature of the beds protects the patient from any sudden temperature changes. Newsome et al. (Ref. 3) conducted a study using air-fluidized beds. The investigators concluded that this device "has proven to be a useful adjunct in the care of extensively burned patients." They found that decubitus ulcers did not form, and old ulcers healed, when the beds were used. The authors stated that patients found this bed more comfortable than conventional beds, in which the patient had to change positions frequently. Sharbaugh and Hargest (Ref. 4) and Sharbaugh, Hargest, and Wright (Ref. 5) stated that air-fluidized beds have been found to remain "uncontaminated" and "essentially bacteria-free." These studies demonstrate the efficacy of air-fluidized beds, and the Panel recommends a class II classification only to assure electrical safety.

5. Risks to health: Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that air-fluidized beds be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Fourth Meeting of the Physical Medicine Device Classification Panel, March 18, 1975.
2. Sharbaugh, R. J., "Microbiological Aspects of the Air-Fluidized Bed," unpublished paper. Appendix A to Summary Minutes of the Seventh Meeting of the Physical Medicine Device Classification Panel, March 21 through 22, 1976.
3. Newsome, T. W., L. A. Johns, and B. A. Pruitt, "Use of an Air-Fluidized Bed in the Care of Patients with Extensive Burns," *The American Journal of Surgery*, 124:52-56, July 1972.
4. Sharbaugh, R. J. and T. S. Hargest, "Bactericidal Effect of the Air-Fluidized Bed," *The American Surgeon*, 37:583-586, September 1971.
5. Sharbaugh, R. J., T. S. Hargest, and F. A. Wright, "Further Studies on the Bactericidal Effect of the Air-Fluidized Bed," *The American Surgeon*, 39(5): 253-256, May 1973.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5160 as follows:

§ 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) to treat decubitus ulcers (bedsores), severe and extensive burns, and aid circulation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28312 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1235]

Medical Devices; Classification of Powered Flotation Therapy Beds

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered flotation therapy beds into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the General Hospital and the Personal Use Device Classification Panel, that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the

development of the proposed regulation. The Physical Medicine Device Classification Panel and the General Hospital and the Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of powered flotation therapy beds:

1. Identification: A powered flotation therapy bed is a device that may have an electrically heated mattress and is designed to accommodate a large volume of constantly moving water, air, mud, or sand in its mattress. This device is used as an aid to nursing care for the acceleration of healing or prevention of decubitus ulcers (bedsores), for patients with severe or extensive burns, or to aid circulation.

2. Recommended classification: Class II (performance standards). The Physical Medicine Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that powered flotation therapy beds be classified into class II because the Panels believe that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock and to prevent injury to soft tissues. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the potential hazards associated with this device, the Panels members' personal knowledge of, and familiarity with, the device, and a review of the pertinent literature. The literature supports the efficacy of flotation therapy for the treatment and prevention of decubitus ulcers (Refs. 1 and 2). Haper et al. (Ref. 2) state that flotation therapy used during a patient's stay in the hospital would be effective in preventing the formation of decubitus ulcers.

5. Risks to health: The Physical Medicine and the General Hospital and Personal Use Device Classification Panels identified the following risks to health. (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Bodily injury: Soft tissue breakdown could result from electrical failure of the device and/or failure to turn the patient when necessary because of overreliance on the device by the therapist or nurse. The general nature of the device is conducive to over-reliance on its purported efficacy, and this could lead to bodily injury. The water in the mattress could leak onto the floor, resulting in a slippery surface, causing patients and/or personnel to slip or fall. (c)

Cross-infection: If it is improperly cleaned, the device could spread infection to patients.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that powered flotation therapy beds be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Dewis, L., et al., "Treatment of Decubitus Ulcers by Use of a Water Mattress," *Archives of Physical Medicine and Rehabilitation*, 49:290-293, 1968.

2. Harper, P. J., et al., "Experience with A Flotation Unit for Prevention of Decubitus Ulcers," *Journal of the Medical Society*, 72(10):824-826, October 1975.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5170 as follows:

§ 890.5170 Powered flotation therapy bed.

(a) *Identification.* A powered flotation therapy bed is a device with a motorized bed that may have an electrically heated mattress and is designed to accommodate a large volume of constantly moving water, air, mud, or sand in its mattress. This device is used as an aid to nursing care, for the acceleration of healing or prevention of decubitus ulcers (bedsores), for patients with severe or extensive burns, or to aid circulation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document.

Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26313 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1236]

Medical Devices; Classification of Manual Patient Rotation Bed

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual patient rotation beds into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual patient rotation beds:

1. Identification: A manual patient rotation bed is a device that turns a patient who is restrained to a reclining position. This manually operated bed is used to treat patients with severe and extensive burns or decubitus ulcers (bedsores), and to aid circulation.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that manual patient rotation beds be classified into class I because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual patient rotation beds be classified into class I (general controls), with no exemptions, because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5180, to read as follows:

§ 890.5180 Manual patient rotation bed.

(a) Identification. A manual patient rotation bed is a device that turns a patient who is restrained to a reclining position. This manually operated bed is used to treat patients with severe and extensive burns or decubitus ulcers (bedsores), and to aid circulation.

(b) Classification. Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26314 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1237]

Medical Devices; Classification of Powered Patient Rotation Bed

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered patient rotation beds into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered patient rotation beds:

1. Identification: A powered patient rotation bed is a device that turns a patient

who is restrained to a reclining position. It is used to treat patients with decubitus ulcers (bedsores), severe and extensive burns, and urinary tract blockage, and to aid circulation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that powered patient rotation beds be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device, and on the Panel members' personal knowledge of, and familiarity with, the device and a review of the pertinent literature (Refs. 1). Hilt and Schmitt (Ref. 1) describe the procedures to follow in using patient rotation beds. The authors support the use of this device in rehabilitation; however, they emphasize that "the bed should be maintained properly and the motor checked," and that it should be unplugged when the bed is not in use. Thus, the electrical properties of this device should be controlled to lessen the likelihood of malfunction and possible bodily injury to the patient and/or operator.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Decubitus ulcers (bedsores): Decubitus ulcers or other injury to soft tissues may develop if there is overreliance by the therapist on the device. (c) Bodily injury: The patient may fall out of the bed if he or she is not stabilized or restrained properly.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered patient rotation beds be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes there is sufficient information to establish a performance standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hilt, N. E. and E. W. Schmitt, "Use of Special Beds in Nursing Care," in "Pediatric Orthopedic Nursing," C. V. Mosby Co., St. Louis, pp. 48-54, 1975.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5225, to read as follows:

§ 890.5225 Powered patient rotation bed.

(a) *Identification.* A powered patient rotation bed is a device that turns a patient who is restrained to a reclining position. It is used to treat patients with decubitus ulcers (bedsores), severe and extensive burns, and urinary tract blockage, and to aid circulation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26315 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1238]

Medical Devices; Classification of Moist Steam Cabinets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying moist steam cabinets into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of moist steam cabinets:

1. *Identification:* A moist steam cabinet is a device that delivers a flow of heated, moisturized air to a patient in an enclosed unit to treat arthritis and fibrosis (a formation of fibrous tissue) and to increase local blood flow.

2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. *Summary of reasons for recommendation:* The Panel recommends that moist steam cabinets be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazards of electrical shock and burns. The Panel believes that the temperature control should be sufficiently accurate to avoid burns. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel members based their recommendation on the potential hazards associated with this device and their personal knowledge of, and familiarity with, the device.

5. *Risks to health:* (a) Electrical shock: Excessive leakage current could result in injury or a malfunction of the device could

result in electrical shock. (b) Burns: Hot steam burns could result from a faulty temperature control.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that moist steam cabinets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5250, to read as follows:

§ 890.5250 Moist steam cabinet.

(a) *Identification.* A moist steam cabinet is a device that delivers a flow of heated, moisturized air to a patient in an enclosed unit to treat arthritis and fibrosis (a formation of fibrous tissue) and to increase local blood flow.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26318 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1239]

Medical Devices; Classification of Microwave Diathermies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microwave diathermies into class II (performance standards) for use in applying therapeutic deep heat and into class III (premarket approval) for all other uses. The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II (performance standards). 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 provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microwave diathermies:

1. Identification: A microwave diathermy for use in applying therapeutic deep heat is a device that applies high-frequency energy at microwave frequencies (915 megahertz to 2450 megahertz) to specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in medical conditions such as muscle spasms and joint contractures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that microwave diathermies be classified into class II because the Panel believes that, even though more information is needed on microwave diathermy and its biologic effects, the development and application of standards based on the present level of information would improve the safety and effectiveness of the device by providing for electrical standards, minimal and maximal energy output control limits and adequate labeling. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance. The Panel also recommends that these devices be restricted to use by or under the supervision of a physician.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the device, on the Panel members' knowledge of and clinical experience with the device, and on a review of the pertinent literature (Refs. 1 through 4). Michaelson (Refs. 1 and 2) summarizes the physiologic effects of microwaves, the potential hazards of microwaves, and presents data on which proposed environmental safety standards are based. Guy et al. (Ref. 3) present estimates of power absorption and thermal measurements that suggest that beneficial physiologic responses occur with tissue temperature in the range of 40° C to 45° C. Krusen (Ref. 4) summarizes the background of therapeutic microwave diathermy applications, listing specific indications and contraindications. The Panel noted that the Bureau of Radiological Health of the FDA is preparing a proposed draft of a microwave safety standard for therapeutic devices and that the Federal Communications Commission has radiofrequency transmitting requirements for medical diathermy.

5. Risks to health: (a) Adverse tissue response: The devices may cause adverse tissue response that can result in possible cataract formation and central nervous system injury. (b) Electrical shock: Excessive leakage current from improper grounding or a device malfunction can lead to electrical shock. (c) Burns: Contact with uncovered parts of the body at the instrument output terminal or with cables and electrodes that are inadequately insulated may lead to burns.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microwave diathermies be classified into class II (performance standards) for use in delivering therapeutic deep heat. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Like the shortwave diathermy, which is the subject of a proposed classification regulation published elsewhere in this issue of the *Federal Register*, the microwave diathermy is used for therapeutic deep heat. It is also used for additional purposes for which it has not been shown to be safe and effective. Accordingly, although the Panel considered only one use for the microwave diathermy—the delivery of therapeutic deep heat—the agency believes that the device also should be classified with respect to all other intended uses. Therefore, the agency is proposing that microwave diathermy devices be classified into class III (premarket approval) for any use other than delivering therapeutic deep heat. The agency believes that microwave diathermy, when it is used for any purpose other than applying therapeutic deep heat, presents a potential unreasonable risk of injury without proven benefit to the patient because substantial data and clinical investigations do not exist to support these other claims. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device when it is used for any purpose other than applying deep therapeutic heat, and that insufficient information exists to establish a performance standard to provide this assurance.

References

1. Michaelson, S. M., "Microwave Exposure Safety Standards—Physiologic and Philosophic Aspects," *American Industrial Hygiene Association*, 33(3):156, 1972.
2. Michaelson, S. M., "Human Exposure to Non-ionizing Radiant Energy, Potential Hazards and Safety Standards," *Proceedings IEEE*, 60(4):389-421, 1972.
3. Guy, A. W., J. F. Lehmann, and J. B. Stonebridge, "Therapeutic Applications of Electromagnetic Power," *Proceedings IEEE*, 62(1):55-75, 1974.
4. Krusen, F. H. (editor), "Handbook of Physical Medicine and Rehabilitation," W. B. Saunders Co., 2d Ed., 1971.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5275, to read as follows:

§ 890.5275 Microwave diathermy.

(a) *Microwave diathermy for use in applying therapeutic deep heat—(1) Identification.* A microwave diathermy for use in applying therapeutic deep heat is a device that applies high frequency energy at microwave frequencies (915 megahertz to 2450 megahertz) to specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in medical conditions such as muscle spasms and joint contractures.

(2) *Classification.* Class II (performance standards).

(b) *Microwave diathermy for any use other than applying therapeutic deep heat—(1) Identification.* A microwave diathermy for any use other than applying therapeutic deep heat is a device that applies high frequency energy (915 megahertz to 2450 megahertz) to the body for any purpose other than applying therapeutic deep heat for the relief of pain.

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

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[ER Doc. 79-26317 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1241]

Medical Devices; Classification of Shortwave Diathermies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying short wave diathermies into class II (performance standards) for use in applying therapeutic deep heat and into class III (premarket approval) for all other uses. FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that shortwave diathermy (i.e., devices

claiming therapeutic effects through the heating of tissue) be classified into class II (performance standards). 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 provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shortwave diathermy:

1. *Identification:* A shortwave diathermy for use in applying therapeutic deep heat is a device that applies the electromagnetic energy of pulsed and/or continuous radiowaves in the radiofrequency bands of 13 megahertz to 27.12 megahertz to provide therapeutic deep heat in specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in selected medical conditions such as muscle spasms and joint contractures.

2. *Recommended classification:* The Panel recommends that shortwave devices that are claimed to be capable of generating therapeutic heat in specific areas of the body be classified into class II (performance standards) and that establishing a performance standard for these devices be a high priority.

3. *Summary of reasons for recommendation:* The Panel recommends that

shortwave diathermy devices that produce an increase in internal body tissue temperature be classified into class II because the Panel believes that these devices have demonstrated therapeutic effectiveness. The Panel believes that, even though more information is needed on shortwave diathermy and its biological effects, the development and application of standards based on the present level of information would improve the safety and effectiveness of the device by providing for electrical standards, minimal and maximal energy output control limits, and adequate labeling. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a preliminary standard that would require periodic updating as data become available. The Panel also recommends that shortwave devices be restricted to use by or under the supervision of a physician.

4. Summary of data on which the recommendation is based: The Panel based its recommendations on the Panel members' professional knowledge of shortwave devices, a review of the literature, a report by the University of Washington's Department of Rehabilitation Medicine (Ref. 1), and a GAO report addressing the safety and effectiveness of diathermy (Ref. 2). Some of the Panel members have evaluated the clinical application of the devices and tested the performance of the equipment. These devices were discussed by the Panel members at the Panel and Subcommittee meetings of August 14 and 15, 1975, March 21 and 22, 1976, March 18, 1977, October 14, 1977, and March 17, 1978 (Refs. 3 through 7). It was stated that the therapeutic benefits of diathermy are related to a temperature rise (thermal effect) in the body tissues. (Ref. 3). The Panel recognizes that some shortwave devices cannot provide a sufficient increase in tissue temperature and thus are considered therapeutically ineffective. In particular, many of these ineffective devices have used pulsed radiofrequency outputs (Ref. 3). Diathermy is only used for its thermal effects, and the Panel could find no therapeutic value in the nonthermal effects of shortwave treatment (Ref. 4). The Panel noted that the Federal Communications Commission has radiofrequency transmitting requirements for medical diathermy that must be met.

5. Risks to health: (a) Cellular or tissue injury: Nonthermal biological effects of nonionizing radiation may cause cellular or tissue injury. (b) Pacemaker interference: The electromagnetic fields generated by the device may interfere with the circuitry of a cardiac pacemaker. (c) Tissue necrosis (death) and burns: Excessive energy deposition into the tissue may cause excessive heating that results in tissue damage. (d) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

shortwave diathermy devices be classified into class II (performance standards) for use in delivering therapeutic deep heat. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

The Panel noted that the shortwave diathermy is capable of being, and has been offered for use for other than the thermal effects of diathermy. Accordingly, the agency is proposing that shortwave diathermy devices be classified into class III (premarket approval) for any use other than delivering therapeutic deep heat. The agency believes that shortwave diathermy, when it is used for any purpose other than applying therapeutic deep heat, presents a potential unreasonable risk of injury without proven benefit to the patient because substantial data and clinical investigations do not exist to support additional claims made. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device when it is used for any purpose other than applying therapeutic deep heat, and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. The Department of Rehabilitation Medicine, University of Washington, Report No. PB 243-747, Contract No. FDA 74-32, "Review of Evidence for Indications, Techniques of Application, Contraindications, Hazards, and Clinical Effectiveness for Shortwave Diathermy," University of Washington, Seattle, WA, 1974.

2. Food and Drug Administration, Department of Health, Education, and Welfare, "Stronger Measures Needed to Insure that Medical Diathermy Devices are Safe and Effective," A Report to the Senate Committee on Government Operations by the Comptroller General of the United States, Washington, DC, 1976.

3. Summary Minutes of the First Meeting of the Diathermy Subcommittee of the Physical Medicine Device Classification Panel, August 14-15, 1975.

4. Summary Minutes of the Seventh Meeting of the Physical Medicine Device Classification Panel, March 21-22, 1976.

5. Summary Minutes of the Second Meeting of the Electrotherapeutic Subcommittee of the Physical Medicine Device Classification Panel, March 18, 1977.

6. Summary Minutes of the Tenth Meeting of the Physical Medicine Device Classification Panel, October 14, 1977.

7. Summary Minutes of the Eleventh Meeting of the Physical Medicine Device Classification Panel, March 17, 1978.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5290, to read as follows:

§ 890.5290 Shortwave diathermy.

(a) *Shortwave diathermy for use in applying therapeutic deep heat—(1) Identification.* A shortwave diathermy for use in applying therapeutic deep heat is a device that applies the electromagnetic energy of pulsed and/or continuous radiowaves in the radiofrequency bands of 13 megahertz (MHz) to 27.12 MHz to provide therapeutic deep heat in specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in selected medical conditions such as muscle spasms and joint contractures.

(2) *Classification.* Class II (performance standards).

(b) *Shortwave diathermy for any use other than applying therapeutic deep heat—(1) Identification.* A shortwave diathermy for any use other than applying therapeutic deep heat is a device that applies the electromagnetic energy of pulsed and/or continuous radiowaves in the radiofrequency bands of 13 megahertz to 27.12 megahertz to the body for any purpose other than applying therapeutic deep heat for the relief of pain.

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

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments shall be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26318 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1242]

Medical Devices; Classification of Ultrasonic Diathermies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic diathermies into class II (performance standards) for use in applying therapeutic deep heat and into class III for all other uses. The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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 provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in the issue of the Federal Register provides background information concerning the

development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultrasonic diathermies:

1. Identification: An ultrasonic diathermy for use in applying therapeutic deep heat is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to provide therapeutic deep heat in specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in selected medical conditions such as muscle spasms and joint contractures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ultrasonic diathermies be classified into class II because the electrical current used to provide ultrasound should be controlled to prevent injury. The Panel believes that the measurement limitations inherent in the use of the device should be clearly specified by manufacturers in the device labeling. The Panel also recommends that the device be restricted to use by or under the supervision of a physician. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device, on the Panel members' knowledge of, and experience with, the device, and on a review of the pertinent literature (Refs. 1 and 2). Lehmann (Ref. 1) stated that ultrasound has been found to be of established value in treating joint contractures, muscle spasms, and periarthritis (inflammation of tissue around the joints). Lehmann stated that ultrasound is a very powerful and effective heating agent but that there are contraindications for use of the device. If used improperly, ultrasound can cause cavitation (cellular destruction), resulting in possible irreversible damage. The Panel noted that the Bureau of Radiological Health of FDA has promulgated performance safety standards for ultrasonic therapeutic products (21 CFR 1050.10) and that the Federal Communications Commission has radio-frequency transmitting requirements for medical diathermy that must be met.

5. Risks to health: (a) Electrical shock: Faulty design or a malfunction of the device could result in electrical shock. (b) Burns: High current density over time could result in burns to tissues. (c) Inappropriate therapy: Inappropriate therapy could result from inaccurate measurement of applied energy. (d) Cavitation (cellular destruction): Inadequate uniform field distribution or lack of sufficient external pressure on the device applied to the skin could lead to tissue cavitation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultrasonic diathermies be classified into class II (performance standards) for use in delivering therapeutic deep heat. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Like the shortwave diathermy, which is the subject of a proposed classification regulation published elsewhere in this issue of the Federal Register, the ultrasonic diathermy is used for therapeutic deep heat. It is also used for additional purposes in which it has not been shown to be safe and effective. Accordingly, although the Panel considered only one use for the device—the delivery of therapeutic deep heat—the agency believes that the device should also be classified with respect to all other intended uses. Therefore, the agency is proposing that ultrasonic diathermy devices be classified into class III (premarket approval) for any use other than delivering therapeutic deep heat. The agency believes that ultrasonic diathermy, when it is used for any purpose other than applying therapeutic deep heat, presents a potential unreasonable risk of injury without proven benefit to the patient because substantial data and clinical investigations do not exist to support those other claims. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device, when it is used for a purpose other than applying therapeutic deep heat, and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lehmann, J. F., "Diathermy" in "Handbook of Physical Medicine and Rehabilitation," 2d Ed., Edited by Krusen, F. H., F. J. Kottke, and P. M. Ellwood, W. B. Saunders Co., Philadelphia, PA, pp. 297-321, 1971.

2. Rusk, H. A., "Principles of Physical Medicine," in "Rehabilitation Medicine," 4th

Ed., Edited by Taylor, E. J. and C. V. Mosby, St. Louis, MO, pp. 75-80, 1977.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5300, to read as follows:

§ 890.5300 Ultrasonic diathermy.

(a) *Ultrasonic diathermy for use in applying therapeutic deep heat—(1) Identification.* An ultrasonic diathermy for use in applying therapeutic deep heat is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to provide therapeutic deep heat in specific areas of the body. Such tissue heating is used as adjunctive therapy for the relief of pain in selected medical conditions such as muscle spasms and joint contractures.

(1) *Classification.* Class II (performance standards).

(b) *Ultrasonic diathermy for any use other than applying therapeutic deep heat—(1) Identification.* An Ultrasonic diathermy for any use other than applying therapeutic deep heat is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to the body for any purpose other than applying therapeutic deep heat for the relief of pain.

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

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26310 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1243]

**Medical Devices; Classification of
Exercise Components**

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying exercise components into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that these devices be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of exercise components:

1. *Identification:* An exercise component is a device that is used in conjunction with exercise equipment or with other forms of exercise. Examples of an exercise component include a weight, a dumbbell, a strap, and a hand mitt.

2. *Recommended classification:* Class I (general controls). The Panel recommends that exercise components be exempt from registration, device listing, and premarket notification regulations under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulations under section 520(f) of the act (21 U.S.C. 360j(f)).

3. *Summary of reasons for recommendation:* The Panel recommends that these devices be classified into class I and that manufacturers of these devices should

not be required to comply with registration, records and reports, or good manufacturing practice regulations because they are simple devices that present no undue risks to health when used in a normal manner for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. *Summary of data on which the recommendation is based:* The Panel members based their recommendation on their personal knowledge of, and familiarity with, these devices.

5. *Risks to health:* None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that exercise components be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. In response to the Panel's recommendation that manufacturers of an exercise component be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of an exercise component, the agency cannot make the required finding. 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 an exercise component. 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) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of an exercise component be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device

good manufacturing practice (GMP) regulation, published in the *Federal Register* of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of an exercise component be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation 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 GMP regulation, 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 an exercise component 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 an exercise component 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 GMP regulation is still appropriate.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart F by adding new § 890.5350, to read as follows:

§ 890.5350 Exercise component.

(a) *Identification.* An exercise component is a device that is used in conjunction with exercise equipment or with other forms of exercise. Examples of an exercise component include a weight, a dumbbell, a strap, and a hand mitt.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. The device also is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 79-26320 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1244]

**Medical Devices; Classification of
Measuring Exercise Equipment**

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying measuring exercise equipment into class II (performance standards). The FDA is also publishing the recommendation of the Physical

Medicine Device Classification Panel that these devices be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of measuring exercise equipment:

1. Identification: Measuring exercise equipment consists of manual devices used to redevelop muscles, restore motion to joints, and provide general conditioning. These devices display, by means of a gauge, the amount of exercise performed. Examples of measuring exercise equipment are the therapeutic exercise bicycle, the manually propelled treadmill, and the rowing machine.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that measuring exercise equipment be classified into class II because the devices perform measurement functions that indicate the strength or endurance of a patient. Accurate exercise measurements are necessary for the proper diagnosis and prognosis of a patient's condition, the development of the correct treatment regimen, and the therapeutic evaluation of a patient's progress. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable

assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel also recommends that the measurement limitations inherent in the use of these devices should be clearly specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with these devices and their personal knowledge of, and familiarity with, the devices.

5. Risks to health: Inappropriate therapy: Inaccurate determination of the patient's strength or endurance due to a faulty measurement gauge could lead to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that measuring exercise equipment be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes there is sufficient information to establish a standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5360, to read as follows:

§ 890.5360 Measuring exercise equipment.

(a) *Identification.* Measuring exercise equipment consists of manual devices used to redevelop muscles, restore motion to joints, and provide general conditioning. These devices display, by means of a gauge, the amount of exercise performed. Examples of measuring exercise equipment are the therapeutic exercise bicycle, the manually propelled treadmill, and the rowing machine.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28321 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1245]

Medical Devices; Classification of Nonmeasuring Exercise Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonmeasuring exercise equipment into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of nonmeasuring exercise equipment:

1. *Identification:* Nonmeasuring exercise equipment consists of devices used to redevelop muscles, restore motion to joints, and provide general physical conditioning. Examples of nonmeasuring exercise equipment are prone scooter boards, parallel bars, mechanical treadmills, and exercise tables.

2. *Recommended classification:* Class I (general controls). The Panel recommends that nonmeasuring exercise equipment be exempt from registration under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360(f)).

3. *Summary of reasons for recommendation:* The Panel recommends that these devices be classified into class I and that the manufacturers of these devices not be required to comply with registration, records and reports, or good manufacturing practice regulations because these are simple devices that present no undue risks to health when used in a normal manner and for the purposes recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the devices.

4. *Summary of data on which the recommendation is based:* The Panel members based their recommendation on their personal knowledge of, and familiarity with, these devices.

5. *Risks to health:* None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that nonmeasuring exercise equipment be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. In response to the Panel's recommendation that manufacturers of nonmeasuring exercise equipment be exempt from section 510 of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. 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. In the case of registration and listing by manufacturers of nonmeasuring exercise equipment, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing these devices 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 nonmeasuring exercise equipment. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of nonmeasuring exercise equipment be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of nonmeasuring exercise equipment be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the

agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of nonmeasuring exercise equipment 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 nonmeasuring exercise equipment 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 a 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 GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart F by adding new § 890.5370, to read as follows:

§ 890.5370 Nonmeasuring exercise equipment.

(a) *Identification.* Nonmeasuring exercise equipment consists of devices used to redevelop muscles, restore motion to joints, and provide general physical conditioning. Examples of nonmeasuring exercise equipment are prone scooter boards, parallel bars, mechanical treadmills, and exercise tables.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. The devices also are exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the

above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26322 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1246]

Medical Devices; Classification of Powered Exercise Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered exercise equipment into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the Anesthesiology Device Classification Panel that the devices be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation regarding

the classification of powered exercise equipment:

1. Identification: Powered exercise equipment consists of motorized devices used to redevelop muscles, restore motion to joints, and provide general physical conditioning. Examples of powered exercise equipment are the powered treadmill, the powered bicycle, and powered parallel bars.

2. Recommended classification: The Physical Medicine Device Classification Panel and the Anesthesiology Device Classification Panel recommend that powered exercise equipment be classified into class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that powered exercise equipment be classified into class II because the Panels believe that the electrical properties of these devices must be controlled to avoid the potential hazards of electrical shock and burns. Powered exercise equipment provide a measurement function, and the Physical Medicine Device Classification Panel believes that the measurement limitations of these devices should be clearly specified by the manufacturers of the devices. The Anesthesiology Device Classification Panel believes that the design and materials of these devices must be controlled to assure that there are adequate mechanical safety features to prevent bodily injury to the patient. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the potential hazards associated with these devices and the Panel members' personal knowledge of, and familiarity with, the devices.

5. Risks to health: The Physical Medicine Device Classification Panel and the Anesthesiology Device Classification Panel identified the following risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Misdiagnosis or inappropriate therapy: Misdiagnosis or inappropriate therapy could result from faulty gauges causing inaccurate measurements. (c) Bodily injury: Sudden starts or stops of the device, or lack of mechanical safety features, may result in bodily injury.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that powered exercise equipment be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by these devices. A

performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5380, to read as follows:

§ 890.5380 Powered exercise equipment.

(a) *Identification.* Powered exercise equipment consists of motorized devices used to redevelop muscles, restore motion to joints, and provide general physical conditioning. Examples of powered exercise equipment are the powered treadmill, the powered bicycle, and powered parallel bars.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26323 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1248]

Medical Devices; Classification of Infrared Lamps

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public summary a proposed regulation classifying infrared lamps into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II and of the General Hospital and Personal Use

Device Classification Panel that the device be classified into class I. 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 I (general controls) is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 56 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of infrared lamps:

1. Identification: An infrared lamp is a device used to provide topical heating for therapeutic purposes by means of either a tungsten or carbon filament heated to emit a high level of incandescence (approximately 10,000 angstroms) or a solid rod or resistance wire heated to red heat (approximately 20,000 to 40,000 angstroms).

2. Recommended classification: The Physical Medicine Device Classification Panel recommends that this device be classified into class II (performance standards), and that establishing a performance standard for this device be a low priority. The General Hospital and Personal Use Device Classification Panel recommends that this device be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel recommends that infrared lamps be classified into class II because the Panel believes that the electrical properties of the device must be controlled to

avoid the potential hazard of electrical shock. The Panel believes that the radiant intensity of this device must be controlled to avoid pain, blistering, burns, and/or heatstroke caused by overexposure. The desired radiant intensity of this device, as stated by Stoner (Ref. 1) is 0.07 to 0.49 watts/cm² to produce hyperemia (increased local blood flow) during a 1-minute to 20-minute exposure. An increased intensity, with a 3-minute exposure, results in pain and blistering. The Panel also recommends the need for a warning to read "when used therapeutically consult your physician or therapist." The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The General Hospital and Personal Use Device Classification Panel recommends that infrared lamps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Physical Medicine Device Classification Panel based its recommendation on the potential hazards associated with this device, the Panel members' personal knowledge of, and familiarity with, the device, and a review of the pertinent literature (Ref. 1). Stoner (Ref. 1) stated that "exposure to infrared and luminous radiation produces superficial hyperemia, sweating, counterirritation and relaxation of muscles." The author further states that "blistering, burns and heatstroke" may be caused by an "overdosage of infrared radiation." The General Hospital and Personal Use Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: The Physical Medicine Device Classification Panel and the General Hospital and Personal Use Device Classification Panel identified the following risks to health: (a) Contact burns: Contact burns could result from an unprotected heat element. (b) Radiation burns: Overexposure could lead to radiation burns. (c) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. The General Hospital and Personal Use Device Classification Panel identified the following additional risk to health: (d) Glass cuts: Bursting of the lamp due to liquid contact with the lamp could result in glass cuts.

Proposed Classification

FDA agrees with the Physical Medicine Device Classification Panel and is proposing that infrared lamps be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A

performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard to provide such assurance.

FDA disagrees with the General Hospital and Personal Use Device Classification Panel recommendation that infrared lamps be classified into class I (general controls). The agency believes that the device presents a risk to health and that the device should be subject to performance standards.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Stoner, E. K., "Luminous and Infrared Heating," in "Therapeutic Heat and Cold," 2d Ed., Edited by Licht, S., Waverly Press, Inc., Baltimore, MD, pp. 252-265, 1965.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5500, to read as follows:

§ 890.5500 Infrared lamp.

(a) *Identification.* An infrared lamp is a device used to provide topical heating for therapeutic purposes by means of either a tungsten or carbon filament heated to emit a high level of incandescence (approximately 10,000 angstroms) or a solid rod or resistance wire heated to red heat (approximately 20,000 to 40,000 angstroms).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26324 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1249]

Medical Devices; Classification of Iontophoresis Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying iontophoresis devices for the specialized uses (for the diagnosis of cystic fibrosis, and for fluoride uptake acceleration in dentistry, and for local anesthesia of the intact tympanic membrane) into class II (performance standards) and for all other uses into class III. The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel that the device be classified into class II and the recommendation of the Dental Device Classification Panel that the device be classified into class I for fluoride uptake acceleration. 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 provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Johnsie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel and the Dental Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of iontophoresis devices:

1. Identification: An iontophoresis device is a device used to introduce ions of soluble salts (i.e., medications), by use of a direct current, into the tissues of the body for therapeutic or diagnostic purposes. An iontophoresis device for the diagnosis of cystic fibrosis is a device that induces sweating by the introduction of pilocarpine through the use of a direct current. The sweat is collected and its composition and weight are used in the diagnosis of cystic fibrosis. An iontophoresis device for dental application of fluoride is a device used to accelerate the introduction (diffusion) of fluoride ions into tooth structures to reduce hypersensitivity and for fluoride uptake in cavity prevention. An iontophoresis device for the local anesthetizing of the intact tympanic membrane is a device used to induce ions of lidocaine and epinephrine into the tympanic membrane of the ear to cause an anesthetizing effect.

2. Recommended classification: The Physical Medicine Device Classification Panel recommends that iontophoresis devices be classified into class II and that establishing a performance standard for this device be a high priority. The Ear, Nose, and Throat Device Classification Panel recommends that iontophoresis devices be classified into class II and that establishing a performance standard for this device be a high priority. The Dental Device Classification Panel recommends that this device be classified into class I and that it be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice (GMP) regulations under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel recommends that iontophoresis devices be classified into class II because the Panel believes that the electrical current, which is applied to deliver ions through the skin, should be controlled to prevent injury. The Panel also believes that the measurement limitations inherent in the use of the device should be clearly specified

by manufacturers in the device labeling. The Ear, Nose, and Throat Device Classification Panel recommends that iontophoresis devices be classified into class II because the Panel believes that the design and materials of the electrode must be controlled to prevent trauma to the patient. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Dental Device Classification Panel recommends that this device be classified into class I and that manufacturers of this device not be required to comply with premarket notifications, records and reports, or GMP regulations because the Panel believes that the electrical voltage is low and the direct current involved is sufficiently small not to be of danger to the patient. The Dental Device Classification Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Physical Medicine Device Classification Panel considered only the device and not the safe and effective use of the drug used with the device in making its classification recommendation. The Panel based its recommendation on the potential hazards associated with this device, the Panel members' personal knowledge of, and familiarity with, the device, and a review of the pertinent literature (Ref. 1). Harris (Ref. 1) describes the techniques used in iontophoresis for various indications. He states that "iontophoresis has been widely used in clinical practice for many years," and it is of "theoretical and practical value." Harris states, however, that more controlled studies should be conducted to produce therapeutic applications that are soundly based on clinical studies. The Ear, Nose, and Throat Device Classification Panel based its recommendation on the potential hazards associated with this device and the Panel members' personal knowledge of, and familiarity with, the device and a presentation by Dr. Robert Brummett (Ref. 2). At the Panel meeting of November 6 and 7, 1978, Dr. Brummett (Ref. 2) discussed the use of iontophoresis in the anesthetizing process of the tympanic membrane. He summarized various studies (Refs. 8 through 12) and concluded that "the procedure of inducing anesthesia of the tympanic membrane by use of iontophoresis and the appropriate drug is safe and satisfactory." The Dental Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device and on its history of use in dentistry without significant problems.

5. Risks to health: The Physical Medicine Device Classification Panel identified the following risks to health:

(a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Burns: High current densities in tissue over time could result in burns. (c) Cardiac arrest: Cardiac arrest may

be caused by an excessive electrical current passing through the heart. (d) Inappropriate therapy: Inappropriate therapy could result from inaccurate current measurement function. The Ear, Nose, and Throat Device Classification Panel identified the following risks to health: (a) Trauma: Trauma to the ear may be caused by the use of an improperly designed electrode. (b) Bodily injury: Bodily injury may be caused by the use of an inappropriate drug or use of the procedure with a perforated tympanic membrane. The Dental Device Classification Panel identified no risks to health.

Proposed Classification

FDA agrees with the recommendation of the Ear, Nose, and Throat Device Classification Panel and in part with the recommendation of the Physical Medicine Device Classification Panel, and is proposing that iontophoresis devices be classified into class II (performance standards) for use in the diagnosis of cystic fibrosis, in accelerating fluoride introduction to the teeth, and for local anesthesia of the intact tympanic membrane. The agency disagrees with the Dental Device Classification Panel recommendation that iontophoresis devices for fluoride uptake acceleration be classified into class I (general controls). The agency believes that the device presents the risk of electrical shock and that the measurement limitations inherent in the use of the device should be controlled. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device.

The agency also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device for use in the diagnosis of cystic fibrosis, in accelerating fluoride introduction to the teeth in dentistry, and for local anesthesia of the intact tympanic membrane. The agency has reviewed the pertinent available literature on iontophoresis (Refs. 1 through 14). Harris (Ref. 1) states that "many forms of iontophoresis have no other value other than as simple counter-irritants or as psychotherapeutic measures." There is a lack of scientific data supporting the use of iontophoresis for any of the claims being made, and Harris states that "therapeutic applications are not based soundly on clinical experiments * * *". Subcutaneous injection of drugs is quicker, more reliable and more exact and is usually to be preferred." Stillwell (Ref. 3) contends that the therapeutic

value of iontophoresis is limited, and the disadvantages "include the difficulty of estimating the dosage of the drug and, particularly of estimating how much of the drug may act systemically." Limited uses (for the diagnosis of cystic fibrosis, for fluoride uptake acceleration in dentistry and for the local anesthesia of the intact tympanic membrane) of iontophoresis have been studied, documented, and accepted as being safe and effective. Kopito and Shwachman (Ref. 4) state that "the stimulation of sweat by pilocarpine iontophoresis followed by a chemical analysis of sodium and chloride is currently the preferred method for confirming the diagnosis of cystic fibrosis." Steinrud et al. (Ref. 5) concur that "sweat stimulation with pilocarpine iontophoresis followed by sodium-potassium analysis of a measured amount of sweat has proved most valuable in determining the high sweat electrolytes of cystic fibrosis children." Tocci and McKey (Ref. 6) describe the Gibson-Cooke quantitative pilocarpine iontophoresis test as currently being "the most reliable diagnostic test for cystic fibrosis." The authors state that any laboratory can perform this test with accuracy "if there has been proper attention to detail in collecting and preparing the sweat specimen." In a study performed by Tocci and McKey (Ref. 6) with 1,270 subjects, 203 of whom were cystic fibrosis patients, the investigators found that the sweat test was 84 percent reliable with 16 percent false-positive on the first test and 93 percent reliable with 7 percent false-positive results on the retest.

Gangarosa and Park (Ref. 7) conclude that fluoride iontophoresis results in the most rapid and effective relief of dentin hypersensitivity during topical application of fluoride. The use of fluoride iontophoresis has a broad application in dental practice.

Comeau and Brummett (Ref. 8) state that following 12 investigations, using three subjects, the techniques of iontophoresis to produce tympanic anesthesia is safe, effective, and easy. Echols (Ref. 9) demonstrated that lidocaine in the middle ear space does not have any major toxic effects on the eighth nerve. Epley (Ref. 10) finds that the iontophoresis procedure followed by an injection of additional anesthesia enables the surgical procedure to be carried out with ease. Epley (Ref. 10) studied the effectiveness of the anesthetic method in 100 children tympanostomy candidates. He found very little substantial difference between the effectiveness of the iontophoretic anesthesia (pain being the

criterion) with and without the additional anesthesia. However, those children operated on under general anesthesia alone reported post-operative bleeding more often than those children operated on under iontophoresis alone. Epley (Ref. 10), Schleuing, et al. (Ref. 11), and Comeau and Brummett (Ref. 12) attribute the absence of bleeding to the vasoconstricting effect of epinephrine, and the authors cite this hemostasis as an important advantage of iontophoresis. Comeau and Brummett (Ref. 12) state that this vasoconstriction ultimately results in "rapid healing and less chance of infection" * *. The FDA has determined that iontophoresis used in the diagnosis of cystic fibrosis, in the acceleration of fluoride introduction to the teeth, and in the local anesthetizing of the intact tympanic membrane has been shown to be both safe and effective. The agency is proposing, therefore, that iontophoresis devices for these uses be classified into class II (performance standards). The agency recognizes that the Physical Medicine Device Classification Panel members recommended a classification for the device only and did not consider the specific use of the device. The agency believes, however, that the intended use of the device and the device itself cannot be separated. Therefore, the agency is proposing that iontophoresis devices be classified into class III (premarket approval) for any uses except those described above. The agency believes that iontophoresis devices, when used for purposes other than those specifically considered, present a potential unreasonable risk of injury without benefit to the patient because substantial data and clinical investigations do not exist to support the claims made for the devices. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device, and that insufficient information exists to establish a performance standard to provide this assurance with respect to use of the device purposes other than those specifically considered.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, R., "Iontophoresis" in "Therapeutic Electricity and Ultraviolet Radiation," 2d Ed., Edited by Licht, S., Waverly Press, Inc., Baltimore, MD, pp. 156-178, 1967.
2. Brummett, R., "Iontophoretic Anesthesia of the Tympanic membrane," Unpublished

paper, Appendix B to Summary Minutes of the Eighteenth Meeting of the ENT Device Classification Panel, November 8 and 7, 1978.

3. Stillwell, G. K., "Electrical Stimulation and Iontophoresis" in "Physical Medicine and Rehabilitation," W. B. Saunders Co., Philadelphia, PA, pp. 353-359, 1965.
4. Kopito, L. and H. Schwachman, "Studies in Cystic Fibrosis: Determination of Sweat Electrolytes in Situ with Direct Reading Electrodes," *Pediatrics*, 43:794-798, 1969.
5. Steinrud, J. et al., "Screening for Cystic Fibrosis with Chloride Electrode," *British Medical Bulletin*, 21(6):251-255, October 1974.
6. Tocci, P. M. and R. M. McKey, "Laboratory Confirmation of the Diagnosis of Cystic Fibrosis," *Clinical Chemistry*, 22(11):1841-1844, 1976.
7. Gangarosa, L. P. and N. H. Park, "Practical Considerations in Iontophoresis of Fluoride for Desensitizing Dentin," *Journal of Prosthetic Dentistry*, 39(2):173-178, February 1978.
8. Comeau, M. and R. Brummett, "Local Anesthesia of the Ear by Iontophoresis," *Archives of Otolaryngology*, 98:114-120, August 1973.
9. Echols, F. et al., "Anesthesia of the Ear by Iontophoresis of Lidocaine," *Archives of Otolaryngology*, 101:418-421, July 1975.
10. Epley, J. M., "Modified Technique of Iontophoretic Anesthesia for Myringotomy in Children," *Archives of Otolaryngology*, 103:358-360, June 1977.
11. Schleuing, A. J. et al., "Local Anesthesia of the Tympanic Membrane by Iontophoresis," *Transactions of the American Academy of Ophthalmology and Otolaryngology*, 78:453-457, 1974.
12. Comeau, M. and R. Brummett, "Anesthesia of the Human Tympanic Membrane by Iontophoresis of a Local Anesthetic," *Laryngoscope*, 88:277-285, February 1978.
13. Srinivasan, S. et al., "Enhanced Fluoride Uptake by Teeth Through Use of Iontophoretic Techniques," *Pharmacology and Therapeutics in Dentistry*, 2(3-4):253-256, 1975.
14. Gibson, L. E., P. A. di Sant'Agnes, and H. Shwachman, "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis," Cystic Fibrosis Foundation, 1975.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart F by adding new § 890.5525, to read as follows:

§ 890.5525 Iontophoresis device.

(a) Iontophoresis device for the diagnosis of cystic fibrosis:

- (1) *Identification.* An iontophoresis device for the diagnosis of cystic fibrosis is a device that induces sweating by the introduction of pilocarpine through the use of a direct current. The sweat is collected and its composition and weight are used in the diagnosis of cystic fibrosis.

(2) *Classification.* Class II (performance standards).

(b) Iontophoresis device for dental application of fluoride:

(1) *Identification.* An Iontophoresis device for dental application of fluoride is a device used to accelerate introduction (diffusion) of fluoride ions into tooth structures to reduce hypersensitivity and for fluoride uptake in cavity prevention.

(2) *Classification.* Class II (performance standards).

(c) Iontophoresis device for the local anesthetizing of the intact tympanic membrane:

(1) *Identification.* An Iontophoresis device for the local anesthetizing of the intact tympanic membrane is a device used to induce ions of lidocaine and epinephrine into the tympanic membrane of the ear to cause an anesthetizing effect.

(2) *Classification.* Class II (performance standards).

(d) Iontophoresis device for all other purposes:

(1) *Identification.* An Iontophoresis device is a device used to introduce ions of soluble salts (i.e., medications), by use of a direct current, into the tissues of the body for therapeutic or diagnostic purposes.

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

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28325 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1250]

Medical Devices; Classification of Powered External Limb Overload Warning Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered external limb overload warning devices into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered external limb overload warning devices:

1. A powered external limb overload warning device is a device used to warn a patient of an overload or an underload in the amount of pressure placed on a leg.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered external limb overload warning devices be classified into class II because the Panel believes that a standard is necessary to control the electrical properties of this device to avoid the potential hazard of electrical shock. The Panel recommends that the load measurement accuracy and limitations of this device should be clearly specified by the manufacturers in the device labeling. The Panel believes that general controls would not provide sufficient control over these

characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with this device, on their personal knowledge of, and familiarity with, the device, and on a review of the pertinent literature (Ref. 1). Warren and Lehmann (Ref. 1) state that "adequate accuracy in limb loading was achieved when the target for limb loading was set at 30% of the body weight." However, when the target loading was increased to 70 percent of body weight, accuracy was reduced. Load overshoots can occur with the use of this device.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Injury to lower limb: Load control adjustment inaccuracy regarding the set weight or load limit could result in injury to the lower limb.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered external limb overload warning devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Warren, C. G. and J. F. Lehmann, "Auditory Feedback from Limb and Crutch Use to Control Weight Bearing During Ambulation," Archives of Physical Medicine and Rehabilitation, 56:567, December 1975.

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 him (21 CFR 5.1), the Commissioner proposes to amend Part 890 in Subpart F by adding new § 890.5575, to read as follows:

§ 890.5575 Powered external limb overload warning device.

(a) *Identification.* A powered external limb overload warning device is a device used 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).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26326 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1251]

Medical Devices; Classification of Powered Inflatable Tube Massagers

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered inflatable tube massagers into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inflatable tube massagers:

1. Identification: A powered inflatable tube massager is a powered device used to relieve minor muscle aches and pains. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that inflatable tube massagers be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with this device and the Panel members' personal knowledge of, and familiarity with, the device.

5. Risks to health: Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that inflatable tube massagers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5650, to read as follows:

§ 890.5650 Powered inflatable tube massager.

(a) *Identification.* A powered inflatable tube massager is a powered device used to relieve minor muscle aches and pains. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26327 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1252]

Medical Devices; Classification of Physical Therapy Muscle Relaxers

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physical therapy muscle relaxers, whether powered by alternating current (AC) or battery powered, into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II if powered by alternating current and into class I (general controls) if battery powered. 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 I is to require that the device meet only the general controls applicable to all devices. After considering public

comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of physical therapy muscle relaxers:

1. Identification: A physical therapy muscle relaxer is a motorized device used to relieve minor muscle aches and pains. This generic type of device was reviewed by the Panel under the name "powered massager."

2. Recommended classification: Class II (performance standards) if the device is powered by alternating current (AC), class I (general controls) if the device is powered by a battery. The Panel recommends that establishing a performance standard for the AC-powered device be a low priority and that there be no exemptions for the battery-powered device.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered physical therapy muscle relaxers be classified into class II because the Panel believes that the electrical properties of the device must be controlled to prevent potential shock and burn hazards to the patient or user. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that battery-powered physical therapy muscle relaxers be classified into class I because the Panel believes that the risks of electrical shock and burns are minimal with battery-powered devices, and that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with the AC-powered device.

5. Risks to health: The Panel identified the following risk to health for AC-powered physical therapy muscle relaxers: Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. The Panel identified no risks to health for battery-powered physical therapy muscle relaxers.

Proposed Classification

FDA has reviewed the Panel recommendation for powered massagers and has concluded that all physical therapy muscle relaxers, whether battery powered or AC powered, should be subject to performance standards. The agency believes that the battery powered device, as well as the AC-powered device, presents a risk of electrical shock injuries. Although there is less risk of electrical shock from a battery-powered device than from an AC-powered device, there is still enough of a risk of electrical shock from the battery-powered device to justify the application of a performance standard. Therefore, the agency is proposing that all physical therapy muscle relaxers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5660, to read as follows:

§ 890.5660 Physical therapy muscle relaxer.

(a) *Identification.* A physical therapy muscle relaxer is a motorized device used to relieve minor muscle aches and pains.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four

copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William R. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-28328 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1253]

Medical Devices; Classification of Cold Packs

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cold packs into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device

Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cold packs:

1. Identification: A cold pack is a device consisting of a compact fabric envelope containing a specially hydrated (chemically combined with water) pliable silicate gel capable of forming to the contour of the body. It is used when cold therapy is indicated for body surfaces.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class I (general controls) because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cold packs be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5700, to read as follows:

§ 890.5700 Cold pack.

(a) *Identification.* A cold pack is a device consisting of a compact fabric envelope containing a specially hydrated (chemically combined with water) pliable silicate gel capable of forming to the contour of the body. It is used when cold therapy is indicated for body surfaces.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing

Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26329 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1254]

Medical Devices; Classification of Hot or Cold Disposable Packs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hot or cold disposable packs into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II, and the General Hospital and Personal Use Device Classification Panel that the device be classified into class I. 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 I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hot or cold disposable packs:

1. Identification: A hot or cold disposable pack is a device consisting of a sealed plastic bag incorporating chemicals that, upon activation, produces heat or cold. It is used when hot or cold therapy is indicated for body surfaces.

2. Recommended classification: The General Hospital Panel recommends that the device be classified into class I (general controls) with no exemptions. The Physical Medicine Device Classification Panel recommends that this device be classified into class II (performance standards), and that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The General Hospital and Personal Use Device Classification Panel recommends that this device be classified into class I because the Panel believes that there are no known risks to health and that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Physical Medicine Device Classification Panel recommends that this device be classified into class II because the Panel believes that the temperatures achieved and chemicals used are critical and must be controlled to prevent injury to tissue and to minimize the hazards associated with toxic chemicals. At the Panel meeting of October 14, 1977 (Ref. 1), the Physical Medicine Device Classification Panel recommended that the device be classified into class III (premarket approval) because the Panel at that time believed that the labeling of most of these devices lacked sufficient information on temperatures achieved, and lacked chemical hazard warnings. However, at the Panel meeting of March 17, 1978, Dr. Margaret Kenrick (Ref. 2) presented guidelines for the labeling of hot and cold disposable packs and recommended that the Panel change its recommended classification to class II. The standard should include labeling requirements for storage, temperatures achieved, and necessary warnings. The Panel reassessed its previous recommendation on this device and recommended that it be classified into class II with the appropriate labeling requirements. The Panel believes that the minimum and maximum temperatures reached when the chemicals are activated should be clearly stated by manufacturers in the device labeling, and also a warning statement for the hazards associated with the chemicals used should be prominently placed on the label. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and

effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The General Hospital and Personal Use Device Classification Panel based its recommendation on chemical toxicity data obtained from one manufacturer whose test results showed that no primary irritation was produced by the hot and cold pack tested, and the chemicals used were classed as nonirritant. The Physical Medicine Device Classification Panel based its recommendation on the hazards associated with this device, a review of labeling from five different manufacturers, and inspection of several commercially available hot and cold disposable packs. The Panel also reviewed an evaluation made by the Emergency Care Research Institute of 10 different manufacturers (Ref. 3). In this study, all hot packs tested reached at least 10° C above the skin pain threshold. Four cold packs obtained temperatures of 5.5° C below the skin-freezing threshold. Smith and Stetson (Ref. 4) state that at "4° C, a local erythema is produced first and then the skin is anesthetized." They also state that "there is a danger of local necrosis or sclerema" when cooling the skin.

5. Risks to health: The Physical Medicine Device Classification Panel identified the following risks to health: (a) Burns and freezing of tissue: Uncontrolled levels and/or duration of temperatures could lead to burns or freezing of tissues. (b) Skin irritation: Leakage of toxic chemical used in the device onto the skin may result in skin irritation.

Proposed Classification

FDA agrees with the General Hospital and Personal Use Device Classification Panel recommendation and is proposing that hot or cold disposable packs be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency disagrees with the Physical Medicine Device Classification Panel recommendation that hot or cold disposable packs be classified into class II (performance standards) because the agency believes that general controls are sufficient to require the needed labeling under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as requested by the Panel. Section 502 of the act requires information under authority of this act to appear on the labeling and that the labeling be prominently placed on the device. The labeling information must include adequate directions for use, adequate warnings against misuse and warnings against unsafe methods or duration of application.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Tenth Meeting of the Physical Medicine Device Classification Panel, October 14, 1977.
2. Summary Minutes of the Eleventh Meeting of the Physical Medicine Device Classification Panel, March 17, 1978.
3. "Evaluation: Hot and Cold Pack," *Health Devices*, Volume 3, No. 6, pp. 135-150, April 1974.
4. Smith, R. M. and J. B. Stetson, "Therapeutic Hypothermia," in "Therapeutic Heat and Cold," 2d Ed., Edited by S. Licht, Waverly Press, Baltimore, MD, pp. 502-537, 1965.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5710, to read as follows:

§ 890.5710 Hot or cold disposable pack.

(a) *Identification.* A hot or cold disposable pack is a device consisting of a sealed plastic bag incorporating chemicals that, upon activation, produces heat or cold. It is used when hot or cold therapy is indicated for body surfaces.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26330 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1255]

Medical Devices; Classification of Water Circulating Hot or Cold Packs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying water circulating hot or cold packs into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of water circulating hot or cold packs:

1. Identification: A water circulating hot or cold pack is a device used on body surfaces for heat or cold therapy that operates by pumping heated or chilled water through a plastic bag.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that water circulating hot or cold packs be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock. The Panel believes that the temperature control should be sufficiently accurate to prevent burning or freezing of tissues. The Panel

believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.

5. Risks to health: (a) Shock: Electrical leakage current due to improper grounding or faulty circuitry could result in electrical shock. (b) Tissue damage: Burning or freezing of tissue could result from a faulty temperature control.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that water circulating hot or cold packs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5720, to read as follows:

§ 890.5720 Water circulating hot or cold pack.

(a) *Identification.* A water circulating hot or cold pack is a device used on body surfaces for heat or cold therapy that operates by pumping heated or chilled water through a plastic bag.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26331 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1256]

Medical Devices; Classification of Moist Heat Packs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying moist heat packs into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of moist heat packs:

1. Identification: A moist heat pack is a device consisting of silica gel in a fabric container used to retain an elevated temperature for moist heat therapy of body surfaces.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class I (general controls) because this is a simple device that presents no undue risks to health when used in a normal manner for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that moist heat packs be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5730, to read as follows:

§ 890.5730 Moist heat pack.

(a) *Identification.* A moist heat pack is a device consisting of silica gel in a fabric container used to retain an elevated temperature for moist heat therapy of body surfaces.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26332 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]**[Docket No. 78N-1257]****Medical Devices; Classification of Powered Heating Pads****AGENCY:** Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered heating pads into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered heating pads:

1. Identification: A powered heating pad is an electrical device used for dry heat therapy of body surfaces. It is capable of maintaining an elevated temperature during use.

2. Recommended classification: Class II (general standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered heating pads be classified into class II because the Panel believes that the

electrical properties of the device must be controlled to prevent the potential hazard of electrical shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and the potential hazards associated with this device.

5. Risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Burns: Skin burns could result from a faulty thermostatic control or improper use of the device.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered heating pads be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5740, to read as follows:

§ 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device used for dry heat therapy of body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the

above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26333 Filed 8-23-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]**[Docket No. 78N-1258]****Medical Devices; Classification of Pressure-Appling Devices****AGENCY:** Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pressure-applying devices into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of the pressure-applying device:

1. Identification: A pressure-applying device is a table with an adjustable overhead weight

attached. In place of the therapist's hands, a weight is placed on the back of a prone patient. It is used to apply continuous pressure to the paravertebral tissues, with the intended purpose of providing muscular relaxation and neuro-inhibition.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the pressure-applying devices be classified into class I because this is a simple device that presents no risks to health or undue hazards when used in a normal manner for the purpose recommended. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and a review of the pertinent literature (Refs. 1 and 2). Waecker and Thomas (Ref. 1) and Waecker et al. (Ref. 2) found that inhibition and facilitation in sympathetic response were produced and were able to be reproduced in "particular subjects."

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pressure-applying devices be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Waecker, H. F. and P. E. Thomas, "The Modification of Sympathetic Activity by Sustained Pressure on Paravertebral Tissues," *Journal of the American Osteopathic Association*, 60:688-699, April 1961.

2. Waecker, H. F., P. E. Thomas, and D. Simpson, "Further Studies on the Influence of Sustained Paravertebral Pressure on Sympathetic Activity," *Journal of the American Osteopathic Association*, 61:677, April 1962.

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 him [21 CFR 5.1], the Commissioner proposes to amend Part 890 in Subpart F by adding new § 890.5765, to read as follows:

§ 890.5765 Pressure-applying device.

(a) *Identification.* A pressure-applying device is a table with an adjustable overhead weight attached. In place of the therapist's hands, a weight is placed

on the back of a prone patient. It is used to apply continuous pressure to the paravertebral tissues, with the intended purpose of providing muscular relaxation and neuro-inhibition.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-28334 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1259]

Medical Devices; Classification of Powered Muscle Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered muscle stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of powered muscle stimulators:

1. *Identification:* A powered muscle stimulator is a motorized device used to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area.

2. *Recommended classification:* Class II (performance standards). The Physical Medicine Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. *Summary of reasons for recommendation:* The Panels recommend that powered muscle stimulators be classified into class II because the Panels believe that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock and to prevent bodily injury. The Physical Medicine Device Classification Panel recommends that the measurement limitations of this device be clearly specified by the manufacturers in the device labeling. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.

5. *Risks to health:* The Physical Medicine and the General and Plastic Surgery Device Classification Panels identified the following risks to health: (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Cardiac arrest: Excessive electrical current passing through the heart could result in cardiac arrest. (c) Inappropriate therapy: Inappropriate therapy

could result from inaccurate measurement function.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that powered muscle stimulators be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5850, to read as follows:

§ 890.5850 Powered muscle stimulator.

(a) *Identification.* A powered muscle stimulator is a motorized device used to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-85, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26335 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1260]

Medical Devices; Classification of Ultrasound and Muscle Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasound and muscle stimulator into class II (performance standards) for applying therapeutic deep heat and muscle stimulation and into class III for all other uses. FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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 provide for each manufacturer to the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-85, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultrasound and muscle stimulators:

1. *Identification:* An ultrasound and muscle stimulator for use in applying therapeutic deep heat and muscle stimulation is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to provide therapeutic deep heat in specific areas of the body, and passes electrical currents through the affected body area to relax muscles. Such tissue heating and muscle stimulation is used as adjunctive therapy for the relief of pain in

selected medical conditions such as muscle spasms and joint contractures.

2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. *Summary of reasons for recommendation:* The Panel recommends that ultrasound and muscle stimulators be classified into class II because the electrical current used to provide ultrasound and muscle stimulation should be controlled to prevent injury. The Panel believes that the measurement limitations in the use of the device should be clearly specified by manufacturers in the device labeling. The Panel also recommends that the device be restricted to use by or under the supervision of a physician. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the Panel members' knowledge of, and experience with, the device, on a review of the pertinent literature (Refs. 1, 2, and 3), and on the potential hazards associated with this device. Lehmann (Ref. 1) states that ultrasound has been found to be of established value in treating joint contractures, muscle spasm, and periarthritis (inflammation of tissue around the joints). He states that ultrasound is a very powerful and effective heating agent but that there are contraindications for use of the device. Ultrasound, if used improperly, can cause cavitation (cellular destruction), resulting in possible irreversible tissue damage. The Panel noted that the Bureau of Radiological Health of FDA has promulgated performance safety standards for ultrasonic therapeutic products (21 CFR 1050.10) and that the Federal Communications Commission has radiofrequency transmitting requirements for medical diathermy that must be met.

5. *Risks to health:* (a) Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock. (b) Burns: High current density over time could cause burns to tissues. (c) Cardiac arrest: Excessive electrical current passing through the heart could lead to cardiac arrest. (d) Inappropriate therapy: Inappropriate therapy could result from inaccurate measurement function. (e) Cavitation (cellular destruction): Inadequate uniform field distribution of ultrasound source, or lack of sufficient external pressure on the device sound head applied to the skin could lead to cavitation in tissues.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultrasound and muscle stimulators be classified into class II (performance standards) for use in delivering therapeutic deep heat and muscle

stimulation. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Like the shortwave diathermy, which is the subject of a proposed classification regulation published elsewhere in this issue of the *Federal Register*, the ultrasound and muscle stimulator is used for therapeutic deep heat. It is also used for additional purposes for which it has not been shown to be safe and effective. Accordingly, although the Panel considered only two related uses for the device—the delivery of therapeutic deep heat and muscle stimulation—the agency believes that the device should be classified with respect to all other intended uses. Therefore, the agency is proposing that ultrasound and muscle stimulator devices be classified into class III (premarket approval) for any use other than delivering therapeutic deep heat and muscle stimulation. The agency believes that the ultrasound component of the ultrasound and muscle stimulator, when it is used for any purpose other than applying therapeutic deep heat and muscle stimulation, presents a potential unreasonable risk of injury without proven benefit to the patient because substantial data and clinical investigations do not exist to support those other claims. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the ultrasound component of the device, when it is used for a purpose other than applying therapeutic deep heat, and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lehmann, J. F., "Diathermy" in "Handbook of Physical Medicine and Rehabilitation," 2d Ed., Edited by Krusen, F. H., P. J. Kottke, and P. M. Ellwood, W. B. Saunders Co., Philadelphia, PA, pp. 297-321, 1971.

2. Rusk, H. A., "Principles of Physical Medicine" in "Rehabilitation Medicine," 4th Ed., Edited by Taylor, E. J., C. V. Mosby Co., St. Louis, MO, pp. 75-80, 1977.

3. Stillwell, G. K., "Clinical Electric Stimulation" in "Therapeutic Electricity and

Ultraviolet Radiation," 2d Ed., Edited by Licht, S., Waverly Press, Inc., Baltimore, MD, pp. 105-148, 1976.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5860, to read as follows:

§ 890.5860 Ultrasound and muscle stimulator.

(a) *Ultrasound and muscle stimulator for use in applying therapeutic deep heat and muscle stimulation*—(1) *Identification.* An ultrasound and muscle stimulator for use in applying therapeutic deep heat and muscle stimulation is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to provide therapeutic deep heat in specific areas of the body, and passes electrical currents through the affected body area to relax muscles. Such tissue heating and muscle stimulation is used as an adjunctive therapy for the relief of pain in selected medical conditions such as muscle spasms and joint contractures.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasound and muscle stimulator for any use other than applying therapeutic deep heat and muscle stimulation*—(1) *Identification.* An ultrasound and muscle stimulator for any use other than applying therapeutic deep heat and muscle stimulation is a device that applies ultrasonic energy at a frequency beyond 20,000 cycles per second to the body and passes electrical currents through the affected body area, for any purpose other than therapeutic deep heat and muscle stimulation for the relief of pain.

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

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 15, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26336 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1261]

Medical Devices; Classification of Multi-Function Physical Therapy Tables

AGENCY: Food and Drug Administration.

ACTION: Proposed Rules.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multi-function physical therapy tables into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of multi-function physical therapy tables:

1. Identification: A multi-function physical therapy table is a device consisting of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy. This generic type of device was reviewed by the Panel under the name "powered vibration, massage, heat, and traction table."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that multi-function physical therapy tables be classified into class II because the Panel believes that a standard is necessary to control the electrical properties of this device to avoid the potential hazard of electrical shock and to prevent burns or tissue injury. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.

5. Risks to health: (a) Electrical shock: Excessive leakage current or a malfunction of the device could result in electrical shock. (b) Burns: Excessive heat from the device could cause thermal burns to the patient. (c) Bodily injury: Soft tissue trauma could result from a malfunction of the traction component.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that multi-function physical therapy tables be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5880, to read as follows:

§ 890.5880 Multi-function physical therapy table.

(a) Identification. A multi-function physical therapy table is a device consisting of a motorized table equipped

to provide patients with head, traction, and muscle relaxation therapy.

(b) Classification. Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26337 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1262]

Medical Devices; Classification of Powered Traction Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered traction equipment into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 303-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of powered traction equipment:

1. Identification: Powered traction equipment consists of devices used in conjunction with belts and harnesses to exert therapeutic tensile (pulling) forces on the body.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that powered traction equipment be classified into class II because the Panel believes that the electrical properties of the devices must be controlled to avoid the potential hazard of electrical shock. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.
5. Risks to health: Electrical shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered traction equipment be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5900, to read as follows:

§ 890.5900 Powered traction equipment.

(a) *Identification.* Powered traction equipment consists of devices used in conjunction with belts and harnesses to exert therapeutic tensile (pulling) forces on the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26338 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1263]

**Medical Devices; Classification of
Traction Accessories**

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying traction accessories into class I (general controls). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying these devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of traction accessories:

1. Identification: Traction accessories are manual devices used with traction equipment to aid in exerting proper tensile (pulling) forces on the body. Examples of traction accessories are pulleys, straps, head halters, and pelvic belts.

2. Recommended classification: Class I (general controls). The Panel recommends that traction accessories be exempt from registration, device listing, and premarket notification regulations under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), records and reports regulations under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulations under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that these devices be classified into class I (general controls) and that the manufacturers of these devices should not be required to comply with registration, records and reports, or good manufacturing practice regulations because they are simple devices that present no undue risks to health when used in a normal manner for the purpose recommended. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, these devices.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that traction accessories be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The

agency disagrees with the Panel recommendation that manufacturers of traction accessories be exempt from registration, device listing, and premarket notification under section 510 of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from compliance with section 510 of the act only upon a finding that compliance is not necessary for the protection of public health. In the case of traction accessories, the agency cannot make the required finding. To protect the public health, the agency needs to require manufacturers of these devices to register and to list their products with FDA so that the agency can identify the firms and products that is regulates and can conduct necessary inspections and investigations concerning safety, effectiveness, adulteration, or misbranding. Premarket notification by these manufacturers assures that FDA learns of new products and of a significant modifications of existing products for which premarket approval is required.

The agency disagrees with the Panel recommendation that manufacturers of traction accessories be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The agency believes that it cannot properly issue exemptions from regulations that have not yet been promulgated. Whenever the agency proposes device regulations that include records and reports requirements, interested persons can submit comments requesting that certain classes of manufacturers be exempt from those requirements, and FDA will issue any exemptions that are appropriate. The agency disagrees with the Panel recommendation that manufacturers of traction accessories be exempt from the good manufacturing practice (GMP) regulation. 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 adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of traction accessories having defects that could cause harm to users.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5925, to read as follows:

§ 890.5925 Traction accessories.

(a) *Identification.* Traction accessories are manual devices used with traction equipment to aid in exerting proper tensile (pulling) forces on the body. Examples of traction accessories are pulleys, straps, head halters, and pelvic belts.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26339 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1264]

Medical Devices; Classification of Chilling Units

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying chilling units into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:**Panel Recommendation**

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chilling units:

1. Identification: A chilling unit is a refrigerative device used to chill and maintain cold packs at a reduced temperature.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that chilling units be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazards of electrical shock and burns to the user. The Panel believes that the temperature control should be sufficiently accurate to avoid freezing of tissues. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.

5. Risks to health: (a) Electrical shock: Excessive leakage current or a malfunction of the device could result in electrical shock. (b) Freezing of tissues: A faulty temperature control could result in freezing of tissues, causing trauma.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that chilling units be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that

there is sufficient information to establish a standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5940, to read as follows:

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device used to chill and maintain cold packs at a reduced temperature.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26340 Filed 8-27-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1265]

Medical Devices; Classification of Powered Heating Units

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered heating units into class II (performance standards). The FDA is also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II. 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. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being

taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered heating units:

1. Identification: A powered heating unit is a device consisting of an encased cabinet containing hot water used to heat and maintain hot packs at an elevated temperature.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that powered heating units be classified into class II because the Panel believes that the electrical properties of the device must be controlled to avoid the potential hazard of electrical shock to the user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and familiarity with, the device and on the potential hazards associated with this device.
5. Risks to health: Electrical shock: Electrical leakage current due to improper grounding or faulty circuitry could result in electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered heating units be classified into

class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5950, to read as follows:

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device consisting of an encased cabinet containing hot water used to heat and maintain hot packs at an elevated temperature.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4065, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26341 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 890]

[Docket No. 78N-1266]

Medical Devices; Classification of Physical Therapy Pulsators

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physical therapy pulsators, whether powered by alternating current or battery powered, into class II (performance standards). The FDA is

also publishing the recommendation of the Physical Medicine Device Classification Panel that the device be classified into class II if powered by alternating current (AC) and classified into class I (general controls) if battery powered. 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 I is to meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by October 29, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Johnnie W. Bailey, Bureau of Medical Devices (HFK-410), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of physical therapy pulsators:

1. Identification: A physical therapy pulsator is a motorized device incorporated in various kinds of pads, that is held in the hand or attached to the hand or to a table to relax muscles and thereby relieve minor aches and pains. This generic type of device was reviewed by the Panel under the name "powered vibrator."

2. Recommended classification: The Panel recommends that this device be classified into class II (performance standards) if powered by alternating current (AC) and that establishing a performance standard for this device be a low priority. The Panel recommends that the device be classified into class I (general controls) with no exemptions, if it is battery powered.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered physical therapy pulsators be classified into class II because the Panel

believes that the electrical properties of the device should be controlled to prevent electrical shock, and the mechanical intensity should be controlled to prevent trauma to tissue. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that battery-powered physical therapy pulsators be classified into class I because the Panel believes that the risk of electrical shock and burns are minimal with battery-powered devices, and that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the AC-powered device and on the Panel members' personal knowledge of, and familiarity with, the AC-powered and battery-powered device.

5. Risks to health: The Panel identified the following risks to health for AC-powered physical therapy pulsators: (a) Electrical shock: Excessive current could result in injury, or a malfunction of the device could result in electrical shock. (b) Trauma to tissues: Excessive mechanical intensity could cause tissue trauma. The Panel identified no risks to health for battery-powered physical therapy pulsators.

Proposed Classification

FDA disagrees with the Panel recommendation that battery-powered physical therapy pulsators be classified into class I (general controls). The agency believes that the risks of electrical shock and tissue trauma exist with battery-powered physical therapy pulsators as well as with AC-powered physical therapy pulsators. The agency is therefore proposing that all physical therapy pulsators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard to provide such assurance.

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 him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 890.5975, to read as follows:

§ 890.5975 Physical therapy pulsator.

(a) *Identification.* A physical therapy pulsator is a motorized device incorporated in various kinds of pads, that is held in the hand or attached to the hand or to a table to relax muscles and thereby relieve minor aches and pains.

(b) *Classification.* Class II (performance standards).

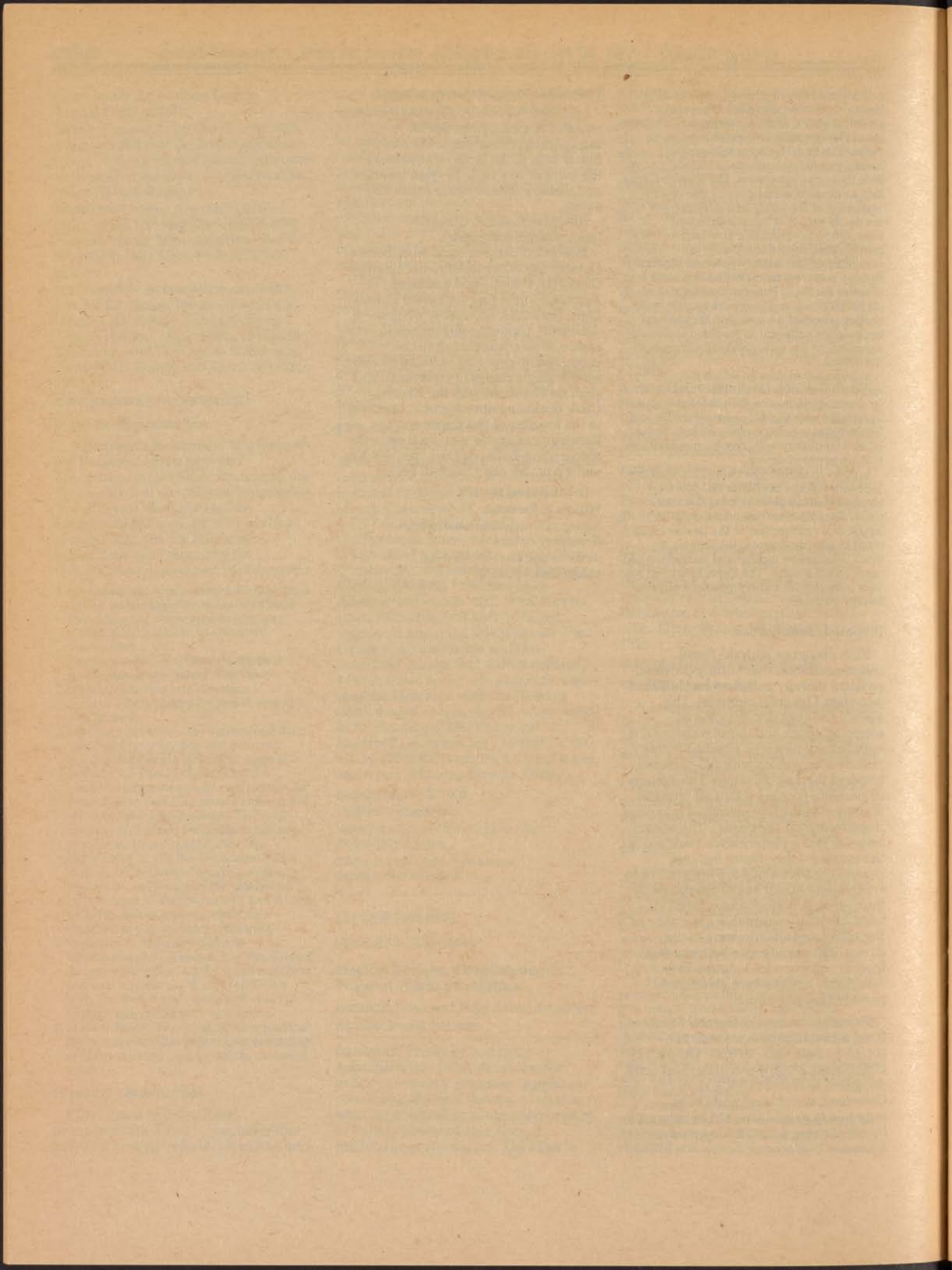
Interested persons may, on or before October 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours at 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 79-26342 Filed 8-27-79; 8:45 am]

BILLING CODE 4110-03-M



United States Department of Justice Federal Register

Tuesday
August 28, 1979

Part III

Merit Systems Protection Board

Equal Employment Opportunity Commission

Discrimination; Interim Rules

MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1200

Interim Regulations for Processing Appealable Actions, Alleging Prohibited Discrimination, Pending Before January 11, 1979

AGENCY: Merit Systems Protection Board.

ACTION: Interim Regulations, request for comments.

SUMMARY: These regulations, published for immediate effect provide interim operating instructions for the processing of certain cases pending before the Merit Systems Protection Board (MSPB) involving allegations of discrimination.

The issuance of preliminary determinations by the board in these cases is authorized by delegation of authority from the EEOC pursuant to Reorganization Plan No. 1 of 1978. In addition the Board requests public comment on these regulations.

DATES: Effective date: August 28, 1979. Comment date: Written comments should be submitted on or before October 29, 1979.

ADDRESS: Comments should be addressed to the Office of the Secretary of the Merit Systems Protection Board, 1717 H Street, N.W., Washington, D.C. 20419.

FOR FURTHER INFORMATION CONTACT: Donald Cox, Deputy General Counsel, Merit Systems Protection Board, Washington, D.C. 20419 (202-653-7157).

SUPPLEMENTARY INFORMATION: On January 1, 1979, certain federal employment enforcement responsibilities, previously vested in the Civil Service Commission under four different statutes, were transferred to the Equal Employment Opportunity Commission (EEOC) pursuant to Reorganization Plan No. 1 of 1978. The enforcement responsibilities transferred were those specified in section 717 of Title VII of the Civil Rights Act of 1964, as amended, section 6(d) of the Fair Labor Standards Act (the Equal Pay Act), section 501 of the Rehabilitation Act of 1973, as amended, and sections 12 and 15 of the Age Discrimination in Employment Act of 1967, as amended. Reorganization Plan No. 1 specifically permitted the EEOC to delegate back to the Civil Service Commission or its successor agency the authority to make preliminary determinations on issues of discrimination prohibited by Section 717 of Title VII of the Civil Rights Act of 1964, as amended, whenever such issues were raised in the course of an appeal

before that agency on other grounds (for example, in an adverse action appeal). The MSPB is the adjudicatory successor to the Civil Service Commission. The EEOC has delegated Title VII authority back to the Board so that the Board may make preliminary decisions on race, color, sex, religion, or national origin issues, when such issues are raised in cases otherwise appealable to the Board. The EEOC has determined that it is within its general powers also to delegate similar authority to the Board to decide age and handicap issues, and has done so. (The Commission did not consider it appropriate to delegate its authority with regard to the Equal Pay Act.) This delegation and accompanying regulations are published elsewhere in this issue of the *Federal Register*.

The regulations of the Board provide for a preliminary determination, on issues of discrimination prohibited by the statutes mentioned above, in any type of case arising before the Board which is covered by the provisions of Reorganization Plan No. 1 of 1978. Basically there are two types of cases which fall within the scope of these regulations. First, there are cases which were previously handled initially by the former Federal Employee Appeals Authority (FEAA) and which were appealable to the former Appeals Review Board (ARB) under the procedures of 5 CFR Part 772 (as in effect prior to January 11, 1979). These organizations were merged into the MSPB. Included in this group are a number of cases which were pending both in the FEAA and the ARB on the effective date of Reorganization Plan No. 1. Second, there are cases previously within the original jurisdiction of the ARB, including those cases arising under 5 CFR Part 713, which involved issues otherwise appealable to the Board.

It should be noted that these regulations are applicable only to those cases pending prior to the effective date of the Civil Service Reform Act of 1978, January 11, 1979 (Pub. L. 95-454). Cases initiated on or after that date will be processed under the new Act and the regulations issued pursuant thereto. That Act establishes a process whereby the Board will render a determination where allegations of discrimination are raised in cases otherwise appealable to the Board ("mixed cases"). Appellants dissatisfied with that determination may then petition the EEOC to review the Board's disposition of these issues. (See Section 205 of the Act, 5 U.S.C. 7702.)

It is the intention of EEOC and MSPB in establishing these regulations and these delegations to process cases

pending before the effective date of the Civil Service Reform Act of 1978 in a manner as consistent as possible with the procedures established by that Act.

Inasmuch as there are presently before the Board a large number of cases to which these regulations and delegations pertain and in view of the fact that many of these cases have been pending for several months, the Commission and the Board recognize that good cause exists to make these regulations immediately effective so that there will be no further delay in case processing.

Issued: August 22, 1979.

By Order of the Board.

Ersa H. Poston,

Vice Chair, Merit Systems Protection Board.

Accordingly, it is proposed Part 1200 be amended to add § 1201.165 as follows:

§ 1201.165 Mixed cases governed by Reorganization Plan No. 1 of 1978.

(a) *Definitions.* (1) *Prohibited discrimination* as used in this section means discrimination prohibited by Section 717 of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e-16(c)); Section 501 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 791); and Sections 12 and 15 of the Age Discrimination in Employment Act of 1967, as amended (29 U.S.C. 631, 633a).

(2) *Initial decision* as used in this section means decision on an appeal rendered by a presiding official of the MSPB pursuant to 29 CFR 1613 or 5 CFR Part 772 (as in effect prior to January 11, 1979) in which issues of prohibited discrimination have been raised.

(3) *Preliminary decision as used in this section means:* (i) An initial decision within the meaning of § 1201.165(a)(2) which has not been reopened by a Board member or as to which no petition to reopen was filed by a party within 35 days after issuance of the decision.

(ii) A decision by the Board itself pursuant to 29 CFR Part 1613 or 5 CFR Part 772, in which issues of prohibited discrimination are addressed, on a decision by the Board denying all petitions to reopen.

(b) *Contents of petition.* A petition for appeal raising issues of prohibited discrimination shall state there was discrimination and provide specific examples of how the appellant was discriminated against.

(c) *Procedures.* (1) Appeals under 29 CFR Part 1613 (43 FR 60901, formerly 5 CFR Part 713) shall be processed by the Board consistent with the provisions set forth in that part. Such appeals shall be

filed in writing with the appropriate Board Field Office.

(2) Appeals under the procedures of 5 CFR Part 772, shall be processed as provided therein, except that under 5 CFR 772.306(b) the discrimination investigation shall be completed and the investigative file and report sent to the Board, within 120 days. Except when this time has been extended upon a verified showing of good cause, the Board may impose the sanctions provided in 5 CFR 1201.43 if an agency fails to timely complete and file the result of such an investigation.

(3) An initial decision on an appeal which includes issues of prohibited personnel discrimination shall be rendered by an employee of the Board, pursuant to 29 CFR 1613 or 5 CFR Part 772, on all issues raised in the appeal.

(4) Unless a petition to reopen is filed with the Board or unless a Board member reopens on his/her own motion, within 35 days from issuance of an initial decision, the initial decision shall become the preliminary decision of the Board.

(d) *Review by EEOC.* (1) *Time for filing.* A petition to review the preliminary decision of the Board on issues of prohibited discrimination shall be filed with the EEOC within 35 days after the initial decision of the Board becomes the preliminary decision.

(2) *Petition filed.* In the event a petition for review is filed with the EEOC, the Board decision shall become final on all issues, other than issues of prohibited discrimination, on the date EEOC's decision on these issues becomes final.

(3) *Petition not filed.* If a petition for review is not filed with the EEOC the decision of the Board shall become final on all issues.

(5 U.S.C. 1205(g))

[FR Doc. 79-26539 Filed 8-27-79; 8:45 am]

BILLING CODE 6325-20-M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1613

Interim Regulations for Processing Appealable Actions, Alleging Prohibited Discrimination, Pending on or Before January 10, 1979

AGENCY: Equal Employment Opportunity Commission.

ACTION: Interim Regulations; request for comments.

SUMMARY: These regulations, published for immediate effect, provide delegations of authority to the Merit

Systems Protection Board to issue preliminary determinations in certain federal EEO cases governed by Reorganization Plan No. 1 of 1978, and temporary operating instructions for the further processing of such cases by EEOC. In addition the Commission requests public comment on these regulations.

DATES: Effective date: August 28, 1979. Comment date: Written comments should be submitted on or before October 29, 1979.

ADDRESS: Comments should be addressed to the Office of the Executive Secretariat, Room 4096, Equal Employment Opportunity Commission, 2401 E Street, Northwest, Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Constance L. Dupre, Associate General Counsel, Legal Counsel Division, Office of the General Counsel, Room 2254, EEOC, 2401 E Street, Northwest, Washington, D.C. 20506, (202) 634-6595.

SUPPLEMENTARY INFORMATION: On January 1, 1979, certain federal equal employment enforcement responsibilities, previously vested in the Civil Service Commission under four different statutes, were transferred to the Equal Employment Opportunity Commission (EEOC) pursuant to Reorganization Plan No. 1 of 1978. The enforcement responsibilities transferred were those specified in Section 717 of Title VII of the Civil Rights Act of 1964, as amended, Section 8(d) of the Fair Labor Standards Act, as amended (the Equal Pay Act), Section 501 of the Rehabilitation Act of 1973 and Sections 12 and 15 of the Age Discrimination in Employment Act of 1967 as amended. Reorganization Plan No. 1 specifically permitted the EEOC to delegate back to the Civil Service Commission or its successor agency the authority to make a preliminary determination on issues of discrimination prohibited by Section 717 of Title VII of the Civil Rights Act of 1964, whenever such issues were raised before that agency in the course of an appeal on other grounds (for example, in an adverse action appeal). The Merit Systems Protection Board (the Board) is the adjudicatory successor to the Civil Service Commission. The EEOC has delegated Title VII authority back to the Board so that the Board may make preliminary decisions on issues of race, color, sex, religion, or national origin, when such issues are raised in appeals otherwise before the Board. The EEOC has determined that it is within its general powers also to delegate similar authority to the Board to decide age and handicap issues, and has done so. (The Commission did not consider it

appropriate to delegate its authority with regard to the Equal Pay Act.) Its regulations to this effect are published below. The complementary regulations of the Board are published elsewhere in this issue of the Federal Register.

It should be noted that these regulations are applicable only to those cases pending before January 11, 1979, the effective date of the Civil Service Reform Act of 1978, Pub. L. 95-454. That Act establishes a process whereby the Board will render a determination where allegations of discrimination are raised in cases before it and dissatisfied appellants can then petition the Equal Employment Opportunity Commission to review the Board's disposition of those issues. See Section 205 of the Act, codified in pertinent part at 5 U.S.C. 7702. It was the intention of the EEOC and the Board in establishing these regulations and these delegations to process cases pending before the effective date of the Civil Service Reform Act of 1978 in a manner as consistent as possible with the procedures established by that Act.

Inasmuch as there are presently pending before the Board a large number of cases to which these regulations and delegations pertain, and in view of the fact that many of these cases have been pending for several months, the Commission and the Board recognize that good cause exists to make these regulations immediately effective so that there will be no further delay in case processing.

These regulations have been reviewed in accordance with Executive Order 12044. They do not require regulatory analysis under Section 3 of that Order.

Issued on August 21, 1979.

For the Commission.

Eleanor Holmes Norton,
Chair.

Therefore, Part 1613 of Title 20 of the Code of Federal Regulations is amended by adding a new Subpart H to read as follows:

Subpart H—Regulations for Processing Appealable Actions, Alleging Prohibited Discrimination, Pending on or Before January 10, 1979

Sec.	
1613.801	Scope.
1613.802	Definitions.
1613.803	Election.
1613.804	Election of Part 1613.
1613.805	Election of Part 772.
1613.806	Petition to EEOC; finality of decisions.

Authority: 42 U.S.C. 2000e-16; 29 U.S.C. 633a; 29 U.S.C. 791; Reorganization Plan No. 1 of 1978.

Subpart H—Regulations for Processing Appealable Actions, Alleging Prohibited Discrimination, Pending on or Before January 10, 1979

§ 1613.801 Scope.

This subpart establishes regulations for the processing of an allegation that an action otherwise appealable to the Merit Systems Protection Board (the Board) was based in whole or in part on discrimination because of race, color, religion, sex, national origin, age, or handicap. This subpart applies only to administrative procedures pending before January 11, 1979, to which Section 205 of the Civil Service Reform Act of 1978, 5 U.S.C. 7702, is inapplicable.

§ 1613.802 Definitions.

(a) As used in this section, the term "prohibited discrimination" means discrimination prohibited by Section 717 of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e-16); Section 501 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 791); and Sections 12 and 15 of the Age Discrimination in Employment Act of 1967, as amended (29 U.S.C. 631 and 633a).

(b) As used in this section, the term "initial decision" means a decision on an appeal, rendered by a presiding official of the Board pursuant to 29 CFR Part 1613 or 5 CFR Part 772 (as in effect prior to January 11, 1979), in which issues of prohibited discrimination have been raised.

(c) As used in this section, the term "preliminary decision" means (1) an initial decision within the meaning of § 1613.802(b), which has not been reopened by a Board member or as to which no petition to reopen was filed by a party within 35 days after issuance of the decision; or (2) a decision by the Board itself pursuant to 29 CFR Part 1613 or 5 CFR Part 772 (as in effect prior to January 11, 1979), in which issues of prohibited discrimination are addressed, or a decision by the Board denying all petitions to reopen.

§ 1613.803 Election.

An appellant who alleges that an action otherwise appealable to the Board was based in whole or in part on prohibited discrimination shall elect to proceed under 29 CFR Part 1613 (43 FR 60901, formerly 5 CFR 713) or under 5 CFR Part 772 (as in effect prior to January 11, 1979). This section is applicable only to persons who had not previously made an election under regulations of the former Civil Service Commission.

§ 1613.804 Election of Part 1613.

(a) When an appellant elects or has elected to proceed under 29 CFR Part 1613 (43 FR 60901, formerly 5 CFR Part 713) the provisions of Part 1613 are applicable to that proceeding.

(b) The Commission hereby delegates to the Merit Systems Protection Board the authority to make initial and preliminary decisions on issues of prohibited discrimination in appeals from final agency decisions under 29 CFR Part 1613 (43 FR 60901, formerly 5 CFR Part 713).

§ 1613.805 Election of Part 772.

(a) When a complainant elects or has elected to proceed under 5 CFR Part 772, the allegations of discrimination shall be referred to the EEO Officer of the agency for investigation in accordance with 29 CFR 1613.216 (43 FR 60901, formerly 5 CFR 713.216).

(b) The Commission hereby delegates to the Merit Systems Protection Board the authority to make initial and preliminary decisions on issues of prohibited discrimination in appeals from final agency decisions under 5 CFR Part 772.

§ 1613.806 Petition to EEOC; finality of decisions.

(a) A petition to review the preliminary decision of the Board shall be filed in writing with the Office of Review and Appeals, EEOC, 2401 E Street, N.W., Washington, D.C. 20506 (1) within 35 days after the initial decision of the Board becomes a preliminary decision (as contemplated in § 1613.802(c)(1)) or (2) within 35 days after the issuance of a preliminary decision by the Board.

(b) A decision of the EEOC on a petition to review the preliminary decision of the Board shall be final when issued.

(c) If a petition to review is not timely filed with the EEOC, the preliminary decision of the Board shall become final on all issues on the day after the expiration of the 35-day period for filing with EEOC, unless the EEOC chooses to exercise its discretion under the standards of 29 CFR 1613.233(b) and accept the late petition.

[FR Doc. 79-26540 Filed 8-27-79; 8:45 am]

BILLING CODE 6570-06-M

Federal Register

Tuesday
August 28, 1979

Part IV

Department of the Interior

Fish and Wildlife Service

Final Frameworks for Late Season
Migratory Bird Hunting

DEPARTMENT OF THE INTERIOR

50 CFR Part 20

Final Frameworks for Late Season Migratory Bird Hunting Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes final frameworks, that is, the outer limits for dates and times when shooting may begin and end, and the numbers of birds which may be taken and possessed under late season migratory bird hunting regulations for the 1979-80 season. These seasons commence on or after September 29, 1979, and include most of those for waterfowl. The Service annually prescribes hunting regulations frameworks to the States. The effects of this final rule are to facilitate the selection of hunting seasons by the States and to establish late season migratory bird hunting regulations for the 1979-80 season.

EFFECTIVE DATE: August 29, 1979.

FOR FURTHER INFORMATION CONTACT: John P. Rogers, Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240, telephone 202-254-3207.

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 703 et seq.), as amended, authorizes and directs the Secretary of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds to determine when, to what extent, and by what means such birds or any part, nest, or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported, or transported.

In the annual process for developing migratory game bird hunting regulations, "early" seasons are separated from "late" seasons. Early seasons are those which may open before September 29 while late seasons open on or after September 29. Regulations are developed independently for early and late seasons. The early season regulations cover mourning doves, white-winged doves, band-tailed pigeons, rails, gallinules, woodcock, common snipe, sea ducks in the Atlantic Flyway, teal in September in the Central and Mississippi Flyways, sandhill cranes in North and South Dakota, an early duck season opening in Iowa, doves in the Virgin Islands and Hawaii,

all migratory game birds in Puerto Rico and Alaska, and some extended falconry seasons. Late seasons include the general waterfowl seasons; special seasons for scaup and goldeneyes; extra scaup and teal in regular seasons; most sandhill crane seasons in the Central Flyway; coots, gallinules, and snipe in the Pacific Flyway; and other special falconry seasons.

Certain general procedures are followed in developing regulations for both the early and the late seasons. Initial regulatory proposals are first announced in mid-February, and opened to public comment. As additional information becomes available, and comments are received and considered to the initial proposals, supplemental proposed rulemakings are announced in the *Federal Register*. At the termination of the comment periods and following a public hearing, the Service develops and publishes the proposed frameworks for times of seasons, season lengths, shooting hours, daily bag and possession limits, and other regulatory restraints or options. Following another public comment period, and after consideration of additional comments, the Service publishes in the *Federal Register* the final frameworks. Using these frameworks, State conservation agencies select hunting season dates and offered options. States may select more restrictive seasons, limits, and options than those offered in the Service's frameworks. The final regulations, reflected in amendments to Subpart K of 50 CFR 20 then appear in the *Federal Register*, and become effective upon publication.

This year the process was implemented as follows. On February 15, 1979, the Service published for public comment in the *Federal Register* (44 FR 9928) proposals to amend 50 CFR 20, with a comment period ending May 16, 1979. That document dealt with the establishment of seasons, limits and shooting hours for migratory birds under §§ 20.101 through 20.107 of Subpart K. On June 13, 1979, the Service published for public comment in the *Federal Register* (44 FR 34082) the second document in the series consisting of a supplemental proposed rulemaking dealing specifically with a number of supplemental or modified proposals arising from comments received on the initial proposals, or from new information.

On June 21, 1979, a public hearing was held in Washington, D.C., to review the status of mourning doves, woodcock, band-tailed pigeons, white-winged doves, and sandhill cranes. The meeting was announced in the *Federal Register*

on February 15, 1979 (44 FR 9928) and June 13, 1979 (44 FR 34082). Proposed hunting regulations for these species were discussed plus those for common snipe; rails; gallinules; migratory game birds in Alaska, Puerto Rico, and the Virgin Islands; mourning doves in Hawaii; September teal seasons in the Mississippi and Central Flyways; and early duck season in Iowa; special sea duck seasons in the Atlantic Flyway; and falconry seasons. Statements or comments were invited.

On June 28, 1979, the Service also published for public comment in the *Federal Register* (44 FR 37857) the third document in the series consisting of supplemental proposed rulemaking dealing specifically with proposed frameworks for early season migratory bird hunting regulations from which, when finalized, States may select season dates, shooting hours, and daily bag and possession limits for the 1979-80 season. On June 28, 1979, the Service published in the *Federal Register* (44 FR 37854) the fourth document in the series of proposed and final rulemakings dealing specifically with final frameworks for the 1979-80 season from which wildlife conservation agency officials in Alaska, Puerto Rico, and the Virgin Islands could select season dates for hunting certain migratory birds in their respective jurisdictions during the 1979-80 season. On July 24, 1979, the Service published in the *Federal Register* (44 FR 43420) the fifth document in the series of proposed and final rulemakings dealing specifically with final frameworks for early season migratory game bird hunting regulations from which State wildlife conservation agency officials selected season dates and daily bag and possession limits for the 1979-80 early season.

On August 2, 1979, a public hearing was held in Washington, D.C., as announced in the *Federal Register* on February 15, 1979 (44 FR 9928) and June 13, 1979 (44 FR 34082) to review information on population status and proposed hunting regulations for waterfowl, coots, and gallinules; sandhill cranes in Colorado, New Mexico, Oklahoma, Texas, Montana and Wyoming; common snipe in the Pacific Flyway; and special falconry regulations. Statements or comments were invited.

On August 8, 1979, the Service published in the *Federal Register* (44 FR 46462) the sixth document in the series of proposed and final rulemakings dealing specifically with a correction to the final frameworks published on July 24, 1979 (44 FR 43420) to include in the final frameworks a page of text

inadvertently omitted from that document.

On August 10, 1979, the Service published for comment in the *Federal Register* (44 FR 47246) the seventh document in the series of proposed and final rulemakings dealing specifically with proposed regulations frameworks for 1979-80 late hunting seasons on certain migratory game birds. On August 20, 1979, the Service published in the *Federal Register* (44 FR 48846) the eighth document in the series of proposed and final rulemakings dealing specifically with amending Subpart K of 50 CFR 20 to set open hunting seasons, certain closed areas, shooting and hawking hours and bag and possession limits for mourning doves, white-winged doves, band-tailed pigeons, rails, woodcock, snipe, and gallinules; September teal seasons; sea ducks in certain defined areas of the Atlantic Flyway; ducks in late September in Iowa; sandhill cranes in designated portions of North Dakota and South Dakota; and migratory game birds in Alaska, Hawaii, Puerto Rico, and the Virgin Islands.

This final rulemaking document is the ninth in the series of proposed, supplemental, and final rulemakings for migratory game bird hunting regulations and deals specifically with final regulations frameworks for 1979-80 late hunting seasons on certain migratory game birds.

These final frameworks also reflect clarifications or corrections to the frameworks which were proposed in the *Federal Register* (44 FR 47246) dated August 10, 1979. These include: a restoration of the goose bag and possession limits in the Lac Qui Parle quota area of Minnesota to those effective during the 1978-79 season, clarification of the canvasback limits in North and South Dakota, and a minor change in the description of waterfowl zones in Massachusetts.

Review of Public Comments and the Service's Response

Various public comments on the proposed late season regulations have been considered during the regulatory development period. The Service replied to public comments on regulations proposed in the *Federal Register* (44 FR 9928) dated February 15, 1979, in the *Federal Register* (44 FR 34082) dated June 13, 1979. Subsequent public comments, including those made at the public hearing held in Washington, D.C., on August 2, 1979, were considered, and responded to in the *Federal Register* (44 FR 47246) dated August 10, 1979, which dealt with proposed frameworks for late season migratory bird hunting. That publication advised that additional

public comments on proposed late season frameworks would be considered through August 20, 1979.

Thirteen additional public comments were received by the Service through August 20, 1979. These originated from 3 Flyway Councils (one submitted two comments), 5 States, 2 sportsmen's clubs, a national conservation organization, and a law institute. The comments from the Atlantic, Mississippi, and Central Flyway Councils were received prior to the public hearing on proposed waterfowl regulations held in Washington, D.C., on August 2, 1979. They were again presented by the Councils at the public hearing. Most of the Councils' recommendations were responded to in the *Federal Register* (44 FR 47246) dated August 10, 1979, and are reflected in the final frameworks. Those recommendations which were not accepted by the Service were discussed in that or prior issues of the *Federal Register*.

The State conservation agencies of Arkansas and Missouri recommended regulatory wording designed to alleviate confusion about the waterfowl season applicable on the St. Francis River, which separates the two States. The boundary is poorly defined, and different hunting seasons are usually selected by Arkansas and Missouri. The two State agencies jointly recommended that the problem area be defined for regulatory purposes, and that the waterfowl season selected by Missouri also apply to the Arkansas portion of the St. Francis River.

Response. The Service concurs with the recommendations. The final frameworks define the area and provide that the waterfowl seasons selected by Missouri shall also apply to the defined Arkansas portion of the river.

Wisconsin opposed the proposal that the opening framework date for waterfowl seasons in the Upper Region of the Mississippi Flyway coincide with the Saturday closest to October 1. Wisconsin considers Saturday waterfowl season openings undesirable because of the heavy hunting pressure placed on local waterfowl and because of crowded hunting conditions. The State recommended that the option be offered only to States interested in the option, and that the change be on an experimental basis.

Response. The Service notes that the proposal was requested by the Upper Region of the Mississippi Flyway Council. States are not obligated to select Saturday opening dates if local situations favor other opening days.

A sportsmen's club in Mississippi urged that the hunting of Canada geese

at Sardis Lake (Reservoir) not be prohibited this year as the Service has proposed.

Response. Canada geese which winter at Sardis Lake are part of the Mississippi Valley Population (MVP) which once wintered in southern parts of the Mississippi Flyway. Both the Service and the Mississippi Flyway Council believe it is desirable that MVP geese be encouraged to reoccupy former wintering areas in the southern part of the Mississippi Flyway. This is an objective of a management plan for MVP geese which has been approved by the Service and the Mississippi Flyway Council. As part of a cooperative effort to meet this objective, hunting of Canada geese is being suspended this season in Arkansas, Louisiana, Mississippi, and southwestern Tennessee. It is believed important that complete protection be given to the remnant flocks of Canada geese which still winter in southern areas such as Sardis Reservoir.

A Michigan duck hunters' association recommended that the waterfowl season in Zones 2 and 3 of Michigan open on October 17, 1979.

Response. The Service establishes frameworks, or time periods, within which State conservation agencies may select hunting season dates. The selection of specific hunting dates within the framework is a State prerogative.

On August 20, 1979, the Institute for Public Representation (IPR), Georgetown University Law Center, Washington, D.C., submitted a comment on behalf of Defenders of Wildlife (Defenders). The comment asserted that consultations and communications between the Service and the four flyway councils during preparation of the hunting regulations were contrary to the Federal Advisory Committee Act, 5 U.S.C., App. I, and to several court decisions related to *ex parte* communications in informal rulemaking. Similar comments had been submitted by IPR on behalf of Defenders on May 16, 1979, and by Defenders themselves on January 17, 1979.

The Department's Associate Solicitor for Conservation and Wildlife responded to these assertions in a letter to Defenders dated May 7, 1979. This letter was published by the Service in the *Federal Register* of June 13, 1979 (44 FR 34082). The Associate Solicitor concluded that the flyway councils are not functioning as advisory committees and that the Service's contacts with the councils are in compliance with the requirements applicable to *ex parte* communications during informal rulemaking.

The advisory committee and *ex parte* questions were discussed again in a meeting held on August 20, 1979, between the Associate Solicitor and representatives from IPR and Defenders. A memorandum of this meeting has been placed in the public file for these regulations. At the meeting, the Associate Solicitor pointed out that procedural subjects such as advisory committee and *ex parte* communications might be dealt with more effectively in a rulemaking proceeding that is separate from the present proceedings being utilized to develop the substantive content of the hunting regulations. The Associate Solicitor then suggested that Defenders and IPR might wish to petition the Service for the issuance of such procedural rules. The Service agrees with the Associate Solicitor's suggestion.

A comment was received from Defenders of Wildlife (Defenders) contending that black duck regulations were inconsistent with the status of the species based on winter counts and harvest levels. Defenders also contended that the limited data concerning breeding populations suggested a downward trend, and that information was lacking to support status quo regulations.

Response. The winter survey population index for black ducks shows a gradual but steady decline. However, the contention that this decline is related directly to hunting regulations and to the size of the black duck harvest is doubtful. Many factors, such as the unusually severe winters which occurred along the Atlantic Coast the past three years, affect black duck harvests, food availability, and distribution. Data in Service files show no correlation between size of black duck harvests and the subsequent winter survey index. The 1978-79 U.S. black duck harvest (343,000) increased 20 percent over the previous year, but was 14 percent below the average harvest (400,000) of the past 11 years. The 1978-79 harvest was slightly below the average harvest of the previous 4 seasons, a period of stable regulations for black duck daily bag and possession limits and season lengths. Harvests during this 4-year period ranged from a low of 281,000 to a high of 430,000, strongly suggesting that factors other than hunting regulations were affecting harvest size. The best and most voluminous waterfowl banding and harvest data available are for the mallard, the species most closely allied with the black duck. Recent studies by Anderson and Burnham (1975), based on an analysis of 700,000 mallard bandings,

failed to demonstrate a direct relationship between harvest levels and population survival rates. Defenders' implication that this relationship exists for black ducks as shown by winter survey indices is unsupported by available data.

Defenders expressed concern about breeding population data derived from surveys in Nova Scotia and New Brunswick. While the 1979 population was lower than the previous year, it equaled or exceeded the average population for the previous 5-year period, and populations measured in the late 1950's and the early 1960's. This suggests that the breeding population in this portion of Maritime Canada is maintaining itself at a satisfactory level.

Defenders contends that data upon which to base a continuation of status quo regulations are inadequate, and were unavailable to them until late in the comment period. The Service is attempting to evaluate changes in black duck hunting regulations according to the plan detailed in an Environmental Assessment titled "Proposed Hunting Regulations on Black Ducks." A 4-year period of stabilized black duck hunting regulations is being conducted in conjunction with a major banding study to evaluate harvest rates and related matters of importance in managing the continental black duck population. Availability of an environmental assessment outlining this study was announced in the *Federal Register* dated July 8, 1976, at page 27987.

Twenty-two States, 5 Provinces, the Canadian Wildlife Service, and the U.S. Fish and Wildlife Service are participating in the banding program. Over 25,000 bands have been placed on black ducks to date. The introduction of different regulations for black ducks at this time would negate much of the effort by these agencies to acquire better information upon which to base future black duck management plans, including regulatory measures. Based on data from previous years, there is no reason to believe that continuing this study to its completion will either jeopardize or adversely affect the black duck.

Virginia reiterated the Atlantic Flyway Council's request for a 15-day subseason during which a daily bag of 4 drake canvasbacks could be taken in "traditional" canvasback hunting areas of Delaware, Maryland, New Jersey, New York, North Carolina, and Virginia.

Response. The Service considered proposal for a special canvasback season in the Atlantic Flyway and responded in the *Federal Register* dated February 15 (44 FR 9928), June 13 (44 FR 34082), and August 10 (44 FR 47246), 1979. The Service notes that population

objectives and harvest management strategies for the canvasback are guided by an Environmental Assessment titled "Proposed Hunting Regulation on Canvasback and Redhead Ducks," issued in August 1976. A special subseason for canvasbacks is not among the strategies listed in the EA. However, in the light of additional information accumulated since the EA was prepared, the Service believes it desirable to reassess population objectives and management strategies for canvasbacks, and intends to do so prior to the 1980-81 season. Part of this reassessment will involve evaluation of data from a canvasback banding program currently underway in the Maryland portion of Chesapeake Bay. In reviewing the Atlantic Flyway Council proposal, note was made of the need for more detailed planning to evaluate effects of the proposed subseason. Recognizing that a proposal for an experimental season must meet requirements of the National Environmental Policy Act and the Administrative Procedure Act, the Service reiterates its willingness to consider an experimental season in traditional hunting areas. Prior to the 1980-81 season, further consideration will be given to canvasback harvest regulations proposals that are supportive of an updated canvasback-redhead environmental assessment.

Steel Shot Regulations

Non-toxic shot requirements in some geographical areas apply to waterfowl regulations being finalized here. On July 17, 1979, the Service published in the *Federal Register* (44 FR 41461) final regulations regarding zones in all flyways in which shotshells loaded with steel shot will be required for waterfowl hunting in seasons commencing in 1979. Minor corrections to the final regulations appeared in the *Federal Register* dated August 10, 1979 (44 FR 47093). The intended effect of establishing these steel shot regulations is to reduce the number of waterfowl deaths caused by ingesting spent lead pellets.

The regulations appear under 50 CFR, §§ 20.21 and 20.108, and will also be summarized in the Service's regulations leaflets to be published late this summer.

NEPA Consideration

The "Final Environmental Statement for the Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FES 75-54)" was filed with the Council on Environmental Quality on June 6, 1975, and notice of availability was published in the *Federal Register* on June 13, 1975 (40

CFR 25241). A number of environmental assessments have been issued by the Service to supplement the above FES. Shooting hours, dove hunting in September, black ducks, canvasbacks and redheads, Atlantic Flyway brant, and greater snow geese are among the subjects of these assessments. The 1975 FES is now out of print but copies of the environmental assessments are available from the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240.

Endangered Species Act Consideration

Section 7 of this act provides that, "The Secretary shall review other programs administered by him and utilized such programs in furtherance of the purposes of this Act," and "by taking such action necessary to insure that actions authorized, funded, or carried out * * * do not jeopardize the continued existence of such endangered or threatened species or result in the destruction or modification of habitat of such species * * * which is determined to be critical."

As in the past, hunting regulations this year are designed, among other things, to remove or alleviate chances of conflict between seasons for migratory game birds and the protection and conservation of endangered and threatened species.

The Service reviewed all migratory bird regulations frameworks being contemplated this year for the early seasons (season lengths, limits, shooting hours, and outside dates) within which States may select seasons for mourning doves, white-winged doves, band-tailed pigeons, rails, woodcock, snipe, and gallinules; for September teal seasons (including the extra teal option during regular seasons), for sea ducks in certain defined areas of the Atlantic Flyway; for a portion of the regular duck season in Iowa to be taken in late September; for sandhill cranes in designated portions of North Dakota and South Dakota; and special falconry regulations. As a result of intra-Service Section 7 consultation, Acting Director Robert S. Cook concluded in a biological opinion dated July 9, 1979, that the proposed 1979-80 early season migratory bird hunting regulations are not likely to jeopardize the continued existence of the five Endangered species considered, or destroy or adversely modify their Critical Habitat or habitat that might be determined critical in the future. Several actions were recommended as means for furthering the conservation of listed species.

The proposed late season regulatory frameworks were likewise subjected to

careful study to insure that they complied with section 7 of the Endangered Species Act. Special attention was given the Aleutian Canada goose (*Branta canadensis leucopareia*), Everglade kite (*Rostrhamus sociabilis plumbeus*), whooping crane (*Grus americanus*), bald eagle (*Haliaeetus leucocephalus*), and peregrine falcon (*Falco peregrinus*). A biological opinion reviewed and evaluated the population and habitat status and trends of these endangered species; factors affecting their status and welfare; management programs underway or planned to enhance the status of the species; and the impacts, if any, of the proposed late season hunting regulations. On August 21, 1979, Director Lynn A. Greenwalt concluded:

"Based on all the information available to me, it is my biological opinion that the migratory bird late hunting seasons are not likely to jeopardize the continued existence of the above listed species or result in destruction or adverse modification of any designated Critical Habitat."

The Service's biological opinion resulting from its consultation under Section 7 is considered a public document and is available for inspection in the Office of Endangered Species and the Office of Migratory Bird Management, Department of the Interior, Washington, D.C. 20240. Copies may also be supplied by mail upon request.

Authorship

The primary author of this final rule is Henry M. Reeves, Office of Migratory Bird Management, working under the direction of John P. Rogers, Chief.

Exception from Executive Order 12044 and 43 CFR Part 14

As discussed in the Federal Register dated February 15, 1979 (44 FR 9929), the Assistant Secretary for Fish and Wildlife and Parks has concluded that the ever decreasing time frames in the regulatory process are mandated by the Migratory Bird Treaty Act and the Administrative Procedure Act. The regulatory process simply has no remaining slack in its timetable between the accumulation of critical summer survey data and the publication of the revised sets of proposed rulemakings. Compliance with the determination of significance and regulatory analysis criteria established under Executive Order 12044 would simply not be possible if the fall hunting season deadlines are to be achieved.

Consequently, the Assistant Secretary for Fish and Wildlife and Parks has approved the exemption of these regulations from the procedures of

Executive Order 12044 and 43 CFR 14 which is provided for in section 6(b)(6) and § 14.3(f), respectively.

Regulations Promulgation

The rulemaking process for migratory game bird hunting, must, by its nature, operate under severe time constraints. However, the service is of the view that every attempt should be made to give the public the greatest possible opportunity to comment on the regulations. Thus, when the proposed rulemakings were published on February 15, June 13, June 28, and August 10, the Service established what it believed were the longest periods possible for public comment. In doing this, the Service recognized that at the periods' close, time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, the Service is of the opinion that the States would have insufficient time to select their season dates, and bag limits; to communicate those selections to the Service, and finally to establish and publicize the necessary regulations and procedures to implement their decisions. The Service therefore finds that "good cause" exists, within the terms of 5 U.S.C. 553(d)(3) and these frameworks will, therefore, take effect immediately upon publication.

Accordingly, the Service prescribes the final frameworks setting forth the species to be hunted, daily bag and possession limits, season dates, shooting hours, and special closures from which State conservation agency officials may select open season dates. Upon receipt of season selections from State officials, the Service will publish in the Federal Register final rulemaking amending certain sections of subpart K of 50 CFR Part 20 to reflect seasons, limits and shooting hours for the contiguous United States for the 1979-80 season.

Final Regulations Frameworks for 1979-80 Late Hunting Seasons on Certain Migratory Game Birds

Pursuant to the Migratory Bird Treaty Act, the Secretary of the Interior has approved final frameworks for season lengths, shooting hours, bag and possession limits, and outside dates within which States may select seasons for hunting waterfowl, coots, and gallinules; sandhill cranes in parts of New Mexico, Texas, Colorado, Oklahoma, Montana, and Wyoming; and common snipe in the Pacific Flyway. Frameworks are summarized below. States may be more restrictive in selecting season regulations, but may not exceed the framework provisions.

General

States in the Pacific, Central and Mississippi Flyways may split their season for ducks or geese into two segments of equal or unequal lengths. States in the Atlantic Flyway may, in lieu of zoning, split their season for ducks or geese into two or three segments of equal or unequal lengths. Exceptions are noted in appropriate sections.

Shooting and hawking hours in all States, on all species, and for all seasons are $\frac{1}{2}$ hour before sunrise until sunset, except that during September teal season the hours are sunrise until sunset.

States in the Mississippi and Central Flyways selecting neither a September teal season nor the point system may select an extra daily bag and possession limit of 2 and 4 blue-winged teal, respectively, for 9 consecutive days designated during the regular duck season. These extra limits are in addition to the regular duck bag and possession limits.

States in the Atlantic Flyway not selecting the point system may select an extra teal limit for 9 consecutive hunting days during the regular duck season of no more than 2 blue-winged teal or 2 green-winged teal or 1 of each daily and no more than 4 singly or in the aggregate in possession.

States in the Atlantic, Mississippi and Central Flyways may select a special scaup-only hunting season not to exceed 16 consecutive days, with daily bag and possession limits of 5 and 10 scaup, respectively, subject to the following conditions:

1. The season must fall between October 1, 1979, and January 31, 1980, all dates inclusive.
2. The season must fall outside the open season for any other ducks except sea ducks.
3. The season must be limited to areas mutually agreed upon between the State and the Service prior to September 1, 1979.
4. These areas must be described and delineated in State hunting regulations.

Or

As an alternative, States in the Atlantic, Mississippi, and Central Flyways, except those selecting a point system, may select an extra daily bag and possession limit of 2 and 4 scaup, respectively, during the regular duck hunting season, subject to conditions 3 and 4 listed above. These extra limits are in addition to the regular duck limits and apply during the entire regular duck season.

Selection of the point system for any State entirely within a flyway must be

on a statewide basis, except if New York selects the point system, conventional regulations may be retained for the Long Island Area. New York may not select the point system within the Upstate zoning option, and Maine, Connecticut, and North Carolina may not select the point system pending completion of zoning studies currently under way.

States that did not select their rail, woodcock, snipe, gallinule, or sea duck seasons in July should do so at the time they make their waterfowl selections.

Frameworks for open seasons and season lengths, bag and possession limit options, and other special provisions are listed below by Flyway.

Atlantic Flyway

Between October 1, 1979, and January 20, 1980, States in this Flyway may select open seasons on ducks, coots, and mergansers of: (a) 50 days, with basic daily bag and possession limits of 4 and 8 ducks, respectively, of which no more than 2 in the daily bag and 4 in possession may be black ducks; or (b) 50 days, with basic daily bag and possession limits of 5 and 10 ducks, respectively, of which no more than 1 in the daily bag and 2 in possession may be black ducks.

Except in closed areas, the limit on canvasbacks and redheads is 1 canvasback daily and 1 in possession or 1 redhead daily and 1 in possession. Under the point system, canvasbacks count 100 points each and redheads count 70 points each, except in closed areas. Areas closed to canvasback and redhead hunting are:

New York—Upper Niagara River between the Peace Bridge at Buffalo, New York, and the Niagara Falls. All waters of Lake Cayuga.

New Jersey—Those portions of Monmouth County and Ocean County lying east of the Garden State Parkway.

Maryland, Virginia and North Carolina—Those portions of each State lying east of U.S. Highway 1.

Under conventional and point system options, the daily bag and possession limits may not include more than 2 and 4 wood ducks, respectively, except that Virginia, North Carolina, South Carolina, Georgia and Florida may split their regular hunting season so that a hunting season not to exceed 9 consecutive days occurs between October 1 and October 15. During this period under conventional regulations, no special restrictions within the regular daily bag and possession limits established for the flyway in 1979 shall apply to wood ducks. Under the point system, the point value of wood ducks shall be 25. For other ducks, daily bag

and possession limits shall be the same as established for the flyway under conventional or point system regulations. For those States using conventional regulations, the 9 consecutive days extra teal option may be selected concurrent with the early wood duck season option. This exception to the daily bag and possession limits for wood ducks shall not apply to that portion of the duck hunting season that occurs after October 15.

The daily bag limit on mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is 10, only 2 of which may be hooded mergansers.

The daily bag and possession limits of coots are 15 and 30, respectively.

The Lake Champlain Area of New York must follow the waterfowl seasons, daily bag and possession limits, and shooting hours selected by Vermont. This area includes that part of New York lying east and north of a boundary running south from the Canadian border along U.S. Highway 9 to New York Route 22 south of Keeseville along New York Route 22 to South Bay, along and around the shoreline of South Bay to New York Route 22, along New York Route 22 to U.S. Highway 4 at Whitehall, and along U.S. Highway 4 to the Vermont border.

In lieu of a special scaup season, Vermont may, for the Lake Champlain Area, select a special scaup and goldeneye season not to exceed 16 consecutive days, with a daily bag limit of 3 scaup or 3 goldeneyes or 3 in the aggregate and a possession limit of 6 scaup or 6 goldeneyes or 6 in the aggregate, subject to the same provisions that apply to the special scaup season elsewhere.

New York may, for Long Island, select season dates and daily bag and possession limits which differ from those in the remainder of the State.

Upstate New York (excluding the Lake Champlain area) may be divided into three zones (West, North, South) on an experimental basis for the purpose of setting separate duck, coot and merganser seasons. Option (a) and (b) for seasons and bag limits is applicable to the zones in the Upstate area within the Flyway framework; only conventional regulations may be selected. Each zone will be permitted the full number of days offered under options (a) or (b). In addition, a two-segment split season without penalty may be selected in each zone. The basic daily bag limit on ducks in each zone and the restrictions applicable to options (a) and (b) of the regular season for the Flyway also apply. Teal and

scaup bonus bird options shall be applicable to the Upstate zones, but the 16-day special scaup season will not be allowed.

The zones are defined as follows:

The West Zone is that portion of Upstate New York lying west of a line commencing at the north shore of the Salmon River and its junction with Lake Ontario and extending easterly along the north shore of the Salmon River to its intersection with Interstate Highway 81, then southerly along Interstate Highway 81 to the Pennsylvania border.

The North and South Zones are bordered on the west by the boundary described above and are separated from each other as follows:

Starting at the intersection of Interstate Highway 81 and New York Route 49 and extending easterly along Route 49 to its junction with Route 8 in Utica, then southerly along Route 8 to its intersection with U.S. Highway 20 in Bridgewater, then easterly along U.S. Highway 20 to the Massachusetts border.

Maine, Massachusetts, Connecticut, Pennsylvania, and North Carolina each may be divided into two zones on an experimental basis for the purpose of setting separate duck, coot and merganser seasons. Option (a) or (b) for seasons and bag limits is applicable to the zones within the Flyway framework; only conventional regulations may be selected in Maine, Connecticut and North Carolina. Both zones will be permitted the full number of days offered under options (a) or (b). In addition, a two-segment split season without penalty may be selected. The basic daily bag limit on ducks in each zone and the restrictions applicable to options (a) and (b) of the regular season for the Flyway also apply. Teal and scaup bonus bird options and the 16-day special scaup season shall be allowed.

The zones are defined as follows:

Maine: North Zone—Game Management Zones 1, 2 and 3. South Zone—Game Management Zones 4 through 8.

Massachusetts: Coastal Zone—Beginning at the New Hampshire-Massachusetts border, that portion of the State east and south of a boundary formed by Interstate 95, south to U.S. Route 1, south to Interstate 93, south to Route 3, south to U.S. Route 6, southwest to Route 28, northwest to Interstate 195, and west to the Rhode Island line. Inland Zone—That portion of the State west and north of the above boundary.

Connecticut: North Zone—That portion of the State north of Interstate 95. South Zone—That portion of the State south of Interstate 95.

Pennsylvania: North Zone—The Lake Erie waters of Pennsylvania and a shoreline margin along Lake Erie from New York on the east to Ohio on the west extending 150 yards

inland, but including all of Presque Isle Peninsula. South Zone—The remainder of the State.

North Carolina: East Zone—That portion of the State east of U.S. Highway 1. West Zone—That portion of the State west of U.S. Highway 1.

As an alternative to conventional bag limits for ducks, a 50-day season with a point-system bag limit may be selected by States in the Atlantic Flyway during the framework dates prescribed. Point values for species and sexes taken are as follows: in Florida only, the fulvous tree duck counts 100 points each; in all States the canvasback counts 100 points each (except in closed areas); the female mallard, black duck, mottled duck, wood duck (except in Virginia, North Carolina, South Carolina, Georgia and Florida during the early wood duck season option), redhead (except in closed areas) and hooded merganser count 70 points each; the blue-winged teal, green-winged teal, pintail, gadwall, wigeon, shoveler, scaup, sea ducks, and mergansers (except hooded) count 10 points each; the male mallard, the wood duck during the early wood duck season option in Virginia, North Carolina, South Carolina, Georgia and Florida, and all other species of ducks count 25 points each. The daily bag limit is reached when the point value of the last bird taken, added to the sum of the point values of the other birds already taken during that day, reaches or exceeds 100 points. The possession limit is the maximum number of birds which legally could have been taken in 2 days.

In any State in the Atlantic Flyway selecting both point-system regulations and a special sea duck season, sea ducks count 10 points each during the point-system season, but during any part of the regular sea duck season falling outside the point-system season, regular sea duck daily bag and possession limits of 7 and 14, respectively, apply.

Coots have a point value of zero, but the daily bag and possession limits are 15 and 30, respectively, as under the conventional limits.

Between October 1, 1979, and January 20, 1980, Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, Pennsylvania, West Virginia, Maryland, and Virginia (excluding those portions of the cities of Virginia Beach and Chesapeake lying east of Interstate 64 and U.S. Highway 17) may select 70-day seasons on Canada geese; the daily bag and possession limits are 3 and 6 geese, respectively. However, in the area comprised of New Jersey, Delaware, the Delmarva Peninsula portions of Maryland and Virginia, and that portion of Pennsylvania lying east and south of

a boundary beginning at Interstate Highway 83 at the Maryland border and extending north to Harrisburg, then east on U.S. Highway 22 to the New Jersey border, the Canada goose season length will be 90 days with the closing framework date extended to January 31, 1980. The daily bag limit within this area will be 4 birds with a possession limit of 8 birds. North Carolina and those portions of the cities of Virginia Beach and Chesapeake lying east of Interstate 64 and U.S. Highway 17 in Virginia may select 50-day seasons on Canada geese within the October 1, 1979, to January 20, 1980, framework; the daily bag and possession limits are 2 and 4 Canada geese, respectively. South Carolina may select a 50-day season on Canada geese within the October 1, 1979, to January 20, 1980, framework; the daily bag and possession limits are 1 and 2 Canada geese, respectively.

The season is closed on Canada geese in Florida and Georgia.

Between October 1, 1979, and January 31, 1980, States in the Atlantic Flyway may select 70-day seasons on snow geese (including blue geese); the daily bag and possession limits are 4 and 8 geese, respectively.

The season is closed on Atlantic brant.

Mississippi Flyway

Between September 29, 1979, and January 20, 1980, States in this Flyway may select concurrent 50-day seasons on ducks, coots, and mergansers, except that in Iowa the framework opening date is September 22 and in Mississippi the framework closing date is January 31. The daily bag limit for ducks is 5, and may include no more than 3 mallards, no more than 2 of which may be female mallards; 1 black duck; and 2 wood ducks (except as noted below). The possession limit is 10, including no more than 6 mallards, no more than 4 of which may be female mallards; 2 black ducks; and 4 wood ducks (except as noted below).

Except in closed areas, the limit on canvasbacks and redheads is 1 canvasback daily and 1 in possession or 1 redhead daily and 1 in possession. Under the point system, canvasbacks count 100 points each and redheads count 70 points each, except in closed areas. Areas closed to canvasback and redhead hunting are:

Mississippi River: Entire river, both sides, from Alton Dam upstream to Prescott, Wisconsin, at confluence of St. Croix River.

Alabama: Baldwin and Mobile Counties.

Louisiana: Caddo, St. Charles, and St. Mary Parishes; that portion of Ward 1 formerly designated as Ward 6 of St. Martin

Parish; and Catahoula Lake in LaSalle and Rapides Parishes.

Michigan—Arenac, Bay, Huron, Macomb, Monroe, St. Clair, Tuscola, and Wayne Counties, and those adjacent waters of Saginaw Bay south of a line extending from Point au Gres in Sec. 6, T18N, R7E (Arenac County) to Sand Point in Sec. 11, T17N, R9E (Huron County), the St. Clair River, Lake St. Clair, the Detroit River and Lake Erie, under jurisdiction of the State of Michigan.

Minnesota—Douglas, Mahanomen, Polk, Pope and Sibley Counties. Where the county line of any of the above counties crosses any portion of a lake, that entire lake is closed. In addition, all land in Sec. 13, T130N, R31W (i.e., land between Lake Christina and Pelican Lake) is closed.

Ohio—Land and water areas comprising Erie, Ottawa and Sandusky Counties.

Tennessee—Kentucky Lake lying north of Interstate Highway 40.

Wisconsin—In the Mississippi River Zone, all that part of Wisconsin west of the Burlington-Northern Railroad in Grant, Crawford, Vernon, LaCrosse, Trempealeau, Buffalo, Pepin and Pierce Counties. Also, the following lakes and waters, including a strip of land 100 yards wide adjacent to the shorelines thereof: Lake Poygan in Winnebago and Waushara Counties and Lakes Winneconne and Butte des Morts, including the connecting waters thereof, in Winnebago County.

The daily bag limit on mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is 10, only 2 of which may be hooded mergansers.

The daily bag and possession limits on coots are 15 and 30, respectively.

As an alternative to conventional bag limits for ducks, a 50-day season with point-system bag and possession limits may be selected by States in the Mississippi Flyway during the framework dates prescribed. Point values for species and sexes taken are as follows: except in closed areas, the canvasback counts 100 points; the redhead (except in closed areas), female mallard, wood duck (except as noted below), black duck and hooded merganser count 70 points each; the pintail, blue-winged teal, cinnamon teal, wigeon, gadwall, shoveler, scaup, green-winged teal and mergansers (except hooded merganser) count 10 points each; the male mallard and all other species of ducks count 25 points each. The daily bag limit is reached when the point value of the last bird taken, added to the sum of the point values of the other birds already taken during that day, reaches or exceeds 100 points. The possession limit is the maximum number of birds which legally could have been taken in 2 days.

Coots have a point value of zero, but the daily bag and possession limits are 15 and 30, respectively, as under the conventional limits.

Kentucky, Arkansas, Tennessee, Louisiana, Mississippi and Alabama may split their regular duck hunting seasons in such a way that a hunting season not to exceed 9 consecutive days may occur between October 1 and October 15. During this period, under conventional regulations, no special restrictions within the regular daily bag and possession limits established for the Flyway shall apply to wood ducks, and under the point system, the point value for wood ducks shall be 25 points. For other species of ducks, daily bag and possession limits shall be the same as established for the Flyway under conventional or point system regulations. In addition, the extra blue-winged teal option available to States in this Flyway that select conventional regulations and do not have a September teal season may be selected during this period. This exception to the daily bag and possession limits for wood ducks shall not apply to that portion of the duck hunting season that occurs after October 15.

In that portion of Louisiana west of a boundary beginning at the Arkansas-Louisiana border on Louisiana Highway 3; then south along Louisiana Highway 3 to Shreveport; then east along Interstate 20 to Minden; then south along Louisiana Highway 7 to Ringgold; then east along Louisiana Highway 4 to Jonesboro; then south along U.S. Highway 167 to Lafayette; then southeast along U.S. Highway 90 to Houma; then south along the Houma Navigation Channel to the Gulf of Mexico through Cat Island Pass—the season on ducks, coots and mergansers may extend 5 additional days, provided that the season opens no later than on November 3, 1979. If the 5-day extension is selected, and if point-system regulations are selected for the State, point values will be the same as for the rest of the State.

The waterfowl seasons, limits, and shooting hours in the Pymatuning Reservoir area of Ohio will be the same as those selected by Pennsylvania. The area includes Pymatuning Reservoir and that part of Ohio bounded on the north by County Road 306 known as Woodward Road, on the west by Pymatuning Lake Road, and on the south by U.S. Highway 322.

Michigan, Illinois, Indiana, Ohio, Missouri, Alabama and Tennessee may select hunting seasons on ducks, coots and mergansers by zones described as follows:

Michigan: *North Zone*—The Upper Peninsula. *South Zone*—The Lower Peninsula.

Illinois: *North Zone*—That portion of the State north of U.S. Highway 50. *South Zone*—The remainder of Illinois.

Indiana: *North Zone*—That portion of Indiana north of State Highway 18. *South Zone*—The remainder of Indiana.

Ohio: *North Zone*—The counties of Darke, Miami, Clark, Champaign, Union, Delaware, Licking, Miskinung, Guernsey, Harrison and Jefferson and all counties north thereof. In addition, the North Zone also includes that portion of the Buckeye Lake area in Fairfield and Perry Counties bounded on the west by State Highway 37, on the south by State Highway 204, and on the east by State Highway 13. *South Zone*—The remainder of Ohio.

Ohio may split its season in each zone into two segments.

Missouri: *North Zone*—That portion of Missouri north of a line running easterly from the Kansas-Missouri border along U.S. Highway 160 to the junction of U.S. Highway 60 in Springfield, along U.S. Highway 60 to the junction of State Highway 21, along State Highway 21 to the junction of State Highway 34, and along State Highway 34 to the Illinois-Missouri border along the Mississippi River at Cape Girardeau. *South Zone*—The remainder of Missouri.

Alabama: *South Zone*—Mobile and Baldwin Counties. *North Zone*—The remainder of Alabama.

Tennessee: *Reelfoot Zone*—Lake and Obion Counties, or a designated portion of that area. *State Zone*—The remainder of Tennessee.

Within each State: (1) the same bag limit option must be selected for both zones; (2) if a special scaup season is selected for a zone, it shall not begin until after the regular season closing date in that zone.

The waterfowl seasons, limits, and shooting hours in the lower St. Francis River area of Arkansas and Missouri shall be the same as those selected by Missouri. The area is defined as that part of the St. Francis River south of U.S. Highway 62 where it is the boundary between Arkansas and Missouri and all sloughs and chutes (but not tributaries) connected to it.

Between September 29, 1979, and January 20, 1980, States in this Flyway, except Louisiana, may select 70-day seasons on geese, with daily bag and possession limits of 5 geese, to include no more than 2 white-fronted geese. Regulations for Canada geese are shown below by State.

Between September 29, 1979, and February 14, 1980, Louisiana may select 70-day seasons on snow (including blue) and white-fronted geese by zones established for duck hunting seasons, with daily bag and possession limits of 5 geese, to include no more than 2 white-fronted geese.

The season on Canada geese is closed in Arkansas, Louisiana and Mississippi. In Minnesota, in the:

(a) Lac Qui Parle Zone (described in State regulations)—the season on Canada geese closes after 50 days or when 7,000 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese or 2 white-fronted geese, or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

(b) Southeastern Zone (described in State regulations)—The season for Canada geese may extend for 70 consecutive days. The daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

(c) Remainder of the State—the season on Canada geese will be concurrent with the duck season. The daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

In Iowa, the season for Canada geese may extend for 70 consecutive days. The daily bag limit is 2 Canada geese. The possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

In Missouri, in the:

(a) Swan Lake Zone (described in State regulations)—the season on Canada geese closes after 70 days or when 25,000 birds have been harvested, whichever occurs first. Through November 25, the daily bag limit is 1 Canada goose or 2 white-fronted geese or 1 of each; the possession limit is 2 Canada and 2 white-fronted geese. After November 25, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

(b) Southeastern Area (east of U.S. Highway 67 and south of Crystal City)—the State may select a 45-day season on Canada geese between December 1, 1979, and January 20, 1980, with a daily bag limit of 2 Canada geese or 2 white-fronted geese or 1 of each; and a possession limit of 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

(c) Remainder of the State—the season on Canada geese may not exceed 45 days. The daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the

aggregate, of which no more than 2 may be white-fronted geese.

In Wisconsin, the harvest of Canada geese is limited to 35,000. In the Horicon Zone, during the first hunting period, the daily bag limit is 1 Canada goose or 2 white-fronted geese or 1 of each, and the possession limit is 1 Canada goose and 2 white-fronted geese; thereafter, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each, and the possession limit is 2 Canada and 2 white-fronted geese. In the Central Zone, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each, and the possession limit is 2 Canada geese and 2 white-fronted geese. Elsewhere in Wisconsin, the daily bag limit is 1 Canada goose or 2 white-fronted geese or 1 of each, and the possession limit is 2 Canada geese and 2 white-fronted geese. In the Horicon Zone and the Central Zone, Canada goose hunting is restricted to those persons holding valid Canada goose hunting permits issued by the State. The Horicon Zone is defined as those portions of the counties of Fond du Lac, Green Lake, Washington and Dodge enclosed by a line beginning at the intersection of State Highway 175 and State Highway 23 in Fond du Lac County, then southerly on State Highway 175 to its intersection with State Highway 33, then westerly on State Highway 33 to the City of Beaver Dam, then northerly on State Highway 33 to its intersection with County Highway A, then northerly on County Highway A to its intersection with County Highway S, then easterly on County Highway S and continuing easterly on County Highway AS to its intersection with County Highway E, then northerly on County Highway E to its intersection with State Highway 23, then easterly on County Highway 23 to the point of beginning.

The Central Zone is defined as those portions of Fond du Lac, Winnebago, Green Lake, Marquette, Columbia and Dodge Counties enclosed by a line beginning in Winnebago County at the intersection of State Highway 21 and U.S. Highway 45, then southerly on U.S. Highway 45 to its intersection with State Highway 175, then southerly on State Highway 175 to its intersection with State Highway 23, then westerly on State Highway 23 to its intersection with County Highway E, then southerly on County Highway E to its intersection with County Highway AS, then westerly on County Highway AS and continuing westerly on County Highway S to its intersection with County Highway A, then southerly on County Highway A to its intersection with State Highway 33,

then southeasterly on State Highway 33 to its intersection with U.S. Highway 151, then southwesterly on U.S. Highway 151 to its intersection with State Highway 73, then northerly on State Highway 73 to its intersection with State Highway 33, then westerly on State Highway 33 to its intersection with State Highway 22, then northerly on State Highway 22 to its intersection with State Highway 23, then northeasterly on State Highway 23 to its intersection with State Highway 49, then northerly on State Highway 49 to its intersection with State Highway 116, then easterly on State Highway 116 to State Highway 21, then easterly on State Highway 21 to the point of beginning.

In Illinois, 70-day seasons on geese may be selected by zones established for duck hunting seasons. The harvest of Canada geese is limited to 35,000, with 29,000 birds allocated to the Southern Illinois Zone (described in State regulations). The daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese. The season on Canada geese may open at a later date in the Southern Illinois Zone and extend to January 20, 1980, or until the Zone's quota of 29,000 birds is reached, whichever occurs first.

In Michigan, in the:

(a) Counties of Baraga, Dickinson, Delta, Gogebic, Houghton, Iron, Keweenaw, Marquette, Menominee and Ontonagon—the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 2 Canada and 2 white-fronted geese.

(b) Southeastern Canada Goose Management Area (described in State regulations)—the Canada goose season will open with the duck season and extend through December 9. Through November 14, the daily bag limit will be 1 Canada goose and 2 white-fronted geese or 1 of each; the possession limit is 2 Canada and 2 white-fronted geese. From November 15 through December 9, the daily bag limit will be 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 2 Canada and 2 white-fronted geese.

(c) Remainder of the State—the daily bag limit is 1 Canada goose or 2 white-fronted geese or 1 of each; the possession limit is 1 Canada goose and 2 white-fronted geese.

In Ohio, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each and the possession limit is 2 Canada and 2 white-fronted geese, except that in the counties of Ashtabula, Trumbull, Marion, Wyandot, Lucas, Ottawa, Erie, Sandusky, Mercer and

Auglaize, the daily bag limit is 1 Canada goose or 2 white-fronted geese or 1 of each.

In Indiana, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 2 Canada and 2 white-fronted geese.

In Kentucky, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese. In the Ballard County Zone (described in State regulations), the harvest of Canada geese is limited to 15,000.

In Tennessee, the daily bag limit is 1 Canada goose and the possession limit is 2 Canada geese, except in that portion of the State west of State Highway 13, where the daily bag and possession limits are 2 Canada geese. The season on Canada geese is closed in that portion of Tennessee bounded on the north by State Highways 20 and 104, and on the east by U.S. Highways 45W and 45.

In Alabama, the season is closed on all geese in the counties of Henry, Russell and Barbour. Elsewhere in Alabama, the daily bag limit is 2 Canada geese or 2 white-fronted geese or 1 of each; the possession limit is 4 Canada and white-fronted geese in the aggregate, of which no more than 2 may be white-fronted geese.

When it has been determined that the quota of Canada geese allotted to the Southern Illinois Zone, the Swan Lake Zone of Missouri, and the Ballard County Zone of Kentucky will have been filled, the season for taking Canada geese in the respective area will be closed by the Director upon giving public notice through local information media at least 48 hours in advance of the time and date of closing.

Geese taken in Illinois and Missouri and in the Kentucky counties of Ballard, Hickman, Fulton, and Carlisle may not be transported, shipped, or delivered for transportation or shipment by common carrier, the Postal Service, or by any person except as the personal baggage of the hunter taking the birds.

Central Flyway

Seasons on ducks (including mergansers) and coots may be selected between September 29, 1979, and January 20, 1980, inclusive, in Central Flyway States and portions of States.

The basic season may include no more than 60 days. Conventional limits on ducks (including mergansers), singly or in the aggregate, are 5 daily and 10 in possession. The aggregate daily bag limit on ducks (including mergansers) may include no more than 1 redhead or

1 canvasback (note areas closed to canvasback hunting), 1 female mallard, 1 hooded merganser, and 2 wood ducks. The possession limit may include no more than 1 redhead or 1 canvasback (note areas closed to canvasback hunting), 2 female mallards, 2 hooded mergansers, and 4 wood ducks. The daily bag and possession limits on coots are 15 and 30, respectively.

North Dakota—that portion lying east of State Highway 3, including all or portions of 27 counties.

South Dakota—all of Marshall County; that portion of Day County east of State Highway 25; that portion of Codington County south of State Highway 20 and west of U.S. Highway 81; that portion of Hamlin County west of U.S. Highway 81; and that portion of Kingsbury County east of State Highway 25 and north of U.S. Highway 14.

As an alternative to conventional bag and possession limits for ducks, point-system regulations may be selected for States and portions of States in this Flyway. The point system season length in the High Plains Mallard Management Unit is 83 days provided that the last 23 days of such season must begin on or after December 8, 1979. The High Plains Unit, roughly defined as that portion of the Central Flyway which lies west of the 100th meridian, shall be described in State regulations. The season length for the Low Plains Unit (those portions of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas not included in the High Plains Mallard Management Unit) may not exceed 60 days.

The point values for species and sexes taken in the Central Flyway are: canvasbacks count 100 points each (note areas closed to canvasback hunting); female mallards, Mexican-like ducks, wood ducks, redheads and hooded mergansers count 70 points each; blue-winged teal, green-winged teal, cinnamon teal, scaup, pintails, gadwalls, wigeon, shovelers, and mergansers (except the hooded merganser) count 10 points each; all other species and sexes of ducks count 20 points each. The daily bag limit is reached when the point value of the last bird taken, when added to the sum of the point values of other birds already taken during that day, reaches or exceeds 100 points. The possession limit is the maximum number of birds which legally could have been taken in 2 days.

Coots have a point value of zero, but the daily bag and possession limits are 15 and 30, respectively, as under conventional limits.

Those portions of Colorado and Wyoming lying west of the Continental Divide, that portion of New Mexico

lying west of the Continental Divide plus the entire Jicarilla Apache Indian Reservation, and that portion of Montana which includes the counties of Hill, Chouteau, Cascade, Meagher, and Park and all counties west thereof, must select open seasons on waterfowl and coots in accordance with the framework for the Pacific Flyway.

States in this Flyway may select goose seasons between September 29, 1979, and January 20, 1980, inclusive.

Montana, Wyoming and Colorado may select, for the Central Flyway portions, seasons of 93 days, with daily bag and possession limits of 2 and 4 geese, respectively.

New Mexico (for the Central Flyway portion) and Texas (for that portion west of U.S. Highway 81) may select seasons of 93 days with a daily bag limit of 5 geese which may include no more than 2 dark (Canada and white-fronted) geese and a possession limit of 5 geese which may include no more than 4 dark geese.

North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas (for that portion east of U.S. Highway 81) may select seasons of 88 days for light (snow, including blue and Ross) geese and seasons of 72 days for dark (Canada and white-fronted) geese subject to the following:

Seasons for light and dark geese need not be concurrent.

The daily bag and possession limits may not exceed 5 geese during periods when such light and dark goose seasons may be concurrent.

The daily bag and possession limits may include no more than 5 light geese.

The daily bag limit may include no more than 2 dark geese and the possession limit may include no more than 4 dark geese subject to the following:

In North Dakota, the daily bag limit may include no more than 1 Canada goose and 1 white-fronted goose or 2 white-fronted geese. The possession limit may include no more than 2 Canada or 2 white-fronted geese or 1 of each. The season on dark geese may not extend beyond November 18, 1979.

In South Dakota, the daily bag limit may include no more than 1 Canada goose and 1 white-fronted goose and the possession limit may include no more than 2 Canada geese or 2 white-fronted geese or 1 of each. The season on dark geese may not extend beyond November 25, 1979, in the counties of Buffalo, Brule, Hughes, Hyde, Lyman, Potter, Stanley, and Sully.

In Nebraska, the season on dark geese may not extend beyond December 16, 1979. The daily bag limit may include no more than 1 Canada goose and 1 white-

fronted goose and the possession limit may include no more than 2 Canada geese or 2 white-fronted geese or 1 of each except that, in that portion of the State west of U.S. Highway 183, prior to November 19, the daily bag limit may include no more than 2 Canada geese and the possession limit no more than 4 Canada geese.

In Kansas, the season on dark geese may not extend beyond December 23, 1979. The daily bag limit may include no more than 1 Canada and 1 white-fronted goose and the possession limit may include no more than 2 Canada geese or 2 white-fronted geese or 1 of each.

In the Oklahoma counties of Alfalfa, Bryan, Johnston, and Marshall, the State may select either:

(a) A season of 72 days with a daily bag limit of no more than 1 Canada goose and 1 white-fronted goose, and a possession limit of no more than 2 Canada geese or 2 white-fronted geese or 1 of each.

OR

(b) A season of 53 days (within the 72-day period selected for the remainder of the State) with a daily bag limit of no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose, and a possession limit of no more than 2 Canada geese or 2 white-fronted geese or 1 of each.

In the remainder of Oklahoma, the daily bag limit may include no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose and the possession limit no more than 2 Canada geese or 2 white-fronted geese or 1 of each.

In that portion of Texas east of U.S. Highway 81, the daily bag limit may include no more than 1 Canada goose or 1 white-fronted goose and the possession limit no more than 2 Canada geese or 2 white-fronted geese or 1 of each.

Colorado, Montana, New Mexico, Oklahoma, Texas, and Wyoming may select a sandhill crane season with daily bag and possession limits of 3 and 6, respectively, within a September 29, 1979-January 31, 1980, framework as follows:

(a) 37 consecutive days from September 29 through November 18, 1979, in the Central Flyway portion of Colorado except the San Luis Valley area, and in the Wyoming counties of Crook, Goshen, Laramie, Niobrara, Platte and Weston.

(b) 93 consecutive days between October 20, 1979, and January 31, 1980, in the New Mexico counties of Chaves, Curry, De Baca, Eddy, Lea, Quay, and Roosevelt, and in that portion of Texas west of a boundary from the Oklahoma border along U.S. Highway 287 to U.S.

Highway 87 at Dumas, along U.S. Highway 87 (including all of Howard and Lynn Counties) to U.S. Highway 277 at San Angelo, and along U.S. Highway 277 to the International Toll Bridge in Del Rio.

(c) 58 consecutive days on or after November 24, 1979, in that portion of Oklahoma west of U.S. Highway 81, and in that portion of Texas east of a boundary from the Oklahoma border along U.S. Highway 287 to U.S. Highway 87 at Dumas, then along U.S. Highway 87 to San Angelo, and west of a line running north from San Angelo along U.S. Highway 277 to Abilene, along State Highway 351 to Albany, along U.S. Highway 283 to Vernon, and then along U.S. Highway 183 east to the Oklahoma border.

(d) 37 consecutive days, to open with the goose season, in all of the Central Flyway portion of Montana except Sheridan County and that area south and west of Interstate Highway 90 and the Big Horn River.

All persons hunting sandhill cranes in the above designated areas of the Central Flyway must obtain and possess valid Federal permits issued by the appropriate State conservation agency on an equitable basis without charge.

Emergency closures of hunting seasons will be considered whenever portions of either the Grays Lake or Aransas flocks of whooping cranes are found in areas where there is risk to their taking by hunters.

Pacific Flyway

Between September 29, 1979, and January 20, 1980, concurrent 93-day seasons on ducks, mergansers, coots, and gallinules may be selected in Pacific Flyway States and portions of States, except as subsequently noted. Basic daily bag and possession limits on ducks are 7 and 14, respectively.

No more than 2 redheads or 2 canvasbacks or 1 of each may be taken daily and no more than 4 singly or in the aggregate may be possessed.

The daily bag and possession limits on mergansers are 5 and 10, respectively, of which no more than 1 daily and 2 in possession may be hooded mergansers.

The daily bag and possession limits on coots and gallinules are 25 singly or in the aggregate.

Waterfowl season dates for the Colorado River Zone of California must coincide with season dates selected by Arizona for waterfowl. Waterfowl season dates for the Northeastern Zone of California must coincide with season dates selected by Oregon for waterfowl, except that the season on geese may differ according to prescribed options

described later. For the Southern Zone of California (as described in Title 14 California Fish and Game Code, Section 502), the State may designate season dates differing from those in the remainder of the State.

For Nevada, county of Clark, the State may designate season dates for waterfowl differing from those in the remainder of the State.

In the Idaho counties of Ada, Bannock, Benewah, Blaine, Bonner, Boundary, Camas, Canyon, Cassia, Elmore, Gem, Gooding, Jerome, Kootenai, Latah, Lewis, Lincoln, Minidoka, Nez Perce, Owyhee, Payette, Power, Shoshone, Twin Falls, Washington, and that portion of Bingham County lying outside the Blackfoot Reservoir drainage; the Oregon counties of Baker, Gilliam, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, and Wasco; and in Washington all areas lying east of the summit of the Cascade Mountains and east of the Big White Salmon River in Klickitat County (all formerly identified as the Columbia Basin Area for ducks), between September 29, 1979, and January 20, 1980, the season lengths for ducks, mergansers, coots and gallinules may be 100 days with all seasons to run concurrently.

Between September 29, 1979, and January 20, 1980, 93-day seasons on geese may be selected in States or portions of States in this Flyway, except as subsequently noted. The basic daily bag and possession limits are 6, provided, that the daily bag limit includes no more than 3 white geese (snow, including blue, and Ross' geese) and 3 dark geese (Canada and white-fronted geese); the daily bag and possession limits are proportionately reduced in those areas where special restrictions apply to Canada geese. In Washington and Idaho, the daily bag and possession limits are 3 and 6 geese, respectively.

The season is closed on the Aleutian Canada goose.

Three areas in California, described as follows, are restricted to the hunting of dark geese (Canada and white-fronted geese) in order to protect the Aleutian Canada goose for which no hunting is allowed and to temporarily reduce harvests on white-fronted geese and cackling Canada geese:

(1) In the counties of Del Norte and Humboldt there will be no open season on dark geese during the 1979-80 waterfowl hunting season.

(2) In the Sacramento Valley in the area described as follows: beginning at Willows in Glenn County proceeding south on Interstate Highway 5 to the junction with Hahn Road north of

Arbuckle in Colusa County; then easterly on Hahn Road and the Grimes-Arbuckle Road to Grimes on the Sacramento River; then south on the Sacramento River to the Tisdale Bypass; then easterly on the Tisdale Bypass to where it meets O'Banion Road; then easterly on O'Banion Road to State Highway 99; then northerly on State Highway 99 to its junction with the Gridley-Colusa Highway in Gridley in Butte County; then westerly on the Gridley-Colusa Highway to its junction with the River Road; then northerly on the River Road to the Princeton Ferry; then westerly across the Sacramento River to State Highway 45; then northerly on State Highway 45 to its junction with State Highway 162; then continuing northerly on State Highway 45-162 to Glenn; then westerly on State Highway 162 to the point of beginning in Willows; the hunting season for taking dark geese will not open until December 15, 1979, and will then continue to the end of the 1979-80 waterfowl hunting season.

(3) In the San Joaquin Valley in the area described as follows: beginning at Modesto in Stanislaus County proceeding west on State Highway 132 to the junction of Interstate 5; then southerly on Interstate 5 to the junction of State Highway 152 in Merced County; then easterly on State Highway 152 to the junction of State Highway 59; then northerly on State Highway 59 to the junction of State Highway 99 at Merced; then northerly and westerly to the point of beginning; the hunting season for taking dark geese will close on November 23, 1979.

Emergency closures may be invoked for all Canada geese should Aleutian Canada goose distribution patterns or other circumstances justify such actions.

In the Washington counties of Adams, Benton, Douglas, Franklin, Grant, Kittitas, Klickitat, Lincoln, Walla Walla, and Yakima, and in the Oregon counties of Gilliam, Morrow, Sherman, Umatilla, Union, Walla, and Wasco, the goose season may be of 100 days duration and must run concurrently with the duck season; and the bag limits for geese are to be the same as in the general goose season in their respective States.

Oregon, for Lake and Klamath Counties, and California, for the Northeastern Zone and the Balance-of-the-State Zone, may select frameworks for season and limits among the following listed seven options. The selected season must occur within that selected for ducks.

For Lake and Klamath Counties, Oregon, and the Northeastern Zone of California:

Option 1. A season of not more than 79 days between November 3, 1979, and January 20, 1980, with a basic goose bag of 6 per day and 6 in possession of which not more than 3 dark and 3 white geese may be in the daily bag.

Option 2. A season of not more than 86 days between October 27, 1979, and January 20, 1980, with a basic goose bag of 4 per day and 4 in possession, of which not more than 2 dark and 2 white geese may be in the daily bag.

Option 3. A season of 93 days between September 29, 1979, and January 20, 1980, with a basic goose bag of 2 per day and 2 in possession of which not more than 1 dark and 1 white goose may be in the daily bag.

For the Balance-of-the-State Zone in California:

Option 4. A season of not more than 88 days between September 29, 1979, and December 25, 1979, with a basic goose bag of 6 per day and 6 in possession of which not more than 3 dark and 3 white geese may be in the daily bag.

Option 5. A season of not more than 93 days between September 29, 1979, and January 1, 1980, with a basic goose bag of 4 per day and 4 in possession of which not more than 2 dark and 2 white geese may be in the daily bag.

Option 6. A season of not more than 93 days between September 29, 1979, and January 20, 1980, with a basic goose bag of 2 per day and 2 in possession of which not more than 1 dark and 1 white goose may be in the daily bag.

For Lake and Klamath Counties, Oregon (only):

Option 7. A season of not more than 93 days between September 29, 1979, and January 20, 1980, with a goose limit the same as that of Option #3, except that any time beginning or after October 27, 1979, the goose limit of Option #1 may be adopted.

In that portion of Idaho lying west of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border (except Boundary, Bonner, Kootenai, Benewah, Shoshone, Latah, Nez Perce, Lewis, Clearwater and Idaho Counties); in the Oregon counties of Baker and Malheur; and in that portion of Montana and Wyoming in the Pacific Flyway, the daily bag and possession limit is 2 Canada geese and the season on Canada geese may not extend beyond January 1, 1979.

In that portion of Idaho lying east of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho

State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border; in that portion of Colorado in the Pacific Flyway; and in Utah except Washington County, the daily bag and possession limits are 2 Canada geese, and the season on Canada geese may be no more than 72 days and may not extend beyond December 23, 1979.

For Nevada the State may experimentally designate season dates on geese in Clark County and on geese in Elko County and that portion of White Pine County within Ruby Lakes National Wildlife Refuge differing from those in the remainder of the State. The daily bag and possession limits are 2 Canada geese throughout the State.

In Arizona, except in the counties of Mohave and Yuma; in that portion of New Mexico in the Pacific Flyway; in Clark County, Nevada; in Washington County, Utah; and in the Southern Zone, except that portion in California Department of Fish and Game District 22, of California, the season on Canada geese may be no more than 72 days. The daily bag and possession limit is 2 Canada geese and the season on Canada geese may not extend beyond January 20, 1980.

In California, the balance of California Fish and Game District 22 in the Southern Zone (that portion of District 22 lying outside the Colorado River Zone), the daily bag limit is 1 Canada goose with 2 in possession and the season on Canada geese may be no more than 72 days and may not extend beyond January 6, 1980.

In the Arizona counties of Mohave and Yuma and in the Colorado River Zone of California, the seasons on Canada geese may be no more than 72 days and may not extend beyond January 6, 1980. The daily bag and possession limits on Canada geese are 2 and 2, respectively, in these areas. The season on geese in the Colorado River Zone of California must be the same as that selected by Arizona.

In the Washington counties of Island, Skagit, Snohomish, and Whatcom, the seasons on snow geese may not extend beyond January 1, 1980; and the daily bag and possession limits on snow geese are 2 and 4, respectively.

Between October 20, 1979, and February 20, 1980, States in this Flyway may select an open season on brant of 93 days with daily bag and possession limits of 4 and 8 brant, respectively.

In Utah, Nevada and Montana, an open season for taking a limited number of whistling swans may be selected subject to the following conditions: (a) the season must run concurrently with the duck season; (b) in Utah, no more

than 2,500 permits may be issued, authorizing each permittee to take 1 whistling swan; (c) in Nevada, no more than 500 permits may be issued, authorizing each permittee to take 1 whistling swan in Churchill County; (d) in Montana, no more than 500 permits may be issued authorizing each permittee to take 1 whistling swan in Teton County; (e) permits and correspondingly numbered metal locking seals must be issued by the appropriate State conservation agency on an equitable basis without charge.

For all States entirely in the Pacific Flyway, open seasons on common snipe must coincide with the duck season locally in effect. For other States partially within the Pacific Flyway seasons between September 1, 1979, and February 28, 1980, and not to exceed 93 days, may be selected. The daily bag and possession limits are 8 and 16, respectively. Any State may split its snipe season without penalty.

Special Falconry Frameworks

Falconry is a permitted means of taking migratory game birds in any State.

Any State listed in 50 CFR 21.29(k) as meeting Federal Falconry Standards may select an extended season for taking migratory game birds in accordance with the following:

1. Seasons must fall within the regular season framework dates and, if offered, other special season framework dates for hunting.

2. Season lengths for all permitted methods of hunting within a given area may not exceed 107 days for any species.

3. Hunting hours shall not exceed ½ hour before sunrise to sunset.

4. Falconry daily bag and possession limits for all permitted migratory game birds shall not exceed 3 and 6 birds, respectively, singly or in the aggregate, during both regular hunting seasons and extended falconry seasons.

5. Each State selecting extended seasons shall report to the Service the results of the special falconry season by March 15, 1980.

6. Each State selecting the special season must inform the Service of the season dates and publish said regulations.

General hunting regulations, including seasons, hours, and limits, apply to falconry in each State listed in 50 CFR 21.29(k) which does not select an extended falconry season.

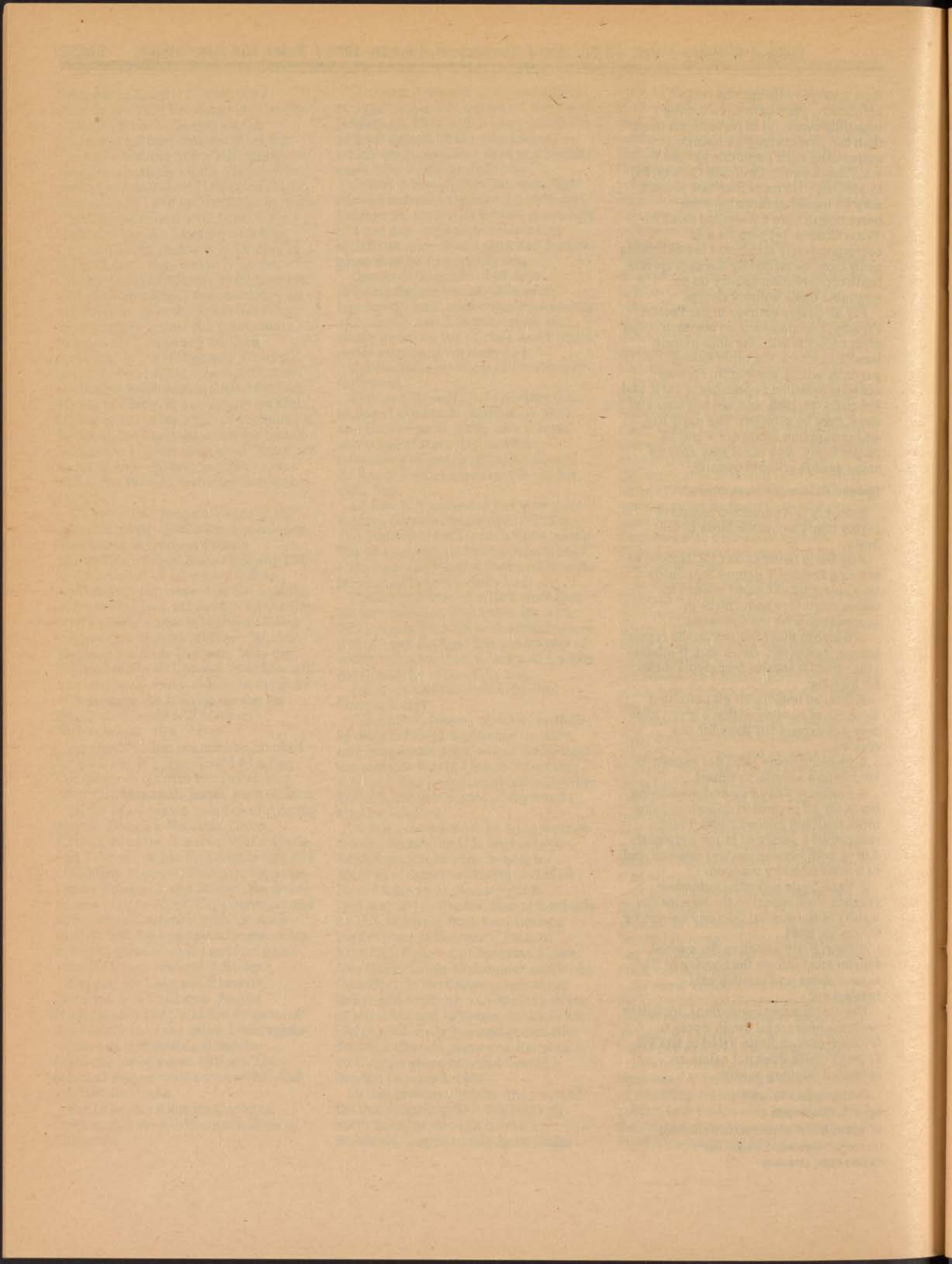
Dated: August 23, 1979.

Lynn A. Greenwalt,

Director, U.S. Fish and Wildlife Service.

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Part V

Department of Labor

Office of the Assistant Secretary for
Labor-Management Relations

Standards of Conduct for Labor
Organizations in the Federal Sector

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Labor-Management Relations

[29 CFR Chapter II]

Standards of Conduct for Labor Organizations in the Federal Sector

AGENCY: Office of the Assistant Secretary for Labor-Management Relations, Department of Labor.

ACTION: Notice of Proposed Regulations.

SUMMARY: The proposed regulations, Parts 207-209 of Title 29 of the Code of Federal Regulations, implement section 7120 of the Civil Service Reform Act of 1978. Section 7120 sets forth standards of conduct for labor organizations in the Federal sector and supersedes the standards of conduct provisions of section 18 of Executive Order 11491, as amended.

The proposed Parts 207-209 adopt with few revisions the portions of the regulations issued under the Executive Order in Parts 201-206 which relate to standards of conduct matters. These portions of Parts 201-206 remain in effect until the adoption of final regulations by the Assistant Secretary implementing section 7120 of the Civil Service Reform Act. The portions of Parts 201-206 which relate to matters other than standards of conduct will remain in effect to the extent that they are incorporated in regulations issued by the Federal Labor Relations Authority, the General Counsel of the Authority, and the Federal Service Impasses Panel implementing the other provisions of Title VIII of the Act.

DATE: Written comments on the proposed regulations must be received on or before October 29, 1979.

ADDRESS: Written comments should be submitted to the Assistant Secretary for Labor-Management Relations, Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Herbert Raskin, (202) 523-7373.

SUPPLEMENTARY INFORMATION: The Federal labor-management relations program of Executive Order 11491, as amended, has been replaced by the statutory program set forth in Title VII of the Civil Service Reform Act of 1978. Under section 7120 of the Act, the Assistant Secretary for Labor-Management Relations retains the responsibility for administering the standards of conduct requirements for labor organizations in the Federal sector previously set forth in section 18 of the Executive Order. The responsibility for

administering other areas of the Federal labor-management relations program (which under the Executive Order were assigned to the Assistant Secretary) have been delegated to the Federal Labor Relations Authority (the Authority), the General Counsel of the Authority, and the Federal Service Impasses Panel (the Panel), agencies which are independent of the Department of Labor.

Under the Executive Order, the Assistant Secretary issued implementing regulations in Parts 201-206 of Title 29 of the Code of Federal Regulations (CFR). The portions of these regulations which relate to the standards of conduct are proposed to be transferred with a few revisions to new Parts 207-209 and remain in effect until the adoption of final regulations by the Assistant Secretary. The portions of Parts 201-206 which relate to matters other than standards of conduct remain in effect to the extent that they are incorporated into the transition rules and regulations of the Authority and the Panel published in the Federal Register of January 2, 1979 (44 FR 5) and 5 CFR Chapter XIV, Part 2400 et. seq. (revised as of July 1, 1979).

The regulations proposed by the Assistant Secretary in Parts 207-209 incorporate with few changes the standards of conduct provisions of the current regulations. In particular, the proposed Part 207 contains definitions and essentially tracks the present Part 201. The proposed Part 208 contains substantive and enforcement provisions and essentially tracks the present Part 204. The proposed Part 209 contains miscellaneous provisions and essentially tracks the present Part 206.

Most of the changes made by the proposed Parts 207-209 are editorial in nature and are necessary in order to eliminate provisions which do not relate to standards of conduct matters, reflect changes in the titles of U.S. Government personnel and agencies, and change references from the Executive Order to the Act. The other changes which are set forth in detail below expand upon the procedures followed in implementing the standards of conduct requirements, extend the time limits with regard to certain enforcement procedures, renumber and consolidate various sections, and make a few other miscellaneous changes. A few revisions were also made in order to ensure that the regulations clearly conform generally to the principles applied to labor organizations in the private sector under the Labor-Management Reporting and Disclosure Act of 1959, as Amended. The primary changes are as follows:

1. The proposed § 208.64 is identical to § 204.64 except that a new subsection (c) has been added to provide for a request for a review by the Assistant Secretary when a complaint of a union officer election is dismissed by the Director of the Office of Labor-Management Standards Enforcement (LMSE). The review is limited to determining whether the dismissal was arbitrary and capricious.

2. Section 208.65 is identical to § 204.65 except that a new subsection (c) has been added to provide for certification to the Assistant Secretary of the results of a union officer election which was supervised pursuant to his order.

3. Section 208.66 is identical to section 204.66 except that a new provision has been added to clarify that a failure to abide by all the terms of a voluntary compliance agreement may result in either the filing of a complaint with the Chief Administrative Law Judge of the Department of Labor for a hearing or referral to the Assistant Secretary for other appropriate action.

4. Section 208.70 is identical to § 204.68 except that a provision has been added to clarify the jurisdiction of the Assistant Secretary in certain cases. Under that provision, when an agreement to take remedial action is reached after a complaint has been filed with the Chief Administrative Law Judge of the Department and the agreement has been approved by the Administrative Law Judge assigned to the case, the matter will be referred to the Assistant Secretary for the issuance of an order.

5. Section 208.91 is identical to § 204.91 except that a provision has been added whereby the Assistant Secretary may, in all standards of conduct matters, adopt without discussion the recommended decision and order of the Administrative Law Judge if timely and proper exceptions have not been filed. Under the current regulations set forth in §§ 203.26 and 204.91, the Assistant Secretary may adopt without discussion the recommended decision and order of the Administrative Law Judge only with regard to violations of the provisions concerning prohibited discipline and members' bill of rights.

6. Section 208.92 is identical to § 204.92 except for a change in the last sentence whereby the Assistant Secretary, when he finds that the remedial action he has ordered has not been taken shall refer the matter to the Federal Labor Relations Authority for appropriate action.

The proposed regulations also make a number of miscellaneous changes in procedures as follows:

1. Section 208.60 provides that when a Regional Administrator of the Labor-Management Services Administration finds that there is a reasonable basis for a complaint concerning an alleged violation of the provisions concerning members' bill of rights or prohibited discipline, he shall refer the matter to the Chief Administrative Law Judge of the Department of Labor for the issuance of a notice of hearing. Currently, under § 204.60 the Regional Administrator shall himself issue the notice of hearing. Accordingly, the provisions of section 208.61 are unnecessary and are proposed to be deleted.

2. Section 208.90(b) provides that a party may file within ten days answering briefs to exceptions taken to the recommended decision and order of an Administrative Law Judge. Presently, under § 204.90(b) answering briefs may only be filed at the discretion of the Assistant Secretary.

3. The time periods during which a party may take certain actions with regard to the enforcement of alleged violations of the standards of conduct has been extended. The current time periods of five, seven and ten days are proposed to be extended to seven, ten and fifteen days, respectively. These extensions are contained in the following proposed sections: §§ 208.59, 208.66, 208.69, 208.72, 208.82, 208.86, 208.87, and 208.88.

4. The requirement that a party to an enforcement proceeding file multiple copies of various documents has been eliminated in the following proposed sections: §§ 208.72, 208.82, 208.86 and 208.88.

5. Two provisions of the current Part 206 have been placed in the proposed Part 208 rather than the proposed Part 209. Section 206.6 is proposed to be renumbered as § 208.61 and § 206.7(g) is proposed to be renumbered as § 208.72(c).

The proposed regulations also eliminate the portions of the current regulations which do not pertain to standards of conduct or which are otherwise unnecessary or repetitious. The eliminated portions include the definitions of certain terms in Part 201, all of Parts 202, 203 and 205, and the following provisions of Part 206 ("Miscellaneous"): §§ 206.3(b), 206.4(c), 206.5 through 206.8, and 206.10.

Finally, the proposed regulations consolidate the two sets of hearing procedures contained in the current regulations into one set applicable to all standards of conduct matters. Under the

current regulations, there is one set of hearing procedures in Part 203 for alleged violations of the bill of rights and prohibited discipline requirements and another set in Part 204 for alleged violations of other standards of conduct requirements. Since the two sets of hearing procedures are virtually identical, the proposed regulations adopt the hearing procedures contained in Part 204 with a few necessary modifications based upon the procedures contained in Part 203.

Under the authority of sections 7120 and 7134 of the Civil Service Reform Act of 1978, — Stat. —, — U.S.C. —, the Assistant Secretary for Labor-Management Relations hereby proposes to withdraw Parts 201 through 206 of Title 29 of the Code of Federal Regulations and issue Parts 207 through 209 to read as follows:

PART 207—GENERAL

Subpart A—Purpose and Scope

Sec.

- 207.1 Purpose and Scope.
- 207.10 Act; LMRDA.
- 207.11 Agency, employee, labor organization, dues.
- 207.12 Authority.
- 207.13 Assistant Secretary
- 207.14 Standards of conduct for labor organizations.
- 207.15 Regional Administrator
- 207.16 Area Administrator
- 207.17 Director.
- 207.18 Administrative Law Judge.
- 207.19 Chief Administrative Law Judge.
- 207.20 Party.
- 207.21 Intervenor.

Authority: Secs. 7120, 7134 of the Civil Service Reform Act of 1978 (— Stat. —; — U.S.C. —).

Subpart A—Purpose and Scope

§ 207.1 Purpose and scope.

The regulations contained in this chapter are issued pursuant to section 7134 of the Civil Service Reform Act of 1978 and are designed to implement the provisions of section 7120 of that Act. They prescribe procedures and basic principles which the Assistant Secretary of Labor will utilize in effectuating the standards of conduct required of labor organizations composed of federal government employees, in accordance with section 7120 of the Act. (Regulations implementing the other provisions of Title VII of the Civil Service Reform Act are issued by the Federal Labor Relations Authority, the General Counsel of the Federal Labor Relations Authority, and the Federal Service Impasses Panel in Title 5 of the Code of Federal Regulations.)

Subpart B—Meaning of Terms as Used in This Chapter

§ 207.10 Act; LMRDA.

"Act" means the Civil Service Reform Act of 1978; "LMRDA" means the Labor-Management Reporting and Disclosure Act of 1959, As Amended.

§ 207.11 Agency, employee, labor organization, dues.

"Agency," "employees," "labor organization," and "dues" have the meanings set forth in section 7103 of the Act.

§ 207.12 Authority.

"Authority" means the Federal Labor Relations Authority as described in sections 7104 and 7105 of the Act.

§ 207.13 Assistant Secretary.

"Assistant Secretary" means the Assistant Secretary of Labor for Labor-Management Relations.

§ 207.14 Standards of conduct for labor organizations.

"Standards of conduct for labor organizations" shall have the meaning as set forth in section 7120 of the Act as amplified in Part 208 of this chapter.

§ 207.15 Regional Administrator.

"Regional Administrator" means the Administrator of a region of the Labor-Management Services Administration, with geographical boundaries as fixed by the Assistant Secretary.

§ 207.16 Area Administrator.

"Area Administrator" means the Administrator of an area office within a region of the Labor-Management Services Administration, with geographical boundaries as fixed by the Assistant Secretary.

§ 207.17 Director.

"Director" means the Director of the Office of Labor-Management Standards Enforcement with the Labor-Management Services Administration of the Department of Labor.

§ 207.18 Administrative Law Judge.

"Administrative Law Judge" means the Chief Administrative Law Judge or any Administrative Law Judge designated by the Chief Administrative Law Judge to conduct a hearing in cases under section 7120 of the Act, as interpreted by Part 208 of this chapter, and such other matters as may be assigned.

§ 207.19 Chief Administrative Law Judge.

"Chief Administrative Law Judge" means the Chief Administrative Law Judge, U.S. Department of Labor, Washington, D.C. 20210.

§ 207.20 Party.

"Party" means any person, employee, group of employees, labor organization, activity or agency: (a) filing a complaint petition, request, or application; (b) named in a complaint, petition, request, or application; or (c) whose intervention in a proceeding has been permitted or directed by the Assistant Secretary, Chief Administrative Law Judge, or Administrative Law Judge, as the case may be.

§ 207.21 Intervenor.

"Intervenor" means a party in a proceeding whose intervention has been permitted or directed by the Assistant Secretary, Chief Administrative Law Judge, or Administrative Law Judge, as the case may be.

PART 208—STANDARDS OF CONDUCT**Subpart A—Substantive Requirements Concerning Standards of Conduct****Sec.**

- 208.1 General.
- 208.2 Bill of Rights of members of Labor organizations.
- 208.3 Application of LMRDA labor organization reporting requirements.

Trusteeships

- 208.26 Purposes for which a trusteeship may be established.
- 208.27 Prohibited acts relating to subordinate body under trusteeship.
- 208.28 Presumption of validity.

Elections

- 208.29 Election of officers.

Additional Provisions Applicable

- 208.30 Removal of elected officers.
- 208.31 Maintenance of fiscal integrity in the conduct of the affairs of labor organizations.
- 208.32 Provision for accounting and financial controls.
- 208.33 Prohibition of conflicts of interest.
- 208.34 Loans to officers or employees.
- 208.35 Bonding requirements.
- 208.36 Prohibitions against certain persons holding office or employment.
- 208.37 Prohibition of certain discipline.
- 208.38 Deprivation of rights under the Act by violence or threat of violence.

Subpart B—Proceedings for Enforcing Standards of Conduct**General**

- 208.50 Investigations.
- 208.51 Inspection of records and questioning.
- 208.52 Report of investigation.
- 208.53 Filing of complaints.

Procedures Involving Bill of Rights or Prohibited Discipline

- 208.54 Complaints alleging violations of § 208.2, Bill of Rights of members of labor organizations or § 208.37, prohibition of certain discipline.

Sec.

- 208.55 Content of complaint.
- 208.56 Service on respondent.
- 208.57 Additional information and report.
- 208.58 Dismissal of complaint.
- 208.59 Review of dismissal.
- 208.60 Actionable complaint.
- 208.61 Transfer and consolidation of cases.
- 208.62 Hearing procedures.

Procedures Involving Election of Officers

- 208.63 Complaints alleging violations of § 208.29, election of officers.
- 208.64 Investigations; dismissal of complaint.
- 208.65 Procedures following actionable complaint.

Procedures Involving Matters Other Than Bill of Rights and Prohibited Discipline

- 208.66 Procedures for institution of enforcement proceedings.
- 208.67 Standards complaint; initiation of proceedings.
- 208.68 Answer.

Subpart C—Hearing and Related Matters

- 208.69 Notice of hearing.
- 208.70 Administrative Law Judge.
- 208.71 Procedure upon admission of facts.
- 208.72 Motions and requests.
- 208.73 Prehearing conferences.
- 208.74 Conduct of hearing.
- 208.75 Intervention.
- 208.76 Duties and powers of the Administrative Law Judge.
- 208.77 Rights of parties.
- 208.78 Rules of evidence.
- 208.79 Burden of proof.
- 208.80 Unavailability of Administrative Law Judges.
- 208.81 Objection to conduct of hearing.
- 208.82 Motions after a hearing.
- 208.83 Waiver of objections.
- 208.84 Oral argument at the hearing.
- 208.85 Transcript.
- 208.86 Filing of brief.
- 208.87 Proposed findings and conclusions.
- 208.88 Submission of the Administrative Law Judge's recommended decision and order to the Assistant Secretary; exceptions.
- 208.89 Contents of exceptions to Administrative Law Judge's recommended decision and order.
- 208.90 Briefs in support of exceptions.
- 208.91 Action by the Assistant Secretary.
- 208.92 Compliance with decisions and orders of the Assistant Secretary.
- 208.93 Stay of remedial action.

Authority: Secs. 7105, 7111, 7120, 7134 of the Civil Service Reform Act of 1978 (— Stat. —, — U.S.C. —).

Subpart A—Substantive Requirements Concerning Standards of Conduct**§ 208.1 General.**

The term "LMRDA" means the Labor-Management Reporting and Disclosure Act of 1959, as amended (29 U.S.C. 401 et seq.). Unless otherwise provided in this part or in the order, any term in any section of the LMRDA, which is incorporated into this part by reference and any term in this part which is also

used in the LMRDA, shall have the meaning which that term has under the LMRDA, unless the context in which it is used indicates that such meaning is not applicable. In applying the standards contained in this subpart the Assistant Secretary will be guided by the interpretations and policies followed by the Department of Labor in applying the provisions of the LMRDA and by applicable court decisions.

§ 208.2 Bill of rights of members of labor organizations.

(a)(1) *Equal rights.* Every member of a labor organization shall have equal rights and privileges within such organization to nominate candidates, to vote in elections or referendums of the labor organization, to attend membership meetings and to participate in the deliberations and voting upon the business of such meetings, subject to reasonable rules and regulations in such organization's constitution and bylaws.

(2) *Freedom of speech and assembly.* Every member of any labor organization shall have the right to meet and assemble freely with other members; and to express any views, arguments or opinions; and to express at meetings of the labor organization his views, upon candidates in an election of the labor organization or upon any business properly before the meeting, subject to the organization's established and reasonable rules pertaining to the conduct of meetings: *Provided,* That nothing herein shall be construed to impair the right of a labor organization to adopt and enforce reasonable rules as to the responsibility of every member toward the organization as an institution and to his refraining from conduct that would interfere with its performance of its legal or contractual obligations.

(3) *Dues, initiation fees, and assessments.* Except in the case of a federation of national or international labor organizations, the rates of dues and initiation fees payable by members of any labor organization in effect on the date this section is published shall not be increased, and no general or special assessment shall be levied upon such members, except—

(i) In the case of a local organization, (a) by majority vote by secret ballot of the members in good standing voting at a general or special membership meeting, after reasonable notice of the intention to vote upon such question, or (b) by majority vote of the members in good standing voting in a membership referendum conducted by secret ballot; or

(ii) in the case of a labor organization, other than a local labor organization or a federation of national or international

labor organizations, (A) by majority vote of the delegates voting at a regular convention, or at a special convention of such labor organization held upon not less than 30 days written notice to the principal office of each local or constituent labor organization entitled to such notice, or (B) by majority vote of the members in good standing of such labor organization voting in a membership referendum conducted by secret ballot, or (C) by majority vote of the members of the executive board or similar governing body of such labor organization, pursuant to express authority contained in the constitution and bylaws of such labor organization: *Provided*, That such action on the part of the executive board or similar governing body shall be effective only until the next regular convention of such labor organization.

(4) *Protection of the right to sue.* No labor organization shall limit the right of any member thereof to institute an action in any court, or in a proceeding before any administrative agency, irrespective of whether or not the labor organization or its officers are named as defendants or respondents in such action or proceedings, or the right of any member of a labor organization to appear as a witness in any judicial, administrative, or legislative proceeding, or to petition any legislature or to communicate with any legislator: *Provided*, That any such member may be required to exhaust reasonable hearing procedures (but not to exceed a 4-month lapse of time) within such organization, before instituting legal or administrative proceedings against such organizations or any officer thereof.

(5) *Safeguards against improper disciplinary action.* (a) No member of any labor organization may be fined, suspended expelled, or otherwise disciplined, except for nonpayment of dues by such organization or by any officer thereof unless such member has been (i) served with written specific charges; (ii) given a reasonable time to prepare his defense; (iii) afforded a full and fair hearing.

(b) Any provision of the constitution and bylaws of any labor organization which is inconsistent with the provisions of this section shall not be a defense to any proceeding instituted against the labor organization under this part of under the Act.

(c) Nothing contained in this section shall limit the rights and remedies of any member of a labor organization under any State or Federal law or before any court or other tribunal, or under the constitution and bylaws of any labor organization.

(d) It shall be the duty of the secretary or corresponding principal officer of each labor organization, in the case of a local labor organization, to forward a copy of each agreement made by such labor organization with any activity or agency to any employee who requests such a copy and whose rights as such employee are directly affected by such agreement, and in the case of a labor organization other than a local labor organization, to forward a copy of any such agreement to each constituent unit which has members directly affected by such agreement; and such officer shall maintain at the principal office of the labor organization of which he is an officer, copies of any such agreement made or received by such labor organization, which copies shall be available for inspection by any member or by any employee whose rights are affected by such agreement. An employee's rights under this paragraph shall be enforceable in the same manner as the rights of a member.

§ 208.3 Application of LMRDA labor organization reporting requirements.

The reporting provisions of Parts 402, 403, and 408 of Chapter IV of this title shall apply to labor organizations subject to the requirements of the Civil Service Reform Act of 1978.

Trusteeships

§ 208.26 Purposes for which a trusteeship may be established.

Trusteeships shall be established and administered by a labor organization over a subordinate body only in accordance with the constitution and bylaws of the organization which has assumed trusteeship over the subordinate body and for the purpose of (a) correcting corruption or financial malpractice, (b) assuring the performance of negotiated agreements or other duties of a representative of employees, (c) restoring democratic procedures, or (d) otherwise carrying out the legitimate objects of such labor organization.

§ 208.27 Prohibited acts relating to subordinate body under trusteeship.

During any period when a subordinate body of a labor organization is in trusteeship, (a) the votes of delegates or other representatives from such body in any convention or election of officers of the labor organization shall not be counted unless the representatives have been chosen by secret ballot in an election in which all the members in good standing of such subordinate body were eligible to participate; and (b) no current receipts or other funds of the subordinate body except the normal per

capita tax and assessments payable by subordinate bodies not in trusteeship shall be transferred directly or indirectly to the labor organization which has imposed the trusteeship: *Provided, however*, That nothing contained in this section shall prevent the distribution of the assets of a labor organization in accordance with its constitution and bylaws upon the bona fide dissolution thereof.

208.28 Presumption of validity.

In any proceeding involving § 208.26, a trusteeship established by a labor organization in conformity with the procedural requirements of its constitution and bylaws and authorized or ratified after a fair hearing either before the executive trusteeship established by a labor organization board or before such other body as may be provided in accordance with its constitution and bylaws shall be presumed valid for a period of 18 months from the date of its establishment and shall not be subject to attack during such period except upon clear and convincing proof that the trusteeship was not established or maintained in good faith for purposes allowable under § 208.26. After the expiration of 18 months the trusteeship shall be presumed invalid in any such proceeding, unless the labor organization shall show by clear and convincing proof that the continuation of the trusteeship is necessary for a purpose allowable under § 208.26.

Elections

§ 208.29 Election of officers.

Every labor organization subject to the order shall conduct periodic elections of officers in a fair and democratic manner. All elections of officers shall be governed by the standards prescribed in sections 401 (a), (b), (c), (d), (e), (f) and (g) of the LMRDA to the extent that such standards are relevant to elections held pursuant to the provisions of section 7120 of the Act.

Additional Provisions Applicable

§ 208.30 Removal of elected officers.

When an elected officer of a local labor organization is charged with serious misconduct and the constitution and bylaws of such organization do not provide an adequate procedure meeting the standards of § 417.2(e) of this title for removal of such officer, the labor organization shall follow a procedure which meets those standards. A labor organization which has adequate procedures in its constitution and bylaws shall follow those procedures.

§ 208.31 Maintenance of fiscal integrity in the conduct of the affairs of labor organizations.

The standards of fiduciary responsibility prescribed in section 501(a) of the LMRDA are incorporated into this subpart by reference and made a part hereof.

§ 208.32 Provision for accounting and financial controls.

Every labor organization shall provide accounting and financial controls necessary to assure the maintenance of fiscal integrity.

§ 208.33 Prohibition of conflicts of interest.

(a) No officer or agent of a labor organization shall, directly or indirectly through his spouse, minor child, or otherwise (1) have or acquire any pecuniary or personal interest which would conflict with his fiduciary obligation to such labor organization, or (2) engage in any business or financial transaction which conflicts with his fiduciary obligation.

(b) Actions prohibited by paragraph (a) of this section include, but are not limited to, buying from, selling, or leasing directly or indirectly to, or otherwise dealing with the labor organization, its affiliates, subsidiaries, or trusts in which the labor organization is interested, or having an interest in a business any part of which consists of such dealings, except bona fide investments of the kind exempted from reporting under section 202(b) of the LMRDA. The receipt of salaries and reimbursed expenses for services actually performed or expenses actually incurred in carrying out the duties of the officer or agent is not prohibited.

§ 208.34 Loans to officers or employees.

No labor organization shall directly or indirectly make any loan to any officer or employee of such organization which results in a total indebtedness on the part of such officer or employee to the labor organization in excess of \$2,000.

§ 208.35 Bonding requirements.

Every officer, agent, shop steward, or other representative or employee of any labor organization subject to the order (other than a labor organization whose property and annual financial receipts do not exceed \$5,000 in value), or of a trust in which a labor organization is interested, who handles funds or other property thereof shall be bonded in accordance with the principles of section 502(a) of the LMRDA. In enforcing this requirement the Assistant Secretary will be guided by the interpretations and policies followed by the Department of Labor in applying the

provisions of section 502(a) of the LMRDA.

§ 208.36 Prohibitions against certain persons holding office or employment.

The prohibitions against holding office or employment in a labor organization contained in section 504(a) of the LMRDA are incorporated into this subpart by reference and made a part hereof. The prohibitions shall also be applicable to any person who has been convicted of, or who has served any part of a prison term resulting from his conviction of, violating 18 U.S.C. 1001 by making a false statement in any report required to be filed pursuant to this subpart, or who has been determined by the Assistant Secretary after an appropriate proceeding pursuant to §§ 208.66 through 208.92 to have willfully violated § 208.27: *Provided, however,* That the duties and responsibilities of the Parole Commission of the U.S. Department of Justice under section 504(a) of the LMRDA shall be assumed under this section by the Assistant Secretary or such other person as he may designate for the purpose of determining whether it would not be contrary to the Act and this section to permit a person barred from holding office or employment to hold such office or employment.

§ 208.37 Prohibition of certain discipline.

No labor organization or any officer, agent, shop steward, or other representative or any employee thereof shall fine, suspend, expel, or otherwise discipline any of its members for exercising any right to which he is entitled under the provisions of the Act or this chapter.

§ 208.38 Deprivation of rights under the Act by violence, or threat of violence.

No labor organization or any officer, agent, shop steward, or other representative or any employee thereof shall use, conspire to use, or threaten to use force or violence to restrain, coerce, or intimidate, or attempt to restrain, coerce, or intimidate any member of a labor organization for the purpose of interfering with or preventing the exercise of any right to which he is entitled under the provisions of the Act or of this chapter.

Subpart B—Proceedings for Enforcing Standards of Conduct

General

§ 208.50 Investigations.

When he believes it necessary in order to determine whether any person has violated or is about to violate any provisions of this part (other than

§ 208.2 Bill of Rights of members of labor organizations or § 208.37, Prohibition of certain discipline) the Director shall have the authority to cause an investigation to be conducted. The authority to investigate possible violations of this part (other than §§ 208.2 or 208.37) shall not be contingent upon receipt of a complaint.

§ 208.51 Inspection of records and questioning.

In connection with such investigation an Area Administrator or his representative may inspect such records and question such persons as he may deem necessary to enable him to determine the relevant facts. Every labor organization, its officers, employees, agents, or representatives shall cooperate fully in any investigation and shall testify and produce the records or other documents requested in connection with the investigation. This section shall be enforced in accordance with the procedures in §§ 208.66 through 208.92.

§ 208.52 Report of investigation.

The Area Administrator's report of investigation (except those relating to complaints under § 208.2, Bill of Rights of members of labor organizations or 208.37, Prohibition of certain discipline) shall be submitted through the Regional Administrator to the Director, who may report to interested persons concerning any matter which he deems to be appropriate as a result of such an investigation.

§ 208.53 Filing of complaints.

A complaint alleging violations of this part may be filed with any area office, or any other office of the Labor-Management Services Administration.

Procedures Involving Bill of Rights or Prohibited Discipline

§ 208.54 Complaints alleging violations of § 208.2, Bill of Rights of members of labor organization or § 208.37, prohibition of certain discipline.

Any member of a labor organization whose rights under the provisions of § 208.2 or § 208.37 are alleged to have been infringed or violated, may file a complaint in accordance with § 208.53. *Provided, however,* That such member may be required to exhaust reasonable hearing procedures (but not to exceed a 4-month lapse of time) within such organization.

§ 208.55 Content of complaint.

(a) The complaint shall contain appropriate identifying information and a clear and concise statement of the facts constituting the alleged violation.

(b) The complainant shall submit with his complaint a statement setting forth the procedures, if any, invoked to remedy the alleged violation, including the dates when such procedures were invoked and copies of any written ruling or decision which he has received.

§ 208.56 Service on respondent.

Upon the filing of a complaint, a copy of the complaint shall be served upon the respondent, and a written statement of such service shall be furnished to the Administrator.

§ 208.57 Additional information and report.

Upon the filing a complaint pursuant to §§ 208.54-208.56, the Area Administrator shall obtain such additional information as he deems necessary and shall report the essential facts, the positions of the parties, and any offers of settlement to the Regional Administrator.

§ 208.58 Dismissal of complaint.

If the Regional Administrator after receipt of a report of the Area Administrator pursuant to § 208.57, determines that a reasonable basis for the complaint has not been established, or that an offer of settlement satisfactory to the complainant has been made, he may dismiss the complaint. If he dismisses the complaint, he shall furnish the complainant with a written statement of the grounds for dismissal, sending a copy of the statement to the respondent.

§ 208.59 Review of dismissal.

The complainant may obtain a review of such action by filing a request for review with the Assistant Secretary within fifteen (15) days of service of the notice of dismissal. A copy of such request shall be served on the Regional Administrator and the respondent, and a statement of service shall be filed with the Assistant Secretary. The request for review shall contain a complete statement of the facts and reasons upon which a request is based.

§ 208.60 Actionable complaint.

If it appears to the Regional Administrator that there is a reasonable basis for the complaint, and that no offer of settlement satisfactory to the complainant has been made, he shall refer the matter to the Chief Administrative Law Judge, U.S. Department of Labor, for the issuance of a notice of hearing as set forth in § 208.69.

§ 208.61 Transfer and consolidation of cases.

In any matter arising pursuant to the regulations in this chapter, whenever it appears necessary in order to effectuate the purposes of the order or to avoid unnecessary costs or delay, the Regional Administrator may consolidate cases within his own region or may transfer such cases to any other region, for the purpose of consolidation with any proceedings which may have been instituted in, or transferred to, such region.

§ 208.62 Hearing procedures.

The proceedings following issuance of the notice of hearing shall be as provided in §§ 208.69 through 208.92 of this chapter.

Procedures Involving Election of Officers

§ 208.63 Complaints alleging violations of § 208.29, election of officers.

(a) A member of a labor organization may file a complaint alleging violations of § 208.29 within 1 calendar month after he has (1) exhausted the remedies available under the constitution and bylaws of the labor organization and of any parent body, or (2) invoked such available remedies without obtaining a final decision within 3 calendar months of such invocation.

(b) The complaint shall contain a clear and concise statement of the facts constituting the alleged violation(s) and a statement of what remedies have been invoked under the constitution and bylaws of the labor organization and when such remedies were invoked.

(c) The complainant shall submit with his complaint a copy of any ruling or decision he has received in connection with the subject matter of his complaint.

§ 208.64 Investigations; dismissal of complaint.

(a) If it is determined after preliminary inquiry that a complaint is deficient in any of the following respects, the Area Administrator shall conduct no investigation: (1) The complainant is not a member of the labor organization which conducted the election being challenged; (2) the labor organization is not subject to the Civil Service Reform Act of 1978; (3) the election was not a regular periodic election of officers; (4) the allegations, if true, do not constitute a violation or violations of § 208.29; (5) the complainant has not complied with the requirements of § 208.63(a).

(b) If investigation discloses (1) that there has been no violation or (2) that a violation has occurred but could not have affected the outcome or (3) that a violation has occurred but has been

remedied, the Director shall issue a determination dismissing the complaint and stating the reasons for his action.

(c) A determination dismissing the complaint may be reviewed by the Assistant Secretary, but only on the basis of deciding whether the Director's decision was arbitrary and capricious. The request for review must be made within fifteen (15) days after service of notice of dismissal.

§ 208.65 Procedures following actionable complaint.

(a) If the Director concludes that there is probable cause to believe that a violation has occurred and has not been remedied and may have affected the outcome of the election, he shall proceed in accordance with §§ 208.66 through 208.92.

(b) The challenged election shall be presumed valid pending a final decision thereon by the Assistant Secretary, and in the interim the affairs of the organization shall be conducted by the officers elected or in such other manner as its constitution and bylaws may provide.

(c) When the Director supervises an election pursuant to an order of the Assistant Secretary issued under § 208.68 or § 208.91, he shall certify to the Assistant Secretary the names of the persons elected. The Assistant Secretary shall thereupon issue an order declaring such persons to be the officers of the labor organization.

Procedures Involving Matters Other Than Bill of Rights and Prohibited Discipline

§ 208.66 Procedures for institution of enforcement proceedings.

Whenever it appears to the Director that a violation of this part (other than § 208.2, Bill of Rights of members of labor organizations or § 208.37, Prohibition of certain discipline) has occurred and has not been remedied, he shall immediately notify any appropriate person and labor organization. Within fifteen (15) days following receipt of such notification, any such person or labor organization may request a conference with the Director or his representatives concerning such alleged violation. At any such conference, the Director may enter into an agreement providing for appropriate remedial action. If no person or labor organization requests such a conference, or upon failure to reach agreement following any such conference, the Director shall institute enforcement proceedings by filing a complaint with the Chief Administrative Law Judge, U.S. Department of Labor, and shall cause a copy of the complaint

to be served on each respondent named therein. If an agreement is reached and the Director concludes that there has not been compliance with all the terms of the agreement, he may refer the matter to the Assistant Secretary for appropriate enforcement action or file a complaint with the Chief Administrative Law Judge.

§ 208.67 Standards complaint; initiation of proceedings.

A complaint filed under § 208.66 shall constitute the institution of a formal enforcement proceeding in the name of the Director, who shall be the only complaining party in the proceeding and shall, where he believes it appropriate, refrain from disclosing the identity of any person who called the violation to his attention (except in proceedings involving violations of section 208.29, Election of Officers). The complaint shall include the following:

- (a) The name and identity of each respondent.
- (b) A clear and concise statement of the facts alleged to constitute violations of the Act or of this part.
- (c) A statement of the relief requested.
- (d) In any complaint filed by the Director on the basis of a complaint received from a member of a labor organization pursuant to § 208.63, a statement setting forth the procedures, if any, followed to invoke available remedies, including the dates when such procedures were invoked, and the substance of any ruling or decision received by the complaining member from the labor organization or any parent body.

§ 208.68 Answer.

(a) Within twenty (20) days from the service of the complaint the respondent shall file an answer thereto with the Chief Administrative Law Judge and shall serve a copy on all parties. The answer shall be signed by the respondent or his attorney.

(b) The answer (1) shall contain a statement of the facts which constitute the grounds of defense, and shall specifically admit, explain, or deny each of the allegations of the complaint unless the respondent is without knowledge, in which case the answer shall so state; or (2) shall state that the respondent admits all of the allegations in the complaint. Failure to file an answer to or plead specifically to any allegation in the complaint shall constitute an admission of such allegation.

Subpart C—Hearing and Related Matters

§ 208.69 Notice of hearing.

The Chief Administrative Law Judge shall issue and cause to be served upon each of the parties a notice of hearing. The notice of hearing shall include the following:

- (a) The name and identity of each party and the case number.
- (b) A statement of the authority and jurisdiction under which the hearing is to be held.
- (c) A statement of the time and place of the hearing which shall be not less than fifteen (15) days after service of the notice of hearing.

§ 208.70 Administrative Law Judge.

Each enforcement proceeding instituted pursuant to this part shall be conducted before an Administrative Law Judge designated by the Chief Administrative Law Judge for the Department of Labor except, however, that when the Administrative Law Judge approves a stipulated agreement for appropriate remedial action, he shall prepare his recommended decision and order adopting that agreement and transfer the case to the Assistant Secretary. The Assistant Secretary may order the remedial action set forth in the stipulation agreement or take such action as he deems appropriate.

§ 208.71 Procedure upon admission of facts.

The admission of all the material allegations of fact in the complaint shall constitute a waiver of hearing. Upon such admission, the Administrative Law Judge without further hearing shall prepare his recommended decision and order in which he shall adopt as his proposed findings of fact the material facts alleged in the complaint.

§ 208.72 Motions and requests.

(a) Motions and requests made prior to the hearing shall be filed with the Chief Administrative Law Judge. The moving party shall serve a copy of all motions and requests on all other parties. Motions during the course of the hearing may be stated orally or filed in writing and shall be made part of the record. Each motion shall state the particular order, ruling, or action desired, and the grounds therefor. The Administrative Law Judge is authorized to rule upon all motions made prior to the filing of his report.

(b) A party may request the attendance of witnesses and/or the production of documents at a hearing held pursuant to this part, by written application before the hearing or orally

during the hearing. Copies of an application filed before the opening of the hearing shall be served on the other parties, who may file written objections to the request within seven (7) days after such service. The Administrative Law Judge after consideration of any objections, shall grant the request provided the specified testimony and/or documents appear to be necessary to the matters under investigation. If the Administrative Law Judge denies the request he shall set forth the basis for his ruling. Upon the failure of any party or officer or employee of any party to comply with such a request which has been granted by the Administrative Law Judge, the Administrative Law Judge and the Assistant Secretary may disregard all related evidence offered by the party failing to comply with the request or take such other action as may be appropriate.

(c) Employees who have been determined to be necessary as witnesses at a hearing shall be granted official time only for such participation as occurs during their regular work hours and when they would otherwise be in a work or paid leave status. Participation as witnesses includes the time necessary to travel to and from the site of a hearing, and the time spent giving testimony and waiting to give testimony, when such time falls during regular work hours. In addition, necessary transportation and per diem expenses shall be paid by the employing activity or agency.

§ 208.73 Prehearing conferences.

(a) Upon his own motion or the motion of the parties, the Administrative Law Judge may direct the parties or their counsel to meet with him for a conference to consider:

- (1) Simplification of the issues;
- (2) Necessity or desirability of amendments to pleadings for purposes of clarification simplification, or limitations;
- (3) Stipulations, admissions of fact, and of contents and authenticity of documents;
- (4) Limitation of the number of expert witnesses; and
- (5) Such other matters as may tend to expedite the disposition of the proceeding.

(b) The record shall show the matters disposed of by order and by agreement in such prehearing conferences. The subsequent course of the proceeding shall be controlled by such action.

§ 208.74 Conduct of hearing.

Hearings shall be conducted by an Administrative Law Judge and shall be open to the public unless otherwise

ordered by the Administrative Law Judge.

§ 208.75 Intervention.

Any person desiring to intervene in a hearing shall file a motion in writing in accordance with the procedures set forth in § 208.72 or, if made at the hearing, may move orally on the record, stating the grounds upon which such person claims an interest. Such a motion shall be filed.

§ 208.76 Duties and powers of the Administrative Law Judge.

It shall be the duty of the Administrative Law Judge to inquire fully into the facts as they relate to the matter before him and to prepare, serve and submit his recommended decision and order pursuant to § 208.88. Upon assignment to him and before transfer of the case to the Assistant Secretary, the Administrative Law Judge shall have the authority to:

- (a) Grant requests for appearance of witnesses or production of documents;
- (b) Rule upon offers of proof and receive relevant evidence;
- (c) Take or cause depositions to be taken whenever the ends of justice would be served thereby;
- (d) Limit lines of questioning or testimony which are immaterial, irrelevant, or unduly repetitious;
- (e) Regulate the course of the hearing and if appropriate, exclude from the hearing persons who engage in misconduct and strike all related testimony of witnesses refusing to answer any questions ruled to be proper;
- (f) Hold conferences for the settlement or simplification of the issues by consent of the parties or upon his own motion;
- (g) Dispose of procedural requests, motions, or similar matters which shall be made part of the record of the proceeding, including motions to amend pleadings; also to recommend dismissal of cases or portions thereof, and to order hearings reopened prior to issuance of his recommended decision and order;
- (h) Examine and cross-examine witnesses and to introduce into the record documentary or other evidence;
- (i) Request the parties at any time during the hearing to state their respective positions concerning any issue in the case or theory in support thereof;
- (j) Continue, at his discretion, the hearing from day-to-day, or adjourn it to a later date or to a different place, by announcement thereof at the hearing or by other appropriate notice;
- (k) Take official notice of any material fact not appearing in evidence in the

record, which is among the traditional matters of judicial notice and also concerning which the Department by reason of its functions is presumed to be expert: *Provided*, That the parties shall be given adequate notice, at the hearing or by reference in the Administrative Law Judge's recommended decision and order of the matters so noticed, and shall be given adequate opportunity to show the contrary.

(l) Correct or approve proposed corrections of the official transcript when deemed necessary.

(m) Take any other action necessary under the foregoing and not prohibited by these regulations.

§ 208.77 Rights of parties.

Any party shall have the right to appear at such hearing in person, by counsel, or by other representative, to examine and cross-examine witnesses, and to introduce into the record documentary or other relevant evidence, except that the participation of any party shall be limited to the extent prescribed by the Administrative Law Judge. Two (2) copies of documentary evidence shall be submitted and a copy furnished to each of the other parties. Stipulations of fact may be introduced in evidence with respect to any issue.

§ 208.78 Rules of evidence.

The technical rules of evidence do not apply. Any evidence may be received, except that an Administrative Law Judge may exclude any evidence or offer of proof which is immaterial, irrelevant, unduly repetitious, or customarily privileged. Every party shall have a right to present his case by oral and documentary evidence and to submit rebuttal evidence.

§ 208.79 Burden of proof.

In a hearing concerning an alleged violation of § 208.2 (Bill of rights of members of labor organizations) or § 208.37 (Prohibition of certain discipline), the complainant shall have the burden of proving the allegations of the complaint by a preponderance of the evidence. In a hearing concerning an alleged violation of other standards of conduct matters, the Director shall have the burden of proof.

§ 208.80 Unavailability of Administrative Law Judges.

In the event the Administrative Law Judge designated to conduct the hearing becomes unavailable, the Chief Administrative Law Judge shall designate another Administrative Law Judge for the purpose of further hearing or issuance of a recommended decision

and order on the record as made, or both.

§ 208.81 Objection to conduct of hearing.

(a) Any objection with respect to the conduct of the hearing, including any objection to the introduction of evidence, may be stated orally or in writing accompanied by a short statement of the grounds for such objection and included in the record. No such objection shall be deemed waived by further participation in the hearing. Such objection shall not stay the conduct of the hearing.

(b) Automatic exceptions will be allowed to all adverse rulings. Rulings by the Administrative Law Judge shall not be appealed prior to the transfer of the case to the Assistant Secretary, but shall be considered by the Assistant Secretary only upon the filing of exceptions to the Administrative Law Judge's recommended decision and order in accordance with § 208.88.

§ 208.82 Motions after a hearing.

All motions made after the transfer of the case to the Assistant Secretary, except motions to correct the record under § 204.76(l), shall be made in writing to the Assistant Secretary. The moving party shall serve a copy of all motion papers on all other parties. A statement of service shall accompany the motion. Answers, if any, must be served on all parties and the original thereof, together with a statement of service, shall be filed with the Assistant Secretary after the hearing, within seven (7) days after service of the moving papers unless it is otherwise directed.

§ 208.83 Waiver of objections.

Any objection not duly urged before an Administrative Law Judge shall be deemed waived.

§ 208.84 Oral argument at the hearing.

Any party shall be entitled, upon request, to a reasonable period prior to the close of the hearing for oral argument, which shall be included in the official transcript of the hearing.

§ 208.85 Transcript.

An official reporter shall make the only official transcript of such proceedings. Copies of the official transcript will be provided to the parties, in accordance with the provisions of 29 CFR 70.62(c), or they may be examined in the Area Office in whose geographic jurisdiction the hearing has been held.

§ 208.86 Filing of brief.

Any party desiring to submit a brief to the Administrative Law Judge shall file the original within ten (10) days after the

close of the hearing: *Provided, however,* That prior to the close of the hearing and for good cause, the Administrative Law Judge may grant a reasonable extension of time. Copies of such brief shall be served on all of the parties to the proceeding. Requests for additional time in which to file a brief under authority of this section made after the hearing shall be made in writing to the Administrative Law Judge and copies thereof served on the other parties. A statement of such service shall be furnished. A request for extension of time shall be received not later than three (3) days before the date such briefs are due. In the absence of the Administrative Law Judge such requests shall be ruled upon by the Chief administrative Law Judge. No reply brief may be filed except by permission of the Administrative Law Judge.

§ 208.87 Proposed findings and conclusions.

Within fifteen (15) days following the close of the hearing, the parties may submit proposed findings and conclusions to the Administrative Law Judge, together with supporting reasons therefor, which shall become part of the record.

§ 208.88 Submission of the Administrative Law Judge's recommended decision and order to the Assistant Secretary; exceptions.

(a) After the close of the hearing, and the receipt of briefs, or findings and conclusions, if any, the Administrative Law Judge shall prepare his recommended decision and order expeditiously. The recommended decision and order shall contain findings of fact, conclusions, and the reasons or basis therefor including credibility determinations, and recommendations as to the disposition of the case including the remedial action to be taken.

(b) The Administrative Law Judge shall cause his recommended decision and order to be served promptly on all parties to the proceeding. Thereafter, the Administrative Law Judge shall transfer the case to the Assistant Secretary including his recommended Decision and order and the record. The record shall include the complaint, the notice of hearing, motions, rulings, orders, official transcript of the hearing, stipulations, objections, depositions, exhibits, documentary evidence and any briefs or other documents submitted by the parties.

(c) Exceptions to the Administrative Law Judge's recommended decision and order may be filed by any party with the Assistant Secretary within fifteen (15)

days after service of the recommended decision and order: *Provided, however,* That the Assistant Secretary may for good cause shown extend the time for filing such exceptions. Requests for additional time in which to file exceptions shall be in writing, and copies thereof shall be served on the other parties. Requests for extension of time must be received no later than three (3) days before the date the exceptions are due. Copies of such exceptions and any supporting briefs shall be served on all other parties, and a statement of such service shall be furnished to the Assistant Secretary.

§ 208.89 Contents of exceptions to Administrative Law Judge's recommended decision and order.

(a) Exceptions to an Administrative Law Judge's recommended decision and order shall:

- (1) Set forth specifically the questions upon which exceptions are taken;
- (2) Identify that part of the Administrative Law Judge's recommended decision and order to which objection is made;
- (3) Designate by precise citation of page the portions of the record relied on, state the grounds for the exceptions and include the citation of authorities unless set forth in a supporting brief.

(b) Any exception to a ruling, finding, conclusion, or recommendation which is not specifically urged shall be deemed to have been waived. Any exception which fails to comply with the foregoing requirements may be disregarded.

§ 208.90 Briefs in support of exceptions.

(a) Any brief in support of exceptions shall contain only matters included within the scope of the exceptions and shall contain, in the order indicated, the following:

- (1) A concise statement of the case containing all that is material to the consideration of the questions presented;
- (2) A specification of the questions involved and to be argued;
- (3) The argument, presenting clearly the points of fact and law relied on in support of the position taken on each question, with specific page reference to the transcript and the legal or other material relied on.

(b) Answering briefs to the exception may be filed with the Assistant Secretary within ten (10) days after service of the exceptions.

208.91 Action by the Assistant Secretary.

(a) After considering the Administrative Law Judge's recommended decision and order, the record, and any exceptions filed, the

Assistant Secretary shall issue his decision affirming or reversing the Administrative Law Judge, in whole, or in part, or making such other disposition of the matter as he deems appropriate: *Provided, however,* That unless exceptions are filed which are timely and in accordance with § 208.89, the Assistant Secretary may, at his discretion, adopt without discussion the recommended decision and order of the Administrative Law Judge, in which event the findings, conclusions, and recommendations of the Administrative Law Judge, as contained in his recommended decision and order shall, upon appropriate notice to the parties, automatically become the decision of the Assistant Secretary.

(b) Upon finding a violation of the Act, the Assistant Secretary may order the respondent to cease and desist from such violative conduct and may require the respondent to take such affirmative action as he deems appropriate to effectuate the policies of the Act.

(c) Upon finding no violation of the Act, the Assistant Secretary shall dismiss the complaint.

208.92 Compliance with decisions and orders of the Assistant Secretary.

When remedial action is ordered, the respondent shall report to the Assistant Secretary, within a specified period that the required remedial action has been effected. When the Assistant Secretary finds that the required remedial action has not been effected, he shall refer the matter to the Federal Labor Relations Authority for appropriate action.

208.93 Stay of remedial action.

In cases involving violations of this part, the Assistant Secretary may direct, subject to such conditions as he deems appropriate, that the remedial action ordered be stayed.

PART 209—MISCELLANEOUS

Sec.

- 209.1 Computation of time for filing papers.
- 209.2 Additional time after service by mail.
- 209.3 Documents in a proceeding.
- 209.4 Service of pleading and other papers under this chapter.
- 209.5 Rules to be construed liberally.

Authority: Secs. 7120, 7134 of the Civil Service Reform Act of 1978 (— Stat. —; — U.S.C. —).

§ 209.1 Computation of time for filing papers.

In computing any period of time prescribed by or allowed by the regulations contained in Part 208 of this chapter, the day of the act, event, or default after which the designated period of time begins to run, shall not be included. The last day of the period so

computed is to be included unless it is a Saturday, Sunday or Federal legal holiday in which event the period shall run until the end of the next day which is neither a Saturday, Sunday, or a Federal legal holiday. When the period of time prescribed or allowed is seven (7) days, or less, intermediate Saturdays, Sundays, and Federal legal holidays shall be excluded from the computations. When these regulations require the filing of any paper, such document must be received by the Assistant Secretary or the officer or agent designated to receive such matter before the close of business of the last day of the time limit, if any, for such filing or extension of time that may have been granted.

§ 209.2 Additional time after service by mail.

Whenever a party has the right or is required to do some act pursuant to these regulations within a prescribed period after service of a notice or other paper upon him and the notice or paper is served on him by mail, five (5) days shall be added to the prescribed period: *Provided, however,* That five (5) days shall not be added if any extension of time may have been granted.

§ 209.3 Documents in a proceeding.

(a) *Title.* Documents in any proceeding under Part 208 of this chapter, including correspondence, shall show the title of the proceeding and the case number, if any.

(b) *Signature.* The original of each document required to be filed under these regulations shall be signed by the party or by an attorney or representative of record for the party, or by an officer of the party, and shall contain the address and telephone number of the person signing it.

§ 209.4 Service of pleading and other papers under this chapter.

(a) *Method of service.* Notices of hearing, decisions, orders and other papers may be served personally or by registered or certified mail or by telegraph. When service is by mail, the date of service shall be the day when the matter served is deposited in the United States mail.

(b) *Upon whom served.* All papers, except as herein otherwise provided, shall be served upon all counsel of record and upon parties not represented by counsel or by their agents designated by them or by law and upon the Assistant Secretary, or his designated officer, or agent or Administrative Law Judge where appropriate. Service upon such counsel or representative shall constitute service upon the party, but a

copy also shall be transmitted to the party.

§ 209.5 Rules to be construed liberally.

(a) The regulations in this chapter may be construed liberally to effectuate the purposes and provisions of the Act.

(b) When an act is required or allowed to be done at or within a specified time, the Assistant Secretary may at any time order the period altered where it shall be manifest that strict adherence will work surprise or injustice or interfere with the proper effectuation of the Act.

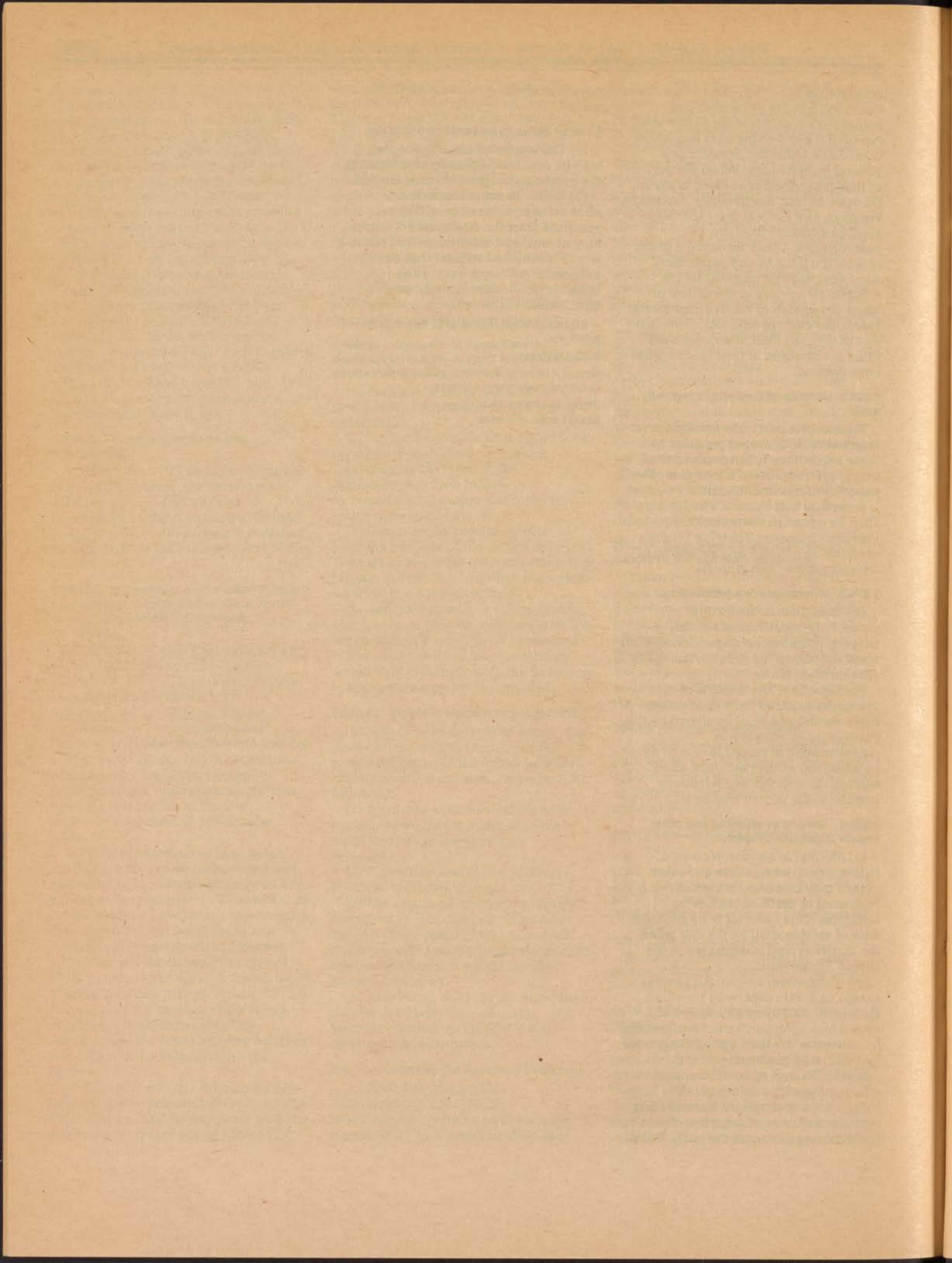
Signed at Washington, D.C. this 26th day of July 1979.

R. C. DeMarco,

Acting Assistant Secretary of Labor for Labor-Management relations.

[FR Doc. 79-26737 Filed 8-27-79; 8:45 am]

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Federal Register

**Tuesday
August 28, 1979**

Part VI

Department of Labor

Mine Safety and Health Administration

**Metal and Nonmetal Mine Safety;
Correction**

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August 22, 1975

Part VI

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Mine Safety and Health Administration

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR 55, 56, and 57

Metal and Nonmetal Mine Safety;
CorrectionAGENCY: Mine Safety and Health
Administration, Department of Labor.

ACTION: Final Rule; Correction.

SUMMARY: This action corrects the Mine Safety and Health Administration's final rules amending 30 CFR Parts 55, 56 and 57 which were published in the Federal Register on June 1, 1979 (44 FR 31908-31920). The final rules added new or revised mandatory safety and health standards for radon daughter exposure; fire protection and control; ventilation; loading, hauling and dumping; travelways and escapeways; hoisting, and sanitary facilities. The corrections are necessary to assure that preamble statements are consistent with the rule itself and to further clarify the application of the rule.

EFFECTIVE DATE: August 28, 1979.

FOR FURTHER INFORMATION CONTACT: Thomas J. Shepich, Administrator, Metal and Nonmetal Mine Safety and Health, Mine Safety and Health Administration, Ballston Tower, No. 3, Room 702, 4015 Wilson Boulevard, Arlington, Virginia 22203, (703) 235-1565.

The following changes are made to correct errors in FR Doc. 79-17078:

1. On page 31910, column 1, paragraph 3, line 7 is corrected to read, "described in § 14.3 of ANSI N13.8-1973".
2. On page 31910, column 2, line 3, insert "and" between "areas" and "in". This line is corrected to read, "areas and in any other location where".
3. On page 31910, column 2, paragraph 1, line 4, delete "still" and substitute "every 2 weeks" with "monthly". This line is corrected to read, "must be sampled monthly".
4. On page 31910, column 2, delete paragraph 2, and substitute the following:

In the event that air samplings reveal a radon daughter concentration in excess of 0.3 WL in the active working area, concentrations must be determined weekly in that area (whether or not uranium is mined) until the weekly determinations are 0.3 WL or less for five consecutive weeks. In addition, this final rule requires air testing in a uranium mine every two weeks when the radon daughter concentration is between 0.1 WL and 0.3 WL. The proposed standard specified monthly testing under like circumstances. The

agency and parties stipulated to the language of the final rule.

5. On page 31910, column 2, delete paragraph 3.

6. On page 31911, column 1, line 6, replace "0.8" with "1/12 WLM". This line is corrected to read "1/12 WLM (e.g. January—08; February—)".

7. On page 31911, column 2, paragraph 1, line 13, insert "non-duplicated" after "However, the". This line is corrected to read, "individual exposures. However, the non-duplicated".

8. On page 31911, column 3, 4th paragraph, delete 3rd sentence and correct 2nd sentence to read:

"The mine operator must provide either a second multipurpose dry-chemical extinguisher or equipment with the equivalent extinguishing capacity appropriate for the particular hazard involved where these same operations occur in close proximity to:

- (1) Specific quantities of combustible liquids (other than those enclosed in noncombustible metal containers); (2) specific quantities of non-fire-retardant wood; (3) specific quantities of combustible plastic; (4) a mine shaft where there is a risk that combustible materials may be ignited by falling sparks or heated material; and (5) a raise or winze where there is a risk that combustible materials may be ignited by falling sparks or heated material [57.4-77(a), 57.4-78(a)]."

9. On page 31913, column 1, paragraph 3, line 11, delete "planned or". This line is corrected to read, "unplanned fan shutdowns".

10. On page 31913, column 2, paragraph 1, delete the entire paragraph and substitute the following:

"The revised standards, like the proposed standard establishes procedures to be followed in the event of fan failure. The language has been changed to provide the mine operator with a guide as to what is considered adequate monitoring of air quality. The revised standard requires such monitoring to consist of testing the air quality within 2 hours of discovery of fan failure for compliance with section 57.5 and 57.21 and every 4 hours thereafter until normal ventilation is restored."

11. On page 31913, 3rd paragraph, delete the first two sentences and substitute the following:

The principal concern at the hearing was a periodic 2-hour testing requirement contained in the proposed rule rather than the continuous operation of main, booster and auxiliary fans. Testing is essential and the agency and all parties agreed that a periodic 4-hour testing provision would be both workable and understandable and

would provide operators with specific and uniform direction with respect to the frequency of testing.

12. On page 31915, column 3, "Hoisting Buckets", line 15, delete "the" after "at" and substitute "a". This line is corrected to read "at a minimum speed for the hoist".

13. On page 31916, column 2, mandatory standard 55.19-78, line 2, 1st sentence, insert "about" between "raised" and "3 feet". The corrected sentence reads, "All buckets shall be stopped after being raised about 3 feet above the shaft bottom".

14. On page 31916, column 3, mandatory standard 56.19-78, line 2, 1st sentence, insert "about" between "raised" and "3 feet". The corrected sentence reads, "All buckets shall be stopped after being raised about 3 feet above the shaft bottom".

15. On page 31918, column 2, mandatory standard 57.5-37(b), replace "therefore;" with "thereafter:". This sentence is corrected to read, "(b) If concentrations of radon daughters less than 0.1 WL are found in an exhaust mine air sample, thereafter:".

Dated: August 24, 1979.

Robert B. Lagather,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-26945 Filed 8-27-79; 8:45 am]

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday).

This is a voluntary program. (See OFR NOTICE FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY*	USDA/ASCS		DOT/SECRETARY*	USDA/ASCS
DOT/COAST GUARD	USDA/APHIS		DOT/COAST GUARD	USDA/APHIS
DOT/FAA	USDA/FNS		DOT/FAA	USDA/FNS
DOT/FHWA	USDA/FSQS		DOT/FHWA	USDA/FSQS
DOT/FRA	USDA/REA		DOT/FRA	USDA/REA
DOT/NHTSA	MSPB/OPM		DOT/NHTSA	MSPB/OPM
DOT/RSPA	LABOR		DOT/RSPA	LABOR
DOT/SLS	HEW/FDA		DOT/SLS	HEW/FDA
DOT/UMTA			DOT/UMTA	
CSA			CSA	

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

*NOTE: As of July 2, 1979, all agencies in the Department of Transportation, will publish on the Monday/Thursday schedule.

REMINDERS

The items in this list were editorially compiled as an aid to **Federal Register** users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.

Rules Going Into Effect Today**HEALTH, EDUCATION, AND WELFARE DEPARTMENT**

Health Care Financing Administration—

8-28-79 / Medicaid programs; exclusion of physicians or practitioner convicted of a criminal offense related to the programs.

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last Listing August 17, 1979

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