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Monday	Tuesday	Wednesday	Thursday	Friday
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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

NOTE: There were no items eligible for inclusion in the list of RULES GOING INTO EFFECT TODAY.

List of Public Laws

This is a continuing listing of public bills that have become law, the text of which is not published in the FEDERAL REGISTER. Copies of the laws in individual pamphlet form (referred to as "slip laws") may be obtained from the U.S. Government Printing Office.

H.R. 7278..... Pub. L. 95–177
To amend section 10 of the Merchant Marine Act, 1936. (Nov. 15, 1977; 91 Stat. 1368). Price: $.50.

H.R. 8499..... Pub. L. 95–178
To amend the Alaska Native Claims Settlement Act. (Nov. 15, 1977; 91 Stat. 1369). Price: $.50.

H.R. 8992..... Pub. L. 95–179
To amend title 3 of the United States Code to change the name of the Executive Protective Service. (Nov. 15, 1977; 91 Stat. 1371). Price: $.50.

H.R. 9512..... Pub. L. 95–180
To amend the Higher Education Act of 1965 to include the Trust Territory of the Pacific Islands in the definition of the term "State" for the purpose of participation in programs authorized by that Act. (Nov. 15, 1977; 91 Stat. 1372). Price: $.50.

H.R. 9704..... Pub. L. 95–181
To amend the Federal Crop Insurance Act, and for other purposes. (Nov. 15, 1977; 91 Stat. 1373). Price: $.50.

H.R. 9836..... Pub. L. 95–182
To authorize the Architect of the Capitol to furnish chilled water to the Folger Shakespeare Library. (Nov. 15, 1977; 91 Stat. 1374). Price: $.50.

S. 1062..... Pub. L. 95–185
To amend section 441 of the District of Columbia Self-Government and Governmental Reorganization Act. (Nov. 15, 1977; 91 Stat. 1383). Price: $.50.

S. 1339..... Pub. L. 95–183
"Energy Research and Development Administration Authorization Act of 1977 and 1978—Military Applications." (Nov. 15, 1977; 91 Stat. 1375). Price: $.60.

S. 1863..... Pub. L. 95–184
"Department of Defense Supplemental Appropriation Authorization Act, 1978". (Nov. 15, 1977; 91 Stat. 1381). Price: $.50.

H.R. 8346..... Pub. L. 95–187
To amend the Urban Mass Transportation Act of 1964 to revise the program of Federal operating assistance provided under section 17 of such Act. (Nov. 16, 1977; 91 Stat. 1385). Price: $.50.

H.R. 9019..... Pub. L. 95–186
To rescind certain budget authority contained in the message of the President of July 19, 1977 (II, Doc. 95–188) submitted pursuant to the Impoundment Control Act of 1974. (Nov. 16, 1977; 91 Stat. 1384). Price: $.50.

H.R. 9710..... Pub. L. 95–188
To extend the authority for the flexible regulation of interest rates on deposits and accounts in depository institutions, to promote the accountability of the Federal Reserve System, and for other purposes. (Nov. 16, 1977; 91 Stat. 1387). Price: $.60.

S. 1528..... Pub. L. 95–190
"Safe Drinking Water Amendments of 1977". (Nov. 16, 1977; 91 Stat. 1393). Price: $.80.

S. 2281..... Pub. L. 95–189
Authorizing an increase in the monetary authroization for nine comprehensive river basic plans. (Nov. 16, 1977; 91 Stat. 1392). Price: $.50.

rules and regulations

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.

[3410-34]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 73—SCABIES IN CATTLE

Areas Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of these amendments is to quarantine a portion of Malheur County in Oregon and a portion of Finney County in Kansas because of the existence of cattle scabies. Psoroptic cattle scabies was confirmed November 8, 1977, in Malheur County and on November 11, 1977, in Finney County. Therefore, in order to prevent the dissemination of cattle scabies it is necessary to quarantine the infested areas.

EFFECTIVE DATE: November 15, 1977.

FOR FURTHER INFORMATION CONTACT:

Dr. Glen O. Schubert, Chief Staff Veterinarian, Sheep, Goats, Equine and Ectoparasites Staff, USDA, APHIS, VS, Federal Building, Room 737, 6505 Belcrest Road, Hyattsville, Md. 20782, 301-436-8322.

SUPPLEMENTARY INFORMATION: These amendments quarantine a portion of Malheur County in Oregon and a portion of Finney County in Kansas because of the existence of cattle scabies. The restrictions pertaining to the interstate movement of cattle from quarantined area as contained in 9 CFR Part 73, as amended, will apply to the areas quarantined.

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

In § 73.1a, a new paragraph (c) relating to the State of Oregon and a new paragraph (d) relating to the State of Kansas are added to read:

§ 73.1a Notice of quarantine.

* * * * *

(c) Notice is hereby given that cattle in a certain portion of the State of Oregon 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:

That portion of Malheur County comprised of all of sec. 21 except Tax Lot 300, T. 19, R. 46.

(d) Notice is hereby given that cattle in a certain portion of the State of Kansas 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:

That portion of Finney County comprised of sec. 2, T. 25, R. 32.

* * * * *

(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 amendments impose certain further restrictions necessary to prevent the interstate spread of cattle scabies and must be made effective immediately to accomplish their purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under 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 the amendments are impracticable and contrary to the public interest, and good cause is found for making the amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 15th day of November 1977.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

NORVAN L. MEYER,
Acting Deputy Administrator, Veterinary Services.

[FR Doc.77-33514 Filed 11-21-77;8:45 am]

[3510-24]

Title 13—Business Credit and Assistance

CHAPTER III—ECONOMIC DEVELOPMENT ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 305—PUBLIC WORKS AND DEVELOPMENT FACILITIES PROGRAM

Minimum Grant Rates

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Final rule.

SUMMARY: This new rule amends existing regulations by specifying the maximum grant rates permissible to those projects located in areas designated under an EDA Planning Directive under the Public Works and Economic Development Act of 1965. This rule is intended to make an administrative change and is effective only until December 31, 1977.

DATES: Effective date: November 16, 1977.

COMMENTS BY: December 22, 1977.

ADDRESSES: Send comments to: Assistant Secretary for Economic Development, U.S. Department of Commerce, Room 7800B, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT:

Information on Regulations: James F. Marten, U.S. Department of Commerce, Room 7009, Washington, D.C. 20230, 202-377-5441.

SUPPLEMENTARY INFORMATION: The Economic Development Administration (EDA) is making these revisions to Part 305 of 13 CFR to accomplish the objective of specifying which maximum grant rates are available to those areas which fall under the exception stated in the addenum to EDA Planning Directive No. 52, Chapter 5.

Because this rule relates to the EDA grant and loan program, it is exempted from the procedures described in section 553 of the Administrative Procedure Act (5 U.S.C. 553). However, in the spirit of the public policy set forth in that Act, interested persons are invited to submit written suggestions on this regulation to the above address.

EDA has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821, as amended by Executive Order 11949, and OMB Circular A-107.

Accordingly, 13 CFR 305.(b)(3) is amended by adding a new paragraph to § 305.5(b)(3)(X) to read as follows:

§ 305.5 Supplementary grants.

* * * * *

(b) * * *

(3) * * *

(X) Projects located in areas designated under the addendum to EDA Planning Directive No. 52, Chapter 5 under Title IV of the Act may only qualify for those maximum grant rates

listed in paragraphs (vi), (vii) and (viii) of this section.

(Pub. L. 94-487, 90 Stat. 2331 (42 U.S.C. 3121 et seq.); Section 701, Pub. L. 89-136, 79 Stat 570 (42 U.S.C. 3211); Department of Commerce Organization Order 10-4, as amended (40 FR 56702, as amended).)

Date: November 16, 1977.

ROBERT T. HALL,
Assistant Secretary for Economic Development.

[FR Doc.77-33589 Filed 11-21-77;8:45 am]

[3510-24]

PART 315—ADJUSTMENT ASSISTANCE FOR FIRMS AND COMMUNITIES

Clarification of Policy

AGENCY: Economic Development Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Administration is revising certain regulations which affect adjustment assistance for firms and communities. These revisions to the regulations are needed to clarify the policy of the Economic Development Administration (EDA) with respect to the adjustment assistance programs. The intended effect of these revisions to the regulations is to clarify the policy of EDA with respect to the adjustment assistance programs.

DATES: Effective date: November 22, 1977. Comments by: December 22, 1977.

ADDRESSES: Send comments to: Assistant Secretary for Economic Development, U.S. Department of Commerce, Room 7800B, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT:

Information on Regulations:
James F. Marten, U.S. Department of Commerce, Room 7009, Washington, D.C. 20230, 202-377-5441.

SUPPLEMENTARY INFORMATION: This publication amends 13 CFR 315 by revising the following regulations:

SUBPART A

1. Section 315.2(a)(4) is amended to provide that, for purposes of certification, related firms may be considered a single firm only if engaged in the production or sale of the product against which the impact of imports is to be measured but that such related firms may be considered a single firm for purposes of determining access to financing, except in circumstances in which it would be economically unwarranted for a related firm to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such related firm. This amendment is intended to clarify EDA policy with respect to the circumstances under which related firms should be considered a single firm in order to prevent unjustifiable benefits.

SUBPART B

1. Section 315.28(b)(7) is amended by deleting the last sentence thereof. This amendment is intended to eliminate an unnecessary sentence discussing the contribution of imports to worker separation and decrease in sales or production.

SUBPART C

1. Section 315.51(a) is amended by providing for an exception to the present regulation which provides that a firm certified as eligible to apply for adjustment assistance may, at any time within two years after the date of such certification, file an application for adjustment assistance under this subpart. This amendment will provide for applications after two years from the date of certification when filed in accordance with an approved amendment to a firm's adjustment proposal where such proposal has been accepted by the Assistant Secretary within two years after the date of certification. This amendment is intended to implement the policy, expressed in the legislative history of Section 252 of the Trade Act, of allowing revision of a firm's initial adjustment proposal after the expiration of the two-year period.

2. Section 315.51(b)(3) is amended by providing for an exception to the present regulation which provides that a firm's own resources include the total resources available from affiliated or related firms. The exception will apply in circumstances in which it would be economically unwarranted for such affiliated or related firms to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such affiliated or related firms. This amendment is intended to clarify EDA policy with respect to the circumstances under which a firm's own resources are considered to include resources of affiliated or related firms. This section is also amended by minor modifications to the last two sentences in the interest of clarity.

3. Section 315.56(c) is added to provide that funds will not be considered available from a firm's own resources or from private sources by reason of such funds being available from a related firm in circumstances where it would be economically unwarranted for the related firm to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such related firm. This addition is intended to clarify EDA policy with respect to the circumstances under which funds will be considered available from a firm's own resources or from private sources.

4. Section 315.62(a)(1)(i) is added to provide that personal guarantees will be required only when necessary to assure the continued interest and effort of the borrower's owners or management on behalf of the borrower. This addition is intended to clarify EDA policy in regard to personal guarantees.

SUBPART E

1. Section 315.98(a)(1)(i) is added to provide that the term "significant number or proportion of the workers" shall mean 200 employees or 5 percent of the total employment force of a Trade Impacted Area. This addition is intended to provide specific criteria for determining whether the number of separated workers in a Trade Impacted Area is sufficient for certification of the communities located in such Area.

2. Section 315.98(a)(2)(i) is added to provide that the term "firms or subdivisions of firms" shall mean those firms or subdivisions of firms employing the significant number or proportion of the workers referred to in Section 315.98(a)(1). This addition is intended to provide specific criteria for determining which firms will be examined to determine whether there has been a decrease in sales or production sufficient for certification of a community.

3. Section 315.98(b)(5) is amended to provide that the term "decreased absolutely" is used in reference to the sales or production of the firms or subdivisions thereof referred to in Section 315.98(a)(2). This amendment is intended to cointhereof referred to in Section 315.98(a)(2) which provides specific criteria for determining which firms will be examined to determine whether there has been a decrease in sales or production sufficient for certification of a community.

4. Section 315.98(b)(7) is amended by deleting the last sentence thereof. This amendment is intended to eliminate an unnecessary sentence discussing the contribution of imports to worker separation and decrease in sales or production.

Because these rules relate to the EDA grant and loan program, they are exempted from the procedures described in section 553 of the Administrative Procedure Act (5 U.S.C. 553). However, in the spirit of the public policy set forth in that Act, interested persons may submit written suggestions regarding this amendment to the above address.

NOTE.—EDA has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821, as amended by Executive Order 11949, and OMB Circular A-107.

Accordingly, 13 CFR, Subparts A, B, C, and E are amended as follows:

Subpart A—General Provisions

1. By revising § 315.2(a)(4) to read as follows:

§ 315.2 Definitions.

(a) * * *

(4) *Firm* as it applies to Subparts B, C, and D includes—

(i) Any individual proprietorship, partnership, joint venture, association, corporation (including a development

corporation), business trust, cooperative, trustee in bankruptcy, or receiver under decree of any court.

(ii) When determined necessary by the Deputy Assistant Secretary for Economic Development Planning to prevent unjustifiable benefits, a firm, together with any predecessor or successor firm, or any affiliated firm controlled or substantially beneficially owned by the same person or persons may be considered a single firm:

(A) For purposes of the determinations regarding workers, sales and production required for certification under § 315.28, related firms may be considered a single firm only if engaged in the production or sale of the product against which the impact of imports is to be measured.

(B) For purposes of the determinations regarding access to financing through the private capital market and availability of funds from the firm's own resources required under § 315.56, related firms may be considered a single firm, except in circumstances in which it would be economically unwarranted for a related firm to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such related firm.

* * * * *

Subpart B—Certification of Eligibility of Firms To Apply for Adjustment Assistance

§ 315.28 [Amended]

1. By amending § 315.28(b)(7) by deleting the last sentence thereof.

Subpart C—Adjustment Assistance for Firms

1. By revising § 315.51 (a) and (b)(3) to read as follows:

§ 315.51 Application for assistance.

(a) A firm certified as eligible to apply for adjustment assistance may, at any time within two years after the date of such certification, file an application with the Assistant Secretary for adjustment assistance under this subpart. Applications may be filed after the expiration of such two-year period only when filed in accordance with an amendment, approved by the Assistant Secretary, to a firm's adjustment proposal which proposal has been accepted by the Assistant Secretary within two years after the date of certification. Applications shall be made on forms provided by the Assistant Secretary and shall contain such financial and supportive information as the Assistant Secretary may require.

(b) * * *

(3) *Reasonable efforts by the firm to use its own resources.* An adjustment proposal must demonstrate that the firm will make maximum use of its own resources and that any funds requested are not otherwise aavilable to the firm, from sources other than the Federal Government, on reasonable terms. The firm's own resources include the total resources available from all affiliated firms or related entities under the ownership and control of substantially the same persons, except in circumstances in which it would be economically unwarranted for such affiliated firms or related entities to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such affiliated firms or related entities. Under certain circumstances, as in the case of a closely held corporation, the firm's resources may extend to the personal resources of shareholders. Evidence required as to the availability of funds shall be in the form and manner as prescribed by the Assistant Secretary.

* * * * *

2. By the addition of § 315.56(c) to read as follows:

§ 315.56 Eligibility for financial assistance.

* * * * *

(c) Funds will be not considered available from the firm's own resources or from private sources by reason of such funds being available from a related firm of the firm applying for assistance in circumstances where it would be economically unwarranted for the related firm to provide the assistance needed because of the cost of providing such assistance in relation to any return that could reasonably be anticipated to such related firm.

3. By the addition of § 315.62(a)(1)(i) to read as follows:

§ 315.62 Administration of financial assistance.

(a) * * *

(1) * * *

(i) Personal guarantees will be required only when necessary to assure the continued interest and effort of the borrower's owners or management on behalf of the borrower.

* * * * *

Subpart E—Certification of Eligibility of Communities To Apply for Adjustment Assistance

1. By the addition of § 315.98(a)(1)(i) to read as follows:

§ 315.98 Criteria for certification.

(a) * * *

(1) * * *

(i) For purposes of this subsection, the term "significant number or proportion of the workers" shall mean 200 employees or 5% of the total employment force of a Trade Impacted Area.

* * * * *

2. By adding § 315.98(a)(2)(i), and by revising § 315.98(b)(5) to read as follows:

§ 315.98 Criteria for certification.

(a) * * *

(2) * * *

(i) For purposes of this subsection, the term "firms or subdivisions of firms" shall mean those firms or subdivisions of firms employing the significant number or proportion of the workers referred to in (a)(1) of this section.

* * * * *

(b) * * *

(5) The term "decreased absolutely" is used in reference to the sales or production of the firms or subdivisions thereof referred to in paragraph (a)(2) of this section irrespective of industry or market fluctuations and relative only to the previous performance of such firms or subdivisions.

* * * * *

§ 315.98 [Amended]

3. By amending § 315.98(b)(7) by deleting the last sentence thereof.

(Section 701, Pub. L. 89-136, 79 Stat. 570 (42 U.S.C. 3211); Section 262, Pub. L. 93-618, 88 Stat. 2034 (19 U.S.C. 2352); Department of Commerce Organization Order 10-4 (September 30, 1975), as amended (40 FR 56702, as amended).)

Dated: November 9, 1977.

ROBERT T. HALL,
Assistant Secretary for Economic Development.

[FR Doc.77-33560 Filed 11-21-77;8:45 am]

[6320-01]

Title 14—Aeronautics and Space

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER A—ECONOMIC REGULATIONS

[Regulation ER-1028, Amdt. 4]

PART 201—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY

Procedures for Applying for "Grandfather" Certificates Pursuant to Section 418 of the Federal Aviation Act

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: A new law amending various provisions of the Federal Aviation Act directs the Board to issue certificates authorizing all-cargo air service to certain carriers that now provide or recently provided all-cargo air service and that apply to the Board on or before December 27, 1977. This final rule prescribes the form and contents for those applications and permits applicants to file tariffs before their 418 certificates are issued.

DATES:

Effective: November 16, 1977.

Adopted: November 16, 1977.

FOR FURTHER INFORMATION CONTACT:

Ernest M. Stern, Bureau of Operating Rights, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 202-673-5335.

SUPPLEMENTARY INFORMATION: Section 17 of Pub. L. 95-163, 91 Stat. 1278 (1977), adding a new section 418 to the Federal Aviation Act, directs the Board to issue certificates authorizing domestic all-cargo air service, without

restriction as to points to be served, to two classes of "grandfather" carriers. The first of these classes consists of those certificated carriers that have, "at any time" between January 1, 1977, and November 9, 1977, provided scheduled all-cargo service in interstate air transportation or between the United States, Puerto Rico and the U.S. Virgin Islands. The second class of carriers consists of all those operating under an exemption issued pursuant to section 416 of the Act (49 U.S.C. § 1386), that have provided scheduled all-cargo air service, in the markets described above, continuously (other than for interruptions caused by labor disputes) during the year ended November 9, 1977 (new § 418(a)(2)). (The requirements of this paragraph are also satisfied if such service has been provided by a "predecessor in interest" of an applicant.)

With respect to both classes of carriers, the Board is directed to issue certificates to all eligible carriers that have, on or before December 26, 1977, submitted an application in such form and containing such information "as the Board shall by regulation require." This final rule prescribes the form and contents for the applications for these certificates, which are to be issued within 60 days of the date on which application has been made.

We wish to call attention to paragraph 201.6(f) of this regulation, which requires applicants to respond promptly to requests by the Board or its staff for additional information. It is impossible to anticipate all the information which may be required to determine whether a particular applicant is qualified to receive a certificate under new section 418(a) (1) or (2), and we expect all applicants that wish to receive a certificate within the 60-day statutory period to comply with their responsibility under this paragraph. It is contemplated that no hearings will be held on any of these applications, and all necessary information will therefore have to be submitted in writing as a part of the carrier's application.

We tentatively conclude that the requirements of NEPA and EPCA are inapplicable to the Board's actions under Pub. L. 95-163. While NEPA instructs agencies to comply with its provisions "to the fullest extent possible," it recognizes that where a clear and unavoidable conflict in statutory authority exists, NEPA must yield. Such a conflict exists here.

The Board has no discretion to postpone the issuance of certificates beyond the 60 days mandated by law if applications are filed in compliance with our regulations. It is not possible for the Board to comply with this mandate and within the 60 days also draft, circulate, receive comments upon, review, and revise an adequate environmental impact statement, let alone one meeting the requirements of Part 312 and the CEQ Guidelines, 40 CFR § 1500 et seq. Moreover, we do not interpret our power to promulgate these regulations as a license to extend the Congressionally imposed timetable for deregulation of all-cargo services. Rather, the regulations are simply a means for the Board to ensure the orderly transition to a deregulated environment for carriers with "grandfather" rights within that timetable. Thus, even if the issuance of a certificate under these regulations constituted a major Federal action significantly affecting the quality of the human environment, ordinarily requiring an environmental impact statement, the preparation of a statement would inevitably cause a clear and fundamental conflict with our mandatory duties under the all-cargo deregulation law. In these circumstances, we cannot reasonably comply with NEPA, and conclude that the NEPA requirements are not applicable, see *Flint Ridge Development Co. v. Scenic Rivers Ass'n. of Oklahoma*, 426 U.S. 776 (1976). The same considerations apply to our responsibility under EPCA to prepare a statement on energy conservation and efficiency.[1]

An additional factor supporting our tentative conclusion that NEPA and EPCA are inapplicable is our severely limited discretion with respect to issuance of the certificates. Fundamentally, both NEPA and EPCA are intended to introduce the consideration of environmental and energy consequences into the decisionmaking process in cases where the Board has power to take such consequences into account in deciding whether to grant or deny an application or to adopt some other alternative. However, in this instance, the Congress has not given us the power to deny a properly-drawn certificate application, and has specifically withheld the power to condition a certificate with respect to the points to be served and the rates charged. In addition, it is obvious that conditions limiting, for example, the type of equipment or frequencies would be inconsistent with the congressional intent to deregulate the all-cargo industry, as well as beyond the Board's authority under long-standing law, see section 401(e)(4) of the Act. Given such limitations on the Board's authority, we see no public interest that could be served in reading NEPA or EPCA to impose a duty upon the Board under those statutes.

In view of these considerations, the Board will not make environmental or energy findings in processing applications under this regulation.

There remains the question of whether the public interest requires that applicants should nevertheless be required to file environmental and energy information, in the interests of disclosing the potential consequences of their operations. Overall, we believe that the benefits of such a requirement are outweighed by the detriments. As we have noted, the provision of the information would serve no immediate regulatory purpose. It would also be burdensome to the all-cargo applicants, many of which are relatively small enterprises when compared to the established combination carriers. Moreover, the information would be almost entirely speculative at this time insofar as new services are concerned, since no specific new operations need be proposed—or undertaken—by the applicants. If need be, the actual environmental and energy consequences of the Congress' deregulation of all-cargo transportation can be assessed in the future in light of actual experience under the new policy. Consequently, we have tentatively decided that enviornmental and energy evaluations need not be filed with applications for all-cargo certificates under this regulation.

Since the rules adopted herein are procedural in nature and are designed to implement the legislative mandate that carriers entitled to "grandfather" certificates under the new law be permitted to operate as soon as possible, the Board finds that notice and public procedures are unnecessary and not in the public interest and that these rules should become effective immediately.

Tariff Filings

We have also determined to permit carriers who file applications for section 418 certificates under the grandfather provisions to file tariffs prior to the issuance of their certificate, so long as (1) such tariffs are filed on at least 60 days' notice, and (2) they are not filed earlier than the date the application for the certificate is filed. Under the statute, the Board must act on an application within the sixty day period, and, in view of our lack of discretion with respect to grandfather carriers, we believe that the advance filing of tariffs is warranted to provide notice of proposed rates and services to the Board and to shippers. The authorization to file tariffs before a certificate is issued is intended only as an option for the carriers and would not preclude the Board, after a certificate is issued and in proper circumstances, from permitting (1) tariffs to be filed on less than statutory notice, or (2) carriers to advance the effective date of tariffs. Where carriers file tariffs in advance of the issuance of a certificate, and such certificate is either not issued or is issued subject to conditions inconsistent with the tariff, it will be necessary that the tariff be rejected or corrected.

Accordingly, the Board amends Part 201 of its Economic Regulations (14 CFR Part 201) as follows:

1. The table of contents to Part 201 is amended by adding a new § 201.6, entitled "All-cargo air service carriers—'grandfather' applications under section 418 of the Act."

[1] We recognize that the Board's EPCA procedures, 14 C.F.R. Part 313, need not be as timeconsuming as the NEPA impact statement rules. Nevertheless, we do not think it possible to prepare an adequate and reasonable energy statement within the 60 days allotted for the processing of the all-cargo certificate applications, in light of the broad scope and nonspecific nature of the applications which we expect to receive and have already received.

2. Add a new § 201.6, to read as follows:

§ 201.6 All-cargo air service carriers—"grandfather" applications under section 418 of the Act.

Applications under paragraphs (a)(1) and (a)(2) of section 418 shall comply with the provisions of §§ 201.1, 201.2, 201.3 and 201.4(a) of this part. Such applications shall be accompanied by an application fee of $15 (in the form of a check, draft, or postal money order, payable to the Civil Aeronautics Board) and shall contain the following information:

(a) The full name and address of the applicant, and, if the applicant is not a natural person, the form of applicant's organization (corporation, partnership, etc.) and the State under whose laws the applicant has been organized.

(b) A statement that the applicant is a citizen of the United States as defined by section 101(13) of the Act. Unless the applicant's officers, directors, and owners are now subject to, and in compliance with, Part 245 of this subchapter, the applicant shall state the name, address, and citizenship of all its officers and directors, and of all persons owning or controlling 5 percent or more of its voting interest.

(c) If the applicant has a valid certificate issued under section 401(d)(1) of the Act and has provided scheduled all-cargo air service at any time between January 1, 1977, and November 9, 1977, the applicant shall so state and shall furnish adequate evidence in support. The evidence shall preferably be from a document subject to official notice under § 302.24(m) of this chapter.

(d) If the applicant operates pursuant to an exemption granted by the Board under section 416 of the Act, and if the applicant or its predecessor in interest has provided scheduled all-cargo air service continuously (other than for interruptions caused by labor disputes) during the 12 month period ending November 9, 1977, then the applicant shall identify (by order number, registration number, etc.) its authority, shall state that it has provided service as described above, and shall furnish adequate evidence in support. The evidence shall preferably be from a document subject to official notice under § 302.24(m) of this chapter. If any part of the service on which the application is based was provided by a predecessor in interest, the applicant shall also supply the information required by this paragraph for that predecessor in interest.

(e) The applicant shall state whether it has in effect liability insurance coverage satisfying the requirements of Subpart E of Part 298 of this subchapter (14 CFR §§ 298.41–.45) and whether it has on file with the Board a certificate or certificates of insurance as required by § 298.41(a). If the carrier does not have such a certificate on file, it shall describe all policies in force, including the names of all insurers, the liability limits, any exclusions from liability (other than exclusions permitted by § 298.44), and the termination date of each policy.

(f) Each applicant shall promptly furnish any additional information pertinent to its application that the Board or its staff may request.

(Secs. 204 and 418 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 91 Stat. 1278 (49 U.S.C. 1324, Pub. L. 95-163).)

By the Civil Aeronautics Board.

CRAIG LINDSAY,
Acting Secretary.

[FR Doc.77-33639 Filed 11-21-77;8:45 am]

[3510-07]

Title 15—Commerce and Foreign Trade

CHAPTER I—BUREAU OF THE CENSUS, DEPARTMENT OF COMMERCE

PART 30—FOREIGN TRADE STATISTICS

Miscellaneous Amendments

AGENCY: Bureau of the Census, Commerce.

ACTION: Final rule.

SUMMARY: These are changes in the Foreign Trade Statistics Regulations for the purpose of clarity and to conform them with existing practices. These changes (1) specify the manner in which the foreign port of lading should be reported on import entries covering merchandise loaded at more than one point; (2) eliminate the implication that Customs Form 7512 requires PEXT and EPEX values and charges; (3) clarify that statistical reporting requirements for merchandise entering the United States from foreign countries and from the Virgin Islands of the United States and other nonforeign areas (except Puerto Rico) are essentially the same; (4) clarify that Census statistical requirements for Customs Form 7512 apply in only those cases where the form is being used as an Immediate Exportation or a Transportation and Exportation entry; and (5) incorporate by reference the new country classification Schedules C-E and C-I in lieu of Schedule C.

EFFECTIVE DATE: November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Emanuel A. Lipscomb, Chief, Foreign Trade Division, Bureau of the Census, Washington, D.C. 20233, 301-763-5342.

The following amendments are made to the regulations published in the FEDERAL REGISTER on March 3, 1976 (41 FR 9134). In accordance with the rulemaking provisions of the Administrative Procedures Act 5 U.S.C. 553, the Bureau finds that notice and opportunity for interested persons to submit written comments (either before or after the promulgation of this amendment) would serve no public interest. These regulations are issued under the authority of title 13, United States Code, section 302; and 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Organization Order No. 35-2A, August 4, 1975, 40 FR 42765.

1. Schedule C as listed in the opening paragraph of § 30.7 and in the first sentence of § 30.7(i) is changed to Schedule C-E so that as amended the opening paragraph of § 30.7 and the first sentence of § 30.7(i) read respectively, as follows.

§ 30.7 Information required on Shipper's Export Declarations.

The following information shall be furnished in the appropriate spaces provided on the Shipper's Export Declaration and shall conform to the requirements set forth in this section. (See § 30.92 for information as to the statistical classification Schedules B, C-E, D, and P referred to in this section. Also see § 30.8 for information required on Form 7513 in addition to these requirements.)

* * * * *

(i) *Place and country of destination.* Country of destination shall be reported on the Shipper's Export Declaration in terms of the names designated in Schedule C-E, *Classification of Country and Territory Designations for U.S. Export Statistics*, as follows.

* * * * *

§ 30.70 [Amended]

2. The opening clause of the first sentence of § 30.70 is amended to read as follows:

Information for statistics on merchandise entering the United States, from foreign countries, U.S. Foreign Trade Zones, and from the Virgin Islands of the United States and other nonforeign areas (except Puerto Rico), is required to be reported by importers on the following Customs entry and withdrawal forms respectively required by U.S. Customs Regulations for individual transactions: Customs Forms 7500, 7501, 7502, 7505, 7506, 7519, 7521, and 7535, and on Customs Form 7512 when used as an intransit entry to document immediate exportation or transportation and exportation. * * *

* * * * *

3. The last sentence of § 30.70(c)(2) is hereby amended to read as follows:

* * * * *

(c) *Foreign port of lading.* * * *

(2) * * * When a single Customs form covers merchandise loaded at more than one foreign port, the foreign port of lading shall be indicated separately in the "Marks and numbers and Country of origin" column immediately below the country of origin designation and on the same line as the merchandise laden at each foreign port.

* * * * *

4. The reference to Schedule C in the first sentence of § 30.70(f)(2) is changed to C-I, so that as amended, the first sentence of § 30.70(f)(2) reads as follows:

* * * * *

(f) *Country of origin.*

(2) Country of origin shall be reported in terms of the names designated in Schedule C-I, *Classification of Country and Territory Designations for U.S. Import Statistics*, unless a more specific geographic area is required to be shown for other purposes * * *.

5. The first and last sentences of § 30.70(g) are hereby amended to read as follows:

* * * * *

(g) *Description of merchandise.* (All forms.) Except on Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry the description of merchandise shall be in terms of the Tariff Act in accordance with the Tariff Schedules of the United States Annotated for Statistical Reporting (TSUSA) and in sufficient detail to permit the identification of the TSUSA statistical reporting number to which each commodity properly belongs. * * * When Customs Form 7512 is used as an Immediate Exportation or Transportation and Exportation entry importers need only report in terms of the first five digits of TSUSA (i.e., in terms of TSUS).

* * * * *

6. Section 30.70(j) is amended to read as follows:

* * * * *

(j) *Value.* (All forms). Except on Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, the dollar value shall be reported on the forms in accordance with the definitions set forth in the Tariff Schedules of the United States Annotated (TSUSA) and sections 402 and 402a of the Tariff Act of 1930, as amended. Moreover the value shall be reported in accordance with the format prescribed in the U.S. Customs Regulations. (On Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, only the Customs value in accordance with sections 402 and 402a of the Tariff Act of 1930, as amended, need be reported.)

* * * * *

7. The penultimate sentence of §30.70(k) is amended to read as follows:

* * * * *

(k) *TSUSA reporting number.* (All forms.) * * * On Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, the reporting number, in terms of the first five digits of TSUSA (TSUS), is required to be shown in the column provided on the form for "Description and Quantity of Merchandise." * * *

8. The reference to Schedule C in § 30.92 is deleted and replaced by separate references to Schedules C–E and C–I, so that as amended § 30.92 reads as follows:

§ 30.92 Statistical classification schedules.

* * * * *

Schedule C–E—Classification of Country and Territory Designations for U.S. Export Statistics. Free from the Bureau of the Census, Washington, D.C. 20233.

Schedule C–I—Classification of Country and Territory Designations for U.S. Import Statistics. Free from the Bureau of the Census, Washington, D.C. 20233.

* * * * *

MANUEL D. PLOTKIN,
Director, Bureau of the Census.

NOVEMBER 17, 1977.

I concur: October 31, 1977.

BETTE B. ANDERSON,
Under Secretary of the Treasury.

[FR Doc.77-33572 Filed 11-21-77;8:45 am]

[6750-01]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket C-2905]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE ACTIONS

Dayco Corp.

AGENCY: Federal Trade Commission.

ACTION: Order to cease and desist.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, among other things, requires a Dayton, Ohio manufacturer and importer of occupational safety products and equipment to cease misrepresenting that its products meet non-existent "government standards," or that they are approved, endorsed or required by the Occupational Safety and Health Administration (OSHA). The firm is also required to cease using, or licensing the use of the "OSHA–SPEC" trademark, and to take steps to prevent the importation of "OSHA–SPEC" branded goods. Additionally, the order prohibits the company from publishing quotations from the OSHA Act or regulations, without including all relevant portions of the quoted section.

DATES: Complaint and Decision and Order issued Oct. 27, 1977.[1]

FOR FURTHER INFORMATION CONTACT:

Paul R. Peterson, Director, Cleveland Regional Office, Federal Trade Commission, Suite 500, Mall Bldg., 118 Saint Clair Ave., Cleveland, Ohio 44114, 216–522–4207.

SUPPLEMENTARY INFORMATION: On Wednesday, August 17, 1977, there was published in the FEDERAL REGISTER 42 FR 41431, a proposed consent agreement with analysis In the Matter of Dayco Corporation, a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows:

Subpart—Advertising Falsely or Misleadingly: § 13.15 Business status, advantages or connections; 13.15–90 Government endorsement; § 13.73 Formal regulatory and statutory requirements; § 13.85 Government approval, action, connection or standards; 13.85–75 Use; § 13.160 Promotional sales plans; § 13.205 Scientific or other relevant facts; § 13.245 Specifications or standards conformance; § 13.247 Statutes and regulations; § 13.270 Trademark registration or use. Subpart—Claiming or Using Endorsements or Testimonials Falsely or Misleadingly; § 13.330 Claiming or using endorsements or testimonials falsely or misleadingly; 13.330–90 United States Government. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533–20 Disclosures. Subpart—Importing, Manufacturing, Selling or Transporting Merchandise: [2] § 13.1060 Importing, manufacturing, selling or transporting merchandise. Subpart—Misbranding or Mislabeling: § 13.1170 Advertising and promotion; § 13.1215 Government, official or other sanction; § 13.1320 Scientific or other relevant facts; § 13.1343 Trademark registration. Subpart—Misrepresenting Oneself and Goods:—Business Status, Advantages or Connections: § 13.1430 Government endorsement, sanction or sponsorship; § 13.1565 Trade names.—Goods: § 13.1632 Government endorsement or recommendation; § 13.1645 Government standards or specifications; § 13.1675 Law or legal requirements: § 13.1740 Scientific or other relevant facts.—Promotional Sales Plans: § 13.1830 Promotional sales plans. Subpart—Neglecting, Unfairly or Deceptively, to Make Material Disclosure: § 13.1852 Formal regulatory and statutory requirements: § 13.1895 Scientific or other relevant facts. Subpart—Offering Unfair, Improper and Deceptive Inducements to Purchase or Deal: § 13.1975 Government penalty; § 13.2063 Scientific or other relevant facts. Subpart—Using Misleading Name:—Goods: § 13.2290 Government endorsement or connection.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45.)

CAROL M. THOMAS,
Secretary.

[FR Doc.77-33527 Filed 11-21-77;8:45 am]

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[1] Copies of the Complaint, Decision and Order filed with the original document.

[2] Amended June 13, 1977.

[6750-01]

[Docket C-2906]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

East Providence Credit Union

AGENCY: Federal Trade Commission.

ACTION: Order to cease and desist.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, among other things, requires an East Providence, Rhode Island credit union to cease failing to provide consumers, in connection with the extension of credit, such material and disclosures as are required by Federal Reserve System regulations.

DATES: Complaint and order issued October 27, 1977.[1]

FOR FURTHER INFORMATION CONTACT:

William M. Gibson, Director, Boston Regional Office, Federal Trade Commission, 150 Causeway St., Room 1301, Boston, Mass. 02114, 617-223-6621.

SUPPLEMENTARY INFORMATION: On Thursday, August 18, 1977, there was published in the FEDERAL REGISTER (42 FR 41649) a proposed consent agreement with analysis In The Matter of East Providence Credit Union, a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows:

Subpart—Advertising Falsely or Misleadingly: § 13.73 Formal regulatory and statutory requirements; 13.73-92 Truth in Lending Act; 13.155 Prices; 13.155-95 Terms and conditions; 13.155-95(a) Truth in Lending Act. Subpart—Misrepresenting Oneself and Goods—Goods: § 13.1623 Formal regulatory and statutory requirements; 13.1623-95 Truth in Lending Act.—Prices: § 13.1823 Terms and conditions; 13.1823-20 Truth in Lending Act. Subpart—Neglecting, Unfairly or Deceptively, to Make Material Disclosure: § 13.1852 Formal regulatory and statutory requirements; 13.1852-75 Truth in Lending Act; 13.1905 Terms and conditions; 13.1905-60 Truth in Lending Act.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 82 Stat. 146, 147; 15 U.S.C. 45, 1601, et seq.)

CAROL M. THOMAS, *Secretary.*

[FR Doc.77-33529 Filed 11-21-77;8:45 am]

[1] Copies of the Complaint, and the Decision and Order filed with the original document.

[6750-01]

[Docket 9065]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Gateway Overseas, Inc., et al.

AGENCY: Federal Trade Commission.

ACTION: Order to cease and desist.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, among other things, requires a New York City employment agency to cease misrepresenting the availability of employment opportunities and the effectiveness of its employment services program; the availability of overseas employment opportunities in all trades, skills and professions; and the demand for American personnel by overseas employers. The order further prohibits use of a mandatory arbitration clause in contracts which commit consumers to arbitrate all disputes at a designated tribunal; and the acceptance of any fee prior to acceptance of employment, other than those fees charged for preparation or duplication of resumes. Additionally, the order requires the firm to maintain complete business records; conspicuously post prescribed disclosure statements and to include such statements in all sales contracts.

DATES: Complaint issued December 19, 1975. Decision issued October 27, 1977.[1]

FOR FURTHER INFORMATION CONTACT:

John F. Dugan, Acting Regional Director, Federal Trade Commission, 2243-EB Federal Building, 26 Federal Plaza, New York, NY., 10007, 212-264-1207.

SUPPLEMENTARY INFORMATION: On Friday, June 10, 1977, there was published in the FEDERAL REGISTER, 42 FR 29915, a proposed consent agreement with analysis In the Matter of Gateway Overseas, Inc., a corporation, and Michael Anderson, individually and as an officer of said corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

A comment was filed and considered by the Commission.

The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows:

Subpart—Advertising Falsely or Misleadingly: § 13.15 Business status, advantages or connections; 13.15-210 Operations as special or other advertising; 13.15-225 Personnel or staff; 13.15-245 Prospects; 13.15-250 Qualifications and abilities; 13.15-265 Service; 13.50 Dealer or seller assistance; 13.55 Demand, business or other opportunities; 13.60 Earnings and profits; 13.115 Jobs and employment service; 13.135 Nature of product or service; 13.143 Opportunities; 13.190 Results; 13.205 Scientific or other relevant facts; 13.225 Services. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533-20 Disclosures; 13.533-25 Displays, in-house; 13.533-45 Maintain records. Subpart—Misrepresenting Oneself and Goods:—Business Status, Advantages or Connections: § 13.1490 Nature; 13.1510 Operations as special or other advertising; 13.1520 Personnel or staff; 13.1535 Qualifications; 13.1553 Services. —Goods: § 13.1608 Dealer or seller assistance; 13.1610 Demand for or business opportunities; 13.1615 Earnings and profits; 13.1670 Jobs and employment; 13.1685 Nature; 13.1697 Opportunities in product or service; 13.1730 Results; 13.1740 Scientific or other relevant facts. Subpart—Offering Unfair, Improper and Deceptive Inducements to Purchase or Deal: § 13.1935 Earnings and profits; 13.2015 Opportunities in product or service; 13.2063 Scientific or other relevant facts.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45.)

CAROL M. THOMAS, *Secretary.*

[FR Doc.77-33530 Filed 11-21-77;8:45 am]

[1] Copies of the Complaint, Decision and Order filed with the original document.

[6750-01]

[Docket C-2786]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Soft Sheen Company, Inc., et al.

AGENCY: Federal Trade Commision.

ACTION: Modifying cease and desist order.

SUMMARY: This is an order modifying a cease and desist order issued January 27, 1976, to conform with obligations of a consent order issued against a competitive firm, by limiting substantiation requirements for safety claims in Provi-

sion I.B., and revising the third warning, pertaining to hair relaxers, in Provision III.

DATES: Complaint and order issued Jan. 27, 1976. Modifying order issued Sept. 30, 1977.[1]

FOR FURTHER INFORMATION CONTACT:

William C. Erxleben, Dir. Seattle Regional Office, Federal Trade Commission, 28th Floor, Federal Bldg., 915 Second Ave., Seattle, Wash. 98174, 206–442–4655.

SUPPLEMENTARY INFORMATION: In the Matter of Soft Sheen, Company, Inc., Et Al. The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, appeared in the FEDERAL REGISTER at 41 FR 7939.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45, 52.)

The Modifying Order to Cease and Desist, including further order requiring report of compliance therewith, is as follows:

ORDER MODIFYING ORDER TO CEASE AND DESIST

On October 28, 1976, respondent Soft Sheen Co., Inc. petitioned the Commission to reopen this proceeding to modify the third warning in Provision III of the consent order issued January 28, 1976 (87 FTC 164), against respondents in this matter. The third warning, which is to be made in connection with the sale and distribution of respondents' hair relaxer and which is to appear on the packaging, package inserts and the labels of the product, reads, "Do not use on bleached, dyed or tinted hair. If you have previously relaxed your hair, relax only the new growth, as described in the directions." Respondent objects to the inclusion of tinted hair in the warning.

On March 18, 1976, Soft Sheen requested by letter that the order's product coverage be limited to hair relaxers. Our request is incorporated into October 28, 1976, petition to reopen.

Complaint counsel support the petition and recommend that the warning be modified to read:

3. Do not use on bleached hair. Do not use on permanently colored hair which is breaking, splitting or otherwise damaged. For hair that has been permanently colored and shows no sign of damage, use only mild strength formula.

4. If you have previously relaxed your hair, relax only the new growth, as described in the directions.

We agree that the petition should be granted. Most if not all, of the products manufactured and sold by Soft Sheen are hair care products, and a substantial portion of the firm's revenues is derived from the sale of hair relaxers. These latter products are generally sold directly to professional beauticians. Under these circumstances, the Commission believes that modification of the order to limit the substantiation requirements for safety claims to hair care products, and for efficacy claims to hair straighteners, will serve adequately to protect the public interest. Furthermore, additional expert information provided to the Commission after issuance of the Soft Sheen order, supports revision of the warning requirement.

Finally, after entry of its order in this matter, the Commission issued a consent order against Revlon, Inc., a competitor of Soft Sheen in the sale of hair relaxers, which includes a warning and product coverage identical to the changes recommended by complaint counsel here. For these reasons, the Commission believes that it is in the public interest to grant the modification sought by Soft Sheen.

Accordingly, *It is ordered*, That the proceeding be, and it hereby is, reopened.

It is further ordered, That the order to cease and desist be, and it hereby is, modified by substituting the following for the WARNING contained in Provision III of the order:

WARNING

1. This product contains potassium hydroxide (lye). You must follow directions carefully to avoid skin and scalp burns, hair loss, and eye injury.

2. Do not use if scalp is irritated or injured.

3. Do not use on bleached hair. Do not use on permanently colored hair which is breaking, splitting, or otherwise damaged. For hair that has been permanently colored and show no sign of damage, use only mild strength formula.

4. If you have previously relaxed your hair, relax only the new growth, as described in the directions.

5. If the relaxer causes skin or scalp irritation, rinse out immediately and neutralize with the shampoo in the kit. If irritation persists or if hair loss occurs, consult a physician.

6. If the relaxer gets into eyes, rinse immediately and consult a physician.

It is further ordered, That the order to cease and desist be, and it hereby is, modified by substituting the following Provision for I.B. of the order, and relettering the remaining paragraphs accordingly:

B. Representing, in any manner, directly or by implication, the efficacy of any hair straightening product or the ingredients therein, unless, at the time such representation is made, respondents have in their possession a reasonable basis, consisting of competent and reliable controlled tests, to support such representation; or misrepresenting in any manner the nature of any such product or its ingredients or the effect of any such product or its ingredients on hair or skin or any other structure of the body.

C. Representing, in any manner, directly or by implication, the safety of any hair c re product or the ingredients therein, unless at the time such representation is made, respondents have in their possession a reasonable basis, consisting of competent and reliable controlled tests, to support such representation.

CAROL M. THOMAS,
Secretary.

[FR Doc.77-33531 Filed 11-21-77;8:45 am]

[1] Copies of the Modifying Order filed with the original documents.

[1505-01]

Title 29—Labor

CHAPTER XXV—PENSION AND WELFARE BENEFIT PROGRAM, DEPARTMENT OF LABOR

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

Acquisition and Holding of Employer Securities and Employer Real Property

Correction

In FR Doc. 77-27315 appearing at page 47198 in the issue for Tuesday, September 20, 1977:

1. The chapter heading should read as set forth above.

2. The second full paragraph, third column, page 47199, beginning with "Although the regulations prescribe," should be designated paragraph (1).

3. In the fourth line of the first full paragraph, middle column, page 47200, "(i) and (i)" should read "(i) and (ii)."

4. The open parenthesis should be deleted from the beginning of the last line of the middle column, page 47200.

5. In the fourth line of § 2550.407a-1 (b), third column, page 47201, "employers" should read "employer."

6. In the fourth line of § 2550.407a-1 (b) (2), third column, page 47201, "of the employer" should read "or the employer."

[4110-12]

Title 45—Public Welfare

SUBTITLE A—OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 12—DISPOSAL AND UTILIZATION OF SURPLUS REAL PROPERTY FOR EDUCATIONAL AND PUBLIC HEALTH PURPOSES

Conveyance of Former Federal Real Estate for Public Health, or Educational Purposes

AGENCY: Office of the Secretary, HEW.

ACTION: Final regulation.

SUMMARY: This final regulation revises regulations on the conveyance of former Federal real estate for public health, or educational purposes. The revisions to the existing Regulations will provide for clarification of terminology, creation of new procedures, and revisions to existing procedures to increase the effectiveness and efficiency of the Federal Property Assistance program.

DATE: Effective on November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

C. A. Patterson, Director, Office of Federal Property Assistance, HEW, Room 514, Reporters Building, 300 Seventh Street SW., Washington, D.C. 20201, 202–755–8836.

SUPPLEMENTARY INFORMATION:

1. Public Participation. No substantive comments were received during the comment period.

2. Editorial changes are reflected throughout Title 45 Code of Federal Reg-

ulations Part 12. The more substantive revisions to existing procedures or new procedures are discussed below.

Part 12 of the regulations is amended to provide specifically for leasing surplus real property at public benefit discount. The enabling legislation gave the Secretary the authority to sell or lease real property for educational or public health purposes. However, the regulations have not provided for leasing. This change will benefit those educational and public health institutions or programs with short-term needs for property.

Paragraph 12.3(c) is amended to permit payment of cash in lieu of use after an initial period of 12 months, or 36 months where construction or major renovation is contemplated. This would replace the requirement that construction commence within 18 months from the date of the deed. This provision will eliminate the need for "deferred use" transfers, a change which will be beneficial in those States where "deferred use" transactions are not permissible under State law.

Subparagraph 12.9(c)(8) of the regulations is revised to eliminate as a standard deed condition the right of the Government to recapture property during a National emergency. The right will be reserved only in cases where the Department of Defense has indicated in its report of excess that the property has a potential for use in a National emergency.

Subparagraph 12.9(c)(9) is amended to simplify the abrogation process by adoption of a single procedure, based upon the unearned current fair market value of the property at the time of abrogation.

The revision is issued under the authority contained in the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 471 et seq.) (Catalog of Federal Domestic Assistance Program Number 13.676 Surplus Property Utilization.)

NOTE.—It is hereby certified that this proposal has been screened pursuant to Executive Order 11821 and OMB Circular A-107, and does not require an Inflationary Impact Statement.

Dated: October 6, 1977.

JOHN D. YOUNG,
Assistant Secretary for Management and Budget.

Approved: November 15, 1977.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Sec.
12.1 Definitions.
12.2 Scope.
12.3 General policies.
12.4 Limitations.
12.5 Awards.
12.6 Notice of available property.
12.7 Applications for surplus real property.
12.8 Assignment of surplus real property.
12.9 General disposal terms and conditions.
12.10 Compliance with the preservation acts.
12.11 Special terms and conditions.
12.12 Utilization.
12.13 Form of conveyance.
12.14 Compliance inspections and reports.
12.15 Reports to Congress.

AUTHORITY: Sec. 203, 63 Stat. 385, as amended; 40 U.S.C. 484.

§ 12.1 Definitions.

(a) "Act" means the Federal Property and Administrative Services Act of 1949, 63 Stat. 377 (40 U.S.C. 471 et seq.). Terms defined in the Act and not defined in this section have the meanings given to them in the Act.

(b) "Accredited" means having the approval of a recognized accreditation board or association on a regional, State, or national level, such as a State Board of Education or Health, State University, or the Middle States Association of College and Secondary Schools. "Approval" as used above describes the formal process carried out by State Agencies and institutions in determining that educational or health organizations or programs meet minimum acceptance standards. A college, university, or secondary school may be said to be accredited if the credits issued by it are and have been accepted for transfer purposes by no fewer than three accredited colleges, universities, or secondary schools not connected or associated with it.

(c) "Administrator" means the Administrator of General Services.

(d) "Assigned property" means real and related personal property which, in the discretion of the Administrator or his designee, has been made available to the Department for transfer for educational or public health purposes.

(e) "Department" means the U.S. Department of Health, Education, and Welfare.

(f) "Disposal agency" means the executive agency of the Government which has authority to assign property to the Department for transfer for educational or public health purposes.

(g) "Excess" means any property under the control of any Federal agency which is not required for its needs and the discharge of its responsibilities, as determined by the head thereof.

(h) "Fair market value" means the highest price which the property will bring by sale in the open market by a willing seller to a willing buyer.

(i) "Holding agency" means the Federal agency which has control over and accountability for the property involved.

(j) "Nonprofit institution" means any institution, organization, or association, whether incorporated or unincorporated, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual, and which has been held to be tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(k) "Off-site property" means surplus buildings, utilities and all other removable improvements, including related personal property, to be transferred by the Department for removal and use away from the site for educational or public health purposes.

(l) "On-site" means surplus real property, including related personal property, to be transferred by the Department for use in place for educational or public health purposes.

(m) "Public benefit allowance" means a discount on the sale or lease price of real property transferred for educational or for public health purposes, representing any benefit determined by the Secretary which has accrued or may accrue to the United States thereby.

(n) "Related personal property" means any personal property: (1) Which is located on and is (i) an integral part of, or (ii) useful in the operation of real property; or (2) which is determined by the Administrator to be otherwise related to the real property.

(o) "Secretary" means the Secretary of Health, Education, and Welfare.

(p) "State" means a State of the United States, and includes the District of Columbia, the Commonwealth of Puerto Rico, and the Territories and possessions of the United States.

(q) "Surplus" when used with respect to real property means any excess real property not required for the needs and the discharge of the responsibilities of all Federal agencies as determined by the Administrator.

§ 12.2 Scope.

This part is applicable to surplus real property located within any State which is appropriate for assignment to, or which has been assigned to, the Department for transfer for educational or for public health purposes, as provided for in section 203(k) of the Act.

§ 12.3 General Policies.

(a) It is the policy of the Department to foster and assure maximum utilization of surplus real property for educational and for public health purposes, including research.

(b) Transfers may be made only to States, their political subdivisions and instrumentalities, tax-supported educational or public health institutions, and nonprofit educational or public health institutions which have been held tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(c) Real property will be requested for assignment only when the Department has determined that the property is suitable and needed for educational or for public health purposes. The amount of real and related personal property to be transferred shall not exceed normal operating requirements of the applicant. Such property will not be requested for assignment unless it is needed at the time of application for educational or for public health purposes or will be so needed within the immediate or foreseeable future. Where construction or major renovation is not required or proposed, the property must be placed into use within twelve (12) months from the date of transfer. When construction or major renovation is contemplated at the time

of transfer, the property must be placed in use within 36 months from the date of transfer. If the applicable time limitation is not met, the transferee shall either commence payments in cash to the Department for each month thereafter during which the proposed use has not been implemented or take such other action as set forth in § 12.12 as is deemed appropriate by the Department. Such monthly payments shall be computed on the basis of the current fair market value of the property at the time of the first payment by subtracting therefrom any portion of the purchase price paid in cash at the time of transfer, and by dividing the balance by the total number of months in the period of restriction. If the facility has not been placed into use within eight (8) years of the date of the deed, title to the property will be revested in the United States, or, at the discretion of the Department, the restrictions and conditions may be abrogated in accordance with § 12.0.

(d) Transfers will be made only after the applicant has certified that the proposed program is not in conflict with State or local zoning restrictions, building codes, or similar limitations.

(e) Organizations which may be eligible include those which provide elementary, secondary, post secondary, vocational, or specialized education, public library services, or similar programs which are primarily educational in character such as child development programs and adult education programs (including such programs for older Americans). Other organizations which are eligible include those which provide care and training for the physically and mentally ill, including medical care of the aged and infirm, clinical services, other public health services (including water and sewer), or similar services devoted primarily to the promotion and protection of public health. Services which have as their principal purpose the providing of custodial or domiciliary care are not eligible. The property applied for must be for a purpose which the eligible organization is authorized to carry out.

(f) An applicant's plan of operation will not be approved unless it provides that the applicant will not discriminate because of race, color, sex, handicap, or national origin in the use of the property.

§ 12.4 Limitations.

(a) Surplus property transferred pursuant to this part will be disposed of on an "as is, where is," basis without warranty of any kind.

(b) Unless excepted by the Administrator in his assignment, mineral rights will be conveyed together with the surface rights.

§ 12.5 Awards.

Where there is more than one applicant for the same property, it will be awarded to the applicant having a program of utilization which provides, in the opinion of the Department, the greatest public benefit. Where the property will serve more than one program, it will be apportioned to fit the needs of as many programs as is practicable.

§ 12.6 Notice of available property.

Reasonable publicity will be given to the availability of surplus real property which is suitable for assignment to the Department for transfer for educational or for public health uses. The Department will establish procedures reasonably calculated to afford all eligible users having a legitimate interest in acquiring the property for such uses an opportunity to make an application therefor. However, publicity need not be given to the availability of surplus real property which is occupied and being used for eligible educational or public health purposes at the time the property is declared surplus, the occupant expresses interest in the property, and the Department determines that it has a continuing need therefor.

§ 12.7 Applications for surplus real property.

Applications for surplus real property for educational or for public health purposes shall be made to the Department through the Regional Office specified in the notice of availability.

§ 12.8 Assignment of surplus real property.

(a) Notice of interest in a specific property for educational or for public health purposes will be furnished the Administrator by the Department at the earliest possible date.

(b) Requests to the Administrator for assignment of surplus real property to the Department for transfer for educational or for public health purposes will be based on the following conditions:

(1) The Department has an acceptable application for the property.

(2) The applicant is willing, authorized, and in a position to assume immediate care, custody, and maintenance of the property.

(3) The applicant is able, willing and authorized to pay the administrative expenses incident to the transfer.

(4) The applicant has the necessary funds, or the ability to obtain such funds, to carry out the approved program of use of the property.

§ 12.9 General disposal terms and conditions.

(a) Surplus real property transfers under this part will be limited to educational or public health purposes. Transferees shall be entitled to a public benefit allowance in terms of a percentage which will be applied against the value of the property to be conveyed. Such an allowance will be computed on the basis of benefits to the United States from the use of such property for educational or for public health purposes. The computation of such public benefit allowances will be in accordance with Exhibits A and B attached hereto and made a part hereof.

(b) A transfer of surplus real property for educational or for public health purposes is subject to the disapproval of the Administrator within 30 days after notice is given to him of the proposed transfer.

(c) Transfers will be on the following terms and conditions:

(1) The transferee will be obligated to utilize the property continuously in accordance with an approved plan of operation.

(2) The transferee will not be permitted to sell, lease or sublease, rent, mortgage, encumber, or otherwise dispose of the property, or any part thereof, without the prior written authorization of the Department.

(3) The transferee will file with the Department such reports covering the utilization of the property as may be required.

(4) In the event the property is sold, leased or subleased, encumbered, disposed of, or is used for purposes other than those set forth in the approved plan without the consent of the Department, all revenues or the reasonable value of other benefits received by the transferee directly or indirectly from such use, as determined by the Department, will be considered to have been received and held in trust by the transferee for the account of the United States and will be subject to the direction and control of the Department. The provisions of this paragraph shall not impair or affect the rights reserved to the United States in paragraph (c)(6) of this section, or the right of the Department to impose conditions to its consent.

(5) Lessees will be required to carry all perils and liability insurance to protect the Government and the Government's residual interest in the property. Transferees will be required to carry such flood insurance as may be required by the Department pursuant to Pub. L. 93-234. Where the transferee elects to carry insurance against damages to or loss of on-site property due to fire or other hazards, and where loss or damage to transferred Federal surplus real property occurs, all proceeds from insurance shall be promptly used by the transferee for the purpose of repairing and restoring the property to its former condition, or replacing it with equivalent or more suitable facilities. If not so used, there shall be paid to the United States that part of the insurance proceeds that is attributable to the Government's residual interest in the property lost, damaged, or destroyed, or, in the case of leases, attributable to the fair market value of the leased facilities.

(6) With respect to on-site property, in the event of noncompliance with any of the conditions of the transfer as determined by the Department, title to the property transferred and the right to immediate possession shall, at the option of the Department, revert to the Government. In the event title is reverted to the United States for noncompliance or voluntarily reconveyed, the transferee shall, at the option of the Department,

be required to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the transferee to adapt the property to the educational or public health use for which the property was transferred. With respect to leased property, in the event of noncompliance with any of the conditions of the lease, as determined by the Department, the right of occupancy and possession shall, at the option of the Department, be terminated. In the event a leasehold is terminated by the United States for noncompliance or is voluntarily surrendered, the lessee shall be required at the option of the Department to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the lessee to adapt the property to the educational or public health use for which the property was leased.

With respect to any reverter of title or termination of leasehold resulting from noncompliance, the Government shall, in addition thereto, be reimbursed for such costs as may be incurred in recovering title to or possession of the property.

Any payments of cash made by the transferee against the purchase price of property transferred shall, upon a forfeiture of title to the property for breach of condition, be forfeited.

(7) With respect to off-site property, in the event of noncompliance with any of the terms and conditions of the transfer, the unearned public benefit allowance shall, at the option of the Department, become immediately due and payable or, if the property or any portion thereof is sold, leased, or otherwise disposed of without authorization from the Department, such sale, lease or sublease, or other disposal shall be for the benefit and account of the United States and the United States shall be entitled to the proceeds. In the event the transferee fails to remove the property or any portion thereof within the time specified, then in addition to the rights reserved above, at the option of the Department, all right, title, and interest in and to such unremoved property shall be retransferred to other eligible applicants or shall be forfeited to the United States.

(8) With respect only to on-site property which has been declared excess by the Department of Defense, such declaration having included a statement indicating the property has a known potential for use during a national emergency, the Department shall reserve the right during any period of emergency declared by the President of the United States or by the Congress of the United States to the full and unrestricted use by the Government of the surplus real property, or of any portion thereof, disposed of in accordance with the provisions of this part. Such use may be either exclusive or nonexclusive. Prior to the expiration or termination of the period of restricted use by the transferee, the Government will not be obligated to pay rent or any other fees or charges during the period of emergency, except that the Government will:

(i) Bear the entire cost of maintenance of such portion of the property used by it exclusively or over which it may have exclusive possession or control;

(ii) Pay the fair share, commensurate with the use of the cost of maintenance of such surplus real property as it may use nonexclusively or over which it may have nonexclusive possession or control;

(iii) Pay a fair rental for the use of improvements or additions to the surplus real property made by the purchaser or lessee without Government aid; and

(iv) Be responsible for any damage to the surplus real property caused by its use, reasonable wear and tear, the common enemy and acts of God excepted. Subsequent to the expiration or termination of the period of restricted use, the obligations of the Government will be as set forth in the preceding sentence and, in addition, the Government shall be obligated to pay a fair rental for all or any portion of the conveyed premises which it uses.

(9) The restrictions set forth in subparagraphs (1) through (7) will extend for thirty (30) years for land with or without improvements; and for facilities being acquired separately from land whether they are for use on-site or off-site, the period of limitations on the use of the structures will be equal to their estimated economic life. The restrictions set forth in subparagraphs (1) through (7) will extend for the entire initial lease period and for any renewal periods for property leased from the Department.

(d) Transferee, by obtaining the consent of the Department, may abrogate the restrictions set forth in paragraph (e) for all or any portion of the property upon payment in cash to the Department of an amount equal to the then current fair market value of the property to be released, multiplied by the public benefit allowance granted at the time of conveyance, divided by the total number of months of the period of restriction set forth in the conveyance document and multiplied by the number of months that remain in the period of restriction as determined by the Department. For purposes of abrogation payment computation, the current fair market value shall not include the value of any improvements placed on the property by the transferee.

(e) Related personal property will be transferred or leased as a part of the realty and in accordance with real property procedures. It will be subject to the same public benefit allowance granted for the real property. Where related personal property is involved in an on-site transfer, the related personal property may be transferred by a bill of sale imposing restrictions for a period not to exceed five years from the date of transfer, other terms and conditions to be the same as, and made a part of, the real property transaction.

§ 12.10 Compliance with the National Environmental Policy Act of 1969 and other related acts (environmental impact).

(a) The Department will, prior to making a final decision to convey or lease, or to amend, reform, or grant an approval or release with respect to a previous conveyance or lease of, surplus real property for educational or for public health purposes, complete an environmental assessment of the proposed transaction in keeping with applicable provisions of the National Environmental Policy Act of 1969, the National Historic Preservation Act of 1966, the National Archeological Data Preservation Act, and other related acts. No permit to use surplus real property shall allow the permittee to make, or cause to be made, any irreversible change in the condition of said property, and no use permit shall be employed, for the purpose of delaying or avoiding compliance with the requirements of these Acts.

(b) Applicants shall be required to provide such information as the Department deems necessary to make an assessment of the impact of the proposed Federal action on the human environment. Materials contained in the applicant's official request, responses to a standard questionnaire prescribed by the Director of the Office of Federal Property Assistance, as well as other relevant information, will be used by the Department in making said assessment.

(c) If the assessment reveals (1) That the proposed Federal action involves properties of historical significance which are listed, or eligible for listing, in the National Register of Historic Places, or (2) that a more than insignificant impact on the human environment is reasonably foreseeable as a result of the proposed action, or (3) that the proposed Federal action could result in irreparable loss or destruction of archeologically significant items or data, the Department will, except as provided for in paragraph (d) below, prepare and distribute, or cause to be prepared or distributed, such notices and statements and obtain such approvals as are required by the above cited Acts.

(d) If a proposed action involves other Federal agencies in a sequence of actions, or a group of actions, directly related to each other because of their functional interdependence, the Department may enter into and support a lead agency agreement to designate a single lead agency which will assume primary responsibility for coordinating the assessment of environmental effects of proposed Federal actions, preparing and distributing such notices and statements, or obtaining such approvals, as are required by the above cited Acts. The procedures of the designated lead agency will be utilized in conducting the environmental assessment. In the event of disagreement between the Department and another Federal agency, the Department wil reserve the right to abrogate its lead agency agreement with the other Federal agency.

§ 12.11 Special terms and conditions.

(a) Applicants will be required to pay all external administrative costs which will include, but not be limited to taxes, surveys, appraisals, inventory costs, legal fees, title search, certificate or abstract expenses, decontamination costs, moving costs, closing fees in connection with the transaction and service charges, if any, made by State Agencies for Federal Property Assistance under the terms of a cooperative agreement with the Department.

(b) In the case of off-site property, applicants will be required to post performance bonds, make performance guarantee deposits, or give such other assurances as may be required by the Department or the holding agency to insure adequate site clearance and to pay service charges. If any, made by State Agencies for Federal Property Assistance under the terms of a cooperative agreement with the Department.

(c) Whenever negotiations are undertaken for disposal to private nonprofit educational or public health organizations of any surplus real property which cost the Government $1 million or more, the Department will give notice to the Attorney General of the United States of the proposed disposal and the terms and conditions thereof. The applicant shall furnish to the Department such information and documents as the Attorney General may determine to be appropriate or necessary to enable him to give the advice as provided for by section 207 of the Act.

(d) Where an applicant proposes to acquire or lease and use in place improvements located on land which the Government does not own, he shall be required, before the transfer is consummated, to obtain a right to use the land commensurate with the duration of the restrictions applicable to the improvements, or the term of the lease. The applicant will be required to assume, or obtain release of, the Government's obligations respecting the land including but not limited to obligations relating to restoration, waste, and rent. At the option of the Department, the applicant may be required to post a bond to indemnify the Government against such obligations.

(e) The Department may require the inclusion in the transfer or lease document of any other provision deemed desirable or necessary.

(f) Where an eligible applicant for an on-site transfer proposes to construct new, or rehabilitate old facilities, the financing of which must be accomplished through issuance of revenue bonds or other financing methods having terms inconsistent with the terms and conditions of transfer prescribed in § 12.9 (c), (d), and (e) of this chapter, the Department may, in its discretion, impose such alternate terms and conditions of transfer in lieu thereof as may be appropriate to assure utilization of the property for educational or for public health purposes.

§ 12.12 Utilization.

(a) Where property or any portion thereof is not being used for the purposes for which transferred, the transferee will be required at the direction of the Department:

(1) To place the property into immediate use for an approved purpose;

(2) To retransfer such property to such other educational or public health user as the Department may direct;

(3) To sell such property for the benefit and account of the United States;

(4) To return title to such property to the United States or to relinquish any leasehold interest therein;

(5) To abrogate the conditions and restrictions of the transfer, as set forth in § 12.9(d), except that, where property has never been placed in use for the purposes for which transferred, abrogation will not be permitted except under extenuating circumstances; or

(6) To make payments as provided for in § 12.3(c).

(b) Where the transferee or lessee desires to place the property in temporary use for a purpose other than that for which the property was transferred or leased, approval from the Department must be obtained, and will be conditioned upon such terms as the Department may impose.

§ 12.13 Form of conveyance.

(a) Transfers or leases of surplus real property will be on forms approved by the Office of General Counsel of the Department and will include such of the disposal or lease terms and conditions set forth in this part and such other terms and conditions as the Office of General Counsel may deem appropriate or necessary.

(b) Transfers of on-site property will normally be by quitclaim deed without warranty of title.

§ 12.14 Compliance inspections and reports.

The Department will make or have made such compliance inspections as are necessary and will require of the transferee or lessee such compliance reports and actions as are deemed necessary.

§ 12.15 Reports to Congress.

The Secretary will make such reports of real property disposal activities as are required by section 203 of the Act and such other reports as may be required by law.

EXHIBIT A **Public Benefit Allowance for Transfer of Real Property for Educational Purposes[1]**

Classification	PERCENT ALLOWED													Maximum Public Benefit Allowance
	Basic Public Benefit Allowance	ORGANIZATION ALLOWANCES								UTILIZATION ALLOWANCES				
		Tax Support	Accreditation	Federal Impact	Public Service Training	Hardship	Inadequacy of Existing School Plant Facilities			Introduction Of New Instructional Programs	Student Health and Welfare	Research	Service to Handicapped	
							10-25%	26-50%	51-100%					
Elementary and High Schools	50	20	20	10	[3]	10	10	20	30	10	10	10	[3]	100
Colleges and Universities	50	20	20		10	10	10	20	30	10	10	10	10	100
Specialized Schools	50	20	20		10	10	10	20	30	10	10	10	10	100
Research & Related Activities	100[2]													100[2]
Public Libraries & Educational Museums	100[2]													100[2]
School Outdoor Education	50	20	20							10	10[3]			100
Central Administrative and/or Service Centers	100	[4]												100 [4]

[1] This public benefit allowance applies only to surplus real property being sold for on-site use. When surplus real property is to be moved from the site, a basic public benefit allowance of 100% will be granted.

[2] Applicable when title to the property use to be made of the property. The public benefit allowance for the over-all program is applicable when such facilities are conveyed as a minor component of other facilities.

[3] This 10% may include recognition of an approvable recreation program operated in such a way as to be accessible to the public yet entirely compatible with, but subordinate to, the educational program.

[4] The maximum allowance available to eligible private, non-profit institutions. Tax-supported institutions receive 100% allowance.

EXHIBIT B — Public Benefit Allowance for Transfer of Real Property for Health Purposes[1]

Classification	PERCENT ALLOWED											
	Basic Public Benefit Allowance	ORGANIZATION ALLOWANCES						UTILIZATION ALLOWANCES				Maximum Public Benefit Allowance
		Tax Support	Accreditation	Hardship	Unmet Needs			Integrated Research Program	Outpatient Services	Public Service	Training Program	
					10 to 25%	26 to 50%	51 to 100%					
Hospitals	50	20	20	10	10	20	30	10	10	10	10	100
Clinics	50	20	20	10	10	20	30					100
Nursing Homes	50	20	20	10	10	20	30				10	100
Public Health Administration	100[2]											100[2]
Public Refuse Disposal Systems	100[2]											100[2]
Water Systems	100[2]											100[2]
Rehabilitation Facility	50	20	20	10	10	20	30	10	10	10	10	100
Special Services	50	20	20	10	10	20	30			10		100

[1] This public benefit allowance applies only to surplus real property being sold for on-site use. When surplus real property is to be moved from the site, a basic public benefit allowance of 100% will be granted.

[2] Applicable when this is the primary use to be made of the property. The public benefit allowance for the overall health program is applicable when such facilities are conveyed as a minor component of other facilities.

[FR Doc.77-33574 Filed 11-21-77;8:45 am]

[4110-39]

CHAPTER XIV—NATIONAL INSTITUTE OF EDUCATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 1480—PROGRAM OF RESEARCH GRANTS ON ORGANIZATIONAL PROCESSES IN EDUCATION

Final Rule for Awarding Federal Funds

AGENCY: National Institute of Education (NIE).

ACTION: Final rule.

SUMMARY: This rule governs a discretionary grant program for research on organizational processes in education. The design of this program is based upon the experience of NIE, other parts of DHEW, and other Federal agencies and extensive discussion by scholars, education professionals, parents, and other members of the public. The program's purpose is to support studies of how elementary and secondary schools and districts carry out essential tasks of any organization, such as setting goals, finding resources, identifying and solving problems, and adapting to changing times. As knowledge of schools' and school districts' organizational behavior grows, policy-makers and professional educators will have better tools for analyzing the administration and management of elementary and secondary schools and better ideas for their improvement.

EFFECTIVE DATE: As required by Section 431(d) of the General Education Provisions Act, as amended (20 U.S.C. 1232(d)), these regulations have been transmitted to the Congress concurrently with the publication of this document in the FEDERAL REGISTER. That section provides that regulations subject thereto shall become effective on the forty-fifth day following the date of such transmission, subject to the provisions therein concerning Congressional action and adjournment.

FOR FURTHER INFORMATION CONTACT:

Richard Werksman, Regulations Officer, Office of Administration and Management, National Institute of Education, room 639-B, Mail Stop 33, 1200 19th Street NW., Washington, D.C. 20208, 202-254-7924.

SUPPLEMENTARY INFORMATION: Under the authority of Section 405 of the General Education Provisions Act, as amended (20 U.S.C. 1221e), a notice of proposed rulemaking which set forth proposed procedural and substantive requirements and criteria governing the submission and review of applications for funds under the Program of Research Grants on Organizational Processes in Education was published in the FEDERAL REGISTER on January 5, 1977 (42 FR 1045). Interested persons were invited to submit written comments concerning the proposed rule. Listed below are the two comments received and the response to each, as well as an explanation of two technical changes which were made to ensure the receipt of information and documents required to operate the research program.

Comment. One comment suggested that research under this program focus on the recruitment and assignment of administrative personnel, rather than being allowed to address the greater variety of organizational processes listed in § 1480.5(a). The comment also recommended that NIE give preference to studies that progress from large initial surveys to in-depth examinations of subsamples, to studies designed to describe partciular regions of the country, to studies having provisions for checks of the internal consistency of data, and—within the area of personnel recruitment and assignment suggested as a primary focus—to studies that assess the political, judicial, and racial forces influencing personnel selection processes and to studies that examine how competence for positions is verified.

Response. No change has been made. Section 1480.5(a) lists several organizational processes eligible for study in this research program, including "* * * the means by which a school or larger administrative unit * * * recruits and assigns personnel * * *." Therefore, the research topics recommended in this comment are eligible, but are not the only topics that will be considered. NIE has determined that a broad range of organizational processes currently warrant study and that, initially at least, there is no sound reason for focusing more narrowly on one particular topic. If in the future NIE becomes convinced that studies of personnel recruitment and assignment are more important and promising than studies of alternative organizational processes, the focus of the program may be narrowed.

Comment. The second comment suggested that the scope of eligibility be expanded to allow study of organizational processes in State educational agencies, as well as in elementary and secondary schools.

Response. No change has been made. As explained in Section 1480.5(c), studies supported under this program may include examination of other relevant organizations—such as school districts, State or Federal agencies, and community groups—to the extent necessary to carry out the main purpose of advancing knowledge about the elementary and secondary school. Therefore, studies of State educational agencies are not ineligible, but they must relate directly to the organizational processes of elementary and secondary schools and must be necessary for increased understanding of those processes. This initial concentration in the program on elementary and secondary schools results from limitations on available funds. If resources expand in subsequent fiscal years, or if NIE is convinced that research needs have changed, the scope of

eligibility may be modified to allow more direct studies of other educational organizations, including State educational agencies.

Other changes. Two technical changes were made to ensure receipt of information and documents required to operate the research program.

Section 1480.8 is changed by eliminating from (b)(2)(i) and (b)(4)(i) the words "* * * where required by the applicant institution." This change is made to increase the probability that institutional officials other than principal investigators who will be responsible for administering funds awarded under this program will be aware that they must become familiar with the applicable rules and that their institutions are agreeing to make available whatever facilities are necessary for the proposed research.

Section 1480.8(d) is changed to require submission of "* * * the number of copies to be prescribed by the Director," rather than specifically requiring the submission of twelve copies of all types of applications for support under this part. This change is made to ensure submission of the number of copies needed in specific reviews (which may vary according to the number of reviewers involved), to meet NIE's record-keeping requirements, and to ensure adherence to the deadlines for application review and response (which are so short as to prohibit the reproduction of additional copies by NIE). State and local governments are required to submit only three copies.

Application Information. The National Institute of Education is not inviting applications in response to this regulation at this time. Notices of closing dates, including application procedures for Fiscal Year 1977, were published in the FEDERAL REGISTER on March 10, 1977 (42 FR 13358) and on June 22, 1977 (42 FR 31645). Application instructions and program information are available from the Research Staff of the Group on School Capacity for Problem Solving, room 815, National Institute of Education, 1200 19th Street NW., Washington, D.C. 20208. Telephone 202-254-6090.

NOTE.—The National Institute of Education has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order No. 11821 and OMB Circular A-107.

Dated: August 25, 1977.

JOHN W. CHRISTENSEN,
Acting Director,
National Institute of Education.

Approved: November 16, 1977.

HALE CHAMPION,
Acting Secretary of Health,
Education, and Welfare.

Title 45 of the Code of Federal Regulations is amended by adding to Subchapter B of Chapter XIV, a new Part 1480, reading as follows:

Sec.
1480.1 Scope.
1480.2 Purpose.
1480.3 Definitions.
1480.4 Applicant eligibility.
1480.5 Eligible research projects.
1480.6 Ineligible projects.
1480.7 Grants; small grants.
1480.8 Application requirements.
1480.9 Review procedures and evaluation criteria.
1480.10 Project duration and budget.

AUTHORITY: Section 405, General Education Provisions Act, as amended (20 U.S.C. 1221e).

§ 1480.1 Scope.

(a) This part establishes rules governing the submission and review of applications for funds under the Program of Research Grants on Organizational Processes in Education, conducted by the National Institute of Education with funds authorized by section 405 of the General Education Provisions Act.

(b) Recipients shall administer funds according to applicable provisions of Subchapter A of this chapter (General Provisions for NIE grants relating to fiscal, administrative, and other matters), except to the extent that such provisions are inconsistent with, or expressly made inapplicable by, the provisions in this part.

§ 1408.2 Purpose.

The purpose of the Program of Research Grants on Organizational Processes in Education is to support studies of how elementary and secondary schools and school districts carry out the essential tasks of any organization, such as setting goals, finding resources, assigning work, monitoring performance, identifying and solving problems, and adapting to changing times.

§ 1480.3 Definitions.

As used in this part:

"Research" includes any activity designed to increase or synthesize basic knowledge about one or more processes or conditions relevant to understanding elementary and secondary school organizations and their context.

§ 1480.4 Applicant eligibility.

(a) A college, university, state or local education agency, other public or private agency, organization, group, or individual is an eligible applicant.

(b) An application from a for-profit organization must be considered as an unsolicited proposal and, if successful, must be awarded a contract rather than a grant. An application from a for-profit organization must be submitted in accordance with criteria specified in this part and in HEW Procurement Regulations, Subpart 3-4.52 (41 CFR Part 3-4).

§ 1480.5 Eligible research projects.

(a) Research funded under this part must be designed to increase or synthesize basic knowledge about one or more organizational processes, or the barriers which impede or prevent these processes, within or related to elementary and secondary schools. Organizational processes include the means by which a school or larger administrative unit makes basic policy choices, sets goals, recruits and assigns personnel, chooses and implements courses of action, allocates resources, establishes organizational forms and structures, gathers and processes information on performance, and takes corrective action based on such evaluation. Interaction among personnel and among organizational units, and changes in processes and interactions within the organization over time, are included.

(b) Research funded under this part must be designed to advance knowledge of basic organizational processes, such as those examples given in paragraph (a) of this section, which appear especially important to understanding elementary and secondary schools. Studies supported under this program may have potential relevance to other kinds of organizations, but must aim to build a body of data and theory particularly useful in designing and managing educational organizations.

(c) Increased understanding of organizational processes related to elementary and secondary schools may require study of other organizations such as school districts, state or Federal agencies, and community groups. Studies supported under this program may include examination of other relevant organizations, to the extent necessary to carry out the main purpose of advancing knowledge about the elementary and secondary school.

(d) Because of the limited funds available, the program will not support large-scale research projects which require gathering of large amounts of new data. At this early stage of development of this program, the Director intends to fund a variety of limited-scale projects, including but not limited to projects which will clarify fundamental concepts, study organizational processes in detail in a few settings, or reanalyze existing data.

(e) A research project may be carried out using any research process or approach consistent with the provisions of § 1480.6.

§ 1480.6 Ineligible projects.

A project whose primary purpose is the operation, development, demonstration, or evaluation of specific programs or materials is not eligible for support under this part. Examples of ineligible projects include:

(a) Operation of an educational program in any elementary or secondary school, postsecondary institution, or other setting or agency.

(b) Improvement of an educational program through the implementation of a new or improved instructional, administrative, or managerial procedure, technique, material, training, or piece of equipment.

(c) Course development through the production of a new curriculum or the improvement of an existing curriculum, including the preparation of new instructional material or the modification of instructional material already in existence.

(d) Development or adaptation in an operational setting of any new or improved instructional, administrative, or managerial procedure, technique, material, training, or piece of equipment.

(e) A demonstration project which shows, exhibits, describes, or explains to others, either in person or through various other communication media, the procedure, technique and/or material which must be employed in the execution of a new or modified instructional task, educational program, or administrative or management process.

(f) Development of a new test or other instrument, either for research or use in educational practice.

(g) Evaluation of the effectiveness of a specific program, curriculum, practice, administrative or management activity, or piece of equipment.

§ 1480.7 Grants; small grants.

(a) *General.* Grants and small grants will be awarded under this part. The same topic areas for investigation, eligibility standards, and evaluation criteria apply to all awards under this part. A simplified application procedure is provided for an application for a small grant, as provided in § 1480.8, and the duration of a small grant award is limited to twelve months, as provided in § 1480.10.

(b) *Small grants.* (1) A small grant is for an amount not to exceed $7500 plus indirect costs (except in the case of an individual applicant not affiliated with any institution, in which case the NIE will not award indirect costs but will reimburse reasonable general and administrative expenses associated with and directly related to the administration of the small grant). In order to achieve a wide distribution of funds available for small grants, the Director expects that most small grants will be for projects with direct costs of about $5,000 or less.

(2) While no restriction exists as to type of project eligible for small grant support, the following are examples of possible projects within the general rules for the program: initial development and testing of a research concept, metaphor, or procedure before design of a larger or longer study; review and synthesis of research findings, methods, trends, or philosophies; summary or secondary analysis of a concluded program of research; projects by investigators who have not previously had any type of research support.

(c) *Grants (other than small grants).* A grant other than a small grant is for an amount in excess of $7500 of direct costs.

§ 1480.8 Application requirements.

(a) *General.* A grant under this part will be awarded only upon a grant application submitted to the Director. An eligible applicant must file an application specifically directed to either the grant or small grants segment of the Program of Research on Organizational Processes in Education.

(b) *Grants (other than small grants).* An applicant for a grant (other than small grant) shall comply with the requirements set forth in this paragraph.

(1) *Preliminary proposal.* An applicant shall submit a preliminary proposal for initial review.

(2) *Preliminary proposal format.* The preliminary proposal must include:

(i) A cover sheet executed by the principal investigator, and by an individual authorized to execute grant applications for the institution, indicating (A) that the preliminary proposal is submitted to the Program of Research Grants on Organizational Processes in Education, National Institute of Education; (B) the title of the study; (C) the name, department, institution, address, and telephone number of each principal investigator; (D) the estimated budget amount; and (E) the proposed starting date and duration of the project.

(ii) A statement preferably not exceeding five typewritten pages summarizing the proposed project, including:

(A) *Description and rationale.* A description of the proposed research, its relation to what is already known and to the problems of American education, and the importance of its expected addition to knowledge.

(B) *Procedures.* A description of the procedures to be followed in carrying out the research including where appropriate such concerns as sampling, data acquisition, instrumentation and data analyses.

(iii) A description of the facilities and arrangements available to the investigator for conducting the research, including access to suitable organizations for study purposes.

(iv) A vita for each principal investigator, including education, applicable experience, and a list of major publications.

(v) An estimated budget covering direct costs (e.g., salaries and benefits, travel, supplies and materials, communication, services, equipment) and indirect costs proposed to be charged against the grant.

(3) *Full proposal.* A full proposal may only be submitted by an applicant who has submitted a preliminary proposal in the required format, and whose preliminary proposal has been reviewed by NIE. Information concerning the strengths and weaknesses of the preliminary proposal, and its standing relative to others reviewed, will be returned to the applicant, and may be used in preparation of the full proposal.

(4) *Full proposal format.* Full proposals must include the following elements. Discussion of objectives and design, as described under paragraphs (b)(4)(iv) and (v) of this section may not exceed 40 pages.

(i) A cover sheet executed by the principal investigator and by an individual authorized to execute grant applications for the institution, indicating (A) that the application is submitted to the Program of Research Grants on Organizational Processes in Education, National Institute of Education; (B) the title of the study; (C) the name, departments, institution, address, and telephone number of each principal investigator; (D) the estimated budget amount; and (E) the proposed starting date and duration of the project.

(ii) An abstract of approximately 200–250 words stating clearly the objectives and plans of the proposed research.

(iii) A table of contents.

(iv) A statement of research objectives, including identification of the problem or issue the proposed research will contribute to solving, the anticipated contribution of the research to that solution, and specific questions the research will address.

(v) A research design, clearly linked to the questions the study will try to answer. The scientific or technical work of the project and methods for its accomplishment must be stated clearly. A discussion of related research with appropriate citations must be included to show that investigators are thoroughly familiar with current and prior research in pertinent fields. Data to be obtained and analytic methods to be used upon that data must be explained.

(vi) An organization and management plan, presenting (A) the arrangements intended for direction, coordination, and control of the project; (B) the roles, responsibilities, and project time-commitments of proposed staff; (C) a schedule for major portions of multi-year projects; (D) explanation of any subcontract arrangement.

(vii) A description of facilities and arrangements available for the research. If new data are proposed to be collected, the proposal must give evidence of access to suitable organizations for study purposes. Letters of agreement to participate must be included, showing that relevant authorities in school or school-related organizations have reviewed the research plans and agrees to take part willingly. A lengthy and complex study which could place special burdens on parts of the education community may require joint planning and management of the entire project. A proposal for such a study must give detailed information to allow reviewers to judge the adequacy of the arrangement.

(viii) A plan for the dissemination of the research findings, including methods for reaching researchers, theorists, and practicing educators.

(ix) A vita and bibliography for each professional staff person, including professional background and employment as well as education, a chronological list of publications, and a listing of prior and current research support for each individual including requests now being considered regardless of source.

(x) An estimate of expenses proposed to be charged against the grant, including direct costs (e.g., salaries and benefits, travel, supplies and materials, communication, services, equipment) and indirect costs. The proposed budget shall include all other details and explanations, and shall be arranged in such a form, as the Director may request, to allow the cost analyses and other reviews called for by Departmental grant administration policies.

(c) *Small grant applications.* An applicant for a small grant shall submit a proposal including all the elements listed in paragraph (b)(4) of this section. Discussion of objectives and design, as described in paragraphs (b)(4)(iv) and (b)(4)(v) of this section, may not exceed eight pages.

(d) *Submission of applications.* All types of applications for support under this part (preliminary and full grant proposals, and small grant proposals) must be submitted in the number of copies to be prescribed by the Director to the address and at the times the Director shall prescribe.

§ 1480.9 Review procedures and evaluation criteria.

(a) *Review cycle.* Applications will be accepted throughout the fiscal year. Applications will be reviewed at periodic intervals during the fiscal year. Notices of closing dates by which applications must reach NIE to be included in each review will be published in the FEDERAL REGISTER. An application for a grant (other than a small grant) which has been disapproved for funding in one review may be revised and submitted for consideration in any later cycle, without submission of another preliminary proposal. Funds available to the program in a fiscal year will be tentatively allocated to each review cycle. But the amount of funds awarded in any particular review cycle may vary depending on the quality of applications received and the amount of funds requested by the most meritorious applications.

(b) *Review procedures.* The Director will evaluate each application through officers and employees of the Institute and, when considered advisable by the Director, by experts or consultants the Director determines are specially qualified in the areas of research involved in the project. In deciding whether or not to fund an application, the Director may take into account not only the rating of the application's contents by officers or employees of the Institute and by experts or consultants, but also any other information and views within the Institute or provided to the Institute by other Federal, state, or local officials or the public which bear upon the evaluation criteria described in paragraph (d) or which are expressly required or permitted to be taken into account by statute, executive order, or other applicable regulation. Only the Director, or a designee who shall be directly responsible to the Director, shall take final action on an application.

(c) *Review of preliminary proposals.* The Director will review each preliminary proposal using the criteria listed in paragraph (d) of this section. The Director will notify each applicant of the approximate ranking of the preliminary proposal among those reviewed, and any strength or weakness found during the review. An applicant whose preliminary proposal addresses a topic outside the area of this program, as described in § 1480.5, or involves an ineligible research procedure as described in § 1480.6, will be notified after the initial review, and may submit a full proposal with corrections. Information provided from the first stage of review is intended to assist in preparation of a full research proposal, which must be reviewed on its own merits in the second stage. Furnishing of comments from the initial review shall not constitute a commitment by the Director to award funds to a project even if each indicated weakness is addressed.

(d) *Evaluation criteria.* The Director shall use the following criteria to evaluate each preliminary, full, and small grant proposal:

(1) Significance of the proposed research for American education, including (i) importance of the research topic from the standpoint of basic knowledge or problems of American education; (ii) likely magnitude of the addition that will be made to knowledge if the project is successful, including the generalizability of the results.

(2) Quality of the proposed research project, including (i) adequacy of the design, methodology, and instrumentation where appropriate; (ii) likelihood of success of the project; and (iii) extent to which the application exhibits thorough knowledge of pertinent previous work and relates the proposed work to it.

(3) Qualifications of the proposed principal investigator and other professional personnel as evidenced by: (i) experience and previous research productivity; and (ii) quality of the discussion and analysis in the application.

(4) Adequacy of the facilities and arrangements available to the investigator to conduct the proposed study, including evidence of access to necessary organizations, groups, and individuals for study purposes and the willingness of study populations to participate in the proposed research.

(5) Reasonableness of the budget for the work to be done and for the anticipated results.

(6) Whether funding the proposed project would contribute to (i) a diversity of projects under the overall program which collectively address a variety of research needs in the area of organizational processes in education; (ii) other research efforts of NIE; or (iii) the educational needs and interests of other Federal agencies.

(e) *Inapplicable criteria.* General criteria in § 1403.10 of this chapter do not apply to applications submitted under this part.

(f) *Disposition of applications.* Following the review of an application, the Director shall either (1) approve the application in whole or in part, for the amount of funds and subject to the conditions the Director finds appropriate for the completion of the approved project; (2) disapprove the application; or (3) defer action on the application.

§ 1480.10 Project duration and budget.

(a) A project supported by a grant under this part (other than a small grant) may be up to three years in duration.

(b) A project supported by a small grant under this part may be up to twelve months in duration.

(c) An application for a grant (other than a small grant) which proposes a multi-year project shall be accompanied by an explanation of the need for multi-year support, an overview of the objectives and activities proposed, and the budget estimates necessary to attain these objectives in any proposed subsequent years.

(d) If the application for a grant (other than a small grant) demonstrates to the Director's satisfaction that multi-year support is needed to carry out the proposed project, the Director may in the initial notification of award for the project (which may be for up to a twelve month period) indicate an intention to assist the project on an appropriate multi-year basis through continuation awards.

(e) A continuation award may be made to a project described in paragraph (d) of this section, subject to the availability of funds.

(f) An application for a continuation award is reviewed on a non-competitive basis to determine:

(1) If the award recipient has complied with award terms and conditions, the General Education Provisions Act, and any applicable regulation; and

(2) The project's effectiveness to date, and any constructive changes proposed as a result of project evaluation.

[FR Doc.77-33573 Filed 11-21-77;8:45 am]

[6712-01]

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

PART 1—PRACTICE AND PROCEDURE

Editorial Amendment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: FCC amends environmental regulations to reflect GAO approval number for environmental statements submitted by applicants.

EFFECTIVE DATE: November 28, 1977.

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

FOR FURTHER INFORMATION CONTACT:

Upton Guthery, Office of General Counsel, 202-632-6444.

In the matter of editorial amendment of § 1.1311, rules of practice and procedure.

Adopted: November 14, 1977.

Released: November 15, 1977.

1. To comply with procedures of the U.S. General Accounting Office, the following note is hereby added at the end of § 1.1311 of the Rules of Practice and

Procedure (Chapter I, of Title 47 of the Code of Federal Regulations):

NOTE.—The reporting requirement contained in § 1.1311 has been approved by the U.S. General Accounting Office under number B-180227 (R0086).

2. Authority for this amendment is contained in Section 4(i) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i). Because the amendment is editorial, the prior notice and effective date provisions of 5 U.S.C. 553 are inapplicable. This is effective November 28, 1977.

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

R. D. LICHTWARDT,
Executive Director.

[FR Doc.77-33587 Filed 11-21-77;8:45 am]

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 33—SPORT FISHING

Opening of Valentine National Wildlife Refuge, Nebraska, to Sport Fishing

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special Regulation.

SUMMARY: The Director has determined that the opening to sport fishing of Valentine National Wildlife Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public.

DATES: January 1, 1978 through December 31, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert M. Ellis, Refuge Manager, Fort Niobrara-Valentine NWR Complex, Valentine, Nebraska 69201, Telephone Number—AC 402-376-3789.

SUPPLEMENTARY INFORMATION:

§ 33.5 Special regulations; sport fishing for individual wildlife refuge areas.

Sport fishing is permitted on the Valentine National Wildlife Refuge, Nebraska, only on the areas designated by signs as being open to fishing. The areas comprising Clear, Dewey, Duck and Pelican Lakes are delineated on maps available at the refuge headquarters and from the office of the Regional Director, U.S. Fish and Wildlife Service, 10597 West Sixth Avenue, Lakewood, Colo. 80215. Sport fishing shall be in accordance with all State regulations and subject to the following conditions:

1. Sport fishing with hook-and-line, bow-and-arrow, and handspear is permitted.

2. Sport fishing may be closed on specific lakes by posing for emergency or special management projects.

3. All recreational use of the refuge, including fishing, is permitted during daylight hours only. Camping is prohibited.

4. The use or possession of live or dead minnows or whole fish for bait, or the possession of any seine or net for capturing live minnows is prohibited. Parts of dead fish or minnows may be used as bait.

5. Boats propelled with oars, paddles, or electric motors may be used. Internal combustion type motors are prohibited, and may not be mounted on boats used on refuge lakes.

6. Cars and other motorized vehicles are not permitted on the ice.

7. Littering is not allowed and waste receptacles are available for public use.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 33. The public is invited to offer suggestions and comments at any time.

NOTE.—The U.S. 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.

NOVEMBER 7, 1977.

ROBERT M. ELLIS,
Refuge Manager.

[FR Doc.77-33590 Filed 11-21-77;8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Subchapter A—General

[Docket No. 77C-0153]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

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

Chromium Oxide Greens and Chromium Hydroxide Green; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of August 16, 1977, of a regulation concerning the use of chromium oxide greens and chromium hydroxide green in externally applied drugs and cosmetics, including those intended for use in the area of the eye. The document also revises a specification for the color additive to further clarify its composition.

DATE: Effective date confirmed: August 16, 1977. Revision effective date: November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of July 15, 1977 (42 FR 36451) added §§ 73.1326, 73.1327, 73.2326, and 73.2327 to Subparts B and C, respectively, of Part 73 (21 CFR Part 73) to provide for the safe use of chromium oxide greens and chromium hydroxide green in externally applied drugs and cosmetics, including those intended for use in the area of the eye. The regulation also amended § 81.1(g) (21 CFR 81.1(g)), by deleting chromium oxide greens and chromium hydroxide green from the provisionally listed colors.

No objections to or requests for hearing on the regulation were filed by the prescribed date, August 15, 1977. One letter was received after the period had expired. It came from a manufacturer of the color additive, and it concerned the regulation as published. Although this letter was submitted after the objection period, the Commissioner of Food and Drugs finds that it is appropriate to address it.

The letter concerned the specification in the regulation (§ 73.1326(b)) that limited boron content to 5 percent as B_2O_3. The manufacturer requested a clarification whether this was for water-soluble or total boron in the color additive. It advised that earlier data it had submitted for the petition (CAP 8C0079 submitted by the Cosmetic, Toiletry, and Fragrance Association, Washington, D.C.) were for water-soluable boron, not total boron, and the data would fall well within this specification if it were for water-soluable boron. However, analysis of batches of its color additive by a new technique showed total boron in excess of 5 percent, and the manufacturer therefore asked that the specification be increased to 8 percent if it referred to total boron.

The Commissioner has evaluated the data submitted by the manufacturer and other available information indicating that boron would be expected to be predominantly complexed in the color additive. Because the complexed boron would not be biologically available, the Commissioner concludes that the specification for boron in chromium hydroxide green may be safely increased to 8 percent.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)) and under authority delegated to the Commissioner (21 CFR 5.1), there being no objections or request for a hearing in response to the regulation of July 15, 1977, the amendments promulgated thereby became effective on August 16, 1977, and Part 73 is amended in the listing in

§ 73.1326(b) by revising the specification for boron to read as follows:

§ 73.1326 Chromium hydroxide green.

* * * * *

(b) * * *

Boron (as B_2O_3), not more than 8 percent.

* * * * *

Effective dates: (1) The amendments promulgated by the regulation of July 15, 1977 became effective on August 16, 1977; (2) the amendment set forth above is effective November 22, 1977.

Dated: November 16, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-33677 Filed 11-21-77;8:45 am]

[6560-01]

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[FRL 818-3; FAP6H5119/R30]

PART 193—TOLERANCES FOR PESTICIDES IN FOOD ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

Propylene Oxide

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends 21 CFR 193.380 by establishing a regulation providing for the safe use of the fumigant propylene oxide on cocoa, gums, processed nutmeats (except peanuts), spices, and starch for up to 48 hours at 125 degrees F.

EFFECTIVE DATE: Effective November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. William Miller, Product Manager (PM) 11, Registration Division (WN-567), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington D.C. 20460 (202/755-9315).

SUPPLEMENTARY INFORMATION: On March 12, 1976, notice was given (41 FR 10709) that Union Carbide Corp., Linde Div., PO Box 372, 51 Cragwood Road, Plainfield NJ 07080, had filed a petition (FAP 6H5119) with the Environmental Protection Agency (EPA). This petition proposed that 21 CFR 193.380 be amended by establishing a regulation providing for the safe use of the fumigant propylene oxide and carbon dioxide in the ratio of 8 parts propylene oxide to 92 parts carbon dioxide by weight for the fumigation of cocoa, gums, processed nutmeats (except peanuts), spices, and starch for periods up to 48 hours at 125 degrees F. No comments were received by the Agency in response to this notice of filing.

The food additive propylene oxide is currently used as a package fumigant in or on dried prunes and glacé-fruit and as a fumigant in or on bulk quantities of cocoa, gums, processed spices, starch, and processed nutmeats (except peanuts), when such bulk foods are to be further processed into a final food form. Except in the fumigation of packaged dried prunes and glacé-fruits, it is applied in fumigation chambers not more than one time at a temperature not in excess of 125° F. The maximum period of fumigation shall not exceed 4 hours for cocoa, processed nutmeats (except peanuts), processed spices, and starch. It is also used on edible gums with a maximum duration of 24 hours. When used in accordance with the prescribed conditions of use in 21 CFR 193.380, residue limitations are as follows: 300 parts per million (ppm) of ethylene oxide for cocoa, gums, processed nutmeats (except peanuts), processed spices, and starch; 700 ppm (as propylene glycol) for glacé-fruit and dried prunes. Carbon dioxide, when used to dilute propylene oxide, is essentially a chemically inactive gas, and therefore, the Agency has determined that there would be no adverse effect regarding possible residues resulting from its use.

The data submitted in the petition indicate that this amendment to 21 CFR 193.380 is not expected to increase exposure to propylene oxide or its metabolites. The present level of exposure to propylene oxide was evaluated by the Food and Drug Administration when the food additive of 300 ppm for propylene oxide was established. Based on that review and the fact that exposure to propylene oxide will not be increased, it is concluded that the pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 873; 7 U.S.C. 136 et seq.). Therefore, the regulation is being established as proposed.

Any person adversely affected by this regulation may, by December 22, 1977, file written objections with the Hearing Clerk, EPA, Rm. 1019, East Tower, 401 M St. SW., Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective November 22, 1977, 21 CFR Part 193 is amended as set forth below.

(Section 409(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(c)(1)).)

Dated: November 14, 1977.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

Section 193.380 is amended by adding a new paragraph at (d) and redesignating (d) as (e) to read as follows:

* * * * *

§ 193.380 Propylene oxide.

* * * * *

(d) When used as a mixture with carbon dioxide (92 parts of carbon dioxide to 8 parts of propylene oxide on a weight/weight basis), all commodities listed in paragraph (c) of this section, except glace fruit and dried prunes, may be processed not more than one time for a period not to exceed 48 hours and at a temperature not to exceed 125 degrees F.

(e) To assure safe use of the additive, the label and labeling of the pesticide formulation containing the food additive shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

* * * * *

[FR Doc.77-33414 Filed 11-21-77;8:45 am]

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 75N-0020]

PENICILLIN

Updating and Technical Revisions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document updates and revises the antibiotic drug regulations that provide for certification of penicillin drug products. The numerous revisions are made to: (1) revoke inactive sections; (2) change nomenclature for consistency with the policy of the current official compendia; (3) reindex Part 440 to make it consistent in structure with other updated parts of Subchapter D that provide for antibiotic drugs; and (4) provide technical changes.

DATES: Effective December 22, 1977, except that the effective date for revising the nonproprietary names is May 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Joan M. Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4292.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs proposed, in the FEDERAL REGISTER of March 19, 1976 (41 FR 11533), as corrected in the FEDERAL REGISTER of April 5, 1976 (41 FR 14384), to update and revise regulations for penicillin drugs intended for human use. Interested persons were given 60 days to comment.

Comments were received from four manufacturers. The comments and the Commissioner's conclusions follow:

1. One firm objected to the revised wording of the potency statement in §§ 440.255b *Sterile penicillin G benzathine suspension*, 440.255c *Sterile penicillin G benzathine-penicillin G procaine suspension*, and 440.274b *Sterile penicillin G procaine suspension*. The firm, which manufactures penicillin suspen-

sions in prefilled disposable units, said that the revised statement would not provide an appropriate standard for its products.

The Commissioner concludes that the objection is valid. The current regulations specify that "each container or each milliliter" contains a specified dosage. The reference to "container" was deleted in the proposed amendment. Although the prefilled units produced by the firm are filled to deliver the dosage specified in the labeling, the total volume delivered may not be exactly 1 milliliter. The regulations are therefore revised to retain the original language, specifying that "each container or each milliliter" contains the specified dosage.

In the same comment, some typographical errors were noted—the minimum potency for sterile penicillin G potassium, in § 440.80a(a)(1)(i), should be 1,440 units per milligram instead of 1,400; and § 440.155d for penicillin G benzathine tablets should have designated the iodometric assay as the conclusive potency assay, in accordance with the statement in the preamble to the proposal.

The Commissioner agrees, and the regulations are revised accordingly.

The comment also noted that the minimum potency limit for penicillin G potassium tablets was incorrectly published as "9" instead of "90." This error was corrected in a correction document published in the FEDERAL REGISTER of April 5, 1976 (41 FR 14384).

2. One comment made several objections and requests:

a. The firm asked that the concentration of the solution used to determine penicillin V content be lowered from 50 milligrams per 100 milliliters of diluent to 20 milligrams per 100 milliliters of diluent. The firm said that the higher concentration yields absorbance values that are too high to provide accurate readings on most nonrecording instruments.

The Commissioner finds that the requested change is an improvement over the proposed method, and the regulations are revised accordingly.

b. The firm asked that the Karl Fischer moisture test remain as an alternative method for determining the moisture of penicillin V potassium, sterile penicillin G potassium, and penicillin G potassium for injection.

The Commissioner finds it preferable to designate one method as official for determining moisture. Based on the experience of FDA, the Commissioner concludes that the loss-on-drying method is more appropriate than the Karl Fischer method for these drug products. But a manufacturer may prefer to use the Karl Fischer method, which can give satisfactory results. Section 436.2 (21 CFR 436.2) allows use of alternative assay methods provided the results are as accurate as the official method. In case of dispute, however, the results obtained from the designated official method would be conclusive.

c. The firm asked that the hydroxylamine colorimetric assay be included as an alternative potency assay in several dosage form monographs.

The Commissioner agrees that a hydroxylamine colorimetric assay is appropriate as an alternative potency assay for several penicillin drug products. But because the general method in § 436.205 (21 CFR 436.205) is not entirely suitable for dosage form drugs, such alternative potency assay cannot be adopted at this time. The Food and Drug Administration is currently developing an appropriate hydroxlamine colorimetric assay procedure for certain penicillin dosage forms and plans to publish the procedure in the FEDERAL REGISTER in the near future.

d. The firm also asked that the lower pH limit in § 440.171b(a)(1) be 2.0 instead of 3.0, as proposed.

In light of information submitted as part of the comment, the Commissioner has no objection to adopting the limit requested, and the regulation is revised accordingly.

e. The firm objected to the deletion of the provision, under certain circumstances, for a 3 percent moisture limit for penicillin V potassium tablets.

The Commissioner has considered this objection and finds that the 3 percent exemption for moisture is inappropriate for penicillin V potassium tablets currently being certified. According to FDA records, the only tablet that has been the subject of such an exemption from the 1.5 percent limit is V-Kor Tablets, which consisted of three separate compressed layers containing penicillin, antihistamines, and analgesics. Drying of these tablets after compression to reduce the moisture content to a limit of 1.5 percent or less could cause a separation at the point of lamination. Therefore, the 3 percent limit was approved for this product only. V-Kor Tablets were removed from the market as a result of the Drug Efficacy Study Implementation notice, published in the FEDERAL REGISTER of November 17, 1971 (36 FR 21879). This exemption has never applied to any other penicillin V potassium tablet.

On the basis of FDA certification records for the past 2 years, the Commissioner finds that the 1.5 percent limit for penicillin V potassium tablets is reasonable.

3. Comments were received from two manufacturers concerning the proposed revocation of § 440.81 *Buffered crystalline penicillin.* Both firms produce a product containing penicillin G potassium or penicillin G sodium blended with buffers, which they manufacture for sale in bulk to other firms that package it for dispensing. They questioned whether their products are adequately provided for under the proposed regulations.

The Commissioner has considered the comments and agrees that some revisions are necessary to the proposed regulations. He finds that the regulations should provide for certification of these drug products without requiring sampling of the unbuffered bulk during an early stage of processing. Because of the method of manufacturing the buffered bulk product, it is impractical to sample the unbuffered bulk penicillin G potassium or penicillin G sodium for certification testing. Since it is the policy of FDA that, in the antibiotic regulations, each Subpart A is reserved for bulk drugs containing no added substances such as buffers and excipients, it is necessary to establish a new subpart to provide for buffered bulks that are intended for further manufacturing or repacking. The Commissioner is therefore adding new Subpart K—Bulk Drug Formulations for Repacking or for Manufacturing Use to Part 440. The new subpart contains new § 440.1080a *Sterile penicillin G potassium, buffered and new* § 440.1081a *Sterile penicillin G sodium, buffered.* Sections 440.280b and 440.281b as proposed are further revised to provide that the antibiotic drugs used in the manufacture of these dosage forms conform to the requirements of §§ 440.1080a and 440.1081a, respectively. Because §§ 440.280b and 440.281b are now intended only for dosage forms, the references in these monographs, as proposed, to use in manufacturing or repacking are being deleted.

4. One firm asked that sufficient time be provided to permit orderly changes in labeling in accordance with the revised nomenclature.

The Commissioner finds that additional time for revising labeling to reflect the name changes is justified and that use of labeling that complies with all other requirements is not contrary to the public health. Therefore, the effective date is revised, as set forth below, to allow 6 months for revising nomenclature.

In addition, Part 460 (21 CFR Part 460) currently has no authority citation. An authority citation is being added.

In the proposed document, the names of the penicillins which included waters of hydration were amended to delete the hydrate except for ampicillin trihydrate. Since that time, the Commissioner has reconsidered this action and feels that it is scientifically correct to include the water of hydration. Therefore the final rule making document has been revised to include monohydrate wherever the drug contains one water of hydration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 430,

436, 440, and 460 are being amended, as follows:

PART 430—ANTIEIOTIC DRUGS: GENERAL

a. Part 430 is amended as follows:

1. In § 430.5 the following amendments are made: Paragraph (a)(1)(ii) is revoked and reserved; in paragraph (a)(1)(iii), the term "phenoxymethyl penicillin" is revised to read "penicillin V" wherever it appears; paragraph (b)(1)(ii) is revoked and reserved; in paragraph (b)(1)(iii), the term "phenoxymethyl penicillin" is revised to read "penicillin V"; in paragraph (b)(1)(x), the term "procaine penicillin G" is revised to read "penicillin G procaine" wherever it appears. As amended, the affected text in paragraphs (a)(1) and (b)(1) reads as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(1) * * *

(ii) [Reserved]

(iii) *Penicillin V.* The term "penicillin V master standard" means a specific lot of crystalline penicillin V that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin V working standard.

* * * * *

(b) * * *

(1) * * *

(ii) [Reserved]

(iii) The term "penicillin V working standard" means a specific lot of a homogeneous preparation of penicillin V.

* * * * *

(x) The term "penicillin G procaine working standard" means a specific lot of a homogeneous preparation of penicillin G procaine.

* * * * *

2. Section 430.6 is amended as follows: Paragraph (a)(1)(ii) is revoked and reserved; in paragraph (a)(1)(iii), the term "phenoxymethyl penicillin" is revised to read "penicillin V" wherever it appears. The amended paragraphs read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

(a) * * *

(1) * * *

(ii) [Reserved]

(iii) *Penicillin V.* The term "unit" applied to penicillin V means the penicillin activity (potency) contained in 0.590 microgram of the penicillin V master standard.

* * * * *

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

b. The following amendments are made to Part 436:

1. Section 436.33(b) table is amended as follows:

A. The following items are deleted: "Aluminum penicillin," "Chloroprocaine penicillin O," "Clemizole penicillin G," "Diethylaminoethyl ester penicillin G hydriodide," "Hydrabamine penicillin G [3]" and "Sodium nafcillin."

B. The following names are rearranged and reinserted alphabetically into the table: Benzathine cloxacillin is revised to read "Cloxacillin benzathine"; "Benzathine penicillin G" is revised to read "Penicillin G benzathine"; "Benzathine phenoxymethyl penicillin" is revised to read "Penicillin V benzathine"; "Calcium chlortetracycline syrup" is revised to read "Chlortetracycline calcium syrup"; "Calcium novobiocin" is revised to read "Novobiocin calcium"; "Calcium oxytetracycline" is revised to read "Oxytetracycline calcium"; "Disodium carbenicillin" is revised to read "Carbenicillin disodium"; "Hydrabamine phenoxymethyl penicillin [3]" is revised to read "Penicillin V hydrabamine [3]"; "Phenoxymethyl penicillin" is revised to read "Penicillin V"; "Potassium hetacillin" is revised to read "Hetacillin potassium"; "Potassium penicillin G" is revised to read "Penicillin G potassium"; "Potassium phenethicillin" is revised to read "Phenethicillin potassium"; "Potassium phenoxymethyl penicillin" is revised to read "Penicillin V potassium"; "Procaine penicillin G" is revised to read "Penicillin G procaine"; "Sodium ampicillin" is revised to read "Ampicillin sodium"; "Sodium cephalothin" is revised to read "Cephalothin sodium"; "Sodium colistimethate" is revised to read "Colistimethate sodium"; "Sodium novobiocin" is revised to read "Novobiocin sodium"; "Sodium cloxacillin monohydrate" is revised to read "Cloxacillin sodium monohydrate"; "Sodium dicloxacillin monohydrate" is revised to read "Dicloxacillin sodium monohydrate"; "Sodium methicillin" is revised to read "Methicillin sodium monohydrate"; "Sodium nafcillin monohydrate" is revised to read "Nafcillin sodium monohydrate"; "Sodium oxacillin" is revised to read "Oxacillin sodium monohydrate"; and "Sodium penicillin G" is revised to read "Penicillin G sodium"; "Zinc bacitracin" is revised to read "Bacitracin zinc."

As amended, the table in paragraph (b) reads as follows:

§ 436.33 Safety test.

* * * * *

(b) * * *

Antibiotic drug	Diluent (diluent number as listed in § 436.31)	Test dose: Concentration in units or milligrams of activity per milliliter	Test dose: Volume in milliliters to be administered to each mouse	Route of administration as described in paragraph (c) of this section
Amoxicillin trihydrate	9	20 mg	0.5	Intravenous.
Amphotericin B	6	50 mg	.4	Oral.
Amphotericin B for injection	3	0.05 mg	.3	Intravenous.
Ampicillin	9	20 mg	.5	Do.
Ampicillin sodium	3	40 mg	.5	Do.
Ampicillin trihydrate	9	20 mg	.5	Do.
Bacitracin	4	200 units	.5	Do.
Bacitracin methylene disalicylate	5	1,000 units	1.0	Oral.
Bacitracin zinc	3	4,000 units	.5	Do.
Benzylpenicilloyl-polylysine injection	(1)	4 mg	.5	Do.
Capreomycin sulfate	4	3.0 mg	.5	Intravenous.
Carbenicillin disodium	3	40 mg	.5	Do.
Carbenicillin indanyl sodium	3	100	.5	Oral.
Cefazolin sodium	3	50 mg	.5	Intravenous.
Cephacetrile sodium	3	60 mg	.5	Do.
Cephalexin monohydrate [3]	12	10 mg	.5	Oral.
Cephaloglycin [3]	5	120.0 mg	.5	Do.
Cephaloridine	3	50 mg	.5	Intravenous.
Cephalothin sodium	3	40 mg	.5	Do.
Cephapirin sodium	3	40 mg	.5	Do.
Cephradine	10	40 mg	.5	Oral.
Cephradine Sterile	14	23 mg	.5	Intravenous.
Cephradine for injection	1	23 mg	.5	Do.
Chloramphenicol	4	5 mg*	.5	Do.
Chloramphenicol palmitate	5	60 mg	1.0	Oral.
Chloramphenicol sodiumsuccinate	4	20 mg	.5	Intravenous.
Chlortetracycline	(1)	2 mg	.5	Do.
Chlortetracycline bisulfate	3	2 mg	.4	Do.
Chlortetracycline calcium syrup	3	25 mg	.5	Oral.
Chlortetracycline hydrochoride	3	2 mg	.5	Intravenous.
Clindamycin hydrochloride hydrate	4	4 mg	.5	Do.
Clindamycin palmitate hydrochloride	3	50 mg	1.0	Oral.
Clindamycin phosphate	4	20 mg	.5	Intravenous.
Cloxacillin benzathine	10	10 mg	.5	Do.
Cloxacillin sodium monohydrate	3	16 mg	.5	Do.
Colistin sulfate	3	0.6 mg	.5	Oral.
Colistimethate sodium	3	1.5 mg	.5	Intravenous.
Cycloserine	4	32 mg	.5	Do.
Demeclocycline	(1)	2mg	.5	Do.
Demeclocycline hydrochloride	3	2mg	.5	Do.
Dicloxacillin sodium monohydrate	4	20 mg	.5	Do.
Dihydrostreptomycin sulfate	3	2 mg	.5	Do.
Doxycycline hyclate	4	5 mg	.5	Do.
Doxycycline hyclate for injection	4	2 mg	.5	Do.
Doxycycline monohydrate	(1)	100 mg	.5	Oral.
Erythromycin	5	30 mg	1.0	Do.
Erythromycin estolate	5	40mg	.5	Do.
Erythromycin ethylcarbonate	5	100 mg	.5	Do.
Erythromycin ethylsuccinate	3	80 mg	.5	Do.
Erythromycin gluceptate	3	2 mg	.5	Intravenous.
Erythromycin lactobionate for injection	3	3 mg	.5	Do.
Erythromycin stearate	(1)	80 mg	.5	Oral.
Gentamicin sulfate	4	1 mg	.5	Intravenous.
Gramicidin [3]	5	5 mg	.5	Subcutaneous.
Griseofulvin	5	200 mg	.5	Oral.
Hetacillin	11	45 mg [2]	.4	Intravenous.
Hetacillin potassium	4	8 mg [2]	.5	Do.
Kanamycin sulfate	3	2 mg	.5	Do.
Lincomycin hydrochloride monohydrate	4	4 mg	.5	Do.
Methacycline hydrochloride	3	2 mg	.5	Do.
Methicillin sodium monohydrate	4	100 mg	.5	Do.
Minocycline hydrochloride	3	2 mg	.5	Do.
Mitomycin [3]	3	0.2 mg	.5	Do.
Nafcillin sodium monohydrate	4	16 mg	.5	Do.
Neomycin sulfate	4	0.2 mg	.5	Do.
Novobiocin calcium	4	2 mg	.5	Do.
Novobiocin sodium	4	4 mg	.5	Do.
Nystatin	6	1,200 units	.5	Intraperitoneal.
Oleandomycin phosphate	4	8 mg	.5	Intravenous.
Oxacillin sodium monohydrate	4	20 mg	.5	Do.
Oxytetracycline	(1)	2 mg	.5	Do.
Oxytetracycline calcium	5	25 mg	.5	Oral.
Oxytetracycline hydrochloride	3	2 mg	.5	Do.
Paromomycin sulfate	3	8 mg	.5	Do.
Penicillamine	10	100 mg	1.0	Do.
Penicillin G benzathine	4	4,000 units	.25	Intravenous.
Penicillin G potassium	3	4,000 units	.5	Do.
Penicillin G procaine	4	2,000 units	.5	Do.
Penicillin G sodium	3	4,000 units	.5	Do.
Penicillin V	4	2,000 units	.5	Do.
Penicillin V benzathine	4	4,000 units	.25	Do.
Penicillin V hydrabamine [3]	(1)	100 mg	.5	Oral.
Penicillin V potassium	4	2,000 units	.5	Intravenous.
Phenethicillin potassium	4	4,000 units	.5	Do.
Polymyxin B sulfate	4	1,200 units	.5	Do.
Rifampin	10	6 mg	1.0	Oral.
Rolitetracycline	3	2 mg	.5	Intravenous.
Rolitetracycline nitrate	3	2 mg	.5	Do.
Spectinomycin hydrochloride	4	16 mg	.5	Do.
Streptomycin sulfate	3	2 mg	.5	Do.
Streptonicozid sulfate	3	1 mg	.5	Do.
Tetracycline	(1)	2 mg	.5	Do.
Tetracycline hydrochloride	3	2 mg	.5	Do.
Tetracycline phosphate	(1)	2 mg	.5	Do.
Troleandomycin	4	200 mg	.5	Oral.
Vancomycin hydrochloride	4	4 mg	.5	Intravenous.
Viomycin sulfate	4	2 mg	.5	Do.

[1] To prepare the sample solution, proceed as directed in the individual section of the antibiotic drug regulations in this chapter for the antibiotic to be tested.

[2] Ampicillin activity.

[3] Use the observation period specified in the individual section of the antibiotic drug regulations in this chapter for the antibiotic to be tested in lieu of the 48-hr-observation period specified in par. (d) of this section.

§ 436.105 [Amended]

2. Section 436.105 *Microbiological agar diffusion assay* is amended in the tables in paragraphs (a) and (b) by revising the name "phenoxymethyl penicillin" to read "Penicillin V" and reinserting the item alphabetically into the tables.

3. Section 436.204 is amended as follows:

a. In the table in paragraph (b)(1), the item "Penicillin O" is deleted, the name "Phenoxymethyl penicillin" is revised to read "Penicillin V", and the name "Potassium L-phenethicillin" is revised to read "L-phenethicillin potassium" and the last item is reinserted alphabetically into the table.

b. In paragraph (b)(2), the table is revised. The amended text reads as follows:

§ 436.204 Iodometric assay.

* * * * *

(b) * * *

(1) * * *

Antibiotic	Initial solvent	Diluent (solution number as listed in § 436.101(a))	Final concentration in units or milligrams of activity per milliliter of standard solution
Amoxicillin	None	Distilled water	1.0 mg.
Ampicillin	do	do	1.25 mg.
Cephalexin	do	do	2 mg.
Cephaloridine	do	do	2 mg.
Cephalothin	do	do	2 mg.
Cephapirin	do	do	2 mg.
Cloxacillin	do	do	1.25 mg.
Dicloxacillin	do	do	1.25 mg.
L-phenethicillin potassium	do	1	2,000 units.
Methicillin	do	1	1.25 mg.
Nafcillin	do	1	1.25 mg.
Oxacillin	do	1	1.25 mg.
Penicillin G	do	1	2,000 units.
Penicillin V	2 ml methyl alcohol.	1	2,000 units.

(2) * * *

Antibiotic	Initial solvent	Diluent (solution number as listed in § 436.101(a))	Final concentration in units or milligrams of activity per milliliter of sample
Amoxicillin trihydrate	None	Distilled water	1.0 mg.
Ampicillin	do	do	1.25 mg.
Ampicillin sodium	do	1	1.25 mg.
Ampicillin trihydrate	do	Distilled water	1.25 mg.
Cephalexin	do	do	2 mg.
Cephaloridine	do	do	2 mg.
Cephalothin sodium	do	do	2 mg.
Cephapirin sodium	do	do	2 mg.
Cloxacillin sodium monohydrate	do	do	1.25 mg.
Dicloxacillin sodium monohydrate	do	1	1.25 mg.
Methicillin sodium monohydrate	do	1	1.25 mg.
Nafcillin sodium monohydrate	do	1	1.25 mg.
Oxacillin sodium monohydrate	do	1	1.25 mg.
Penicillin G benzathine blank solution	do	Distilled water	2,000 units.
Penicillin G benzathine inactivated solution	do	1*N* NaOH	2,000 units; allow to stand in 1*N* NaOH for 15 min. before assaying.
Penicillin G potassium	do	1	2,000 units.
Penicillin G procaine	2 ml methyl alcohol.	1	2,000 units.
Penicillin G sodium	None	1	2,000 units.
Penicillin V	2 ml methyl alcohol.	1	2,000 units.
Penicillin V benzathine blank solution	None	Distilled water	2,000 units.
Penicillin V benzathine inactivated solution	do	1*N* NaOH	2,000 units; allow to stand in 1*N* NaOH for 15 min. before assaying.
Penicillin V hydrabamine	do	Chloroform	2,000 units.
Penicillin V potassium	do	1	2,000 units.
Phenethicillin potassium	do	1	2,000 units.

4. Section 436.205 is amended as follows:

a. In the table in paragraph (b) by changing the name "Phenoxymethyl penicillin" to read "Penicillin V" and the name "Procaine penicillin G" to read "Penicillin G procaine," and both items are reinserted alphabetically into the table.

b. In paragraph (c), the table is revised. The amended text reads as follows:

§ 436.205 Hydroxylamine colorimetric assay.

* * * * *

(b) * * *

Antibiotic	Diluent (solution number as listed in § 436.101(a))	Final concentration in milligrams per milliliter of standard
Amoxicillin	Distilled water.	1.0
Ampicillin	do	1.25
Cefazolin [1]		1.0
Cephacetrile	Distilled water.	2.0
Cephaloridine	do	1.0
Cephalothin	do	2.0
Cephapirin	do	1.0
Cloxacillin	1	1.25
Dicloxacillin	1	1.25
Methicillin	1	1.25
Nafcillin	1	1.25
Oxacillin	1	1.25
Penicillin G	1	1.25
Penicillin G procaine	17	2.0
Penicillin V	17	1.25
Phenethicillin	1	1.25

[1] To prepare the working standard solution, proceed as directed in the individual section of the antibiotic drug regulation in this chapter for the antibiotic to be tested.

(c) * * *

Antibiotic	Diluent (solution number as listed in § 436.101(a))	Final concentration in units or milligrams of activity per milliliter of sample
Amoxicillin trihydrate	Distilled water.	1.0
Ampicillin:	do	1.25
Ampicillin sodium	do	1.25
Ampicillin trihydrate	do	1.25
Cefazolin sodium	1	1.0
Cephacetrile sodium	Distilled water.	2.0
Cephaloridine	do	1.0
Cephalothin sodium	do	2.0
Cephapirin sodium	do	1.0
Cloxacillin sodium monohydrate.	1	1.25
Dicloxacillin sodium monohydrate.	Distilled water.	1.25
Methicillin sodium monohydrate.	1	1.25
Nafcillin sodium monohydrate.	1	1.25
Oxacillin sodium monohydrate.	1	1.25
Penicillin G potassium	1	1.25
Penicillin G procaine	17	2.0
Penicillin G sodium	1	1.25
Penicillin V	17	1.25
Penicillin V potassium	1	1.25
Phenethicillin potassium	1	1.25

* * * * *

5. In Subpart E, the following new § 436.214 is added.

§ 436.214 Heat stability.

Store an accurately weighed portion of the sample of approximately 30 milligrams in an unstoppered 50-milliliter Erlenmeyer flask for 4 days in an electric oven at 100° C±1° C. At the end of this period, remove the flask from the oven and allow to cool in a desiccator. Accurately weigh an unheated portion of the original sample of approximately 30 milligrams. Assay both the heated and unheated samples for potency as directed

in § 436.204 or § 436.205 of this chapter. Determine the percent loss from the difference in potency between the unheated original sample and the heat-treated sample.

6. In Subpart F, the following new § 436.316 is added.

§ 436.316 Determination of penicillin G content.

(a) *Reagents.* The reagents are freshly prepared every three days and are of such quality that when used in this procedure with an authentic sample of penicillin G, not less than 97 percent of penicillin G is recovered.

(1) *Amyl acetate (iso-amyl acetate) solution.* Saturate the amyl acetate (boiling range 138.5° C—141.5° C) with the *N*-ethyl piperidine salt of penicillin G by adding 2 milligrams of the salt for each 1.0 milliliter of the solvent. Cool this solution to 0° C—8° C and filter it through a sintered-glass filter immediately before use.

(2) *Acetone solution.* Saturate reagent grade acetone with the *N*-ethyl piperidine salt of penicillin G using 3 milligrams of salt for each 1 milliliter of acetone. Cool this solution to 0° C—8° C and filter it through a sintered-glass filter immediately before use.

(3) *N-ethyl piperidine solution.* *N*-ethyl piperidine (boiling range 129.5° C—131.0° C) should be stored in brown bottles in a refrigerator. Dilute 1.0 milliliter of this reagent with 4.0 milliliters of amyl acetate. Saturate this solution with the *N*-ethyl piperidine salt of penicillin G, using about 3 milligrams of the salt for each 1.0 milliliter of solution. Cool this solution to 0° C—8° C and filter it through a sintered-glass filter immediately before use.

(4) *Phosphoric acid solution.* Prepare by dissolving 1.0 milliliter of reagent grade phosphoric acid (85 percent) in 4.0 milliliters of water. Cool to 0° C—8° C and shake before using.

(5) *Silica gel.* Use dry silica gel (mesh size 6–16, Tyler standard). Place about 0.5 gram of the silica gel in a micro filter funnel (approximately 10-millimeter diameter) having a fritted-glass disc of medium porosity.

(b) *Procedure.* Accurately weigh from 60 to 70 milligrams of the sample to be tested, except if penicillin G procaine is to be tested weigh 90 to 100 milligrams of sample, into a glass test tube or glass vial of approximately 10-milliliter capacity. Add 2.0 milliliters of water to dissolve or suspend (procaine) the penicillin and cool to 0° C—5° C. Add 2.0 milliliters of amyl acetate solution and 0.5 milliliter of phosphoric acid solution, stopper and shake the container vigorously for approximately 15 seconds. For penicillin G procaine, add a second 0.5-milliliter portion of phosphoric acid solution and shake vigorously. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). If any penicillin procaine remains undissolved, add a third 0.5-milliliter portion of phosphoric acid solution, shake the container vigorously, and centrifuge. After centrifuging, remove as much of the amyl acetate layer as possible, usually about 1.7 milliliters to 1.8 milliliters, with a suitable hypodermic needle and syringe and place the portion removed into the filter funnel containing silica gel, described in paragraph (a)(5) of this section. Allow the amyl acetate to remain in contact with the silica gel for exactly 20 seconds, then apply suction and collect the filtrate in a small test tube placed in a suction flask surrounded by cracked ice. Pipet a 1.0-milliliter aliquot of the amyl acetate filtrate into a tared flat-bottom glass tube (approximately 15 x 50 millimeters) containing 1.0 milliliter of acetone solution and 0.5 milliliter of *N*-ethyl piperidine solution. The time elapsing between accidification and the addition of the filtrate to the above reagents should not be more than 3 minutes. Place the glass tube containing the mixture into a large weighing bottle, stopper the bottle and allow to stand for not less than 2 hours in a refrigerator at 0° C—8° C. Remove the liquid from the precipitate by means of a tared micro filter stick and wash with a total of 1.0 milliliter of acetone solution adding the latter by means of a hypodermic syringe equipped with a fine needle. Place the filter stick inside the glass tube, dry under vacuum at room temperature for not less than 1 hour, and weigh. (The *N*-ethyl piperidine penicillin G residues can be saved for saturating reagents).

(c) *Calculations.* Calculate the percent penicillin G content as follows:

$$\text{Percent penicillin G content} = \frac{\text{Milligrams } N\text{-ethyl piperidine penicillin precipitate} \times 149.4}{\text{Weight of sample in milligrams}}$$

PART 440—PENICILLIN ANTIBIOTIC DRUGS

c. Part 440 is amended as follows:

§ 440.9a [Amended]

1. Section 440.9a *Sterile sodium ampicillin* is amended by changing the name "sodium ampicillin" to read "ampicillin sodium" in the heading and in paragraphs (a)(1) and (a)(1)(x).

§ 440.13a [Amended]

2. Section 440.13a *Sterile disodium carbenicillin* is amended by changing the name "disodium carbenicillin" to read "carbenicillin disodium" in the section heading and in paragraphs (a)(1) and (a)(1)(vii).

§ 440.15 [Amended]

3. Section 440.15 *Sodium cloxacillin* is amended as follows:

a. By changing the name "sodium cloxacillin" to read "cloxacillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(v) to read "Its cloxacillin content is not less than 82.5 percent."

c. By changing "sodium cloxacillin content," to read "cloxacillin content," in paragraph (a)(3)(i).

d. By deleting the word "sodium" the four times it appears with "sodium cloxacillin" in the heading, text, and formula in paragraph (b)(5).

§ 440.19 [Amended]

4. Section 440.19 *Nonsterile sodium dicloxacillin mononhydrate* is amended as follows:

a. By changing the name "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and in paragraphs (a)(1) and (a)(1)(viii).

b. By deleting the word "nonsterile" from the section heading and first sentence of paragraph (a)(1).

§ 440.19a [Amended]

5. Section 440.19a *Sterile sodium dicloxacillin monohydrate* is amended as follows:

a. By changing the name "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and in paragraphs (a)(1) and (a)(1)(x).

b. By revising the text of paragraph (a)(2) to read "If this drug is packaged for dispensing, in addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'sterile dicloxacillin sodium'."

§ 440.25 [Amended]

6. Section 440.25 *Nonsterile hetacillin* is amended by deleting the word "Nonsterile" from the section heading.

§ 440.29 [Amended]

7. Section 440.29 is amended as follows:

a. By revising the section heading to read § 440.29 *Hetacillin potassium.*

b. By changing the name "potassium hetacillin" to read "hetacillin potassium" in paragraphs (a)(1) and (a)(1)(vi).

c. By revising the text of paragraph (a)(1)(v) to read "Its hetacillin content is not less than 82 percent and not more than 95.5 percent".

d. By changing "postassium hetacillin content," to read "hetacillin content," in paragraph (a)(3)(i).

e. By deleting the word "potassium" the four times its appears in paragraph (b)(5).

f. By deleting the figures "X 427.57" and "X 389.48" from the formula therein, and as amended the formula reads:

$$\text{Percent hetacillin} = \frac{c \times 5{,}000 \times 100}{\text{weight of sample in milligrams}}$$

§ 440.29a [Amended]

8. Section 440.29a *Sterile potassium hetacillin* is amended as follows:

a. By changing the name "potassium hetacillin" to read "hetacillin potassium" in the section heading and in paragraphs (a)(1) and (a)(1)(viii).

b. By revising the text of paragraph (a)(1)(vii) to read "Its hetacillin content is not less than 82 percent and not more than 95.5 percent."

c. By changing "potassium hetacillin content," to read "hetacillin content," in paragraph (a)(3)(i).

By changing "potassium hetacillin content," to read "hetacillin content," in the heading and text in paragraph (b)(7).

d. By changing "potassium hetacillin and X 389.48" from the formula therein, and as amended the formula reads:

$$\text{Percent hetacillin} = \frac{c \times 500}{\text{Weight of sample in milligrams}}$$

§ 440.36a [Amended]

9. Section 440.36a *Sterile sodium methicillin* is amended as follows:

a. By changing the name "sodium methicillin" to read "methicillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(vii) to read "Its methicillin content is not less than 81.5 percent."

c. By changing "sodium methicillin content," to read "methicillin content," in paragraph (a)(3)(i).

d. By deleting the word "sodium" from the heading, text, and two places in the formula in paragraph (b)(7).

§ 440.41 [Amended]

10. Section 440.41 *Nonsterile sodium nafcillin monohydrate* is amended as follows:

a. By deleting the word "Nonsterile" from the section heading and by changing the name "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section hearing and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(vi) to read "Its nafcillin content is not less than 82.7 percent."

c. By changing "sodium nafcillin monohydrate content," to read "nafcillin content," in paragraph (a)(3)(i).

d. By changing "sodium nafcillin monohydrate" to read "nafcillin" in the heading, text, and two places in the formula in paragraph (b)(6).

§ 440.41a [Amended]

11. Section 440.41a *Sterile sodium nafcillin monohydrate* is amended as follows:

a. By changing the name "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(viii) to read "Its nafcillin content is not less than 82.0 percent."

c. By changing "sodium nafcillin monohydrate content," to read "nafcillin content," in paragraph (a)(3)(i).

d. By changing the heading of paragraph (b)(3) to read *"Nafcillin content."*

§ 440.49 [Amended]

12. Section 440.49 *Sodium oxacillin* is amended as follows:

a. By changing the name "sodium oxacillin" to read "oxacillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(v) to read "Its oxacillin content is not less than 81.5 percent and not more than 95.0 percent."

c. By changing "sodium oxacillin content," to read "oxacillin content," in paragraph (a)(3)(i).

d. By deleting the word "sodium" from the heading and the two times it appears in the formula in paragraph (b)(5).

§ 440.49a [Amended]

13. Section 440.49a *Sterile sodium oxacillin* is amended as follows:

a. By changing the name "sodium oxacillin" to read "oxacillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(1)(vii) to read "Its oxacillin content is not less than 81.5 percent and not more than 95.0 percent."

c. By changing "sodium oxacillin content," to read "oxacillin content," in paragraph (a)(3)(i).

d. By deleting the word "sodium" from the heading of paragraph (b)(7).

§ 40.53a [Revoked]

14. Section 440.53a *Sterile aluminum penicillin (aluminum penicillin salt)* is revoked.

15. Section 440.55a is revised to read as follows:

§ 440.55a Sterile penicillin G benzathine.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin G benzathine is the *N,N'*-dibenzylethylenediamine salt of penicillin G. It is so purified and dried that:

(i) Its potency is not less than 1,090 units and not more than 1,272 units per milligram.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its moisture content is not less than 5.0 percent and not more than 8.0 percent.

(vi) Its pH in a saturated aqueous solution (about 100 milligrams per milliliter) is not less than 5.0 and not more than 7.5.

(vii) Its penicillin G content is not less than 57.9 percent and not more than 71.6 percent.

(viii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, moisure, pH, penicillin G content, and crystallinity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay—*(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately measured representative portion of the sample in sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately, further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(d) of this chapter, using a solution containing 4,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using a saturated aqueous solution prepared by suspending about 100 milligrams of sample per milliliter.

(7) *Penicillin G content.* Accurately weigh approximately 50 milligrams of the sample, dissolve in absolute methyl alcohol, and dilute to 100 milliliters with absolute methyl alcohol. Treat a portion of the working standard in the same manner. Using a suitable spectrophotometer equipped with a quartz cell and absolute methyl alcohol as the blank, determine the absorbence at 263 nanometers. Calculate the percent penicillin G as follows:

$$\text{Percent penicillin G} = \frac{\text{Absorbance of sample} \times \text{weight in milligrams of standard} \times \text{percent penicillin G in standard}}{\text{Absorbance of standard} \times \text{weight in milligrams of sample}}$$

(8) *Crystallinity.* Proceed as directed in § 436.203 of this chapter.

§ 440.57 [Amended]

16. Section 440.57 *Benzathine phenoxymethyl penicillin* is amended as follows:

a. By changing "benzathine phenoxymethyl penicillin" to read "penicillin V benzathine" in the section heading and paragraph (a)(1).

b. By changing "phenoxymethyl penicillin" to read "penicillin V" in paragraphs (a)(1), (a)(1)(v), (a)(3)(i), (b)(1)(i) and (b)(5), including the formula therein.

§ 440.59a [Revoked]

17. Section 440.59a *Sterile chloroprocaine penicillin O (penicillin O chloroprocaine* salt) is revoked.

§ 440.60a [Revoked]

18. Section 440.60a *Sterile dibenzylamine penicillin G (dibenzylamine penicillin G salt)* is revoked.

§ 440.61a [Revoked]

19. Section 440.61a *Sterile diethylaminoethyl ester penicillin G hydriodide (penicillin G diethylaminoethyl ester hydriodide)* is revoked.

§ 440.63a [Revoked]

20. Section 440.63a *Sterile ephedrine penicillin (penicillin ephedrine salt), ephedrine penicillin G (penicillin G ephedrine salt)* is revoked.

§ 440.65a [Revoked]

21. Section 440.65a *Sterile l-ephenamine penicillin G (penicillin G l-ephenamine salt)* is revoked.

§ 440.66 [Revoked]

22. Section 440.66 *Hydrabamine penicillin G (hydrabamine penicillin G salt)* is revoked.

§ 440.69 [Amended]

23. Section 440.69 *Hydrabamine phenoxymethyl penicillin* is amended as follows:

a. By changing "hydrabamine phenoxymethyl penicillin" to read "penicillin V hydrabamine" in the section heading and paragraph (a)(1).

b. By changing "phenoxymethyl penicillin" to read "penicillin V" in paragraphs (a)(1), (a)(1)(vi), (a)(3)(i), (b)(1) and (b)(1)(i), and (b)(6), including the formula therein.

24. Section 440.71 is revised to read as follows:

§ 440.71 Penicillin V.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin V is 3,3-dimethyl - 7-oxo-6-(2-phenoxyacetamido) - 4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 1,525 units nor more than 1,780 units per milligram.

(ii) It passes the safety test.

(iii) Its moisture content is not more than 2.0 percent.

(iv) Its pH in a saturated aqueous solution is not less than 2.5 and not more than 4.0.

(v) Its penicillin V content is not less than 90 percent and not more than 105 percent.

(vi) It is crystalline.

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, each package shall bear on its outside wrapper or container and the immediate container the statement "For use in the manufacture of nonparenteral drugs only."

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, safety, moisture, pH, penicillin V content, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay—*(1) *Potency.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample (aproximately 30 milligrams) in 2.0 milliliters of absolute methyl alcohol. Further dilute an aliquot of this solution with sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(iii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

(2) *Safety.* Proceed as directed in § 436.33 of this chapter.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a saturated aqueous solution prepared by adding approximately 30 milligrams per milliliter.

(5) *Penicillin V content.* Accurately weigh approximately 20 milligrams of sample, dissolve in absolute methyl alcohol, and dilute to 100 milliliters with absolute methyl alcohol. Treat a portion of the working standard in the same manner. Using a suitable spectrophotometer equipped with a quartz cell and absolute methyl alcohol as the blank, determine the absorbance of the peak at 276 nanometers. Calculate the percent penicillin V as follows:

$$\text{Percent penicillin V} = \frac{\text{Absorbance of sample} \times \text{weight in milligrams of standard} \times \text{percent penicillin V in standard}}{\text{Absorbance of standard} \times \text{weight in milligrams of sample}}$$

(6) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

25. Section 440.73 is revised to read as follows:

§ 440.73 Penicillin V potassium.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium is the potassium salt of 3,3-dimethyl-7-oxo-6-(2-phenoxyacetamido) - 4 - thia - 1 - azabicyclo[3.2.0]heptane - 2 - carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 1,380 units nor more than 1,610 units per milligram.

(ii) It passes the safety test.

(iii) Its loss on drying is not more than 1.5 percent.

(iv) Its pH in an aqueous solution containing 30 milligrams per milliliter is not less than 4.0 and not more than 7.5.

(v) Its penicillin V content is not less than 81.2 percent and not more than 94.7 percent.

(vi) It is crystalline.

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, each package shall bear on its outside wrapper or container and the immediate container the statement "For use in the manufacture of nonparenteral drugs only."

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, safety, loss on drying, pH, penicillin V content, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay—*(1) *Potency.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(iii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

(2) *Safety.* Proceed as directed in § 436.33 of this chapter.

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 30 milligrams per milliliter.

(5) *Penicillin V content.* Dissolve and dilute approximately 20 milligrams of the sample, accurately weighed to 100 milliliters with 0.1*N* sodium hydroxide solution. Treat a portion of the penicillin V working standard in the same manner. Using a suitable spectrophotometer equipped with a quartz cell and 0.1*N* sodium hydroxide solution as the blank, determine the absorbance of the peak at 275 nanometers. Calculate the percent penicillin V as follows:

$$\text{Percent penicillin V} = \frac{\text{Absorbance of sample} \times \text{weight in milligrams of standard} \times \text{percent penicillin V in standard}}{\text{Absorbance of standard} \times \text{weight in milligrams of sample}}$$

(6) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

26. Section 440.74a is revised to read as follows:

§ 440.74a Sterile penicillin G procaine.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin G procaine is 3,3 - dimethyl - 7 - oxo - 6 - (2 - phenyl - acetamido) - 4 - thia - 1 - azabicyclo [3.2.0]heptane-2-carboxylic acid 2-(diethylamino) ethyl *p*-aminobenzoate compound (1:1). It is so purified and dried that:

(i) Its potency is not less than 900 and not more than 1,050 units per milligram.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its moisture content is not less than 2.8 percent and not more than 4.2 percent.

(vi) Its pH in a saturated aqueous solution (about 300 milligrams per milliliter) is not less than 5 and not more than 7.5.

(vii) Its penicillin G content is not less than 51.0 percent and not more than 59.6 percent.

(viii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, moisture, pH, penicillin G content, and crystallinity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay—*(1) *Potency.* Use any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(iii) *Hydroxylamine colorimetric assay.* Proceed as directed § 436.205 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except add sufficient penicillinase to diluting fluid A and swirl the flask to completely solubilize the sample before filtration. If the product contains lecithin, use diluting fluid D in lieu of A.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using a saturated solution prepared by suspending 300 milligrams of sample per milliliter.

(7) *Penicillin G content.* Proceed as directed in § 436.316 of this chapter.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

27. Section 440.80a is revised to read as follows:

§ 440.80a Sterile penicillin G potassium.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin G postassium is potassium 3,3 - dimethyl - 7 - oxo-6-(2 - phenylacetamido) - 4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylate. It is so purified and dried that:

(i) Its potency is not less than 1,440 units and not more than 1,680 units per milligram. If it is packaged for dispensing, its potency is satifactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its loss on drying is not more than 1.5 percent.

(vi) Its pH in an aqueous solution containing 60 milligrams per milliliter is not less than 5.0 and not more than 7.5.

(vii) Its penicillin G content is not less than 80.8 percent and not more than 94.3 percent.

(viii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, loss on drying, pH, penicillin G content, and crystallinity.

(ii) Samples required:

(*a*) If the batch is packaged for repacking or for use in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams

(*2*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Sample preparation.* Dissolve an accurately weighed portion of the sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration; also, if it is packaged for dispensing, reconstitute as directed in the labeling. Then using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute with solution 1 to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Use any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(*c*) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter.

(7) *Penicillin G content.* Proceed as directed in § 436.316 of this chapter.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

§ 440.81 [Revoked]

28. Section 440.81 *Buffered crystalline penicillin* is revoked.

29. The following § 440.81a is added to read as follows:

§ 440.81a Sterile penicillin G sodium.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin G sodium is sodium 3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylate. It is so purified and dried that:

(i) Its potency is not less than 1,500 units and not more than 1,750 units per milligram. If it is packaged for dispensing, its content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its loss on drying is not more than 1.5 percent.

(vi) Its pH in an aqueous solution containing 60 milligrams per milliliter is not less than 5.0 and not more than 7.5.

(vii) Its penicillin G content is not less than 84.5 percent and not more than 98.5 percent.

(viii) It is crystalline.

(ix) It passes the test for heat stability if it does not show a loss of more than 10 percent of its original potency.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, loss on drying, pH, penicillin G content, crystallinity, and heat stability.

(ii) Samples required:

(*a*) If the batch is packaged for repacking or for use in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*2*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Sample preparation.* Dissolve an accurately weighed portion of the sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration; also, if it is packaged for dispensing, reconstitute as directed in the labeling. Then using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative aliquot from each container. Dilute with solution 1 to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Use any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(*c*) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter.

(7) *Penicillin G content.* Proceed as directed in § 436.316 of this chapter.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(9) *Heat stability.* Proceed as directed in § 436.214 of this chapter.

§ 440.82 [Amended]

30. Section 440.82 *Potassium phenethicillin* is amended by changing the name "potassium phenethicillin" to read "phenethicillin potassium" in the section heading and in paragraph (a)(1) and by changing the name "Phenoxymethyl penicillin" to read "Penicillin V" in the last sentence of paragraph (b)(8).

§ 440.115 [Amended]

31. Section 440.115 is amended by revising the section headiing to read § 440.115 *Cloxacillin sodium monohydrate oral dosage forms.*

§ 440.115a [Amended]

32. Section 440.115a *Sodium cloxacillin capsules* is amended as follows:

a. By changing "sodium cloxacillin" to read "cloxacillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By reviising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'cloxacillin sodium capsules'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The cloxacillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, cloxacillin content, identity, and crystallinity."

§ 440.115b [Amended]

33. Section 440.115b *Sodium cloxacillin for oral solution* is amended as follows:

a. By changing "sodium cloxacillin" to read "cloxacillin sodium monohydrate" in the section heading and wherever it appears in paragraph (a)(1) and (a)(3)(ii)(*a*).

b. By revising the second sentence of paragraph (a)(1) to read "When reconstituted as directed in the labeling, each milliliter contains the equivalent of 25 milligrams or 50 milligrams of cloxacillin."

c. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'cloxacillin sodium for oral solution'."

d. By revising the text of paragraph (a)(3)(i)(*a*) to read "The cloxacillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, cloxacillin content, identity, and crystallinity."

§ 440.119 [Amended]

34. Section 440.119 is amended by revising the section heading to read § 440.119 *Dicloxacillin sodium monohydrate oral dosage forms.*

§ 440.119a [Amended]

35. Section 440.119a *Sodium dicloxacillin monohydrate capsules* is amended as follows:

a. By changing "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1), (a)(3)(i)(*a*), and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'dicloxacillin sodium capsules'."

§ 440.119b [Amended]

36. Section 440.119b *Sodium dicloxacillin monohydrate for oral suspension* is amended by changing "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1), (a)(3)(i)(*a*), and (a)(3)(ii)(*a*) and by revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'dicloxacillin sodium for oral suspension'."

§ 440.129 [Amended]

37. Section 440.129 *Potassium hetacillin capsules* is amended as follows:

a. By changing "potassium hetacillin" to read "hetacillin potassium" in the sec-

tion heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(3)(i)(*a*) to read "The hetacillin potassium used in making the batch for potency, safety, moisture, pH, hetacillin content, identity, and crystallinity."

§ 440.141 [Amended]

38. Section 440.141 is amended by revising the section heading to read § 440.141 *Nafcillin sodium monohydrate oral dosage forms.*

§ 440.141a [Amended]

39. Section 440.141a *Sodium nafcillin monohydrate tablets* is amended as follows:

a. By changing "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section heading and in paragraph (a)(1).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'nafcillin sodium tablets'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The nafcillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, crystallinity, nafcillin content, and identity."

§ 440.141b [Amended]

40. Section 440.141b *Sodium nafcillin monohydrate capsules* is amended as follows:

a. By changing "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'nafcillin sodium capsules'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The nafcillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, crystallinity, nafcillin content, and identity."

§ 440.141c [Amended]

41. Section 440.141c *Sodium nafcillin monohydrate for oral solution* is amended as follows:

a. By changing "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By revising the second sentence of paragraph (a)(1) to read "When reconstituted as directed in the labeling, each milliliter contains the equivalent of 50 milligrams of nafcillin."

c. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'nafcillin sodium for oral solution'."

d. By revising the text of paragraph (a)(3)(i)(*a*) to read "The nafcillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, crystallinity, nafcillin content, and identity."

§ 440.149 [Amended]

42. Section 440.149 is amended by revising the section heading to read § 440.149 *Oxacillin sodium monohydrate oral dosage forms.*

§ 440.149a [Amended]

43. Section 440.149a *Sodium oxacillin capsules* is amended as follows:

a. By changing "sodium oxacillin" to read "oxacillin sodium monohydrate" in the section heading and wherever it appears in paragraph (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'oxacillin sodium capsules'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The oxacillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, oxacillin content, crystallinity, and identity."

§ 440.149b [Amended]

44. Section 440.149b *Sodium oxacillin for oral solution* is amended as follows:

a. By changing "sodium oxacillin" to read "oxacillin sodium monohydrate" in the section heading and wherever it appears in paragraph (a)(1) and (a)(3)(ii)(*a*).

b. By revising the second sentence of paragraph (a)(1) to read "When reconstituted as directed in the labeling, each milliliter contains the equivalent of either 25 milligrams or 50 milligrams of oxacillin."

c. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'oxacillin sodium for oral solution'."

d. By revising the text of paragraph (a)(3)(i)(*a*) to read "The oxacillin sodium monohydrate used in making the batch for potency, safety, moisture, pH, oxacillin content, crystallinity, and identity."

§ 440.153 [Revoked]

45. Section 440.153 *Aluminum penicillin tablets* is revoked.

§ 440.155 [Amended]

46. Section 440.155 is amended by revising the section heading to read § 440.155 *Penicillin G benzathine oral dosage forms.*

§ 440.155a [Revoked]

47. Section 440.155a *Benzathine penicillin G and crystalline penicillin tablets* is revoked.

§ 440.155b [Revoked]

48. Section 440.155b *Benzathine penicillin G and phenoxymethyl penicillin tablets* is revoked.

49. Section 440.155c is revised to read as follows:

§ 440.155c Penicillin G benzathine oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G benzathine oral suspension contains penicillin G benzathine with one or more suitable dispersing agents, buffer substances, preservatives, colorings, and flavorings. Each milliliter contains penicillin G benzathine equivalent to 30,000 units or 60,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its pH is not less than 6.0 and not more than 7.0. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a (a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G benzathine used in making the batch for potency, safety, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The penicillin G benzathine used in making the batch: 10 packages, each containing approximately 300 miligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately measured representative volume of the sample in sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, using a representative aliquot of the drug prepared for assay as described in paragraph (b)(2) of that section.

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

50. Section 440.155d is added to read as follows:

§ 440.155d Penicillin G benzathine tablets.

(a)) *Requirements for certification*—(1) *Standards of identity, strength quality, and purity.* Penicillin G benzathine tablets contain penicillin G benzathine with one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. Each tablet

contains penicillin G benzathine equivalent to 200,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its moisture content is not more than 8.0 percent. The tablets shall disintegrate within 1 hour. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G benzathine used in making the batch for potency, safety, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The penicillin G benzathine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Using the penicillin G working standard as the standard of comparison, assay for potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing 200 milliliters of absolute methyl alcohol. Blend for 1 minute. Add an additional 300 milliliters of absolute methyl alcohol and blend again for 2 to 3 minutes. Immediately further dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Weigh and finely powder six tablets. Transfer two accurately weighed portions of the tablets, each equivalent to 200,000 units of penicillin G, to two separate 100-milliliter volumetric flasks. Dilute one flask, which is to be used as the blank, to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and proceed as directed in § 436.204(d) of this chapter. In lieu of directions in § 436.204(e)(1), (2), and (3), to the other flask add 10 milliliters of 1.0*N* NaOH and mix well. Allow to stand for 15 minutes, then add 10 milliliters of 1.2*N* HCl, and dilute to volume with distilled water. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask and proceed as directed in § 436.204(c)(4) of this chapter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

§ 440.157 [Amended]

51. Section 440.157 *Benzathine phenoxymethyl penicillin oral suspension* is amended as follows:

a. By changing "benzathine phenoxymethyl penicillin" to read "penicillin V benzathine" in the section heading, wherever it appears in paragraphs (a)(1), (a)(3)(i)(*a*), and (a)(3)(ii)(*a*).

b. By changing "phenoxymethyl penicillin" in paragraphs (a)(1), (a)(3)(i)(*a*), and (b)(1)(i) to read "penicillin V".

§ 440.160 [Revoked]

52. Section 440.160 *Dibenzylamine penicillin and potassium penicillin powder, buffered* is revoked.

§ 440.166 [Revoked]

53. Section 440.166 *Hydrabamine penicillin G oral suspension* is revoked.

§ 440.169 [Amended]

54. Section 440.169 is amended by revising the section heading to read § 440.169 *Penicillin V hydrabamine oral dosage forms.*

§ 440.169a [Amended]

55. Section 440.169a *Hydrabamine phenoxymethyl penicillin chewable tablets* is amended as follows:

a. By changing "hydrabamine phenoxymethyl penicillin" to read "penicillin V hydrabamine" in the section heading and wherever it appears in paragraphs (a)(1), (a)(2), (a)(3)(i)(*a*), (a)(3)(ii)(*a*).

b. By changing "phenoxymethyl penicillin" to read "penicillin V" in paragraphs a)(1), (a)(3)(i)(*a*), (b)(1), and (b)(1)(i).

§ 440.169b [Amended]

56. Section 440.169b *Hydrabamine phenoxymethyl penicillin oral suspension* is amended as follows:

a. By changing "hydrabamine phenoxymethyl penicillin" to read "pencillin V hydrabamine" in the section heading and wherever it appears in paragraphs (a)(1), (a)(3)(i)(*a*), and (a)(3)(ii)(*a*).

b. By changing "phenoxymethyl penicillin" to read "penicillin V" in paragraphs (a)(1), (a)(3)(i)(*a*), (b)(1), and (b)(1)(i).

§ 440.171 Penicillin V oral dosage forms.

57. Section 440.171 *Phenoxymethyl penicillin oral dosage forms* is revised to read as set forth above.

58. Section 440.171a is revised to read as follows:

§ 440.171a Penicillin V capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V capsules are composed of penicillin V with one or more suitable and harmless lubricants. Each capsule contains either 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 2 percent. The penicillin V used conforms to the standards prescribed by § 440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V used in making the batch for potency, safety, moisture, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient absolute methyl alcohol to give a solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter. Immediately dilute an aliquot of the methyl alcohol solution with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the methyl alcohol with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

59. Section 440.171b is revised to read as follows:

§ 440.171b Penicillin V for oral suspension.

(a) *Requirements for certificatiton*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V for oral suspension is composed of penicillin V with or without one or more suitable and harmless suspending agents, colorings, flavorings, and buffer substances. When reconstituted as directed in the labeling, each milliliter contains 25 milligrams (40,000 units), 50 milligrams (80,000 units) or 208.3 milligrams (333,333 units) of penicillin V. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 2.0

and not more than 4.0. The penicillin V used conforms to the standards prescribed by § 440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V used in making the batch for potency, safety, moisture, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Dissolve an accurately measured representative volume of the sample in sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately further dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute as directed in the labeling. Dissolve an accurately measured representative portion of the sample in absolute methyl alcohol and dilute with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the sample reconstituted as directed in the labeling.

60. The following new § 440.171c is added:

§ 440.171c Penicillin V tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V tablets are composed of penicillin V with or without one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 125 milligrams (200,000 units), 300 milligrams (500,000 units), or 500 milligrams (800,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 3 percent. It shall disintegrate within 1 hour. The penicillin V used conforms to the standards prescribed by § 440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V used in making the batch for potency, safety, moisture, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient absolute methyl alcohol to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter. Immediately dilute an aliquot of the methyl alcohol solution with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the methyl alcohol solution with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

§ 440.173 Penicillin V potassium oral dosage forms.

61. Section 440.173 *Potassium phenoxymethyl penicillin oral dosage forms* is revised to read as set forth above.

62. Section 440.173a is revised to read as follows:

§ 440.173a Penicillin V potassium capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium capsules are composed of penicillin V potassium and one or more suitable lubricants and fillers. Each capsule contains penicillin V potassium equivalent to 250 milligrams (400,000 units) or 500 milligrams (800,000 units) of penicillin V. The potency is satisfactory if it is not less than 90 percent and more than 115 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its loss on drying is not more than 2.0 percent. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V potassium used in making the batch for potency, safety, loss on drying, pH, crystallinity, and penicillin V content.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Using the penicillin V working standard as the standard of comparison, assay by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

63. Section 440.173b is revised to read as follows:

§ 440.173b Penicillin V potassium chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium chewable tablets are composed of penicillin V potassium with suitable diluents, binders, buffers, colorings, and flavorings. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams or units of penicillin V that it is represented to contain. The loss on drying is not more than 1.5 percent. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "penicillin V potassium tablets".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter,

each such request shall contain:

(i) Results of tests and assays on: (*a*) The penicillin V potassium used in making the batch for potency, safety, loss on drying, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in §436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

64. The following § 440.173c is added:

§ 440.173c Penicillin V potassium tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium tablets are composed of penicillin V potassium with or without one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units), 250 milligrams (400,000 units), or 500 milligrams (800,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its loss on drying is not more than 1.5 percent. It shall disintegrate within 1 hour. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on: (*a*) The penicillin V potassium used in making the batch for potency, safety, loss on drying, pH, penicillin V content and crystallinity.

(*b*) The batch for potency, loss on drying, and disintegration time.

(ii) Samples required:

(*a*) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

65. The following new § 440.173d is added:

§ 440.173d Penicillin V potassium for oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V potassium for oral solution is composed of penicillin V potassium with or without one or more suitable and harmless suspending agents, colorings, flavorings, buffer substances, and preservatives. When reconstituted as directed in the labeling, each milliliter contains penicillin V potassium equivalent to either 25 milligrams (40,000 units) or 50 milligrams (80,000 units) of penicillin V. Its potency is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.5. The penicillin V potassium used conforms to the standards prescribed by § 440.73(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on: (*a*) The penicillin V potassium used in making the batch for potency, safety, loss on drying, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The penicillin V potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Dilute an accurately measured representative portion of the suspension with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the sample when reconstituted as directed in the labeling.

§ 440.174 [Revoked]

66. Section 440.174 *Procaine penicillin in oil capsules* is revoked.

§ 440.180 Penicillin G potassium oral dosage forms.

67. Section 440.180 *Penicillin oral dosage forms* is revised to read as set forth above.

68. Section 440.180a is revised to read as follows:

§ 440.180a Penicillin G potassium tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium tablets are composed of penicillin G potassium with or without one or more suitable and harmless buffer substances, dilutents, binders, lubricants, colorings, and flavorings. Each tablet contains penicillin G potassium equivalent to 100,000 units, 200,000 units, 250,000 units, 400,000 units, 500,000 units, 800,000 units or 1,000,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its loss on drying is not more than 1 percent. The tablets shall disintegrate within 1 hour. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeded in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G potassium used in making the batch for potency, safety, loss on drying, pH, penicillin G content, and crystallinity.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: Potency, loss on drying, and disintegration time of tablets collected during the time of tableting the batch; and, unless the tablets are packaged into dispensing-size containers immediately after they are compressed or the manufacturer has submitted to the Commissioner, and it has been accepted, information adequate to prove that such tests are not necessary, loss on drying of the tablets collected during each day of packaging the batch.

(*2*) If the person who requests certification is not the manufacturer of the batch: Potency, loss on drying, and disintegration time of tablets collected during each day the tablets are being packaged into dispensing-size containers.

(ii) Samples required:

(*a*) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: A minimum of 36 tablets. If, after tableting, such person packaged the batch into dispensing-size containers: 20 tablets, collected at equal intervals during each day the tablets are being packaged, except that this sample is not required if the tablets are packaged immediately after they are compressed or if the manufacturer has been exempted by the Commissioner from such requirement.

(*2*) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of tablets filled by such person into dispensing-size containers during each day's packaging operations): A minimum of 36 tablets collected by taking single tablets at such intervals throughout each day of packaging the tablets so that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

§ 440.180b [Revoked]

69. Section 440.180b *Penicillin-streptomycin tablets; penicillin-dihydrostreptomycin tablets* is revoked.

70. Section 440.180c is revised to read as follows:

§ 440.180c Penicillin G potassium capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium capsules are composed of penicillin G potassium and a suitable and harmless diluent. Each capsule contains penicillin G potassium equivalent to 250,000 units or 400,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its loss on drying is not more than 1.5 percent. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G potassium used in making the batch for potency, safety, loss on drying, pH, pencillin G content, and crystallinity.

(*b*) *The batch:*

(*1*) If the person who requests certification is the manufacturer of the batch: Potency and loss on drying of capsules collected during the time of encapsulating the batch; and, unless the capsules are packaged into dispensing-size containers immediately after they are encapsulated or the manufacturer has submitted to the Commissioner, and it has been accepted, information adequate to prove that such tests are not necessary, loss on drying of capsules collected during each day of packaging the batch.

(*2*) If the person who requests certification is not the manufacturer of the batch: Potency and loss on drying of capsules collected during each day the capsules are being packaged into dispensing-size containers.

(ii) Samples required:

(*a*) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: A minimum of 30 capsules. If after encapsulating, such person packaged the batch into dispensing-size containers: 20 capsules collected at equal intervals during each day the capsules are being packaged, except that this sample is not required if the capsules are packaged immediately after they are filled or if the manufacturer has been exempted by the Commissioner from such requirement.

(*2*) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of capsules filled by such person into dispensing-size containers during each day's packaging operations): A minimum of 30 capsules collected by taking single capsules at such intervals throughout each day of packaging the capsules that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

§ 440.180d [Revoked]

71. Section 440.180d *Penicillin and novobiocin capsules* is revoked.

§ 440.180e [Revoked]

72. Section 440.180e *Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension* is revoked.

73. Section 440.180f is revised to read as follows:

§ 440.180f Penicillin G potassium for oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium for oral solution contains penicillin G potassium and one or more suitable and harmless buffers, colorings, flavorings, diluents, and preservatives. Each milliliter contains penicillin G potassium equivalent to 20,000 units, 25,000 units, 40,000 units, 50,000 units, 80,000 units, or 100,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of penicillin G that it is represented to contain. Its moisture

content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 5.5 and not more than 7.5. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G potassium used in making the batch for potency, safety, loss on drying, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Transfer an accurately measured representative portion into a suitable volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1).

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution obtained after reconstituting the drug as directed in the labeling.

74. The following § 440.180g is added to read as follows:

§ 440.180g Penicillin G potassium tablets for solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium tablets for solution are composed of penicillin G potassium. Each tablet contains penicillin G potassium equivalent to 100,000 units, 200,000 units, or 250,000 units of penicillin G. The potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its loss on drying is not more than 1 percent. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to compling with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G potassium used in making the batch for potency, safety, loss on drying, pH, penicillin G content, and crystallinity.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: Potency and loss on drying of tablets collected during the time of tableting the batch; and, unless the tablets are packaged into dispensing-size containers immediately after they are compressed, or the manufacturer has submitted to the Commissioner, and it has been accepted, information adequate to prove that such tests are not necessary, loss on drying of the tablets collected during each day of packaging the batch.

(*2*) If the person who requests certification is not the manufacturer of the batch: Potency and loss on drying of the tablets collected during each day the tablets are being packaged into dispensing-size containers.

(ii) Samples required:

(*a*) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: A minimum of 30 tablets. If, after tableting, such person packaged the batch into dispensing-size containers: 20 tablets collected at equal intervals during each day the tablets are packaged, except that this sample is not required if the tablets are packaged immediately after they are compressed or if the manufacturer has been exempted by the Commissioner from such requirement.

(*2*) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of tablets filled by such person into dispensing-size containers during each day's packaging operations): A minimum of 30 tablets collected by taking single tablets at such intervals throughout each day of packaging the tablets that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

§ 440.209 [Amended]

75. Section 440.209 *Sterile sodium ampicillin* is amended by changing "sodium ampicillin" to read "ampicillin sodium" in the section heading and the text.

§ 440.213 [Amended]

76. Section 440.213 *Sterile disodium carbenicillin* is amended by changing "disodium carbenicillin" to read "carbenicillin disodium" in the section heading and the text.

§ 440.219 Dicloxacillin sodium monohydrate injectable dosage forms.

77. Section 440.219 *Sodium dicloxacillin monohydrate injectable dosage forms* is revised to read as set forth above.

§ 440.219a [Amended]

78. Section 440.219a *Sterile sodium dicloxacillin monohydrate* is amended by changing "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and the text.

§ 440.219b [Amended]

79. Section 440.219b *Sodium dicloxacillin monohydrate for injection* is amended as follows:

a. By changing "sodium dicloxacillin monohydrate" to read "dicloxacillin sodium monohydrate" in the section heading and in paragraphs (a)(1), (a)(3)(i)(*a*) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'dicloxacillin sodium for injection'."

§ 440.229 Hetacillin potassium injectable dosage forms.

80. Section 440.229 *Potassium hetacillin injectable dosage forms* is revised to read as set forth above.

§ 440.229a [Amended]

81. Section 440.229a *Sterile potassium hetacillin* is amended by changing "potassium hetacillin" to read "hetacillin potassium" in the section heading and the text.

§ 440.229b [Amended]

82. Section 440.229b *Potassium hetacillin for injection* is amended as follows:

a. by changing "potassium hetacillin" to read "hetacillin potassium" in the section heading and wherever it appears in paragraphs (a)(1), (a)(3)(ii)(*a*) and (b)(4).

b. By revising the text of paragraph (a)(3)(i)(*a*) to read "The hetacillin potassium used in making the batch for potency, moisture, pH, hetacillin content, identity, and crystallinity."

§ 440.236 [Amended]

83. Section 440.236 *Sodium methicillin for injection* is amended as follows:

a. By changing "sodium methicillin" to read "methicillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'methicillin sodium for injection'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The methicillin sodium monohydrate used in making the batch for potency, moisture, pH, methicillin content, crystallinity, and identity."

§ 440.241 [Amended]

84. Section 440.241 *Sodium nafcillin monohydrate for injection* is amended as follows:

a. By changing "sodium nafcillin monohydrate" to read "nafcillin sodium monohydrate" in the section heading and wherever it appears in paragraph (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'nafcillin sodium for injection'."

c. By revising the text of paragraph (a)(3)(i)(*a*) to read "The nafcillin sodium monohydrate used in making the batch for potency, moisture, pH, crystallinity, nafcillin content, and identity."

§ 440.249 [Amended]

85. Section 440.249 *Sodium oxacillin for injection* is amended as follows:

a. By changing "sodium oxacillin" to read "oxacillin sodium monohydrate" in the section heading and wherever it appears in paragraphs (a)(1) and (a)(3)(ii)(*a*).

b. By revising the text of paragraph (a)(2) to read "In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled 'oxacillin sodium for injection'."

c. By revising paragraph (a)(3)(i)(*a*) to read "The oxacillin sodium monohydrate used in making the batch for potency, moisture, pH, oxacillin content, crystallinity, and identity."

§ 440.253 [Revoked]

86. Section 440.253 *Aluminum penicillin in oil* is revoked.

§ 440.255 Penicillin G benzathine injectable dosage forms.

87. Section 440.255 *Benzathine penicillin G injectable dosage forms* is revised to read as set forth above.

§ 440.255a [Revoked]

88. Section 440.255a *Benzathine penicillin G in oil* is revoked.

89. Section 440.255b is revised to read as follows:

§ 440.255b Sterile penicillin G benzathine suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G benzathine suspension is an aqueous suspension of penicillin G benzathine and one or more suitable suspending or dispersing agents, buffer substances, and preservatives. Each container or each milliliter contains penicillin G benzathine equivalent to 300,000 units or 600,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its pH is not less than 5.0 and not more than 7.5. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G benzathine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, sterility, pyrogens, safety, and pH.

(ii) Samples required:

(*a*) The penicillin G benzathine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume, remove an accurately measured representative portion from each container. Dilute the portion thus obtained with sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single-dose container; or if the labeling specifies the amount of potency in a given volume, remove an accurately measured representative portion from each container. Using the sample thus obtained, proceed as directed in § 436.204(b)(2) of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, and medium F in lieu of medium E. During the period of incubation, shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(d) of this chapter, using a solution containing 4,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *pH* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

90. Section 440.255c is revised to read as follows:

§ 440.255c Sterile penicillin G benzathine-penicillin G procaine suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G benzathine-penicillin G procaine suspension is an aqueous mixture of penicillin G benzathine and penicillin G procaine with or without suitable and harmless buffer substances, suspending agents, and preservatives. Each container or each milliliter contains penicillin G benzathine and penicillin G procaine each equivalent to either 150,000 units or 300,000 units. Its penicillin G benzathine content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. Its penicillin G procaine content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its pH is not less than 5.0 and not more than 7.5. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(a)(1). The penicillin G procaine used conforms to the standards prescribed by § 440.74a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G benzathine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*b*) The penicillin G procaine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*c*) The batch for penicillin G benzathine content, penicillin G procaine content, sterility, pyrogens, safety, and pH.

(ii) Samples required:

(*a*) The penicillin G benzathine used in making the batch: 10 packages, each

containing approximately 500 milligrams.

(b) The penicillin G procaine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(c) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Total potency.* Assay for total potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic needle and syringe, place one dose of the drug in a 100-milliliter volumetric flask and add sufficient methyl alcohol to dissolve the benzathine penicillin G. Dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and shake well. Immediately further dilute an aliquot with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Using a suitable hypodermic needle and syringe, withdraw 2 one-dose portions of sample. Place one portion into an appropriate-sized volumetric flask and add 20 milliliters of 0.5*N* NaOH for each 300,000 units of benzathine penicillin G, mix well, being sure that all penicillin is in solution, and allow to stand for 15 minutes. Add 1 milliliter of 1.2*N* HCl for each 2 milliliters of 0.5*N* NaOH, mix, and dilute with distilled water to obtain a concentration of 2,000 units per milliliter. Dilute the other portion, which is to be used as the blank solution, with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a concentration of approximately 2,000 units per milliliter.

(ii) *Penicillin G procaine content*—(a) *Reagents*—(1) *Sodium nitrite solution.* Dissolve 0.1 gram of sodium nitrite in 100 milliliters of distilled water. Prepare a fresh solution every week and store under refrigeration.

(2) *Ammonium sulfamate solution.* Dissolve 0.5 gram of ammonium sulfamate in 100 milliliters of distilled water and store under refrigeration.

(3) *N-(1-naphthyl)-ethylenediamine solution.* Dissolve 0.1 gram of *N*-(1-naphthyl) - ethylenediamine dihydrochloride in 100 milliliters of distilled water. Prepare fresh solutions every week and store under refrigeration.

(4) *Standard procaine solution.* Prepare a standard solution containing 27.55 milligrams of procaine hydrochloride U.S.P. in a liter of distilled water (each milliliter of the standard solution is equivalent to 60 units of penicillin G procaine).

(b) *Preparation of sample solution.* Using a suitable hypodermic needle and syringe, withdraw a one dose portion of the sample and place it into an appropriate-sized volumetric flask. Add 20 milliliters of 0.5*N* NaOH for each 300,000 units of penicillin G benzathine, mix well, being sure that all penicillin is in solution, and allow to stand for 15 minutes. Add 1 milliliter of 1.2*N* HCl for each 2 milliliters of 0.5*N* NaOH, mix, and dilute with distilled water to obtain a concentration of 60 units of penicillin G procaine per milliliter. Transfer a 3.0-milliliter aliquot of this solution to a 50-milliliter volumetric flask and add 2 milliliters of water to give a volume of 5 milliliters.

(c) *Procedure.* Transfer respectively, 1.0, 2.0, 3.0, 4.0, and 5.0 milliliters of the standard procaine solution to each of five 50-milliliter volumetric flasks and transfer 5.0 milliliters of distilled water to a sixth 50-milliliter volumetric flask. Add 4.0, 3.0, 2.0, and 1.0 milliliters of water to the first four flasks, respectively, to give each a volume of 5 milliliters. To each flask of the standard and sample solutions, add 0.5 milliliter of 4*N* HCl, 1.0 milliliter of sodium nitrite solution, 1.0 milliliter of ammonium sulfamate solution, and 1.0 milliliter of *N*-(1-naphthyl)-ethylenediamine solution. Mix and wait two minutes after each addition. Dilute each flask to volume with distilled water. Using a sutable photoelectric colorimeter, determine the absorbancy of each solution at 550 nanometers. The instrument is balanced so that the zero concentration reads 0 absorbancy. Plot the standard curve on coordinate graph paper. Obtain the procaine penicillin content of the solution for assay directly from the point on the standard curve corresponding to its absorbancy.

(iii) *Penicillin G benzathine content.* The sum of the penicillin G procaine content determined as directed in paragraph (b)(1)(ii) of this section subtracted from the total potency determined as directed in paragraph (b)(1)(i) of this section represents the penicillin G benzathine content.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation, shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(d) of this chapter, using a solution containing 4,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted aqueous suspension.

91. Section 440.255d is added to read as follows:

§ 440.255d Sterile penicillin G benzathine for suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G benzathine for suspension is a dry mixture of penicillin G benzathine and one or more suitable suspending or dispersing agents, and with or without one or more suitable preservatives and buffer substances. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its moisture content is not less than 5.0 percent and not more than 8.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.5. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillin G benzathine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(b) The batch for potency, sterility, pyrogens, safety, moisture, and pH.

(ii) Samples required:

(a) The penicillin G benzathine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) If the batch is packaged for repacking:

(i) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(ii) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(2) If the batch is packaged for dispensing:

(i) For all tests except sterility: A minimum of 10 immediate containers.

(ii) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dissolve the portion thus obtained with sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately, further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the

reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Using the sample thus obtained, proceed as directed in § 436.204(b)(2) of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, and medium F in lieu of medium E. During the period of incubation shake the tubes at least once daily.

(3) *Pyrogens.* Proceed as directed in § 436.32(d) of this chapter, using a solution containing 4,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using the suspension obtained when the product is reconstituted as directed in the labeling.

§ 440.259 [Revoked]

92. Section 440.259 *Chloroprocaine pencillin O for aqueous injection* is revoked.

§ 440.261 [Revoked]

93. Section 440.261 *Diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection)* is revoked.

§ 440.265 [Revoked]

94. Section 440.265 *1-ephenamine penicillin G injectable dosage forms* is revoked.

§ 440.265a [Revoked]

95. Section 440.265a *1-ephenamine penicillin G in oil* is revoked.

§ 440.265b [Revoked]

96. Section 440.265b *1-ephenamine penicillin G for aqueous injection* is revoked.

§ 440.274 Penicillin G procaine injectable dosage forms.

97. Section 440.274 *Procaine penicillin G injectable dosage forms* is revised to read as set forth above.

98. Section 440.274a is revised to read as follows:

§ 440.274a Sterile penicillin G procaine with aluminum stearate suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G procaine with aluminum stearate suspension is penicillin G procaine in a refined vegetable oil with one or more suitable and harmless dispersing agents and hardening agents. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. Its moisture content is not more than 1.4 percent. The penicillin G procaine used conforms to the standards prescribed by § 440.74a(a)(1). If the hardening agent is a refined hydrogenated and deodorized peanut oil, it is free from rancidity; it has an iodine value of not more than 10; its free fatty acid content as oleic acid is not more than one-tenth of 1 percent and its melting point is 64° C±2° C.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G procaine used in making the batch for potency, pyrogens, safety, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, sterility, and moisture.

(ii) Samples required:

(*a*) The penicillin G procaine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 5 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion of the sample or the entire contents of a single dose container into a 50-milliliter volumetric flask. Add 4 milliliters of chloroform and mix thoroughly. Dilute to volume with absolute ethyl alcohol. Mix well. Immediately further dilute with sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1 unit of penicillin G per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium B in lieu of medium A.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

99. Section 440.274b is revised to read as follows:

§ 440.274b Sterile penicillin G procaine suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G procaine suspension is an aqueous mixture of penicillin G procaine and one or more suitable suspending or dispersing agents, buffer substances, and preservatives. It may contain procaine hydrochloride in a concentration not exceeding 2.0 percent and one or more suitable stabilizing agents. Each container or each milliliter contains penicillin G procaine equivalent to 300,000 units, 500,000 units, or 600,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its pH is not less than 5.0 and not more than 7.5. The penicillin G procaine used conforms to the standards prescribed by § 440.74a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G procaine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, sterility, pyrogens, safety, and pH.

(ii) Samples required:

(*a*) The penicillin G procaine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents, if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume, remove an accurately measured representative portion from each container. Dissolve the sample thus obtained in 50 to 100 milliliters of absolute methyl alcohol and add sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Immediately further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents, if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume, remove an accurately measured representative portion from each container. Dissolve and dilute the sample thus obtained with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to be prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except add sufficient penicillinase to diluting fluid A and swirl the flask to completely solubilize the procaine penicillin before filtration. If the product contains lecithin, use diluting fluid D in lieu of diluting fluid A. If the product contains sodium carboxymethylcellulose, add sufficient sterile carboxymethylcellulase to diluting fluid A or D to completely solubilize the sodium carboxymethylcellulose before filtration. If the preparation contains homogenizers or suspending agents that prevent solubilization, proceed as directed in paragraph (e)(2) of that section, except use medium B in lieu of medium A.

(3) *Pyrogens.* Proceed as directed in § 436.32(a), using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted drug.

100. The following new § 440.274c is added:

§ 440.274c Sterile penicillin G procaine for suspension.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Sterile penicillin G procaine for suspension is a dry mixture of penicillin G procaine and one or more suitable suspending or dispersing agents, buffer substances, and preservatives. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its moisture content is not less than 2.8 and not more than 4.2 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.5. The penicillin G procaine used conforms to the standards prescribed by § 440.74a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G procaine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, sterility, pyrogens, safety, moisture, and pH.

(ii) Samples required:

(*a*) The penicillin G procaine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) If the batch is packaged for repacking:

(*i*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*ii*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(*2*) If the batch is packaged for dispensing:

(*i*) For all tests except sterility: A minimum of 10 immediate containers.

(*ii*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—*(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: If it is packaged for repacking, dissolve an accurately weighed sample, equivalent to one dose, in 50 to 100 milliliters of absolute methyl alcohol and add sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. If it is packaged for dispensing, reconstitute as directed in the labeling. Then using a suitable hypodermic syringe and needle, remove all of the withdrawable contents, if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dissolve the sample thus obtained in 50 to 100 milliliters of absolute methyl alcohol and add sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Immediately further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: If it is packaged for repacking, dissolve and dilute an accurately weighed sample, equivalent to one dose, with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the prescribed concentration. If it is packaged for dispensing, reconstitute as directed in the labeling. Then using a suitable hypodermic needle and syringe, remove all of the withdrawable contents, if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume, remove an accurately measured representative portion from each container. Dissolve and dilute the sample thus obtained with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except add sufficient penicillinase to diluting fluid A and swirl the flask to completely solubilize the procaine penicillin before filtration. If the product contains lecithin, use diluting fluid D in lieu of diluting fluid A. If the product contains sodium carboxymethylcellulose, add sufficient sterile carboxymethylcellulose to diluting fluid A or D to completely solubilize the sodium carboxymethylcellulose before filtration. If the preparation contains homogenizers or suspending agents that prevent solubilization, proceed as directed in paragraph (e)(2) of that section, except use medium B in lieu of medium A.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using the suspension obtained when reconstituted as directed in the labeling.

§ 440.280 Penicillin G potassium injectable dosage forms.

101. Section 440.280 *Penicillin injectable dosage forms* is revised to read as set forth above.

§ 440.280a [Amended]

102. Section 440.280a *Sterile sodium penicillin, calcium penicillin, crystalline penicillin (crystalline penicillin sodium, crystalline penicillin potassium, crystalline penicillin G sodium, crystalline penicillin G potassium, crystalline penicillin O sodium, crystalline penicillin O potassium)* is amended by changing the name to read "Sterile penicillin G potassium" in the section heading and in the text.

103. Section 440.280b is revised to read as follows:

§ 440.280b Penicillin G potassium for injection.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium for injection is a dry mixture of penicillin G potassium and the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids. It may contain citric acid in a quantity not more than 0.15 percent of its total solids in place of a corresponding amount of sodium citrate. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its loss on drying is not more than 1.5 percent. Its pH is not less than 6.0 and not more than 8.5. The penicillin G potassium, buffered, used conforms to the standards prescribed by § 440.1080a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on: (*a*) The penicillin G potassium, buffered, used in making the batch for potency,

loss on drying, pH, penicillin G content, and crystallinity.

(b) The batch for potency, sterility, pyrogens, safety, loss on drying, and pH.

(ii) Samples required: (a) The penicillin G potassium, buffered, used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Then, using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove or expel an accurately measured representative portion from each container. Dilute with solution 1 to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(c) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter or, if the diluent is included in a disposable syringe combination, use the solution obtained when the drug is reconstituted as directed in the labeling.

§ 440.280c [Revoked]

104. Section 440.280c *Crystalline penicillin and bacitracin* is revoked.

§ 440.280d [Revoked]

105. Section 440.280d *Crystalline penicillin and epinephrine in oil* is revoked.

§ 440.281 Penicillin G sodium injectable dosage forms.

106. Section 440.281 *Buffered crystalline penicillin* is revised to read as set forth above.

107. The following new section § 440.281a is added to read as follows:

§ 440.281a Sterile penicillin G sodium.

The requirements for certification and the tests and methods of assay for sterile penicillin G sodium packaged for dispensing are described in § 440.81a.

108. Section 440.281b is added to read as follows:

§ 440.281b Penicillin G sodium for injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G sodium for injection is a dry mixture of penicillin G sodium and the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids. It may contain citric acid in a quantity not more than 0.15 percent of its total solids in place of a corresponding amount of sodium citrate. Its potency is satisfactory if it is not less than 6.0 and not more than than 120 percent of the number of units of penicillin G that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its loss on drying is not more than 1.5 percent. Its pH is not less than 6.0 and not more than 7.5. The penicillin G sodium, buffered, used conforms to the standards prescribed by § 440.1081a(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on: (a) The penicillin G sodium, buffered, used in making the batch for potency, loss on drying, pH, penicillin G content, crystallinity, and heat stability.

(b) The batch for potency, sterility, pyrogens, safety, loss on drying, and pH.

(ii) Samples required: (a) The penicillin G sodium, buffered, used in making the batch: 10 packages, each containing approximately 60 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Then using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute with solution 1 to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(b) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(c) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of thischapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter.

Subparts D–J—[Reserved]

§ 440.563 [Revoked]

109. Subpart F, consisting of § 440.563 *Ephedrine penicillin tablets,* is revoked.

110. New Subpart K, consisting of new §§ 440.1080a and 440.1081a, is added to Part 440 to read as follows:

Subpart K—Bulk Drug Formulations for Repacking or for Manufacturing Use

§ 440.1080a Sterile penicillin G potassium buffered.

(a) *Requirements for certification.*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium, buffered, is a dry mixture of penicillin G potassium and the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids. It may contain citric acid in a quantity not more than 0.15 percent of its total solids in place of a corresponding amount of sodium citrate. The sodium citrate and citric acid used in making the batch must conform to all U.S.P. specifications. It is so purified and dried that:

(i) Its potency is not less than 1,355 units and not more than 1,595 units per milligram.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its loss on drying is not more than 1.5 percent.

(vi) Its pH is not less than 6.0 and not more than 8.5.

(vii) Its penicillin G content is not less than 76.3 percent and not more than 89.8 percent.

(viii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, loss on drying, pH, penicillin G content, and crystallinity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay.*—(1) *Potency.*—(i) *Sample preparation.* Dissolve an accurately weighed sample in sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(*c*) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter.

(7) *Penicillin G content.* Proceed as directed in § 436.316 of this chapter.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

§ 440.1081a Sterile penicillin G sodium, buffered.

(a) *Requirements for certification.*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G sodium, buffered, is a dry mixture of penicillin G sodium and the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids. It may contain citric acid in a quantity not more than 0.15 percent of its total solids in place of a corresponding amount of sodium citrate. The sodium citrate and citric acid used in making the batch must conform to all U.S.P. specifications. It is so purified and dried that:

(i) Its potency is not less than 1,420 units and not more than 1,667 units per milligram.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its loss on drying is not more than 1.5 percent.

(vi) Its pH is not less than 6.0 and not more than 7.5.

(vii) Its penicillin G content is not less than 80 percent and not more than 93.8 percent.

(viii) It is crystalline.

(ix) It passes the test for heat stability if it does not show a loss of more than 10 percent of its original potency.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, loss on drying, pH, penicillin G content, crystallinity, and heat stability.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay.*—(1) *Potency.*—(i) *Sample preparation.* Dissolve an accurately weighed sample in sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Assay for potency by any of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(*c*) *Hydroxylamine colorimetric assay.* Proceed as directed in § 436.205 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, using a solution containing 2,000 units of penicillin G per millimeter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 60 milligrams per milliliter.

(7) *Penicillin G content.* Proceed as directed in § 436.316 of this chapter.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(9) *Heat stability.* Proceed as directed in § 436.214 of this chapter.

PART 460—ANTIBIOTIC DRUGS INTENDED FOR USE IN LABORATORY DIAGNOSIS OF DISEASE

d. In Part 460, the following authority citation is added to precede the "source" note in the table of contents:

AUTHORITY: Sec. 507, 59 Stat. 463, as amended (21) U.S.C. 357).

Effective date: This amendment shall become effective December 22, 1977 except that the effective date for revising the nonproprietary names (e.g., "phenoxymethyl penicillin to penicillin V" and "Sodium penicillin G to penicillin G sodium" shall be May 22, 1978. Any preparation under this order that is labeled after May 22, 1978 and does not bear the appropriate revised name is misbranded.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357).)

Dated: November 11, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-33332 Filed 11-21-77;8:45 am]

[4110-03]

SUBCHAPTER F—BIOLOGICS

[Docket No. 75N-0312]

BLOOD PRODUCTS

Single Donor Plasma (Human)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document issues Additional Standards for Single Donor Plasma (Human) products. These standards contain many of the provisions of the "Minimum Requirements: Single Donor Plasma (Human)," which were developed in 1954 and published in uncodified form by the Department of Health, Education, and Welfare, together with changes and additions that reflect more recent experience and scientific knowledge.

DATES: Effective November 22, 1977, except that the effective date for labeling requirements is May 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1920.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs proposed in the FEDERAL REGISTER of November 11, 1975 (40 FR 52619) to amend Part 640 (21 CFR Part 640) by adding new Subpart D to prescribe Additional Standards for Single Donor Plasma (Human) products. The shipping temperatures and dating periods for Single Donor Plasma (Human) products including Recovered Plasma (Human) were also proposed as amendments to §§ 600.15 and 610.53, (21 CFR 600.15 and 610.53) respectively.

Single Donor Plasma (Human) is the fluid portion of one unit of human blood intended for intravenous use which, in a closed system, has been collected, stabilized against clotting, and separated from the cells. The manner in which the Single Donor Plasma (Human) is processed determines the uses and names by which it is known.

Interested persons were given until January 12, 1976 to file written comments with the Hearing Clerk, Food and Drug Administration. Fifty-nine letters, each containing a number of comments, were received. The comments and the Commissioner's responses are as follows:

1. Ten comments on the proposal's preamble questioned the indication for use of Single Donor Plasma (Human) for the treatment of hypovolemia (abnormally decreased volume of circulating fluid [plasma] in the body); the use of plasma separated from blood 26 days after blood collection; and the use of freshly frozen Single Donor Plasma (Human) for the treatment of Factor IX deficiencies, since Factor IX is not labile. In addition, the comments suggested other uses of Single Donor Plasma (Human) products, such as for clotting defects associated with liver disease and hemorrhagic disorders. These additional uses were not identified in the proposal.

The Commissioner recognizes that there are differences of opinion in the medical community concerning uses of Single Donor Plasma (Human) products, as suggested by the comments. For this reason, and in accordance with § 601.25 (21 CFR 601.25), he has requested that the Panel on Review of Blood and Blood Derivatives review available data and recommend appropriate uses for each Single Donor Plasma (Human) product. In the interim, the Commissioner advises that FDA will continue to approve labeling for those indications for which the products have been routinely used in the past. The Commissioner will propose to amend the additional standards for Single Donor Plasma (Human), if necessary, in implementing the Panel recommendations.

2. Three comments on proposed §§ 600.15 and 610.53 asked why Single Donor Plasma (Human) and Single Donor Plasma (Human) with factors removed should be required to be shipped and stored at −18° C and suggested that ambient temperature is adequate.

The Commissioner advises that the −18° C shipping and storage temperature is necessary to prevent degradation and leaching of the phthalate plasticizer from the plasma container during the 5-year dating period. Such leaching may occur at higher temperatures, particularly above freezing. Additionally, −18° C is a temperature at which cold-growing and other microbial organisms do not multiply should there be any contamination during collection of the source material. Accordingly, the comments are rejected.

3. Seventeen comments on proposed §§ 600.15 and 610.53 said that the categories of Single Donor Plasma (Human) products are excessive. Three of these comments questioned the need for Single Donor Plasma (Human), Platelet Rich, since it is now seldom used because of the availability of the platelet concentrate preparation. The majority of the comments suggested that there is no justification for labeling units as having had Platelet Concentrate (Human) Removed, since this component would not be present in a viable condition in the plasma, unless specifically processed as required for Single Donor Plasma (Human), Platelet Rich. Six comments questioned the need for the label Single Donor Plasma (Human), Cryoprecipitated Antihemophilic Factor Removed, since, unless the plasma was separated and frozen as required for Single Donor Plasma (Human), Fresh Frozen, the antihemophilic factor would not be available for therapeutic use. Six comments recommended that the categories of products include liquid Single Donor Plasma (Human) with suggested dating periods of 26 days, 30 days, 90 days, or 1 year.

The Commissioner advises that the need to include Single Donor Plasma (Human), Platelet Rich, as a specific category has been reviewed by the Panel on Review of Blood and Blood Derivatives. It is their opinion that Single Donor Plasma (Human), Platelet Rich, is a useful product, and although it does not offer the advantage of the concentrate, there is no reason not to designate it as an acceptable category of Single Donor Plasma (Human).

It has been the practice to use descriptive terms, in addition to the proper name, to advise users that a component has been removed by physical means, to differentiate it from a final product not subjected to this additional processing. However, with the publication of Current Good Manufacturing Practices for Blood and Blood Components (21 CFR Part 606), products must be processed according to published Additional Standards, thereby standardizing production techniques. Accordingly, the Commissioner accepts the comments, and §§ 600.15 and 610.53 are revised to delete all categories except Single Donor Plasma (Human); Single Donor Plasma (Human), Fresh Frozen; and Single Donor Plasma (Human), Platelet Rich.

On the other hand, the Commissioner is also adding to §§ 600.15 and 610.53 a fourth category, Single Donor Plasma (Human), Liquid, with a dating period of 26 days. This is consistent with the requirement that Single Donor Plasma (Human) be separated from whole blood within 26 days after collection, thereby limiting the exposure of Single Donor Plasma (Human), Liquid, to any additional extraction of phthalate from the polyvinyl chloride containers currently in use. In addition, § 600.15(a) is being amended for Single Donor Plasma (Human), Platelet Rich to be consistent with the amendment published in the FEDERAL REGISTER of February 25, 1977 (42 FR 10982) modifying the shipping temperature for Platelet Concentrate (Human).

4. Five comments on proposed § 610.53 recommended that Single Donor Plasma (Human), Fresh Frozen, be stored at −30° C or colder for the best preservation of the antihemophilic factor.

The Commissioner is aware that the stability of the product is slightly increased at the colder temperature. However, he believes that the slight increase in stability obtained with −30° C is outweighed by the consequent burden on processors and users to purchase additional freezers capable of maintaining −30° C storage temperature. The Panel on Review of Blood and Blood Derivatives also considered this question and agreed that existing data demonstrate adequate stability with −18° C storage. Accordingly, the comments are rejected.

5. One comment on proposed § 610.53 asked why Single Donor Plasma (Human) was given a dating period of 5 years, while Single Donor Plasma (Human), Fresh Frozen, was given a dating period of only 1 year.

The Commissioner advises that the labile clotting factor, Factor VIII, which is present in Single Donor Plasma (Human), Fresh Frozen, may not be stable when stored for more than 1 year. To assure satisfactory potency of this factor, the fresh frozen product must be stored for not more than 1 year at the required storage temperature.

6. One comment on proposed § 640.30 (a) suggested that the definition be changed to state that the plasma has been separated from red blood cells rather than from "cells."

The Commissioner agrees that the term "cells" is intended to mean red blood cells. The comment is accepted, and § 640.30(a) of the final regulations is amended accordingly.

7. Three comments on proposed § 640.-30(a) objected to the requirement that a closed system be used to separate Single quires use of blood collection containers with attached satellites. One of these comments said there are occasional needs to prepare Cryoprecipitated Antihemo-

philic Factor (Human) from a unit of Single Donor Plasma (Human) that has no satellite container and questioned what could be done with the remaining plasma.

Blood intended for processing into Single Donor Plasma (Human) must be collected in a closed system requiring containers with attached satellites to preclude the possibility of contamination of the plasma and the red blood cells during separation. The Commissioner concludes that the benefits obtained from collection in a closed system far outweigh the extra cost of using the required containers with satellites. Accordingly, the comment objecting to the use of a closed system is rejected.

For clarification, it should be noted that Whole Blood (Human) may be collected in containers without satellites. However, plasma separated from such containers of blood may not be labeled as Single Donor Plasma (Human), but must be labeled as Recovered Human Plasma for further manufacturing. The regulations concerning Cryoprecipitated Antihemophilic Factor (Human), §§ 640.50 through 640.56 as amended in the FEDERAL REGISTER of April 29, 1977 (42 FR 21772), require that it must be collected and processed in a closed system. The plasma remaining after separation of Cryoprecipitated Antihemophilic Factor (Human) may be labeled as Single Donor Plasma (Human). If a unit of Single Donor Plasma (Human) has, for any reason, been entered during processing, the plasma must be labeled Recovered Human Plasma and not Single Donor Plasma (Human).

8. One comment on proposed § 640.30 (b) suggested revision to reverse the sequence of the wording since more Single Donor Plasma (Human) is collected from whole blood donors than is collected by plasmapheresis.

The Commissioner agrees with this comment, and the sequence is reversed accordingly.

9. Three comments on proposed § 640.31(c) questioned the intent of the paragraph and suggested that if it was to eliminate donors who might transmit hepatitis B surface antigen (HB_sAg) due to recent exposure to blood products, this prohibition should be stated directly. Two of these comments said the paragraph is unnecessarily restrictive since immunized individuals would be prevented from being Single Donor Plasma (Human) donors even though they may be free of demonstrable antibodies. One of these comments suggested that a test for unexpected antibodies be required of all donors or that the units of Single Donor Plasma (Human) be crossmatched.

The Commissioner agrees that eliminating all donors who have ever been immunized is not necessary, since some individuals may not have developed significant titers of antibody. Accordingly, § 640.31(c) is clarified to eliminate only those donors who may have been immunized with human red cells within 6 months to preclude transmission of hepatitis viruses. Similarly, donors who have been immunized with blood group substances need not be eliminated as satisfactory donors since these substances are derived from nonhuman sources and do not carry any hepatitis viruses. Accordingly, the Commissioner is also amending § 640.31(c) to delete the phrase "or blood group substances." Until agreement can be reached by blood-banking experts regarding the need to test all Whole Blood (Human) donors for unexpected antibodies, it is not appropriate to require such testing. Therefore, § 640.35 is amended to delete paragraph (h) which referenced the test for unexpected antibodies, which is no longer required.

10. Two comments on proposed § 640.32 suggested that all whole blood be stored at 20° to 24° C until the plasma is separated, regardless of whether Platelet Concentrate (Human) or Single Donor Plasma (Human) is to be prepared.

The Commissioner concedes that storage of all units of whole blood at 20° to 24° C prior to separation of plasma may provide greater flexibility and reduce the necessity for two different methods of storage. However, since the requested change would involve a change in the Whole Blood (Human) regulations, and since this change was not proposed, it would be inappropriate to make the change without opportunity for interested persons to comment. The Commissioner will consider, at another time, a proposal to amend the Whole Blood (Human) regulations. In the interim, interested persons are invited to submit data and information concerning amendment of the Whole Blood (Human) regulations to require that whole blood be stored at 20° to 24° C until removal of the plasma, after which the red blood cells shall be stored at 1° to 6° C. Accordingly, the comments are rejected.

11. One comment on proposed § 640.32 said Single Donor Plasma (Human) standards should include provisions for transportation, as provided in § 640.4(i) concerning Whole Blood (Human).

The Commissioner advises that proposed § 640.32(a) includes, through reference to § 640.4, provisions for transportation and storage. For clarification, § 640.32(a) is amended in the final rule by adding the phrase "transported and stored" after the reference to collection.

12. One comment on proposed § 640.32 said the "12° range" limitation in the storage of red blood cells should be deleted.

The Commissioner proposed the 2-degree range to be consistent with the existing requirements for Whole Blood (Human) and Red Blood Cells (Human). It is recognized that the 2-degree range is unnecessarily restrictive and that any variation within the 1° to 6° C storage temperature will adequately protect the safety, purity, potency, and effectiveness of the product during its dating period. Accordingly, the comment is accepted, and § 640.32 is amended to delete the 2-degree range requirement.

Having reconsidered this matter, the Commissioner is also deleting the 2-degree range prescribed for Whole Blood (Human) in § 640.4(i), Red Blood Cells (Human) in § 640.11(a), and Platelet Concentrate (Human) in §§ 640.24(d)(2) and 640.25(a) since it is unnecessarily restrictive. Section 610.53 is changed to reflect these amendments. Additionally, it has come to the Commissioner's attention that the storage temperature prescribed in § 610.53 for Whole Blood (Human) and Red Blood Cells (Human) is erroneously stated to be 1° to 10° C, and that § 640.2(e)(3) should be clarified. These regulations are being amended to read 1° to 6° C for storage and, in § 640.2(e)(3), to read 1° to 6° C for storage and 1° to 10° C for shipping.

13. One comment on proposed § 640.33(a) said Rh grouping required by § 640.5(c) should not be required for this product. Four additional comments recommended that the test results for blood group designations be deleted from § 640.35(c) of the labeling requirements because the test is not medically important.

The Commissioner agrees that only the ABO group designation is necessary since it has clinical importance. The remaining blood group designations of the source blood were proposed because tests to identify the blood groups are routinely performed, and the results may be of some interest to the patient's physician. Accordingly, the Commissioner accepts the comments, and § 640.33(a) is amended to delete reference to § 640.5(c). In addition, § 640.35(c) is revised to require that only the ABO group designation of the source blood be identified in the labeling of Single Donor Plasma (Human) products.

14. Four comments on proposed § 640.33(b) questioned the requirement that pilot samples must accompany the final product. One additional comment suggested that only integrally attached samples, such as segments, be permitted as pilot samples.

The Commissioner proposed that pilot samples accompany the final product to provide the user the opportunity to do compatibility testing, if desired. However, since compatibility testing is not required, the Commissioner has decided to delete this provision. Accordingly, paragraph (b) is deleted and paragraph (c) is redesignated as paragraph (b).

15. The Commissioner is revising proposed § 640.34, which describes the categories of Single Donor Plasma (Human) products, to be consistent with the amendments to §§ 600.15 and 610.53 discussed in item 3 above. Paragraphs (d), (e), and (f) of proposed § 640.34 are deleted. Section 640.34 is amended to describe the products in the same order as now listed in proposed §§ 600.15 and 610.53. In addition, new paragraphs are added to describe Single Donor Plasma (Human), Liquid and to clarify that Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human), or both, may be removed from Single Donor Plasma (Human), with

appropriate labeling for the remaining product.

16. One comment on proposed § 640.34(a) questioned the requirement of limiting to 4 hours the time for transfer of Single Donor Plasma (Human) to the final container and placing it at −18° C storage.

The Commissioner advises that it is necessary to restrict the time to accomplish the transfer. The 4-hour limit was selected as a reasonable length of time. However, after further consideration, the Commissioner concludes that the transfer time should be extended to 6 hours to be consistent with the requirement that Single Donor Plasma (Human), Fresh Frozen be transferred and frozen solid within 6 hours. Accordingly, the final regulation is amended in § 640.34(a) to change the "4 hours" to read "6 hours."

17. Four comments on proposed § 640.34 said the proper names should be changed. One comment suggested the name Single Donor Plasma (Human) be changed to "intravenous plasma" to distinguish the plasma products from recovered plasma intended for further manufacture. One comment suggested that "Fresh Frozen Plasma (Human)" be used as a substitute for Single Donor Plasma (Human), Fresh Frozen. One comment suggested that the name Single Donor Plasma (Human), Frozen, should be used for plasma with Cryoprecipitated Antihemophilic Factor (Human) Removed, to distinguish it from Single Donor Plasma (Human), Fresh Frozen. One comment recommended that "(Human)" should be deleted from all the proper names.

The Commissioner rejects the comments on revising the proper names of these Single Donor Plasma (Human) products, other than to eliminate the need to indicate the removal of components, when components have been removed. The categories are recognized in the blood-banking field and are self-descriptive.

The Commissioner advises that changes in proper names, including deletion of the term ("Human"), are being reviewed for all licensed biologics. If the term ("Human") is deleted, it will be removed from all products at one time.

18. One comment on proposed § 640.34(b) concerning Single Donor Plasma (Human), Fresh Frozen, questioned the wording "frozen within 6 hours after phlebotomy" and asked if this meant that the product must be placed in a —18° C freezer within 6 hours, or must be frozen within 6 hours.

The Commissioner intended that the unit reach a frozen state within 6 hours and not merely placed in a freezer. For clarification, the word "solid" is added.

19. Three comments on proposed § 640.34(c) (redesignated § 640.34(d) in the final regulations) concerned the allowable level of red blood cells that could remain in Single Donor Plasma (Human), Platelet Rich. Two of the comments said the level is to restrictive. One comment said the presence of red blood cells has not been convincingly shown to be harmful. The comments also noted that the regulation regarding Platelet Concentrate (Human) standard does not have a limit for red blood cells.

The Commissioner advises that the proposed requirement that Single Donor Plasma (Human) Platelet Rich contain no more than 20,000 red blood cells per cubic millimeter is intended to prevent unexpected high levels of red blood cells. As noted in the comments, the standard for Platelet Concentrate (Human) does not contain such a requirement. Moreover, § 640.34(h) (redesignated § 640.34(g) in the final regulations) provides for gross visual inspection to determine the presence of red blood cells. For these reasons, the Commissioner agrees that it is not necessary to specify a specific upper limit for red blood cell contamination. Accordingly, the comments are accepted, and the limitation on the number of red blood cells is eliminated.

20. One comment on proposed § 640.34(c) (redesignated § 640.34(d) in the final regulations) noted that agitation of Single Donor Plasma (Human), Platelet Rich during storage was not required, but made no recommendation.

The Commissioner requested the Panel on Review of Blood Derivatives to consider this question. The Panel stated that recent studies suggest that the product will be more effective if it is agitated during storage at 20° to 24° C. Accordingly, § 640.34(d) is amended, and a new paragraph (n) is added to § 640.35 of the final regulations to require gentle and continuous agitation of the product during storage at 20° to 24° C.

21. Three comments on proposed § 640.34(c) (redesignated § 640.34(d) in the final regulations) protested that 250,000 platelets per cubic millimeter is too high, especially when one takes into account the dilution of the plasma with anticoagulant.

The Commissioner advises that the proposed standard was reviewed by the Panel on Review of Blood and Blood Derivatives. The Panel concluded that the count is achievable provided monitoring of the procedure is adequate, including monitoring the centrifuge equipment during operation. The count is also consistent with that required for Platelet Concentrate (Human), which has been shown by analyses of samples submitted to the Bureau to be readily attainable. Accordingly, the comments are rejected.

22. One comment on proposed § 640.34(g) (redesignated § 640.34(f) in the final regulations) suggested that the regulation should make provision for reasonable discoloration of the plastic.

The Commissioner recognizes that the method of fabricating plastic film may produce some discoloration. Accordingly, the comment is accepted, and § 640.34(f) is amended in the final regulations to replace the phrase "be colorless" with the phrase "have no color added to the plastic."

23. One comment on proposed § 640.34(h) (redesignated § 640.34(g) in the final regulations) said the requirement to determine the amount of hemoglobin in the product by visual inspetcion is unusual. The comment offered no objections or alternative suggestion.

The Commissioner advises that the amount of hemoglobin in the final product can easily be determined by comparing the product with a known control sample and not issuing it if more than 25 milligrams of hemoglobin per 100 milliliters of plasma is present. This gross inspection provides reasonable quality control to assure that there will be no gross contamination with red blood cells.

24. Three comments on proposed §§ 640.34(h)(3) (redesignated § 640.34(g)(3) in the final regulations) said the anticoagulant in the source blood is transferred with the plasma at the time of separation and could be considered an unpermitted preservative.

The intent of the prohibition was to prevent the addition of a preservative to the plasma after its separation. For clarification, § 640.34(g)(3) is amended in the final regulations by replacing the phrase "shall not contain a preservative" with "no preservative shall be added to the final product."

25. One comment on proposed § 640.35 said the labeling requirements for Whole Blood (Human) and Red Blood Cells (Human) indicating whether the donor was "paid" or "volunteer" should apply to Single Donor Plasma (Human).

In the FEDERAL REGISTER of February 25, 1977 (42 FR 11019), the Commissioner proposed to amend the biologics regulations to require that each container of whole blood and blood components (red blood cells, cryoprecipitated antihemophilic factor, platelet concentrate, and single donor plasma) intended for transfusion shall bear the label statement "Paid Donor", or "Volunteer Donor", as applicable. When a final order based upon the February 25 proposal is promulgated, it will apply to Single Donor Plasma (Human) and these regulations will be amended.

26. Five comments on proposed § 640.35(b) said the volume of source blood and the volume of anticoagulant have no clinical applicability and should be deleted. Three additional comments noted that only the volume of Single Donor Plasma (Human) has clinical applicability.

The Commissioner agrees that the volume of source blood has little clinical applicability, and therefore the requirement is deleted in the final regulation. However, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)) and the regulations promulgated thereunder (21 CFR 201.10) require complete listing of all active ingredients, and the quality of contents of the final product. These regulations are applicable to blood products, which are also drugs. Accordingly, the volume of plasma and volume and type of anticoagulant are retained in the final regulations.

27. Seven comments concerning § 640.35 (f) and (g) said identification of the type of serological tests for syphilis is unnecessary, the type of test for HB_sAg is

redundant since third generation testing is required by law, and the word "results" should be eliminated and "interpretation" or "result" should be substituted as a more accurate requirement.

The Commissioner concludes that the label should state that the Single Donor Plasma (Human) is nonreactive for syphilis, since this is clinically important information. The Commissioner accepts the suggestion to delete identification of the type of serological test for syphilis since this is of almost no medical importance. Similarly, § 640.35(g) is amended to delete the requirement to state the type of test for HB_sAg, since § 610.40 requires third generation testing for HB_sAg. The Commissioner agrees with the comment suggesting use of the term "result" rather than "results," and § 640.35(f) of the final regulations is amended accordingly. Consistent with the labeling requirements for other blood products as revised in the FEDERAL REGISTER of August 19, 1976 (41 FR 35062), the Commissioner is also amending § 640.35 (f) and (g) to provide alternative label statements concerning the tests for syphilis and hepatitis, respectively.

28. One comment on proposed § 640.35 (k) (redesignated § 640.35(j) in the final regulations) recommended that the range of 30° to 37° C be omitted in order to provide for thawing at room temperature. The comment said this would enable multiple units to be thawed at one time in anticipation of use during subsequent days.

The Commissioner advises that the 30° to 37° C range was proposed to provide a reasonable time for thawing while minimizing the time the product is exposed to room temperature or higher. Accordingly, the comment is rejected.

29. Twelve comments on proposed § 640.35(l) (redesignated § 640.35(k) in the final regulations) objected to the requirement to use the product within 2 hours after thawing. Four comments suggested that the time be extended from 4 to 12 hours. One comment proposed that the product be used immediately after thawing.

The 2-hour limitation was proposed as a reasonable length of time after thawing. However, data now show that even the labile clotting factor is stable for 6 hours thereafter. For this reason, the additional standards for Cryoprecipitated Antihemophilic Factor (Human) provide for a 6-hour interval. The Commissioner concludes that the same interval would not result in excessive leaching of phthalates for the Single Donor Plasma (Human) products, and § 640.35 (k) of the final regulations is amended accordingly.

30. One comment on proposed § 640.35 (m) (redesignated § 640.35(l) in the final regulations) said the instructions to use a filter in the administration set should indicate the kind of filter and mesh size.

The Commissioner advises that the requirement was proposed to alert users that specially designed filtering equipment is necessary. However, data upon which the Commissioner would designate one specific filter type or mesh size are currently inadequate. Accordingly, the comment is rejected. However, the Commissioner invites the submission of data or information on types and sizes of filters. At such time as adequate data are available, the regulation will be amended to specify a type and size of filter.

31. One comment on proposed § 640.35 (n) (redesignated § 640.35(m) in the final regulations) suggested that the term "ABO Group" be used in place of the phrase "compatible recipients" if that was intended.

The Commissioner advises that this is the intent of the requirement, and § 640.35(m) is amended in the final regulations to use the phrase "ABO group compatible." "This conforms with the elimination of the Rh testing requirement discussed in item 13 of this preamble.

32. One comment on proposed § 640.35 (n) (redesignated § 640.35(m) in the final regulations) expressed concern that the statement "recommendation for" was not strong enough and suggested that the statement read "for administration to ABO group compatible recipients only" or "assure absence of lytic A, and/or B."

The Commissioner agrees that the instruction should be strengthened. Accordingly, the comment is accepted and the final order is amended to read, "Instructions to administer to ABO group compatible recipients."

33. One comment on proposed § 640.35 (o) said this paragraph concerning use of the product in certain coagulation defects should be a part of the circular, where it could be more fully developed.

The Commissioner agrees with this comment, and paragraph (o) is deleted in the final regulation.

34. One comment on proposed § 640.35 (r) and (s) (redesignated § 640.35 (q) and (r), respectively, in the final regulations) objected to including the names, addresses, and license numbers of all locations involved in the processing of Single Donor Plasma (Human).

The Commissioner does not consider the requirement to be unduly burdensome. Under normal circumstances, the label would include two establishments at most, the establishment collecting the blood and the establishment separating the plasma. Accordingly, the comment is rejected.

35. Twenty-one comments concerned § 640.36—plasma diverted for further manufacturing. Most objected to the proposed requirement to ship this plasma at −18° C, the prohibition against pooling the plasma prior to shipment, and the required use of a closed system.

The Commissioner did not intend that this regulation apply to all plasma intended for further manufacture. Rather, it would have permitted a manufacturer, to divert units originally processed as Single Donor Plasma (Human) for either blood derivatives or reagent use by relabeling them for such use. Since the product was prepared in a closed system, is pyrogen-free, and has been stored as a single donor product, it is an excellent resource for further manufacturing.

The proposal was not intended to apply to plasma that is recovered from outdated units of whole blood, with no intermediate step of preparing a transfusible product (Single Donor Plasma (Human)). Recovered plasma intended for a licensed final product is presently separated, pooled, and shipped in a liquid state to a manufacturer of derivatives or reagents under the short supply provisions. Further, this plasma does not require a closed system for separation. However, because of the confusion resulting from proposed § 640.36, the Commissioner has determined that separate additional standards proposed for all recovered plasma would be useful, and he will issue these for comment in the near future. Accordingly, section 640.36 is deleted in the final rule.

Additional background data and information on which the Commissioner relies in promulgating these regulations are on public display in the office of the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 600, 610, and 640 are amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. In Part 600, § 600.15(a) is amended by deleting the entry "Single donor plasma (human), frozen" and adding alphabetically the following new entries, to read as follows:

§ 600.15 Temperatures during shipment.

* * * * *

(a) *Products.*

Product	*Temperature*
* * *	* *
Single donor plasma (human).	−18° C or colder.
Single donor plasma (human), fresh frozen.	−18° C or colder.
Single donor plasma (human), liquid.	1° to 10° C.
Single donor plasma (human), platelet rich.	Between 1° and 10° C or all reasonable methods to maintain the temperature as close as possible to a range between 20° and 24° C.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

2. In Part 610, § 610.53 is amended by deleting the 2-degree range from the storage temperature requirements for the entry "Platelet Concentrate (Human)", by changing the storage temperatures for entries "Red Blood Cells (Human)" and "Whole Blood (Human)" to 1° to 6° C, by revising the dating period and storage temperature requirements for the entry "Single Donor Plasma (Human)", and by

adding alphabetically four new entries, to read as follows:

§ 610.53 Dating periods for specific products.

* * * * *	
Platelet concentrate (human).	72 hours from time of collection of source blood, provided labeling recommmends storage at 20° to 24° C or between 1° to 6° C.
* * * * *	
Red blood cell (human).	(a) Twenty-one days from date of collection of source blood, provided labeling recommends storage between 1° and 6° C and the hermetic seal is not broken during processing. Section 610.51 does not apply.
	Twenty-four hours after plasma removal, provided labeling recommends storage between 1° and 6° C, if the hermetic seal is broken during processing. Section 610.51 does not apply.
	(b) *Frozen:* 3 years, provided labeling recommends storage at −65° C or colder. Twenty-four hours after removal from storage at −65° C or colder, provided labeling recommends storage between 1° and 6° C. Section 610.51 does not apply.
* * * * *	
Single donor plasma (human).	5 years (−18° C or colder). Section 610.51 does not apply.
Single donor plasma (human), fresh frozen.	1 year (−18° C or colder). Section 610.51 does not apply.
Single donor plasma (human), liquid.	26 days (1° and 6° C).
Single donor plasma (human), platelet rich.	72 hours (20° to 24° C or between 1° and 6° C). Section 610.51 does not apply.
* * * * *	
Whole blood (human) collected in.	(a) ACD solution—21 days, provided labeling recommends storage between 1° and 6° C. Section 610.51 does not apply.
	(b) Heparin solution—48 hours provided labeling recommends storage between 1° and 6° C. Section 610.51 does not apply.
	(c) CPD solution—21 days, provided labeling recommends storage between 1° and 6° C. Section 610.51 does not apply.
* * * * *	

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

3. Part 640 is amended as follows:

a. In § 640.2, by revising paragraph (e)(3) to read as follows:

§ 640.2 General requirements.

* * * * *

(e) * * *

(3) The blood has been stored continuously at 1° to 6° C and shipped between 1° and 10° C;

* * * * *

b. In § 640.4 by revising paragraph (i) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(i) *Storage.* Immediately after collection, unless the blood is to be used as a source for Platelet Concentrate (Human), it shall be placed in storage at a temperature between 1° and 6° C unless it must be transported from the donor clinic to the processing laboratory. In the latter case, the blood shall be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a range between 1° and 6° C until it arrives at the processing laboratory, where it shall be stored at a temperature between 1° and 6° C. Blood from which Platelet Concentrate (Human) is to be prepared shall be held in an environment maintained at a temperature range of 20° to 24° C until the platelet concentrates are separated. The red blood cells shall be placed in storage at a temperature between 1° and 6° C immediately after the platelet concentrates are separated.

c. In § 640.11 by revising paragraph (a) to read as follows:

§ 640.11 General requirements.

(a) *Storage.* Immediately after processing, the Red Blood Cells (Human) shall be placed in storage and maintained at a temperature between 1° and 6° C.

* * * * *

d. In § 640.24 by revising paragraph (d)(2) to read as follows:

§ 640.24 Processing.

* * * * *

(d) * * *

(2) 1° to 6° C resuspended in 20 to 30 milliliters of plasma.

e. In § 640.25 by revising paragraph (a) to read as follows:

* * * * *

§ 640.25 General requirements.

(a) *Storage.* Immediately after processing, Platelet Concentrate (Human) shall be placed in storage at the temperature range suitable to the volume of resuspension plasma. If stored at 20° to 24° C, a continuous gentle agitation of the platelet concentrate shall be maintained throughout the storage period. Agitation is optional if stored at a temperature between 1° and 6° C.

* * * * *

f. New Subpart D—Single Donor Plasma (Human)—is added to read as follows:

Subpart D—Single Donor Plasma (Human)

Sec.

640.30 Single Donor Plasma (Human).
640.31 Suitability of donors.
640.32 Collection of source material.
640.33 Testing the blood.
640.34 Processing.
640.35 Labeling.

* * * * *

Subpart D—Single Donor Plasma (Human)

§ 640.30 Single Donor Plasma (Human).

(a) *Proper name and definition.* The proper name of this product shall be Single Donor Plasma (Human). The product is defined as the fluid portion of one unit of human blood intended for intravenous use, which, in a closed system, has been collected, stabilized against clotting, and separated from the red blood cells.

(b) *Source.* (1) Single Donor Plasma (Human) shall be obtained by separating plasma from blood collected from blood donors or by plasmapheresis.

(2) Single Donor Plasma (Human) may be obtained from a unit of Whole Blood (Human) collected by another licensed establishment.

§ 640.31 Suitability of donors.

(a) Whole blood donors shall meet the criteria for donor suitability prescribed in § 640.3.

(b) Plasmapheresis donors shall meet the criteria for donor suitability prescribed in § 640.63, excluding the phrase "other than malaria" in paragraph (c)(9) of that section. Informed consent shall be required as prescribed in § 640.61.

(c) Donors shall not be suitable if they are known to have been immunized within the past 6 months by injection with human red blood cells.

§ 640.32 Collection of source material.

(a) Whole blood shall be collected, transported, and stored as prescribed in § 640.4, except that paragraphs (d)(2) and (h) of that section shall not apply. When whole blood is intended for Single Donor Plasma (Human); Single Donor Plasma (Human), Fresh Frozen; and Single Donor Plasma (Human), Liquid, it shall be maintained at a temperature between 1° and 6° C until the plasma is removed. Whole blood intended for Single Donor Plasma (Human), Platelet Rich shall be maintained as prescribed in § 640.24 until the plasma is removed. The red blood cells shall be placed in storage at a temperature between 1° and 6° C immediately after the plasma is separated.

(b) Plasma obtained by plasmapheresis shall be collected as prescribed in

§§ 640.62, 640.64 (except that paragraph (c)(3) of § 640.64 shall not apply), and 640.65.

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in § 610.40 of this chapter and § 640.5 (a), (b), and (e).

(b) Manufacturers of Single Donor Plasma (Human) collected by plasmapheresis shall have testing and recordkeeping responsibilities equivalent to those prescribed in §§ 640.71 and 640.72.

§ 640.34 Processing.

(a) *Single Donor Plasma (Human).* Single Donor Plasma (Human) shall be separated from the red blood cells within 26 days after phlebotomy, and shall be stored at −18° C or colder within 6 hours after transfer to the final container, unless the product is to be stored as Single Donor Plasma (Human), Liquid.

(b) *Single Donor Plasma (Human), Fresh Frozen.* Single Donor Plasma (Human), Fresh Frozen shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be separated from the red blood cells, frozen solid within 6 hours after phlebotomy, and stored at −18° C or colder.

(c) *Single Donor Plasma (Human), Liquid.* Single Donor Plasma (Human), Liquid shall be separated from the red blood cells within 26 days after phlebotomy and shall be stored at a temperature of 1° to 6° C within 4 hours after filling the final container.

(d) *Single Donor Plasma (Human), Platelet Rich.* Single Donor Plasma (Human), Platelet Rich shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after phlebotomy. The time and speed of centrifugation shall have been shown to produce a product with at least 250,000 platelets per cubic milliliter. The plasma shall be stored at a temperature between 20° to 24° C or between 1° and 6° C, immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20° to 24° C.

(e) *Modifications of Single Donor Plasma (Human).* It is possible to separate Platelet Concentrate (Human) and/or Cryoprecipitated Antihemophilic Factor (Human) from Single Donor Plasma (Human). When these components are to be separated, the plasma shall be collected as described in § 640.32 for Single Donor Plasma (Human).

(1) Platelet Concentrate (Human) shall be separated as prescribed in Subpart C of Part 640, prior to freezing the plasma. The remaining plasma may be labeled as Single Donor Plasma (Human), Fresh Frozen, if frozen solid within 6 hours after phlebotomy.

(2) Cryoprecipitated Antihemophilic Factor (Human) shall be removed as prescribed in Subpart F of Part 640. The remaining plasma may be labeled Single Donor Plasma (Human).

(3) Plasma remaining after both Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human) have been removed may be labeled Single Donor Plasma (Human).

(f) *The final container.* (1) The final container shall have no color added to the plastic and shall be transparent to permit visual inspection of the contents; any closure shall maintain a hermetic seal and prevent contamination of the contents.

(2) The final container material shall not interact with the contents, under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, potency, and effectiveness of the product.

(3) Prior to filling, the final container shall be identified by number so as to relate it to the donor.

(g) *The final product.* (1) The final product shall be inspected immediately after separation of the plasma and shall not be issued for transfusion if there is (i) any abnormality in color or physical appearance, (ii) any indication of contamination, or (iii) more than 25 milligrams hemoglobin per 100 milliliters of plasma as determined by visual inspection.

(2) With the exception of Single Donor Plasma (Human), Platelet Rich; and Single Donor Plasma (Human), Liquid, the final product shall be stored in a manner that will show evidence of thawing and shall not be issued if there is any evidence of thawing of the product during storage or breakage of the container.

(3) No preservative shall be added to the final product.

§ 640.35 Labeling.

In addition to the applicable labeling requirements of § 610.62 of this chapter and in lieu of the requirements of §§ 610.60 and 610.61 of this chapter, the container labels for Single Donor Plasma (Human) products shall bear the following information:

(a) The proper name of the product, using the nomenclature as set forth in § 640.34.

(b) The volume of plasma, and the volume and type of anticoagulant present in the source blood from which the product was prepared.

(c) ABO blood group designation of the source blood.

(d) Donor number.

(e) Expiration date.

(f) The result of the serologic test for syphilis or the statement, "Nonreactive for Syphilis by STS".

(g) The result of the test for hepatitis B surface antigen or the statement "Nonreactive for HBsAg by FDA Required Test".

(h) Instructions to store the product as prescribed in § 610.53 of this chapter.

(i) A warning against further processing of the frozen proudct if there is evidence of breakage or thawing.

(j) Instructions to thaw the frozen product at a temperature between 30° and 37° C.

(k) Instructions to use the frozen product within 6 hours after thawing.

(l) Instructions to use a filter in the administration equipment.

(m) Instructions to administer ABO group compatible recipients.

(n) When applicable, a statement that the product should be gently and continuosuly agitated during storage.

(o) A statement to see the instruction circular for directions for use.

(p) The statement, "Caution: Federal Law Prohibits Dispensing Without a Prescription".

(q) Name, address and license number of the manufacturer.

(r) Where plasma has been prepared from Whole Blood (Human) processed by another licensed establishment, such fact, and the name, address, and license number of the other establishment.

Effective date: This regulation becomes effective November 22, 1977, except requirements for labeling changes shall become effective May 22, 1978.

(Sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262).)

Dated: November 11, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 77-33413 Filed 11-21-77;8:45 am]

[1505-01]

Title 7—Agriculture

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

PART 271—PARTICIPATION OF STATE AGENCIES AND ELIGIBLE HOUSEHOLDS

Food Stamp Program

Correction

In FR Doc.77-32309, appearing at page 58153 in the issue of Tuesday, November 8, 1977, the 16th entry in the next to last column of the table on page 58154, now reading "51", should read, "50".

[3410-05]

CHAPTER VII—AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE (AGRICULTURAL ADJUSTMENT), DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—FARM MARKETING QUOTAS AND ACREAGE ALLOTMENT

[Amdt. 9]

PART 729—PEANUTS

Subpart—Regulations for Determination of Acreage Allotments and Marketing Quotas for 1972 and Subsequent Crops of Peanuts

AGENCY: Agricultural Stabilization and Conservation Service, Department of Agriculture.

ACTION: Final rule.

SUMMARY: This rule provides for the basic penalty rate for the 1977 crop of peanuts. This rule is necessary in order that correct penalties may be collected from peanut producers as provided for under this Part.

EFFECTIVE DATE: November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Paul P. Kume, Production Adjustment Division, Agricultural Stabilization and Conservation Service, USDA, P.O. Box 2415, Washington, D.C. 20013, 202–447–4695.

SUPPLEMENTARY INFORMATION: The marketing of peanuts of the 1977 crop is now underway and it is essential that the basic penalty rate for the 1977 crop be announced immediately. It is hereby determined that compliance with the notice of proposed rulemaking, public procedure, and 30-day effective date provisions of 5 U.S.C. 553 is impracticable and contrary to the public interest. Therefore, this amendment to 7 CFR 729.32 and 729.45 shall become effective upon publication to the 1977 crop of peanuts. The material previously appearing in these sections under centerhead "Regulations for Determination of Acreage Allotments and Marketing Quotas for 1972 and Subsequent Crops of Peanuts" remains in full force and effect as to the crops to which it was applicable.

Title 7 CFR 729.43 provides that the penalty rate shall be equal to 75 percent of the support price for peanuts for the marketing year. The basic support price for peanuts for the 1977 marketing year was announced on August 25, 1977, to be $430.50 per ton (42 FR 54559); thus, 75 percent of support price is calculated to be 21.5 cents per pound.

The regulations in 7 CFR Part 729 are amended as follows:

A new subparagraph (6) is added to paragraph (b) of § 729.43 to read as follows:

§ 729.43 Penalty Rate.

* * * * *

(b) *Future years.* * * *

(6) *1977 crop.* The basic support price for peanuts for the marketing year beginning August 1, 1977, and ending July 31, 1978, is $430.50 per ton or 21.5 cents per pound. Therefore, the basic penalty rate for the 1977 crop of peanuts is 16.1 cents per pound.

(Secs. 358, 358a, 359, 375, 55 Stat. 88, as amended, 81 Stat. 658, as amended, 55 Stat. 90, as amended, 52 Stat. 66, as amended; 7 U.S.C. 1358, 1358a, 1359, 1375.)

Signed at Washington, D.C., on November 10, 1977.

WELDON B. DENNY,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc.77-33464 Filed 11-21-77;8:45 am]

[3410-30]

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—GENERAL REGULATIONS AND POLICIES—FOOD DISTRIBUTION

[Amdt. 38]

PART 250—DONATION OF FOOD FOR USE IN UNITED STATES, ITS TERRITORIES AND POSSESSIONS AND AREAS UNDER ITS JURISDICTION

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule, but with comments requested.

SUMMARY: The Food and Nutrition Service amends the regulations governing the food donation program to reflect changes made in section 707 of the Older Americans Act, as amended, by Pub. L. 95–65, approved July 11, 1977. These changes (1) extend until September 30, 1978, the present method for determining the annual level of commodity assistance to be provided to States for use in nutrition programs for the elderly and (2) permit any State to elect to receive cash payments in lieu of donated foods for use in such programs. A technical amendment is made to the regulations to indicate that foods purchased under section 14 of the National School Lunch Act, as amended, may be donated to nutrition programs for the elderly. In addition, as required by Public Law 95–59, approved June 30, 1977, the regulations are amended to extend until September 30, 1978, the exclusion from eligibility for federally donated foods of certain household members who receive supplemental security income payments or other income supplementation. Finally, this amendment indicates a change of address for the Food and Nutrition Service's Mid-Atlantic and Mountain Plains Regional Offices.

EFFECTIVE DATE: October 1, 1977.

FOR FURTHER INFORMATION CONTACT:

Juan del Castillo, Director, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250 (202–447–8371).

SUPPLEMENTARY INFORMATION: Section 707 of the Older Americans Act, as amended, requires the Secretary of Agriculture to maintain, during the period ending September 30, 1978, a level of not less than 25 cents per meal in donated foods to recipients of grants and contracts under title VII of the Act, which authorizes the Nutrition Program for the Elderly. That amount is subject to adjustment on an annual basis to reflect changes in the series for food away from home of the Consumer Price Index published by the Bureau of Labor Statistics of the Department of Labor. The section, as amended, also provides that any State may elect to receive cash payments in lieu of all or any portion of the donated foods it would otherwise receive during the Federal fiscal year for the purpose of nutrition programs for the elderly. Previously, only a State which had phased out its commodity distribution facilities before June 30, 1974, could elect to receive cash in lieu of donated foods for such programs, and Kansas was the only such State.

Section 8(b)(3) of Pub. L. 93–233, as amended, excludes individuals who reside in certain States from being considered as household members for purposes of the Food Distribution Program for families if they are recipients of Supplemental Security Income (SSI) payments under title XVI of the Social Security Act, or of those States' supplementary payments described in section 1616 of the Act, or if they are recipients of certain other income supplementation. The exclusion is made on the basis that such payments have been specifically increased so as to include the bonus value of food stamps. California is the only State still conducting a needy family food distribution program which is affected by this exclusion. Public Law 95–59, approved June 30, 1977, extends the exclusion until September 30, 1978.

These amendments are published as a final rule in view of the fact that any election by a State to receive cash in lieu of commodities is to be made for the fiscal year 1978, which began on October 1, 1977. Since it is the policy of the Department to invite public comments on amendments to the regulations, however, interested persons may submit written suggestions regarding these changes to the above address. Comments received will be considered in making any further changes deemed desirable.

Accordingly, the food donation program regulations are amended as follows:

1. In § 250.1, paragraph (b)(15) is amended by revising the quoted provisions of §§ 707(a)(4), 707(d)(1), and 707(d)(2), of the Older Americans Act of 1965, as follows:

§ 250.1 General purpose and scope.

* * * * *

(b) *Legislation.* * * *

* * * * *

(15) * * *

(a) * * *

(4) In donating commodities pursuant to this subsection, the Secretary of Agriculture shall maintain an annually programmed level of assistance of not less than 15 cents per meal during the fiscal year ending September 30, 1976, 25 cents per meal during the fiscal year ending

September 30, 1977, and the fiscal year ending September 30, 1978: *Provided*, That this amount shall be adjusted on an annual basis each fiscal year after June 30, 1975, to reflect changes in the series for food away from home of the Consumer Price Index published by the Bureau of Labor Statistics of the Department of Labor. Such adjustment shall be computed to the nearest one-fourth cent. Among the commodities delivered under this subsection, the Secretary shall give special emphasis to high protein foods, meat, and meat alternates. The Secretary of Agriculture, in consultation with the Commissioner (on Aging), is authorized to prescribe the terms and conditions respecting the donating of commodities pursuant to this subsection, and, within ninety days after the date of enactment of this paragraph, the Secretary shall issue regulations governing the donation of such commodities.

* * * * *

(d)(1) Notwithstanding any other provision of law, a State may, for purposes of the programs authorized by this Act, elect to receive cash payments in lieu of donated foods. * * *

(2) When such payments are made, the State agency shall promptly and equitably disburse any cash it receives in lieu of commodities to recipients of grants or contracts. Such disbursements shall only be used by such recipients of grants or contracts to purchase United States agricultural commodities and other foods for their nutrition projects.

* * * * *

2. In § 250.4, paragraph (b)(4) is revised to read as follows:

§ 250.4 Availability of commodities.

* * * * *

(b) *Quantities.* * * *

(4) For the fiscal year ending September 30, 1978, the quantity of commodities to be made available to any State for distribution to nutrition programs for the elderly shall be valued at not less than 25 cents for each meal which the State Agency on Aging, in accordance with regulations and guidelines authorized by the Commissioner on Aging, Department of Health, Education, and Welfare, reports as having been served or where necessary, estimates will be served within the State during the year, adjusted on an annual basis as provided in paragraph (b)(5) of this section: *Provided, however*, that this quantity shall be reduced to the extent that a State elects to receive cash in lieu of commodities in accordance with § 250.10(f) of this part.

* * * * *

3. In § 250.6(e)5, the proviso is deleted, and the following is substituted therefor:

§ 250.6 Obligations of distributing agencies. * * *

* * * * *

(e) *Household distribution* * * *

(5) *The specific criteria to be used in certifying households as in need of food asssistance.* * * * *Provided, however*, That, in applying such standards and in allocating food, no individual who receives supplemental security income shall be considered to be a member of a household for any month during the period ending September 30, 1978, if for such month, such individual resides in California or Massachusetts, which the Secretary of Health, Education, and Welfare has determined qualify as cash-out States pursuant to the provisions of Pub. L. 93–233, as amended.

4. In § 250.8, the first sentence of paragraph (h) is revised to read as follows:

§ 250.8 Eligible recipient agencies. * * *

* * * * *

(h) *Nutrition programs for the elderly.* Nutrition programs for the elderly are eligible to receive foods under section 416, section 32, section 709, and section 14. * * *

* * * * *

5. In § 250.10, paragraphs (f) and (h) are revised to read as follows:

§ 250.10 Miscellaneous provisions. * * *

* * * * *

(f) *Cash in lieu of commodities for nutrition programs for the elderly.* (1) Any State may, for the purposes of the program authorized by title VII of the Older Americans Act of 1965, as amended, elect to receive cash payments in lieu of all or any portion of the donated foods it would otherwise receive under § 250.4(b)(4) of this part during the Federal fiscal year. (2) When such an election is made, it shall be binding on the State for that fiscal year, and the Secretary shall make cash payments to such State equivalent in value to the donated foods it otherwise would have received. Advance cash payments to such State shall be made for each Federal fiscal quarter by means of Letters of Credit issued by FNS through the appropriate United States Treasury Regional Disbursing Office or, where applicable, by means of United States Treasury checks in favor of the State Agency on Aging, based on the best data available to FNS at the time as to the number of meals to be served within the State during that fiscal quarter in nutrition programs for the elderly. (3) The State Agency on Aging desiring to receive funds under this paragraph shall enter into a written agreement with FNS to: (i) promptly and equitably disburse any cash it receives in lieu of commodities to nutrition programs for the elderly after consideration of the needs of such programs and the availability of other resources, including any donated foods available under § 250.4(b)(4) of this part; (ii) establish such procedures as may be necessary to ensure that such disbursements are used by nutrition programs for the elderly solely for the purpose of purchasing United States agricultural commodities and other foods for their feeding operations; (iii) maintain and retain for three years from the close of the Federal fiscal year to which they pertain complete and accurate records of (*a*) all amounts received and disbursed under this paragraph and (*b*) the manner in which consideration was given to the needs and resources as required by subparagraph (3)(i) of this paragraph; and (iv) permit representatives of the Department and of the General Accounting Office of the States to inspect, audit, and copy such records at any reasonable

* * * * *

(h) *Program monitoring.* (1) Distributing agencies shall monitor and review their operations under this part to ensure compliance with the provisions of this part and with any applicable instructions of FNS. (2) State Agencies on Aging which receive cash payments in lieu of donated foods in accordance with the provisions of paragraph (f) of this section shall monitor use of such cash after disbursement to nutrition programs for the elderly to ensure that the amounts so received are expended solely for the purchase of United States agricultural commodities and other foods for such programs.

* * * * *

6. In § 250.11, the paragraphs pertaining to the Mid-Atlantic and Mountain Plains Regions are revised to read as follows:

§ 250.11 Where to obtain information.

* * * * *

Mid-Atlantic Region, Food and Nutrition Service, USDA, One Vahlsing Center, Robbinsville, New Jersey 08691 for the following States: Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Puerto Rico, Virginia, Virgin Islands, and West Virginia.

* * * * *

Mountain Plains Region, Food and Nutrition Service, USDA, 2420 26th Avenue, Room 400–D, Denver, Colorado 80211 for the following States: Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.

* * * * *

NOTE.—The Food and Nutrition Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 and OMB Circular A–197.

(Catalog of Federal Domestic Assistance Program No. 10.550, National Archives Reference Services)

Dated: November 17, 1977.

CAROL TUCKER FOREMAN,
Assistant Secretary for Food and Consumer Services.

[FR Doc.77–33870 Filed 11–21–77;9:22 am]

proposed rules

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.

[3410-30]

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

[7 CFR Part 210]

NATIONAL SCHOOL LUNCH PROGRAM

Identification of Schools in Need of School Breakfast Program

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rulemaking.

SUMMARY: This proposed rule would amend the National School Lunch Program regulations to require State agencies to include in the State Plan of Child Nutrition Operations, information to identify schools in need of the School Breakfast Program. It is believed the proposed action is necessary to encourage the needed expansion of the School Breakfast Program and to achieve better program management.

DATE: Comments must be received on or before December 31, 1977, to be assured of consideration.

FOR FURTHER INFORMATION CONTACT:

William G. Boling, Manager, Child Nutrition Programs, USDA, Washington, D.C. 20250, 202-447-8130.

SUPPLEMENTARY INFORMATION: To be better able to determine schools in need of a breakfast program, it is believed that additional information should be provided in each State Plan of Child Nutrition Operations. Information, such as the number of schools not participating in the School Breakfast Program in the State classified as "Title I schools" (receiving grants under Title I of the Elementary and Secondary Education Act of 1965, as amended), the number of schools in the State with 25 percent or more of the enrollment eligible for free and reduced price meals, and the number of schools without food service, would provide an indication of the number of schools which possibly would need a breakfast program. Further, the State Plan would indicate the State's plans to work to initiate a breakfast program in these schools. Also, the State agency would be asked to identify the outreach efforts to be made to extend the Breakfast Program to schools in need.

Section 210.4a, paragraph (b) would be revised to read as follows:

§ 210.4a State Plan of Child Nutrition Operations.

* * * * *

(b) A State Plan of Child Nutrition Operations, as a minimum, shall include the following information:

(1) The detailed action program the State agency proposes to undertake to use the Federal funds provided under this Act and the Child Nutrition Act of 1966, as amended, and funds other than Federal funds (including an estimate of such funds) available to and under the control of the State agency to:

(i) Furnish a free or reduced price lunch and breakfast to every needy child;

(ii) Extend the National School Lunch Program and the School Breakfast Program to every school within the State, giving priority to schools in areas with a high concentration of needy children and to schools identified by the State agency as in need of a school breakfast program. As a minimum, such priority shall be given to schools referred to in subsection (b)(7) (i), (ii), and (iii) of this section; and

(iii) Identify the outreach efforts to be made to extend the benefits of the School Breakfast Program to schools meeting the State's need criteria;

(2) The number of schools in the State not participating in the National School Lunch Program, together with the average daily attendance in such schools;

(3) A plan for the conduct of audits which shall:

(i) Delineate the positive action to be taken by the State agency and School Food Authorities to achieve the audit frequency required in § 210.17 of this part;

(ii) Provide a description of the organization of the State agency in adequate detail to demonstrate the independence of the audit function; and

(iii) Provide a systematic method to assure timely and appropriate resolution of audit findings and recommendations.

(4) A plant to monitor program performance and measure progress as set forth under § 210.14(a);

(5) The State's criteria for determination of especially needy schools under the School Breakfast Program, for rates of reimbursement in excess of those specified in § 220.9(b) of this chapter, and how such criteria will be made known to School Food Authorities;

(6) The number of schools in the State not participating in the School Breakfast Program together with the average daily attendance in such schools; and

(7) (i) The number of schools in the State classified as "Title I schools" (receiving grants under Title I of the Elementary and Secondary Education Act of 1965, as amended), not currently participating in the School Breakfast Program;

(ii) The number of schools in the State with 25 percent or more of the enrollment eligible for free and reduced price meals not currently participating in the School Breakfast Program;

(iii) The number of schools in the State without food service;

(iv) Of the schools in (b)(7) (i), (ii), and (iii) of this section, the number in which the State plans to work to initiate a school breakfast program during the school year, and the State's timeframe and plans to work to initiate a school breakfast program in all such schools.

(v) The number of other schools in which the State plans to work to initiate a school breakfast program during the school year, and the State's criteria for targeting these schools.

(8) State agencies operating under a State school breakfast mandate which includes schools classified as "Title I schools" (receiving grants under Title I of the Elementary and Secondary Education Act of 1965, as amended) and schools in the State with 25 percent or more of the enrollment eligible for free and reduced price meals, may describe the mandate in lieu of the information required in § 210.4a(b)(7) of this section.

Dated: November 17, 1977.

CAROL TUCKER FOREMAN,
Assistant Secretary.

[FR Doc.77-33533 Filed 11-21-77;8:45 am]

[1505-01]

Commodity Credit Corporation

[7 CFR Part 1464]

TOBACCO LOAN PROGRAM

1977 Fire-Cured, Dark Air-Cured and Virginia Sun-Cured Tobacco

Correction

In FR Doc. 77-31624, appearing at page 57466 in the issue of Thursday, November 3, 1977, the following changes should be made:

1. On page 57467, first column, the 24th entry in the left hand column of the table, now reading, "V4L," should read, "C4L."

2. On page 57467, first column, the next to last entry in the right hand column of the table, now reading, "37," should read, "57."

3. On page 57467, first column, the number of the last section heading, now reading, "§ 146.18," should read "§ 1464.-18."

[1505–01]

Food Safety and Quality Service

[9 CFR Part 381]

POULTRY SLAUGHTERING PRACTICES

Notice of Proposed Rulemaking

Correction

In FR Doc. 77–24123 appearing at page 41873 in the issue for Friday, August 19, 1977, in the third column, the 4th line of the paragraph designated "Why is this Proposal Needed?" now reading "processing digestive tract contents. Also" should have read "processing poultry carcasses accidentally contaminated during slaughter with digestive tract contents. Also".

[6320–01]

CIVIL AERONAUTICS BOARD

[14 CFR Part 241]

[EDR–339, Docket No. 30537; Dated: November 10, 1977]

UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR CERTIFICATED AIR CARRIERS

Proposed Amendment to CAB Form 41 To Provide for the Reporting of Ratemaking Revenues and Statistics

AGENCY: Civil Aeronautics Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Board's Uniform System of Accounts and Reports for Certificated Air Carriers to require the monthly submission of passenger revenue and traffic data by type of fare for the Mainland-Alaska, Mainland-Hawaii, and Mainland-Puerto Rico/Virgin Islands operations of the domestic trunk carriers in a manner identical to that now filed for 48-State operations on CAB Form 41 Schedule P–13 "Passenger Revenue and Traffic Data by Type of Fare—48 States." In addition, this notice proposes to add the Mainland-Puerto Rico/Virgin Islands market to the list of markets for which data are reported on Schedule P–2(a) "Revenue Market Report" and Schedule T–7 "Statistical Market Report."

DATE: Comments must be received on or before December 22, 1977.

ADDRESSES: Comments should be sent to Docket 30537, Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. Comments may be examined at the Docket Section, Civil Aeronautics Board, Room 711, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C., as soon as they are received.

FOR FURTHER INFORMATION CONTACT:

Mr. Raymond Kurlander, Director, Bureau of Accounts and Statistics, 1825 Connecticut Avenue NW., Washington, D.C. 20428, 202–673–5270.

SUPPLEMENTARY INFORMATION:

CAB FORM 41 SCHEDULE P–13

In ER–956 adopted May 10, 1976, the Board established CAB Form 41 Schedule P–13 "Passenger Revenue and Traffic Data by Type of Fare—48 States" to provide the information necessary to monitor the 48-State fare level and the results of particular discount fares. This action was taken to implement the policy adopted in Phase 5 of the *Domestic Passenger Fare Investigation* in which the Board stated that the overall fare level should be computed on a hypothetical full normal-fare basis—i.e., as if discount fares not based on cost savings were excluded from the fare structure.

On February 22, 1977, Eastern Air Lines, Inc. (Eastern) petitioned the Board for a rulemaking proceeding amending Part 241 of the Board's Economic Regulations to provide for the filin of fare level data on a separate Schedule P–13 report for operations in the Mainland U.S.-Puerto Rico/Virgin Islands ratemaking entity. In support of the petition, Eastern cites the investigation of *Mainland U.S.-Puerto Rico/Virgin Islands Fares*, Docket 24353, in which the Board decided to treat discount traffic, revenues, and expenses for this ratemaking entity in the same manner as in the domestic 48-State ratemaking entity. To property implement this policy, the petitioner believes that a Schedule P–13 reporting requirement is necessary since the Board currently lacks discount fare data to complete a ratemaking analysis adjusted for discount fare dilution in the Mainland U.S.-Puerto Rico/Virgin Islands ratemaking entity.

We tentatively agree with Eastern that a need exists for discount fare data for the Mainland U.S.-Puerto Rico/Virgin Islands ratemaking entity. The fare level data which would be reported would provide the Board with the information necessary to evaluate tariff filings and to properly monitor the results of particular discount fares. This is not now possible due to the lack of recurrent, accurate data. In addition, we have also tentatively concluded that a need exists for discount fare data to monitor two additional ratemaking entities—i.e., Mainland U.S.-Alaska and Mainland U.S.-Hawaii.

For the Mainland U.S.-Hawaii entity, the Board would use discount fare data to develop an entity return on investment (fare level) adjusted according to standards established by the Board in the *Hawaii Fares Investigation*, Docket 25474, Order 76–10–37. In this investigation, the Board, while deciding not to allow cross-subsidization of discount fares by normal fares, permitted in certain instances the adjustment for dilution when a need is demonstrated as in the case of military and children's fares. Access to current data on discount fares would be the logical next step in the implementation of that decision. The reasons for supporting this proposed requirement are precisely those underlying the Board's adoption of Regulation ER–956. Those reasons are, namely, to provide the Board with necessary data for monitoring the entity fare level, in light of the policy adopted in Docket 25474, and for monitoring the results of particular discount fares.

Regarding the Mainland U.S.-Alaska ratemaking entity, the Board would utilize the discount fare data that would be reported on Schedule P–13 to evaluate tariff filings and to measure the effect on yields resulting from discount fare dilution. This information is not being provided by the carriers as part of their tariff filings, and we believe that this information would be useful regardless of the outcome of the *Alaska Fares Investigation*, Docket 29198. Without data with which to determine the adjustment or normal fare yields needed to permit carriers an opportunity to earn the rate-of-return recognized for Mainland U.S.-Alaska operations, the interests of both the carriers and the traveling public would not be protected.

CAB FORM 41 SCHEDULES P–2(a) AND T–7

Schedules P–2(a) "Revenue Market Report" and T–7 "Statistical Market Report" are primarily used for ratemaking purposes within the Board. In keeping with our goal of improving and simplifying reporting requirements, these schedules are under continuous review by the Board's staff to highlight areas where such reporting changes are possible. The changes we are proposing to these schedules are a result of this continuing review of reporting requirements.

In order to make Schedules P–2(a) and T–7 more useful to both the Board's staff and the public, we are proposing to add Virgin Islands operations to these reports by establishing a new market entitled "Mainland-Puerto Rico/Virgin Islands." The information that would be reported would enable the Board to determine the total expenses allocable to passenger operations for this market, thus increasing the accuracy of ratemaking determinations. At this time, the Board cannot make this ratemaking adjustment because the data for freight, mail, and other items related to Mainland-Virgin Islands operations are buried in the carriers' Latin American operations reported on CAB Form 41 Schedule P–1.2 "Statement of Operations."

This proposal also clarifies Schedules P–2(a) and T–7 by incorporating the "market concept" contained in Accounting and Reporting Interpretation Letter No. 19 (IL No. 19) issued by the Director, Bureau of Accounts and Statistics under delegated authority. This interpretation, dated December 16, 1971, informed the carries that the data to be reported for any given market should be limited to the service segments operated between the two named market regions.

During our review of Schedules P–2 (a) and T–7, we noted that data for both military and civilian charters were reported in the nonscheduled columns. Since these schedules are not used in setting rates for military charters, we are

proposing to amend the instructions to exclude the reporting of data for these charters.

Turning now to Schedule P–2(a) individually, we are proposing to change the format of this schedule by substituting CAB Form 41 account numbers for the data lines that are now contained on the schedule. The use of account numbers would not increase the amount of data to be reported, but would merely make the schedule more informative and easier to complete by the carrier.

BURDEN

We believe that the burden in filing the proposed discount fare data for three additional ratemaking entities on Schedule P–13 would be minimal. Much of the data is similar to that which has been collected on an ad hoc basis in fare investigations. By regularizing the data reported, the carriers would be relieved of having to submit discount fare data on these ratemaking entities for fare investigations and tariff filings. At the same time, more reliable and useful information would be received because uniform reporting among carriers would be assured. In addition, since this proposed reporting requirement would apply only to the trunk carriers which have reported in a similar manner for domestic 48-State operations, the costs and initial problems of implementing the proposal should be relatively minor.

As for the burdens this proposal would cause in connection with the changes to Schedules P–2(a) and T–7, we believe that they are less than those involved with Schedule P–13. The only new reporting requirement that would be imposed relates to the addition of Virgin Islands operations to the Mainland-Puerto Rico market.

Nevertheless, comments are requested from interested parties as to the burdens that would be incurred if this proposal is finalized. In addition, we are requesting the carriers affected by the proposal to provide us with their estimate of the costs that would be incurred in implementing the changes to each schedule. Respondents should use the following format in commenting on burden.

Schedule _____
Cost to:

	Prepare this report initially	Prepare this data on a recurring basis
Direct labor	$	$
Data processing		
Printing copying		
Overhead		
Other (specify)		

PROPOSED RULE

It is proposed to amend Part 241 of the Economic Regulations (14 CFR Part 241) as follows:

Section 22 [Amended]

1. Amend Section 22—General Reporting Instructions, by revising the "List of Schedules in CAB Form 41 report" in paragraph (a), to reflect the new title of Schedule P–13, "Passenger Revenue and Traffic Data by Type of Fare," the revised list in pertinent part to read as follows:

* * * * *

List of schedules in CAB Form 41 Report

Schedule No.	Schedule title	Filing freqeuncy
* *	* * *	*
P–12(a)	Fuel Consumption by Type of Service and Specific Operational Markets.	Do.
P–13	Passenger Revenue and Traffic Data by Type of Fare.	Do.
T–1	Traffic and Capacity Statistics by Class of Service.	Do.
*	* * *	*

Section 2 [Amended]

2. Amend Section 24—Profit and Loss Elements, as follows:

A. By revising paragraph (c) and by adding new paragraphs (d) and (e) to Schedule P–2(a) to read in pertinent part as follows:

(a) * * *
(b) * * *
(c) Markets to be reported are:

Mainland—Hawaii.
Mainland—Alaska.
Mainland—Puerto Rico/Virgin Islands.
Mainland—Bermuda.
Mainland—Bahamas.
Mainland—Mexico.
Hawaii—Alaska.

and such other markets as may be designated by the Board.

(d) For purposes of this schedule, the data to be reported for any given market shall be limited to the service segments operated between the two named market regions.

(e) For purposes of this schedule, military charter services performed under contract with the Department of Defense should not be reported.

B. By revising the title and text of Schedule P–13 to read as follows:

Schedule P–13—Passenger Revenue and Traffic Data by Type of Fare.

(a) * * *

(b) A separate copy (original only) of this schedule shall be filed for each of the following ratemaking entities only if the carrier conducts operations in that entity.

Domestic 48—State.
Mainland U.S.—Puerto Rico/Virgin Islands.
Mainland U.S.—Alaska.
Mainland U.S.—Hawaii.

(c) * * *

(d) Column 2 shall report the total revenue passenger-miles for each fare category.

(e) Column 3 shall report the total passenger revenue for each fare category.

(f) * * *

(g) Column 5 shall report the number of revenue passenger emplanements for each fare category.

(h) * * *

* * * * *

Section 25 [Amended]

3. Amend Section 25—Traffic and Capacity Elements, by revising paragraph (c) and by adding new paragraphs (d) and (e) to Schedule T–7 to read in pertinent part as follows:

(a) * * *
(b) * * *
(c) Markets to be reported are:

Mainland—Hawaii.
Mainland—Alaska.
Mainland—Puerto Rico/Virgin Islands.
Mainland—Bermuda.
Mainland—Bahamas.
Mainland—Mexico.
Hawaii—Alaska.

and such other markets as may be designated by the Board.

(d) For purposes of this schedule, the data to be reported for any given market should be limited to the service segments operated between the two named market regions.

(e) For purposes of this schedule, military charter services performed under contract with the Department of Defense should not be reported.

4. Amend CAB Form 41 by revising Schedules P–2(a) and P–13 as shown in the attached Exhibits A and B.

REQUEST FOR COMMENTS

Interested persons may take part in this rulemaking by submitting 20 copies of written data, views, or arguments on the subjects discussed. All relevant material received by the dates shown at the beginning of this notice will be considered by the Board before taking final action on the proposed rules.

Individual members of the general public who wish to express their interest as consumers by informally taking part in this proceeding may do so by submitting comments in letter form to the Docket Section, without having to file additional copies.

(Secs. 204(a), 407, Federal Aviation Act of 1958, as amended, 72 Stat. 743 and 766 (49 U.S.C. 1324, 1377).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

EXHIBIT A

REVENUE MARKET REPORT	Air Carrier _____ Operation _____ Market _____ Period Ended _____, 19____

ITEM		QUARTER		12 MONTHS TO DATE	
		SCHEDULED SERVICE	NONSCHEDULED SERVICE	SCHEDULED SERVICE	NONSCHEDULED SERVICE
TRANSPORT REVENUES	3900				
Passenger-first class	01.1				
Passenger-coach	01.2				
U. S. Mail-priority	05.1				
U. S. Mail-nonpriority	05.2				
Foreign mail	05.3				
Property-express	06.1				
Property-freight	06.2				
Property-excess passenger baggage	06.3				
Charter and special-passenger	07.1				
Charter and special-property	07.2				
Reservations cancellation fees	19.1				
Miscellaneous operating revenues	19.9				
Total transport revenues					
TRANSPORT-RELATED REVENUES:					
Public Service Revenues (Subsidy)	4808				
Transport Related Revenues	4898				
Total Public Service and Transport-Related Revenues					

Schedule P–2(a)

CAB Form 41

PASSENGER REVENUE AND TRAFFIC DATA
BY TYPE OF FARE

Air Carrier _____
Ratemaking Entity _____
Month Ended _____, 19__

Type of Fare	Revenue Passenger-Miles (000)	Passenger Revenue ($000)	Passenger Yield (¢)	Revenue Passenger Enplanements (No.)	Average On-Flight Trip Length (Miles)
(1)	(2)	(3)	(4)	(5)	(6)
Coach					
1. Full					
2. Economy/Commuter					
3. Night Coach					
4. Military Reservation					
5. Children's Fares					
Group Fares:					
6. Tour Based					
7. Other					
Excursion Fares:					
8. Tour Based					
9. Other					
10. Other Discount 1/					
Total					
First Class					
12. Full					
13. Deluxe Night Coach					
14. Children's Fares					
15. Other					
Total					
Grand Total					

1/ Report separately for (1) any other type of fare amounting to five percent or more of total revenue passenger-miles; and (2) any fare for which monthly reports are specifically required by Board order.

Schedule P-13

CAB Form 41

EXHIBIT B

[FR Doc.77-33423 Filed 11-21-77;8:45 am]

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

[Docket No. FI-3270]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for City of Charlotte, Mecklenburg County, N.C.; Correction

AGENCY: Federal Insurance Administration, HUD.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations that appeared on page 44907 of the FEDERAL REGISTER of September 7, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, 202-755-5581 or toll free line 800-424-8872, Room 5270, 451 Seventh Street, SW., Washington, D.C. 20410.

The following corrections are made:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Kings Branch	I-77 (upstream side)	639
	Arrowood Rd. (upstream side).	597
Briar Creek Tributary No. 1.	Barclay Downs Dr. (upstream side).	601

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, February 27, 1969, as amended (39 FR 2787, January 24, 1974).)

Issued: October 13, 1977.

PATRICIA ROBERTS HARRIS,
Secretary.

[FR Doc.77-33644 Filed 11-21-77;8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-3648]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for Town of Sorrento, Ascension Parish, La.; Correction

AGENCY: Federal Insurance Administration, HUD.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations that appeared on page 45126 of the FEDERAL REGISTER of September 8, 1977 (42 FR 45126).

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, 202-755-5581 or toll free line 800-424-8872, Room 5270, 451 Seventh Street, SW., Washington, D.C. 20410.

The following is a correction of location descriptions for previously published base (100-year) flood elevations:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Bayou Conway	Intersection of Wilfred St. and Conway St.	6
	Intersection of Brittany and Robert Sts. (unchanged).	7
Bayou Francois	Intersection of Vivyan Amant Sts.	5

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended (39 FR 2787, January 24, 1974).)

Issued: October 13, 1977.

PATRICIA ROBERTS HARRIS,
Secretary.

[FR Doc.77-33645 Filed 11-21-77;8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 818-7]

APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Air Pollution Control, State and County Regulations, State of Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: It is the purpose of this notice to acknowledge receipt of and invite public comments on the approval/disapproval of the December 10, 1976, revisions to the Nevada State Implementation Plan (SIP), especially as to their consistency with the Clean Air Act.

DATES: Comments may be submitted up to December 22, 1977.

ADDRESSES: Send comments to: Frank M. Covington, Director, Air and Hazardous Materials Division, Attn.: Morris I. Goldberg, Air Programs Branch, EPA Region IX, 215 Fremont Street, San Francisco, Calif. 94105.

FOR FURTHER INFORMATION CONTACT:

Morris Goldberg, 415-556-7473.

SUPPLEMENTARY INFORMATION: The December 10, 1976 submittal contains revisions to the SIP as follows:

STATE REGULATORY REVISIONS

Article 1—Definitions

Article 2—General Provisions

Regulation 2.5—Scheduled maintenance.
Regulation 2.6—Testing and sampling.
Regulation 2.7—Confidential information.
Regulation 2.8—Administrative fines.
Regulation 2.16—Notification and recordkeeping.
Regulation 2.17—Monitoring requirements.

Article 3—Registration Certificates and Operating Permits

Regulation 3.1—General.
Regulation 3.2—Registration certificates.

Article 4—Visible Emissions from Stationary Sources

Regulation 4.3—Exceptions.

Article 7—Particulate Matter

Regulation 7.1—Indirect heat transfer fuel burning equipment.
Regulation 7.2—Industrial sources.

Article 8—Sulfur Emissions

Regulation 8.2—Indirect heat transfer fuel burning equipment.

Article 11—Mobile Equipment

Regulation 11.7—Exceptions to this article.
Regulation 11.8—Motor vehicle inspection standard.
Regulation 11.9—Prescribed inspection test procedures.
Regulation 11.10—Exhaust gas analyzer performance specifications.

NON-REGULATORY REVISIONS

Section 3—Air Quality Data

Sub-Section 3.2—SO_2 Data.

Section 4—Emissions Summary

Sub-section 4.2—Exceptions.

Section 5—Control Strategy

Subsection 5.1—Approach.
Table 5.1—Classification of regions.
Table 5.2—Set 1 pollutants (Region 13).
Summary of control strategy analysis.

Section 10—Air Quality Surveillance Network

Table—Monitoring network.
Table—Sampling sites modifications.

In addition, regulations were submitted concerning new source review and emissions from existing copper smelters. These regulations will be considered in separate FEDERAL REGISTER actions. Ambient air quality standards and ambient air quality aesthetic standards which were included in the revisions are not being addressed because they do not contribute to the attainment or maintenance of the National Ambient Air Quality Standards.

The State has also submitted regulations concerning Standards of Performance for New Stationary Sources (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPS). These regulations implement sections 111 and 112 of the Clean Air Act, and are not appropriate for inclusion in a State Implementation Plan under section 110 of the Act. Therefore, these regulations will be neither approved nor disapproved by EPA as part of an applicable implementation plan. They will, however, be reviewed in determining whether to delegate authority to implement and enforce the NSPS and NESHAPS in the APCD under the appropriate provisions of sections 111 and 112. Announcement of such delegation will appear in a separate FEDERAL REGISTER notice.

Pursuant to section 110 of the Clean Air Act as amended, and 40 CFR Part 51, the Administrator is required to approve or disapprove revisions to the SIP. The Regional Administrator hereby issues this notice setting forth these revisions as proposed rulemaking and advises the public that interested persons may participate in this rulemaking by submitting written comments to the Region IX Office. Relevant comments received on or before December 22, 1977 will be considered. Comments received will be available for public inspection at the Region IX Office and the EPA Public Information Reference Unit.

Copies of the proposed revisions are available for public inspection during normal business hours at the following locations:

Clark County District Health Department, 625 Shadow Lane, Las Vegas, Nev. 89106.
W shoe County District Health Department, 10 Kirman Avenue, Reno, Nev. 89502.
State Environmental Commission, 201 South Fall Street, Capitol Complex, Carson City, Nev. 89710.
Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, Calif. 94105.
Public Information Reference Unit, Room 2922 (EPA Library), 401 "M" Street SW., Washington, D.C. 20460.

(Sections 110 and 301(a) of the Clean Air Act, as amended [42 U.S.C. §§ 7410 and 7601 (a)].)

Dated: November 11, 1977.

PAUL DE FALCO, Jr.,
Regional Administrator.

[FR Doc.77-33532 Filed 11-21-77;8:45 am]

[4110-83]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Resources Administration

[42 CFR Part 121]

NATIONAL GUIDELINES FOR HEALTH PLANNING

Extension of Comment Period

AGENCY: Public Health Service, HEW.

ACTION: Extension of period for public comment.

SUMMARY: This notice amends an advance notice of proposed rulemaking published in the FEDERAL REGISTER on September 23, 1977 (42 FR 48502) setting forth proposed National Guidelines for Health Planning as required by the National Health Planning and Resources Development Act of 1974. Because of the exceptional interest generated by the proposed guidelines which has resulted to date in some 10,000 communications from institutions and individuals, the final date for receiving comments on these guidelines has been extended to December 9, 1977.

DATE: Comments must be received by December 9, 1977.

FOR FURTHER INFORMATION CONTACT:

Daniel I. Zwick, Associate Administrator, OPEL, HRA, Center Bldg., Room 10-22, 3700 East-West Highway, Hyattsville, Md. 20782, 301-436-7270.

Dated: November 18, 1977.

HAROLD MARGULIES,
Deputy Administrator,
Health Resources Administration.

[FR Doc.77-33884 Filed 11-21-77;10:19 am]

[4310–09]

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[43 CFR Part 426]

ACREAGE LIMITATION

Extension of Time for Comments

AGENCY: Bureau of Reclamation, Interior.

ACTION: Extension of time for comments.

SUMMARY: On August 25, 1977, there was published in the FEDERAL REGISTER (42 FR 43044) a proposed rule to establish policies and procedures to meet the Secretary's responsibilities in administering the acreage limitation and other provisions of reclamation law. The comment period on the proposed rule was set to expire on November 23, 1977. By this publication, the comment period is extended until December 31, 1977.

DATE: Comments on or before December 31, 1977.

ADDRESS: Send comments to: Commissioner, Bureau of Reclamation, Department of the Interior, 18th and C Streets NW., Washington, D.C. 20240, Attention: Code 410.

FOR FURTHER INFORMATION CONTACT:

Mr. Vernon S. Cooper, Special Projects Officer, Division of Water and Land, Bureau of Reclamation, 202–343–5104.

Dated: November 15, 1977.

GUY R. MARTIN,
Assistant Secretary of the Interior.

[FR Doc.77–33575 Filed 11–21–77;8:45 am]

[6712–01]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 1, 73]

[Docket No. 21473; FCC 77–777]

AM BROADCAST STATIONS

Conversion of Radiation Patterns; Inquiry

AGENCY: Federal Communications Commission.

ACTION: Notice of inquiry.

SUMMARY: The Commission is initiating an inquiry to determine whether the method of calculating directional antenna patterns for AM radio stations should be changed to facilitate the use of computer calculations. If so, existing directional antenna patterns for all U.S. AM stations would be changed to this method and be called standard patterns. Also involved would be the conversion of the patterns to the metric system. This inquiry is being initiated on the Commission's own motion in an attempt to simplify the processing of AM applications and, if the changes are adopted, should speed the processing of AM construction permit applications.

DATES: Comments must be received on or before January 23, 1978. Reply comments must be received on or before February 22, 1978.

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

FOR FURTHER INFORMATION CONTACT:

John Boursy, 202–632–6908.

SUPPLEMENTARY INFORMATION:

Adopted: November 9, 1977.

Released: November 17, 1977.

In the matter of amendment of the rules governing the conversion of radiation patterns for AM broadcast stations, Docket No. 21473.

1. In 1971, we adopted new rules governing the design of radiation patterns for AM broadcast stations with directional antennas. *Report and Order in Docket No. 16222*, 27 FCC 2d 77, 20 RR 2d 1745 (1971). The amended rule (§73.150) provides for a defined method of calculation of radiation patterns which could be computerized. The patterns calculated in this manner are called "standard patterns." The rules (§ 73.152) were also amended to provide for the use of a modified standard pattern to take into account deviations from the standard pattern when the directional array has actually been constructed and put into operation. Recently, we made some minor changes in the method of calculating standard patterns. *Report and Order in Docket No. 20645*, 60 FCC 2d 927, 37 RR 2d 649 (1976). However, the requirement of using a standard pattern applies only to applications for new stations and major changes in existing stations. *Report and Order in Docket No. 16222, supra*, at para. 44. Thus, very few stations actually have standard patterns instead of the former theoretical patterns with MEOV.[1] Therefore, the potential benefits of computerization have been limited. The only way to realize the maximum potential of computerization and the standard pattern is to convert as many stations as possible to the standard pattern. Therefore, we believe we should consider the possibility of conversion. This Notice will discuss the problem involved in a complete conversion by the U.S. stations and solicit suggestions on methods of dealing with these problems. We also wish to receive comments on any problems which we have not discovered.

2. The first question is whether we should attempt a conversion at all. When we adopted the standard pattern rules, we looked forward to this eventuality. Id., at para. 45. Since that time the number of pending AM applications has increased dramatically. The increase has provided us with a strong incentive to find methods of streamlining the processing of applications. One method is increased computerization of the processing. In the area which takes a major amount of processing time, the nighttime portion of the application, a significant amount of time is consumed in considering the measured patterns (or, in the case of protection of foreign stations, the notified patterns) of the stations. If all domestic stations were converted to standard patterns, the savings in processing time would be significant, both for the Commission staff and for applicants or their consulting engineers. Neighboring countries might also receive some benefits since they, like us, would no longer use MEOV in their calculations concerning U.S. stations.

3. While time would be saved if all patterns were standard patterns, there are some potential detriments which must be considered before concluding that all stations should be converted to standard patterns. Currently, the interference level of a nighttime operation is computed in accordance with § 73.182(o) of the rules. Basically, that Section provides for consideration of the stronger interfering signals while excluding the weaker signals. If the signal from a proposed operation is sufficiently weak, the signal is not considered to increase the interference. Conversion to standard patterns would change the predicted signal levels at most, if not all, stations. The changes could easily result in increases in predicted interference levels (and therefore decreases in predicted service area) or in decreases in predicted interference levels (and therefore increases in predicted service area), depending on the exact relationship and interaction between the signals comprising the RSS[2] under the current situation and the signals comprising the RSS if all stations were converted to

[1] MEOV is the abbreviation for "Maximum Expected Operating Value(s)." Because theoretical patterns are rarely achieved in practice, most applicants, in the days prior to standard patterns, proposed theoretical patterns with MEOV. The MEOV was larger than the calculated theoretical radiation and often represented the consulting engineer's estimate of the radiation that would actually occur. Interference studies used the MEOV rather than theoretical values, and an applicant adjusting the directional antenna would only be required to adjust the array to within the MEOV rather than the more stringent theoretical values. Now, the standard pattern obviates the need for MEOV.

[2] RSS is the abbreviation for "Root Sum Square." In this context, it is tht nighttime interference level of a station. It is computed from the root sum square of the nighttime limitation from each station on the channel, in descending order, provided that a limitation does not enter the RSS if it is less than fifty percent of the RSS of the limitations of greater magnitude. This is referred to as the "RSS 50 percent exclusion method." Since the nighttime limitation from a given station is directly proportional to the radiation from that station, a change from measured or theoretical (with MEOV) to standard pattern radiation will result in a change in the nighttime limitation (and, therefore, the RSS) if there is a difference between the measured or theoretical radiation and the standard radiation.

standard patterns. It is expected, then, that the predicted service areas and protection from predicted interference would be increased for some stations, but decreased for others. Indeed, in the case of certain Class III stations, they may be converted from Class III–A stations to Class III–B stations, or vice-versa.[3] To a lesser extent, this same shifting of predicted service areas and interference would occur with the daytime operations. However, since these changes would be only in the method and results of calculation and would not involve any physical adjustments to any directional antennas, there would be no changes in actual service areas and actual interference levels. Therefore, we believe these changes could be accomplished via rulemaking rather than on a case-by-case basis. *WBEN, Inc. v. United States*, 396 F. 2d 601 (2d Cir), cert. denied, 393 U.S. 914 (1968).

4. At this stage, we feel that the benefits to be derived from the simplification of the overall allocation process outweigh the shifts in interference and service areas since these shifts will occur primarily on paper. (However, there may be future changes when applicants propose facilities that are not permissible with the present RSS, but are permissible with the new RSS.) We are open-minded on this point and are willing to entertain arguments that the present system is better. Attached to this Notice is an Appendix showing the present RSS of stations on 930 kilohertz and the RSS that would result if all stations were converted to standard patterns. We have chosed 930 kilohertz arbitrarily; 930 kilohertz was not chosen because we think it is more typical than any other frequency. We have not attempted to modify the standard patterns pursuant to § 73.152, although such modification would occur in a complete conversion. We also welcome any similar studies which commenting parties might submit. With regard to our study on 930 kilohertz, it should be noted that the change in RSS is relatively small, often less than one decibel (dB). In fact, since all stations are currently authorized to operate with at least their theoretical values of radiation, and since the change between the RSS composed of purely theoretical values and the RSS composed of notified values for foreign stations and standard pattern values for domestic stations, there will be changes in the authorized RSS of less than 0.5 dB in each case. Even if this were to occur in fact rather than solely on paper (as proposed here), it would be impossible for a listener to perceive this small change.

5. If we should convert to standard patterns, the next question is whether we should convert all theoretical patterns to standard patterns. The benefits discussed above would accrue primarily with conversion of the nighttime patterns. Some benefits would, however, also be realized with conversion of the daytime patterns. The shifts in predicted interference and service areas would also be less with conversion of the daytime patterns. Therefore, we believe that the daytime patterns should be converted as well as the nighttime patterns. Because the daytime patterns would be converted, the patterns used in the determination of presunrise powers would be standard patterns. Currently, the permissible presunrise radiation is determined, and the ratio between the actual radiation (theoretical or MEOV, whichever is greater) and the permissible radiation leads to the permissible presunrise power. With the standard pattern, the permissible power would be derived from the ratio between the permissible radiation and the standard pattern radiation. Since relatively few of the stations with presunrise service authorizations use directional antennas, there would be little overall effect on presunrise operation.

6. The primary benefits resulting from conversion would occur in performing nighttime channel studies by computer without the current need to adjust for measured, theoretical or notified values. Since the computer channel studies are required primarily for Class II and Class III nighttime proposals, the greatest benefits will be seen in this area. Clearly, then, all Class III stations would be converted. However, conversion of some Class II stations may result in predicted infringements on the existing 0.5 mV/m-50 percent nighttime secondary service areas of some Class I stations. (Of course, as noted in paragraph 3, there would be no actual changes in service areas since there would be no actual adjustments to the directional antennas.) Accordingly, we wish to receive specific comments on the effects that such a conversion would have on the service areas of domestic Class I stations in addition to the general comments requested above concerning the interference levels and service areas of all stations.

7. We now proceed to the logistics of conversion. Conversion will not be a simple process. We would like to convert simply by stating that all stations now have standard patterns. However, that is not realistic. While standard patterns could be computed from the currently authorized theoretical patterns, they would not take into account those cases where the currently authorized measured patterns exceed the would-be standard patterns. Nor would they take into account those cases with MEOV greater than the standard patterns. Therefore, it may be necessary to convert to modified standard patterns (pursuant to § 73.152) in these cases. (In this proceeding, when we discuss conversion to standard patterns, we intend that the conversion also encompass conversion to modified standard patterns, if necessary.) Since the augmentation resulting in the modified standard pattern will vary in the individual cases, it will be necessary to convert each one individually rather than simultaneously. Also, the patterns will have to be plotted and notified to foreign countries, in keeping with our one-pattern approach, wherever possible. Moreover, the number of patterns involved is not small. Most stations which operate during nighttime hours operate with directional antennas. In addition, they may use different directional antennas for their daytime operations. And daytime-only stations may also use directional antennas. Finally, there are a few stations which use separate directional antennas for operation during critical hours. Since so few existing stations operate with standard patterns, there would be more than 2,000 patterns which would have to be converted. This means that more than 2,000 patterns would have to be recalculated and replotted. The plots would include all necessary stacked and vertical sections. Then, the plots would have to be checked for accuracy. Finally, the patterns would have to be notified to foreign countries in accordance with our international agreements. We simply cannot absorb that workload with our present staff and continue to process applications at our present speed. As we see it, there are several methods of implementation which could be chosen. We will outline each, and we invite comments on them as well as suggestions concerning other methods or the combining of these methods.

8. The traditional method would be to require existing licensees and permittees to recalmulate and replot their patterns. After submission to the Commission, Commission staff would verify the calculations and plots. In this manner the workload of the initial calculations and plotting would be spread over the licensees and permittees rather than concentrated on Commission staff. Also, the choice of augmentation to encompass measured values would rest with the licensees and permittees rather than be-

[3] Class III–A stations are defined in § 73.182 (a) (3) (i) while Class III–B stations are defined in § 73.182 (a) (3) (ii). The portions of the definitions which are pertinent to this discussion state that a Class III–A station is protected to its 2.5 mV/m groundwave contour at night, while a Class III–B station is protected to its 4.0 mV/m groundwave contour at night. This means, in effect, that a Class III station with an RSS of 2.5 mV/m or less is a Class III–A station while a Class III station with an RSS of more than 2.5 mV/m is a Class III–B station. Since a Class III–B station is protected only to its 4.0 mV/m nighttime groundwave contour, its RSS can be increased up to and including 4.0 mV/m if it is currently less than 4.0 mV/m. However, the RSS of a Class III–A station can be increased only up to and including 2.5 mV/m. If the conversion to standard patterns should occur, it may be that the RSS of an individual Class III station may change from slightly less than 2.5 mV/m to slightly more than 2.5 mV/m. This change would not only convert the station's class from III–A to III–B, but would also permit the increasing of its RSS to 4.0 mV/m rather than the previously permissible 2.5 mV/m. A change in the opposite direction is also possible. It may be that we are concerned over nothing since no stations may fall into this category. We note that in our study of 930 kHz which is discussed in paragraph 4 of this Notice, no stations fell into this category. However, we have not examined the other regional channels to determine whether this might occur. (Of course, this possibility arises only when the nighttime power is one kilowatt.)

ing imposed upon them. Within this broad category are various ways in which implementation could occur:

(a) Each licensee and permittee would be required to submit the new standard pattern with its license renewal application. The Commission could then assign staff to verify the patterns. In this manner, all stations would be converted to standard patterns in three years. There are disadvantages. For instance, we would probably have to institute a "freeze" on the filing of applications for these three years so that the conversion from theoretical to standard patterns would not adversely affect applications which had been prepared in good faith.

(b) The stations could be divided by frequency and all those on specific frequencies would submit their patterns by specified dates. Then, Commission staff assigned to verify the patterns could work at an appropriate pace without falling behind or being left without work as might occur with alternative a. To accomplish this in an orderly manner, several sequential "mini-freezes" might be instituted to prohibit the filing of applications on particular frequencies until all stations on these frequencies were converted to standard patterns.

9. A less traditional manner of conversion would have Commission staff performing all of the work and notifying the licensees and permittees of the end results. Actual implementation might occur in either of the ways outlined in the preceding paragraph. We are inclined to reject this alternative because we do not have the staff or facilities to perform this work. Moreover, this would require imposition of augmentation on the stations without their suggestions. We simply mention this alternative for completeness.

10. A third method of conversion would be the combination of the previous two methods. The permittees and licensees would specify the augmentation to encompass the measured values but the Commission would plot the patterns. Economies of scale would be possible here since the Commission would be able to use computer techniques to plot the patterns, a method which may be financially infeasible if each individual station were responsible.

11. The final method of conversion would involve the Commission's contracting out the necessary work. The contractor might be one (or several) of the consultants which normally practice before the Commission. Contracting the work out might permit economies of scale which are not possible if each licensee were responsible for the calculations and plotting. The contractor might, for instance, enter all of the parameters for all of the stations into a data base and then allow a computer to calculate and plot the patterns, thereby requiring relatively little human effort. One detriment arising from this approach would be the delegation to the contractor of the authority to decide how particular "problem" cases (see below) would be handled, whereas our other possibilities leave that authority in the hands of the Commission directly or require Commission approval of the licensees choice. In addition, there is the possibility of conflicts of interest arising from conversions being performed by consultants who have represented parties whose interests are in opposition to parties whose patterns are being converted. Since work of this nature and magnitude has never been contracted out by the Commission, we wonder whether any potential contractors would be interested. Therefore, we solicit showings of interest and suggestions on what the Commission might include in any Request for Proposals. This is not a Request for Proposals. We note that we have not budgeted any money for this approach. This means that implementation of this approach might take longer to initiate than one of the other approaches. We also are interested in "guesstimates" of the cost of such a contract.

12. We previously alluded to "problem" cases. Some of these cases are well known and quite common, and we think it appropriate to solicit suggestions on solving these "problems." We predict that our major problems will arise where the standard pattern would cause new or increased interference to stations in foreign countries in contravention of our international agreements. This could occur because the standard pattern has a defined "null fill" designed to prevent predictions of unrealistic supression in nulls. However, many theoretical patterns were originally authorized with MEOV less than the standard pattern radiation. Therefore, conversion to standard patterns may result in new or increased calculated interference; on the other hand, it may result in lesser calculated interference or the total elimination of calculated interference if the standard pattern radiation is less than the existing MEOV.[4] As noted above, we believe that the trade-off is acceptable domestically in view of the benefits to be derived from conversion to the standard pattern. However, because of treaty restrictions, this is not true where foreign stations are concerned. Two possible solutions present themselves:

(a) We could retain the present two-pattern approach. Presently, for stations without standard patterns, the station has two patterns: the notified pattern and the measured pattern. One of the aims in adopting the standard pattern was to achieve a single-pattern system. "Further Notice of Proposed Rule Making in Docket No. 16222," 34 FR 18942 at para. 66 (1969). The standard pattern was designed to replace the measured pattern as well as to be notified to foreign countries. We believe that a single-pattern approach is best, but we also suggest that a two-pattern approach (the two patterns being the standard pattern and the currently notified pattern) might be the best solution in cases where notification of the standard pattern would result in objections from foreign countries. In this case, the standard pattern would be used domestically while the notified pattern would be used towards foreign stations. Adjustments of the directional array would use the notified pattern as the outer limits on radiation towards foreign stations while the standard pattern would be used for limits on radiation towards domestic stations. We note that we suggest this only for those cases where a standard pattern cannot be derived from the present theoretical pattern without causing interference to foreign countries. It is not meant to be a suggestion that applicants can submit a standard pattern to be used domestically and a theoretical pattern to be used internationally, a practice we thoroughly disapprove of.

(b) We could require that the parameters of the pattern be modified to create a standard pattern which would not cause increased interference. The problem arising from this approach is that there will be severe restrictions on the possible parameters since the towers have already been constructed, leaving only adjustments in field ratios and phasing. Moreover, it may not be possible to design an array which would not cause new or increased interference. For instance, the minimum radiation possible from a standard pattern is 6.3 mV/m, and any existing radiations of lesser value would be exceeded simply by the adoption of any standard pattern. Thus, we might, in any event, be forced into alternative a, above.

13. Additional potential problems also involve notification of the standard patterns to neighboring countries. Depending on the order of notification of stations on a particular frequency, an individual standard pattern may or may not be acceptable because of the changing RSS of stations in the foreign countries. For instance, an early notification might reduce the limit from that station, thereby lowering the RSS of a foreign station so that a second notification would not be acceptable although it would have been with the initial RSS. Avoiding these situations may require that we notify simultaneously standard patterns for all stations on one frequency. Therefore, we might be forced into a frequency-by-frequency conversion rather than working over the renewal cycle; see paragraph 8, above.

14. Another problem could arise when the presently authorized parameters do not depict the presently authorized pattern. There are several of these situations in existence, most of which arose in the 1940 "NARBA shift" where changes in frequency occurred without taking into account the effect of the changes in electrical height and spacing of the existing towers on the shape of the pattern. Should we simply use the authorized

[4] However, as discussed in paragraph 3, the actual interference levels will remain unchanged since no physical adjustments in the directional antenna systems of the stations will be required. Thus, the change will be only in the method and result of the calculation; there would be no actual change in the existing interference.

parameters in deriving a standard pattern? We think, at the very least, that the electrical height and spacing should be recomputed in accordance with the actual physical values and the actual frequency. Then, should the field ratios and/or phasing be changed so that the authorized theoretical pattern will be depicted, or should we continue to use the present field ratios and phasing with the resultant changes in the pattern? We are inclined to use the present field ratios and phasing unless a licensee submits values to the contrary. However, we wish to tap the expertise available outside the Commission for other suggestions and comments.

15. The present standard pattern rules require an assumed loss resistance of at least one ohm at the current loop (or base if the tower is less than 90 electrical degrees in height) of each tower. As noted previously, we propose to compute the standard pattern based on the current theoretical pattern. The question then arises whether we should follow this policy even when the assumed loss resistance for the present theoretical pattern is less than one ohm and, in some cases, negative. The alternative would be to shrink the size of the theoretical pattern so that it would be no larger than would occur with an assumed loss resistance of one ohm. This latter approach would appear more realistic, but we recognize that some of these stations have measured patterns which indicate that the larger pattern is, in fact, obtained. Comments on these two approaches are requested.

16. There are several stations which use top-loaded and/or sectionalized towers. Some of these were authorized many years ago based on methods which we would not use at this time. Thus, we have towers with no known vertical radiation characteristics in equation form, or, sometimes, in measured form. Conversion to standard patterns implies the use of computer calculations which further implies the use of equations to calculate the vertical radiation characteristics, pattern, etc. We suggest that, in these cases, the burden of deriving appropriate equations for loop current and vertical radiation characteristics be placed on the licensee or permittee.

17. We have proposed the use of augmentation (pursuant to § 73.152 of the rules) to take account of measured patterns which exceed standard patterns. There is also the question whether stations should be able to augment their standard patterns to achieve their currently authorized MEOV even though the measured radiation is less than the MEOV. On the one hand, the theory of augmentation is that augmentation should occur only when the measured pattern exceeds the standard pattern. Thus, ideally, augmentation should be used only to encompass measured values. The more closely the augmentation approaches measured values, then the less change there will be in the calculated interference level and service areas domestically. Also, many MEOV are unreasonably high from the standpoint of what will actually occur. On the other hand, many stations have had substantial MEOV for years and, at various times although perhaps not now, have needed the additional leeway provided by the MEOV. Eliminating this may create problems in the future since readjustments of the directional antenna would be further restricted. Thus, it may be that a station might, in the future, be required to submit an application requesting augmentation when it finds that adjustment of the directional antenna within the new standard pattern is impossible; such an application might not be necessary if the MEOV were retained in the form of additional augmentation. We believe both approaches have some validity. Therefore, we request comments on whether augmentation should be restricted to measured values, or whether it should be permitted to achieve the currently authorized MEOV. If we choose the latter approach, should we take any action in those cases where the MEOV is clearly unrealistic? For instance, should we limit the amount of augmentation so that the RMS of the measured pattern is no less than 85 percent of the RMS of the augmented pattern, as required by § 73.151(a) of the rules?

18. Until now, this discussion has concerned directional antennas. However, it must be recognized that many stations operate nondirectionally. Some of these nondirectional operations also have measured radiations which must be used, in lieu of the theoretical radiation, in calculating the radiation from the stations. Just as measured radiations are not susceptible to computerization where directional antennas are involved, so too it is difficult to computerize measurement data from nondirectional stations. Therefore, we suggest that we drop the use of measurement data in determining radiation from nondirectional operations and, instead, rely on the predicted radiation from the antenna. (Measurement data would, of course, still be used domestically in determining ground conductivity.) In this manner, complete computer calculations of nighttime interference would be possible except for consideration of any foreign stations with MEOV.

19. Another suggestion concerns the metric system. Our present allocation scheme mixes metric and traditional British units. For instance, radiation from a station is determined in millivolts per meter at one mile. We recognize that complete conversion to the metric system is desirable. We have already announced our intention to convert to the metric system. FCC 76-737 (August 3, 1976). Thus, we forsee the day when we will be talking in terms of millivolts per meter at one kilometer. (Indeed, some patterns from foreign countries have been labeled in this manner.) At that time, it will be desirable to have all of the patterns labeled and plotted in that manner. Since we do not want to convert all the patterns to standard patterns and, a few years later, convert all the patterns to the metric system, we suggest that both conversions be accomplished at the same time. Conversions of the patterns would require simultaneous conversion of, for instance, our groundwave field intensity curves and our skywave field factor curves. Thus, we would be using millisiemens per meter instead of millimhos per meter. Also, those stations which currently have standard patterns would convert to metric standard patterns. The metric units are well defined in "Metric Practice," ANSI Z210.1-1976, ASTM E 380-76, IEEE Std 268-1976. There should be relatively few problems in converting to the units specified in that joint standard. However, we note that the metric unit for plane angle is the radian rather than the degree traditionally used by the Commission and broadcasters. Conversion to purely metric units would require that phase angles, tower heights, azimuths between towers, and orientation of towers be specified in radians rather than degrees. Since the standards permits the use of the degree as the unit for plane angle, Id., at para. 3.3.2.2, we could continue using the degree for phase angles, tower heights, etc. However, problems with conversion from degrees to radians would, basically, involve only antenna monitors. Most antenna monitors use analog meters with pointers; conversion would simply require new scales in the metric system. Conversion of those monitors with digital readouts would presumably be slightly more complicated. Therefore, we solicit comments on the desirability of converting the patterns (and related material) to the metric system at this time, and, in particular, comments on whether we should convert to radians.

20. We have previously expressed our concern with patterns generated with field ratios and phasing of unrealizable precision. "Report and Order in Docket No. 20645," *supra*, at para. 21. Since all patterns will have to be recalculated, assuming the final decision is to convert to standard patterns, we propose that we limit the number of significant figures used in these calculations to no greater precision than can be obtained with available equipment. Also, we propose to adopt rules to limit the precision used in future applications. We do not now, however, propose specific limitations, but rather will wait until the "Notice of Proposed Rulemaking."

21. Our final question involves enforcement of the conversion effort. Should we choose the alterative of licensees and permittees submitting converted patterns for Commission approval, we expect that, for some reason or other, some will not do so. Were an application involved, we could simply return the application for failure to prosecute. However, such a solution here would be counter-productive. One sanction might be to withhold grant of the renewal of a station's license until compliance occurred. Another would be to impose forfeitures for failure to comply. Yet another alternative might have the Commission staff or an independent contractor perform the conversion; this latter alternative is less desirable since, without sanctions, it

might lead to laxity on the part of many licensees and permittees. Comments on various methods of enforcement and their effectiveness are requested.

22. In the "Report and Order in Docket No. 16222", supra, at para. 41, we emphasized that we would make every effort to persuade Canada and Maxico to adopt the standard pattern for new assignments. We also indicated that we would have to reach an understanding with our neighbors prior to the conversion by existing stations to standard pattern format. To this end, representatives of the Commission staff have held preliminary discussions with representatives of the Canadian Department of Communications concerning the possible conversion by all domestic stations to the standard pattern. We hope to have reached an understanding by the time this rulemaking proceeding is concluded.

23. The proposals here are general in nature and, sometimes, conflicting. We expect that the comments may also be generalized and conflicting. When we have had the benefit of reviewing the comments and reply comments filed as a result of this Notice, we expect to issue a "Notice of Proposed Rule Making" which will present specific and concrete proposals in this matter.

24. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested parties may file comments, accompanied by other pertinent material on or before January 23, 1978, and reply comments on or before February 22, 1978. In addition to the material filed in this proceeding, material in Docket No. 16222 will be considered. "Report and Order in Docket No. 16222," supra, at para. 45.

25. In accordance with the provisions of § 1.419 of the rules, an original and 5 copies of all comments, replies, pleadings, and other documents shall be furnished the Commission. 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 in Washington, D.C. (1919 M Street, NW.).

26. Authority for the institution of this proceeding is contained in Section 403 of the Communications Act of 1934, as amended.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Acting Secretary.

APPENDIX.—*RSS of U.S. stations on 930 kHz with present facilities and all standard patterns*

Call	Location	Present measured	All theoretical	All standard	ΔRSS (decibel)
KAGI	Grants Pass, Oreg	12.27	12.16	12.77	+0.35
KHJ	Los Angeles, Calif	2.03	2.04	2.16	+0.54
KITE	Terrell Hills, Tex	26.57	25.11	26.37	−0.07
KIUP	Durango, Colo	9.25	10.00	10.52	+1.12
KOGA	Ogallala, Nebr	12.26	13.77	14.47	+1.44
KSDN	Aberdeen, S. Dak	11.54	10.83	11.38	−0.12
KSEI	Pocatello, Idaho	3.77	4.03	4.61	+1.75
KTKN	Kechikan, Alaska	1.88	1.88	1.93	+0.23
KWOC	Poplar Bluff, Mo	11.00	10.38	10.92	+0.06
WBCK	Battle Creek, Mich	13.00	12.47	13.11	+0.07
WBEN	Buffalo, N.Y	1.88	1.96	2.06	+0.79
WEKO	Cabo Rojo, P.R	3.71	3.72	3.72	+0.02
WEOL	Elyria, Ohio	4.18	4.19	4.47	+0.58
WFMD	Frederick, Md	10.72	11.81	12.41	+1.27
WGNT	Huntington, W. Va	7.37	7.41	7.79	+0.48
WITN	Washington, N.C	18.91	21.76	22.86	+1.65
WJAX	Jacksonville, Fla	2.92	2.87	2.91	−0.03
WKCT	Bowling Green, Ky	10.07	9.72	10.22	+0.13
WKXY	Sarasota, Fla	17.77	17.38	18.26	+0.24
WKY	Oklahoma City, Okla	1.96	1.93	1.83	−0.60
WMGR	Bainbridge, Ga	12.55	12.55	13.18	+0.43
WPAT	Paterson, N.J	22.54	21.97	23.07	+0.20
WSLI	Jackson, Miss	7.85	7.16	7.54	−0.35
WSOC	Charlote, N.C	7.40	7.40	7.78	+0.43
WTAD	Quincy, Ill	4.61	4.54	4.82	+0.39
WWNH	Rochester, N.H	18.79	21.16	22.23	+1.46

NOTE.—Above is a tabulation of the RSS in millivolt/meter of each domestic station on 930 kHz. The tabulation includes the present RSS of each station, based on measured and notified patterns; the RSS of each station, based on only the theoretical patterns; and the RSS of each station, if all domestic stations were converted to standard patterns. In addition, the change in the RSS (in dB) in the conversion from measured to standard patterns is shown. In all of these calculations, only authorized patterns for authorized stations were used. In computing the RSS, KOGA was always considered with its standard pattern and WEKO was always considered with its augmented pattern. Other than WEKO, augmented patterns were not used; it must be recognized that in a complete conversion standard patterns, there would be some augmentation, in which case the new RSS would be closer to the existing RSS.

[FR Doc.77-33504 Filed 11-21-77;8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 95]

[Docket No. 21000]

SPURIOUS AND HARMONIC EMISSIONS FOR CLASS D TRANSMITTERS OPERATING IN THE CITIZENS RADIO SERVICE

Further Attenuation; Order Extending Time for Filing Replies

AGENCY: Federal Communications Commission.

ACTION: Extension of time in Docket 21000.

SUMMARY: The time for filing Reply Comments in Docket 21000 has been extended to January 3, 1978 at the request of the Association of Maximum Service Telecasters, Inc. in order to provide sufficient time to develope an adequate engineering analysis of the various filed comments.

DATES: Reply Comments must be received on or before January 3, 1978.

ADDRESSES: Send comments to: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

John A. Reed, Office of Chief Engineer, 202-632-7093.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of the Commission's rules to address the matter of further attenuation to the spurious and harmonic emissions for Class D transmitters operating in the Citizens Radio Service under Part 95; Docket No. 21000.

Adopted: November 15, 1977.

Released: November 16, 1977.

1. On November 16, 1976, the Commission adopted a Notice of Inquiry and Proposed Rule Making in the above entitled matters (see 42 FR 42362). Since that time, the Commission has received numerous requests for an extension of time to file comments in this proceeding. These resulted in the extension of the original March 2, 1977, comment date to May 31, 1977, August 29, 1977, and finally October 17, 1977. The original April 1, 1977, reply comment date was extended to June 30, 1977, September 28, 1977, and finally November 17, 1977.

2. Since these extensions, the Commission has received a request for an additional extension of the reply comment date from the Association of Maximum Service Telecasters, Inc. (MST). Such an extension would, according to MST, provide sufficient time to develop an adequate engineering analysis of the various comments and the Commission's recent study on this issue.

3. In light of this request and because of the technical nature of this proceeding and its impact on both the manufacturers and licensees, a 45 day extension of time from November 17, 1977, to January 3, 1978, for filing Reply Comments is hereby ORDERED pursuant to the authority granted by Section 0.241(d).

RAYMOND E. SPENCE,
Chief Engineer.

[FR Doc.77-33588 Filed 11-21-77;8:45 am]

notices

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.

[3410-15]

DEPARTMENT OF AGRICULTURE

Rural Electrification Administration

ASSOCIATED ELECTRIC COOPERATIVE, INC.

Intent To Prepare Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration intends to prepare an Environmental Impact Statement in accordance with section 102 (2)(C) of the National Environmental Policy Act of 1969, in connection with a possible loan gurantee for Associated Electric Cooperative, Inc., P.O. Box 754, Springfield, Mo. 65801. These funds will finance the construction of a 630 MW (net) coal-fired generating unit at the existing Thomas Hill Power Plant in Randolph County, Mo., pollution control equipment, approximately 135 miles of 345 kV transmission line, together with related terminal facilities in the counties of Randolph, Audrain, Boone, Callaway, Osage, Maries, Phelphs, and Pulaski, Mo. The possible loan gurantee would also include financing for the acquisition and development of the Bee Vier and Prairie Hill coal mine properties located in Macon, Randolph, and Chariton counties.

Interested persons are invited to submit comments which may be helpful in preparing the draft EIS.

Comments should be forwarded to the Assistant Administrator—Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250, with a copy to Associated, whose address was given above. Additional information may be obtained at the borrower's office during regular business hours.

Any loan which may be made pursuant to this possible application will be subject to, and release of funds thereunder will be contingent upon, REA's reaching satisfactory conclusions with respect to environmental effects and final action will be taken only after compliance with Environmental Statement procedures required by the National Environmental Policy Act of 1969.

Dated at Washington, D.C., this 11th day of November, 1977.

DAVID A. HAMIL,
Administrator, Rural Electrification Administration.

[FR Doc. 77-33596 Filed 11-21-77; 8:45 am]

Food and Nutrition Service

DONATED FOODS TO NUTRITION PROGRAMS FOR THE ELDERLY

Level of Assistance

Notice is hereby given that pursuant to section 707(a)(4) of the Older Americans Act of 1965, as amended (42 U.S.C. 3045f), the level of assistance in food commodities or, where applicable, cash in lieu thereof, to be provided by the Secretary of Agriculture to recipients of grants or contracts under Title VII of the Act will be increased for the period October 1, 1977, through September 30, 1978, to 29.25 cents per meal. The legislation requires the Secretary, in donating foods or cash in lieu thereof to nutrition programs for the elderly funded under Title VII, to maintain a minimum level of assistance during that period of not less than 25 cents per meal, adjusted to the nearest one-fourth cent to reflect changes in the series for food away from home of the Consumer Price Index published by the Bureau of Labor Statistics (BLS) of the Department of Labor. The minimum level of assistance at 29.25 cents per meal includes such an adjustment and reflects an 8.1 percent increase in that series as reported by BLS for the period September 1976 through August 1977.

Effective date: This notice is effective as of October 1, 1977.

Dated: November 18, 1977.

CAROL TUCKER FOREMAN,
Assistant Secretary for Food and Consumer Services.

[FR Doc. 77-33786 Filed 11-21-77; 9:12 am]

[6325-01]

CIVIL SERVICE COMMISSION

FEDERAL EMPLOYEES PAY COUNCIL

Change of Meeting Date

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the President's Pay Agent announces the following meeting:

NAME: Federal Employees Pay Council.

DATE AND TIME: December 2, 1977, 9:30 a.m. (rescheduled from Nov. 18, 1977).

PLACE: U.S. Civil Service Commission, 1900 E Street NW., Washington, D.C., Room 5A06A.

TYPE OF MEETING: Open.

CONTACT PERSON: Merlin S. Berry, Committee Management staff for the President's Pay Agent, U.S. Civil Service Commission, 1900 E Street NW., Washington, D.C., telephone 202-632-5595.

PURPOSE OF COMMITTEE: To make recommendations to the President's Pay Agent with respect to the process and procedures leading to, and amounts of, annual comparability adjustments in Federal white-collar pay.

AGENDA: Discussions on the 1978 comparability adjustment for the statutory pay systems of the Federal Government, which are defined in section 5301 of title 5, United States Code.

SUPPLEMENTARY INFORMATION: After meeting was announced (Nov. 1, 1977, 42 FR 57146), it was learned that the officials of the President's Pay Agent would not be available for the meeting scheduled for November 18, 1977. In order that all of the officials could attend this meeting, it is being rescheduled for December 2, 1977.

For the President's Pay Agent.

RICHARD H. HALL,
Committee Management Officer for the President's Pay Agent.

[FR Doc. 77-33583 Filed 11-21-77; 8:45 am]

[3510-07]

DEPARTMENT OF COMMERCE

Bureau of the Census

ANNUAL WHOLESALE TRADE

Consideration

Notice is hereby given that the Bureau of the Census is planning to conduct in 1978 the Annual Wholesale Trade Survey. This survey will be conducted under title 13, United States Code, sections 182, 224 and 225. This survey will be conducted to collect data covering year-end inventories and annual sales of firms engaged in wholesale trade. Additional items requesting payroll and operating expenses, capital expenditures, and changes in depreciable assets are included as supplemental data for the 1977 Census of Business. This survey, which would provide data for 1977, is the only source available on a comparable classification and a timely basis for use as a benchmark for developing wholesale estimates.

Information and recommendations received by the Bureau of the Census indicate that the data will have significant application to the needs of the public, the distributive trades, and governmental agencies, and that the data are not publicly available from nongovernment or other governmental sources.

Such a survey, if conducted, shall begin not earlier than December 22, 1977.

Reports will be required only from a selected sample of merchant wholesale firms operating in the United States, with probability of selection based on sales size. The sample will provide, with measurable reliability, statistics on the subjects specified above.

Copies of the proposed forms and a description of the collection methods are available upon request to the Director, Bureau of the Census, Washington, D.C. 20233.

Any suggestions or recommendations concerning the subject matter of this proposed survey will receive consideration if submitted in writing to the Director of the Bureau of the Census on or before December 22, 1977.

Dated: November 17, 1977.

MANUEL D. PLOTKIN,
Director, Bureau of the Census.

[FR Doc. 77-33567 Filed 11-21-77; 8:45 am]

[3510-07]

SURVEY OF DISTRIBUTORS' STOCKS OF CANNED FOODS

Determination

In conformity with title 13, United States Code, section 182, 224, and 225, and due Notice of Consideration having been published September 29, 1977 (42 FR 51635), I have determined that year-end data on stocks of 30 canned and bottled products, including vegetables, fruits, juices, and fish, are needed to aid the efficient performance of essential Government functions, that the data have significant application to the needs of the public and industry, and that they are not publicly available from nongovernmental or other governmental sources. This is a continuation of the survey conducted in previous years.

All respondents will be required to submit information covering their December 31, 1977 inventories of 30 canned and bottled vegetables, fruits, juices, and fish. Reports will not be required from all firms, but will be limited to a scientifically selected sample of wholesalers and retail multiunit organizations handling canned foods in order to provide, with measurable reliability, year-end inventories of the specified canned food items. These stocks will be measured in terms of actual cases, with separate data requested for "all sizes smaller than No. 10" and for "sizes No. 10 or larger." (In addition, multiunit firms reporting separately by establishment will be requested to update the list of their establishments maintaining canned food stocks.)

Report forms will be furnished to firms covered by the survey. Copies of the forms are available on request to the Director, Bureau of the Census, Washington, D.C. 20233.

I have, therefore, directed that this annual survey be conducted for the purpose of collecting these data.

Dated: November 17, 1977.

MANUEL D. PLOTKIN,
Director, Bureau of the Census.

[FR Doc. 77-33565 Filed 11-21-77; 8:45 am]

[3510-07]

Bureau of the Census

SURVEY OF 1977 RECEIPTS, CAPITAL EXPENDITURES, FIXED ASSETS, PAYROLL AND OTHER OPERATING EXPENSES FOR SELECTED SERVICE INDUSTRIES

Determination

In accordance with title 13, United States Code, sections 131, 193, 195, 224, and 225 and with due notice of consideration having been published October 11, 1977 (42 FR 54851), I have determined that certain 1977 data for selected service industries are needed to provide a sound statistical basis for the formation of policy by various governmental agencies and are also applicable to a variety of public and business needs. This survey is a continuation of similar ones conducted in the past (the last was for the 1972 data year) and will make available on a comparable basis data covering capital expenditures, fixed assets and some operating expenses. These data are not publicly available on a timely basis from public or governmental sources.

Reports will be required from a sample of service firms in the United States. The sample will provide, with measurable reliability, statistics on the aforementioned subjects. Reports will be requested from all mail panel cases and three panels of area sample cases in the Bureau's current monthly survey of selected services.

Report forms will be mailed to the firms included in the survey and will be due 20 days after they are received. Copies of the forms are available upon written request to the Director, Bureau of the Census, Washington, D.C. 20233.

I have, therefore, directed that the survey be conducted in 1978 for the purpose of collecting these data.

Dated: November 17, 1977.

MANUEL D. PLOTKIN,
Director, Bureau of the Census.

[FR Doc. 77-33585 Filed 11-21-77; 8:45 pm]

[3510-25]

Domestic and International Business Administration

UNIVERSITY OF LOUISVILLE, 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, Special Import Programs Division, Office of Import Programs, Washington, D.C. 20230, on or before December 12, 1977.

Amended regulations issued under cited Act (15 CFR Part 301) prescribe the requirements applicable to comments.

A copy of each application is on file, and may be examined during ordinary Commerce Department business hours at the Special Import Programs Division, Department of Commerce, Washington, D.C. 20230.

Docket No. 78-00023. Applicant: University of Louisville, 2301 South Third Street, Louisville, Ky. 40208. Article: Complete Bat Detector Kit. Manufacturer: OMC Instruments, Ltd., United Kingdom. Intended use of article: The article is intended to be used for the identification and investigation of ultrasonic sound emissions of bats. In addition, the article will be used to train graduate students in the course "Methods in Anatomy." Application received by Commissioner of Customs: October 27, 1977.

Docket No. 78-00025. Applicant: NASA Headquarters, Washington, D.C. 20546. Article: Rank Mark-I Microelectrophoresis Apparatus and Accessories. Manufacturer: Rank Bros., United Kingdom. Intended use of article: The article is intended to be used for free fluid electrophoresis of particles, and will provide ground baseline particle mobility data for zero-gravity space processing applications. Application received by Commissioner of Customs: October 28, 1977.

Docket No. 78-00026. Applicant: National Aeronautics and Space Administration Headquarters, Contracts Divi-

sion, Code JHC-4, Washington, D.C. 20546. Article: Three (3) Dynamic Flowmeters. Manufacturer: O.N.E.R.A., France. Intended use of article: The article is intended to be used to ascertain the oscillatory flow component of liquid oxygen perturbated by a positive displacement pulser as it flows through a turbopump. The accurate determination of the flow disturbance, both upstream and downstream of the turbopump are essential in the use of the four terminal network method for establishing the transfer function characteristics of the turbopump and subsequently the Space Shuttle Main Engine System. The determination of the transfer functions is essential in the definition of the Space Shuttle Vehicle dynamic characteristic relative to the Pogo phenomenon. Application received by Commissioner of Customs: October 28, 1977.

Docket No. 78-00027. Applicant: University of Minnesota, Department of Chemistry, 207 Pleasant Street SE., Minneapolis, Minn. 55455. Article: Programmable Circulating Thermostat, Model CT-C, with accompanying accessory pump unit, Model PC-B. Manufacturer: Sodev, Inc., Canada. Intended use of article: The article is intended to be used in the investigation of the temperature dependence of the rates of hydrolysis of a congener series of aliphatic amino acid esters by the enzyme α-chymotrypsin. The temperature dependence will reveal the underlying thermodynamic parameters that provide a physical description of the catalytic process. The objective of this investigation is to gather the precise data necessary to extract the free energies, enthalpies and entrophies of activation of the various rate constants involved in the catalytic process at high enough level of accuracy and precision that a detailed mechanistic interpretation is possible. Two types of experiments to be conducted involve: (1) Measurement of reaction progress curves at a set of fixed temperatures, and (2) measurement of initial rates of reaction in a temperature scanning mode. Application received by Commissioner of Customs: October 27, 1977.

Docket No. 78-00030. Applicant: The Medical College of Pennsylvania, 3300 Henry Avenue, Philadelphia, Pa. 19129. Article: Electron Microscope, Model JEM-100S. Manufacturer: JEOL, Ltd., Japan. Intended use of article: The article is intended to be used for the study of developing and regenerating brain and virus-infected cells. The ultrastructural changes of neurons during development and the ultrastructure modifications of single cells infected with virus will be studied. Experimental modifications of the developing and mature brain and drug treatments of virus-infected cells will be followed by study of the brain and cells with the article. The article will also be used to train graduate and medical students in the use of the electron microscope in the course "Anatomical Techniques in Biological Research." Application received by Commissioner of Customs: October 28, 1977.

Docket No. 78-00031. Applicant: Washington University School of Medicine, 660 South Euclid Avenue, St. Louis, Mo. 63110. Article: Ultrahigh Resolution Scanning System, ASID-4 with accessories. Manufacturer: JEOL, Ltd., Japan. Intended use of article: The article is an accessory to an existing electron microscope that will be used for continuation of investigations of the mechanism of action of insulin in adipocytes from its initial binding to the hormone receptor on the plasma membrane through and including its alteration of lipolysis, protein synthesis, calcium binding and distribution, plasma membrane ATPase activity and membrane phosphorylation. Application received by Commissioner of Customs: October 28, 1977.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Special Import Programs Division.

[FR Doc. 77-33580 Filed 11-21-77; 8:45 am]

[3510-24]

Economic Development Administration

WOLVERINE WORLD WIDE, INC.

Petition for a Determination of Eligibility To Apply for Trade Adjustment Assistance

A petition by Wolverine World Wide, Inc., 9341 Courtland Drive, Rockford, Mich. 49341, a producer of footwear for men, women, and children, was accepted for filing on November 11, 1977, pursuant to section 251 of the Trade Act of 1974 (Pub. L. 93-618) and § 315.23 of the Adjustment Assistance Regulations for Firms and Communities (13 CFR Part 315). Consequently, the U.S. Department of Commerce has initiated an investigation to determine whether increased imports into the United States of articles like or directly competitive with those produced by the firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of the petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Chief, Trade Act Certification Division, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

JACK W. OSBURN, Jr.,
Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc. 77-33581 Filed 11-21-77; 8:45 pm]

[3510-03]

Maritime Administration

[Docket No. S-583]

PRUDENTIAL LINES, INC.

Application

Notice is hereby given that Prudential Lines, Inc., One World Trade Center, Suite 3601, New York, N.Y. 10048, has filed an application dated November 7, 1977, for a 1-year operating-differential subsidy agreement (ODSA) pursuant to Title VI (46 U.S.C. 1171-1183) of the Merchant Marine Act, 1936, as amended, to provide the same services on Trade Routes (TR) 2, 4, 10, and 23, 24, 25, as Prudential currently provides under its existing ODSA, Contract No. FMB-49. If this application is granted, the one-year contract will begin upon the termination of Prudential's present ODSA, Contract No. FMB-49, currently due to expire on December 31, 1977, and will run until the earlier of (1) December 31, 1978, including voyages in progress on that date, or (2) completion of the administrative processing of Prudential's application for a 20-year ODSA (Docket S-465) to replace Contract No. FMB-49.

The number of vessels, service descriptions, and sailing maxima under the proposed 1-year contract are the same as in Prudential's existing contract. Service will be provided with four LASH, ten C4s and four C4 Combo vessels as follows:

Service	Sailing maximum
TR 2 (U.S. Atlantic/West Coast South America)	62
TR 4 (U.S. Atlantic/Caribbean)	40
TR 10 (U.S. North Atlantic/Mediterranean, including Portugal and Atlantic Spain south of Portugal—TR 10 service also includes certain TR 13 ports)	50
TRs 23, 24, 25 (U.S. Pacific/Atlantic and Pacific Coasts of South America, Mexico, Canal Zone, and Caribbean)	42

Interested parties may inspect this application in the Office of the Secretary, Maritime Subsidy Board, Room 3099B, Department of Commerce Building, 14th and E Streets NW., Washington, D.C. 20230.

Any person having an interest in such application who desires to offer views and comments thereon for consideration by the Maritime Subsidy Board should submit them in writing, in triplicate, to the Secretary, Mari-

time Subsidy Board, Washington, D.C. 20230, by the close of business on November 30, 1977.

The Maritme Subsidy Board will consider these views and comments, and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 11.504, Operating-Differential Subsidies (ODS).)

By Order of the Maritime Subsidy Board/Maritime Administration.

Date: November 18, 1977.

JAMES S. DAWSON, Jr.,
Secretary.

[FR Doc. 77-33673 Filed 11-21-77; 8:45 am]

[3510-12]

National Oceanic and Atmospheric Administration

COASTAL ZONE MANAGEMENT

Public Hearings on Draft Environmental Impact Statement

Notice is hereby given that the Office of Coastal Zone Management, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, will hold public hearings for the purpose of receiving comments on the draft environmental impact statement for the Coastal Management Program of the State of Michigan.

The hearings will be held on Tuesday, December 13, 1977, in the Peninsula Room of the Ramada Inn in Marquette, Mich., and on Wednesday, December 14, 1977, at Northwestern Michigan College in Room S-217 of the Science Building in Traverse City, Mich. The final hearing will be held on Thursday, December 15, 1977, at the Michigan Department of Public Health in the Roy Manty Conference Room of the Baker/Olin Building in Lansing, Mich. Each of the hearings will be from 7 to 10 p.m.

The views of interested persons and organizations are solicated. These may be expressed orally or in written statements.

Presentations will be scheduled on a first-come, first-served basis, but may be limited to a maximum of ten minutes or as otherwise appropriate. Priority will be given to those with written statements. Time will be available at the end of the meeting for persons without statements to present their views orally. The Office of Coastal Zone Management staff may question any speaker following presentation of his/her statement. No verbatim transcript of the hearing will be maintained, but staff present will record the general thrust of the remarks.

Persons or organizations wishing to be heard on this matter should contact the Office of Coastal Zone Management as soon as possible so that an appearance schedule may be drawn up and definite times established for presentations. Please contact:

June Cradick, National Oceanic and Atmospheric Administration, Office of Coastal Zone Management, 3300 Whitehaven Street NW., Washington, D.C. 20235, phone 202-634-4242.

Written comments may also be submitted by mail to the Office of Coastal Zone Management. Such comments should be received before January 3, 1978, to assure adequate consideration for inclusion in the final environmental impact statement.

Copies of the draft environmental impact statement may be obtained by contacting the Office of Coastal Zone Management or:

Mr. Chris Shafer, Coastal Zone Management Program, Department of Natural Resources, Division of Land Use Programs, Stephen T. Mason Building, Lansing, Mich. 48926.

Copies of this draft environmental impact statement are available for public review at all planning and development regional agencies and Department of Natural Resources regional and district offices in the State of Michigan.

Comments may address the adequacy of the impact statement and/or the nature of the Michigan Coastal Management Program.

Following consideration of the comments received at these hearings, as well as written comments submitted, the Office of Coastal Zone Management will prepare the final environmental impact statement pursuant to the National Environmental Policy Act of 1969 and implementing guidelines.

Dated: November 16, 1977.

T. P. GLEITER,
Assistant Administrator for Administration.

[FR Doc. 77-33577 Filed 11-21-77; 8:45 am]

[3510-17]

Office of the Secretary

PRIVACY ACT OF 1974

Adoption of Additional Systems of Records

The purpose of this notice is to adopt in final form 2 additional systems of records, one for Commerce's National Bureau of Standards, and the other for the White House Conference on Balanced National Growth and Economic Development.

1. On August 1, 1977, the Department of Commerce gave notice (42 FR 38928) that it proposed to adopt an additional system of records for the National Bureau of Standards, entitled Participants in Experiments, Studies, and Surveys—Commerce/NBS-9.

The purpose of information in this system is to provide research data to develop findings or recommendations. This system encompasses all participants in NBS experiments. It is a consolidation of three previously noticed NBS systems and is an extension of the categories of participants covered in those three systems, by the substitution of general provisions for the more particular provisions of those three systems. The routine uses of these records were expanded to allow information in this system to be disclosed to Federal agencies and other outside organizations which have sponsored the research in connection with which the data were obtained.

The three previously noticed systems (Commerce/NBS-4, Participants in Clinical Dental Projects; Commerce/NBS-5, Participants in Human Factors Studies; and Commerce/NBS-6, Participants in Psychoacoustic Experiments) are now deleted, effective with the date of this notice.

A new system report, dated July 22, 1977, was submitted to the Office of Management and Budget and the Congress as required by the Privacy Act. Interested persons were invited to submit written data views, or arguments on or before August 31, 1977. No comments were received in response to the notice.

Therefore, the Department adopts the additional system effective October 1, 1977. Because the complete text of the new system was published in the FEDERAL REGISTER on September 21, 1977, page 47714, as part of the Department's annual republication of all Privacy Act systems of records, and the system is adopted without change, there is no need to republish at this time. The September 21, 1977, republication document should be annotated on pages 47684 (table of contents) and 47712-13 (system descriptions) to indicate that Commerce/NBS-4, -5, and -6 are now deleted.

2. On September 7, 1977, the Department of Commerce gave notice (42 FR 44832) that it proposed to adopt a system of records for the White House Conference on Balanced National Growth and Economic Development, entitled Mailing List and Correspondence File—Commerce/WHC-1.

The purpose of this system is to develop a mailing list and correspondence file which will help obtain the broadest possible interest and participation in the Conference. This Conference, authorized by Pub. L. 94-487, Title II, October 12, 1976, and Pub. L. 95-31, Title II, May 23, 1977, is to develop recommendations for further action toward balanced national growth and economic development and to take account of present economic conditions and trends. The Department of Commerce has been designated by the President as the lead

agency in planning and conducting the Conference.

A new system report, dated August 30, 1977, was submitted to the Office of Management and Budget and the Congress as required by the Privacy Act. The Department requested the Office of Management and Budget to waive the 60-day advance notice requirement for this system. The waiver was granted by OMB in a letter dated September 28, 1977. Interested persons were invited to submit written data views, or arguments on or before October 7, 1977. No comments were received in response to the notice.

Therefore, the Department adopts the additional system effective October 7, 1977. Because the complete text of the new system was published in the FEDERAL REGISTER on September 21, 1977, page 47729, as part of the Department's annual republication of all Privacy Act systems of records, and the system is adopted without change, there is no need to republish at this time.

AUTHORITY: 5 U.S.C. 552a, sec. 3, Privacy Act of 1974 (Pub. L. 93-579, 88 Stat. 1896).

Dated: November 11, 1977.

GUY W. CHAMBERLIN, Jr.
Acting Assistant Secretary for Administration.

[FR Doc. 77-33672 Filed 11-21-77; 8:45 am]

[3128-01]

DEPARTMENT OF ENERGY

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF EXCEPTIONS AND APPEALS OF THE FEDERAL ENERGY ADMINISTRATION

Week of September 19 Through September 23, 1977

Notice is hereby given that during the week of September 19 through September 23, 1977, the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Exceptions and Appeals of the Federal Energy Administration. The following summary also contains a list of submissions which were dismissed by the Office of Exceptions and Appeals and the basis for the dismissal. On October 1, 1977, the Office of Administrative review of the Department of Energy's Economic Regulatory Administration assumed the responsibilities which had previously been exercised by the FEA Office of Exceptions and Appeals.

APPEALS

Cabot Corp., Washington, D.C., FXA-1323 through FXA-1327, natural gas liquids

Cabot Corp. filed an Appeal from a Decision and Order, which the FEA issued to it on April 19, 1977. *Cabot Corp.*, Case Nos. FEE-3926 through FEE-3930 (decided Apr. 19, 1977) (unreported decision). In that Decision, the FEA granted in part five Applications for Exception which Cabot had filed from the provisons of 10 CFR 212.165. As a result of the approval of the exception relief Cabot was permitted to increase its selling prices for the natural gas liquid products and natural gas liquids (NGL's) which it produces at five natural gas processing plants during the period April 19, 1977, through September 30, 1977. The Cabot Appeal, if granted, would have permitted the firm to increase the prices it charges for NGL's to reflect increased depreciation costs which the firm has incurred. In its Appeal, Cabot contended that the April 19, 1977, Decision and Order is erroneous in fact and in law because of the exclusion of depreciation expenses from the FEA's calculation of nonproduct cost increases. In support of this contention, Cabot argued that since the applicable regulations now permit refiners to reflect increased depreciation costs in their prices for NGL's on a dollar-for-dollar basis, the FEA should similarly permit natural gas processors to reflect increased depreciation costs in the prices which they charge for NGL's. In considering the Cabot Appeal, the FEA noted that the regulatory standards which are aplicable to one segment of the petroleum industry are not necessarily automatically applicable to other segments of the petroleum industry through the exceptions process. The FEA therefore determined that Cabot's argument in this regard did not by itself lead to the conclusion that the April 19 Appeal is erroneous. In addition, the FEA observed that the considerations which led it to adopt the general principle of excluding depreciation expenses in this type of case did not appear to be significantly affected by the fact that the price regulations applicable to crude oil refiners now permit the pass-through of increased depreciation expenses. Nevertheless, the FEA stated that it would consider departing from this general principle when a strong showing was made that the increased depreciation expenses per unit of output experienced by a firm are attributable to new capital investment at a particular gas plant instead of declining production. Since Cabot failed to make any such showing, its Appeal was denied.

Exxon International Co., New York, N.Y., FFA-1441, freedom of information

Exxon International Co. appealed from a denial by the FEA Information Access Officer of a Request for Information which the firm had filed under the Freedom of Information Act (the Act). In its initial request, Exxon sought data concerning the monthly purchases of aviation gasoline by each of 40 specified airlines at 17 airports during 1976. The FEA Information Access Officer determined that 43 copies of Forms FEO-17 (Applications for Assignment or Adjustment of Base Period Supply Volume) contained data which was responsive to Exxon's request but withheld all of the documents on the ground that they contained confidential commercial and financial information which was exempt from mandatory disclosure under section 552(b)(4) of the Act. In its Appeal, Exxon contended that much of the Information which it sought is already in the public domain and the release of the remaining information would not injure the competitive position of any airline concerned.

In considering the Exxon Appeal, the FEA determined that the public release of the information requested by Exxon could result in competitive injury to the airlines involved. The FEA also determined that although some related information had been published by certain government and industry organizations, the type of data which would disclose the detailed information which Exxon requested has not been published. The FEA therefore concluded that the data which Exxon had requested constituted the type of commercial information which should be treated as confidential for purposes of Exemption 4 of the Act and that its release would not be in the public interest. Accordingly, the Exxon Appeal was denied.

Mobil Oil Corp., Los Angeles, Calif., FXA-1183; Texaco, Inc., Los Angeles, Calif., FXA-1220; Gulf Oil Corp., Houston, Tex., FXA-1222, motor gasoline

The Mobil Oil Corp., Texaco, Inc., and the Gulf Oil Corp. filed Appeals from a Decision and Order which the Federal Energy Administration issued to the Ashland Oil Co. of California on January 14, 1977. *Ashland Oil Co. of California*, 5 FEA Par. 83,038 (January 14, 1977). Pursuant to the January 14 Decision and Order, the Regional Administrator of FEA Region IX assigned Mobil, Texaco, and Gulf to supply certain volumes of motor gasoline to Ashland to replace equivalent volumes of motor gasoline which Ashland would otherwise have been entitled to receive from its principal base period supplier, Coastal States Gas Producing Company (Coastal States). The firm's Appeals, if granted, would result in an order vacating the January 14 Order. In considering the Appeals in a consolidated proceeding, the FEA determined that the appellants failed to submit any factual material which indicated that the level of exception relief afforded to Ashland was excessive or that the FEA had erred in finding that the exception relief was necessary to prevent Ashland from incurring a serious financial hardship. With respect to Gulf's claim that it was improper for the FEA to require Gulf to supply Ashland in view of Gulf's prior sale of the Hercules, California refinery to Coastal States, the FEA found that this claim should be properly raised in an Appeal of the Assignment Order. Based on these findings, the FEA denied the Appeals.

Quaker State Oil Refining Co., Oil City, Pa., FXA-1264, crude oil

Quaker State Oil Refining Co. filed an Appeal from a Decision and Order which the FEA issued to it on March 18, 1977. *Quaker State Oil Ref. Co.*, 5 FEA Par. 83,107 (March 18, 1977). In the March 18 Order the FEA denied the firm's request for exception relief from 10 CFR 211.67 (the Old Oil Entitlements Program). The Appeal, if granted, would have resulted in the issuance of additional entitlements to Quaker State to compensate it for the relatively high cost which it incurs for purchasing stripper well crude oil. In considering the Appeal, the FEA held that Quaker State was not experiencing a gross inequity since the firm had failed to establish that its operations were significantly and adversely affected by the manner in which the Entitlements Program applied to its crude oil cost structure. The FEA also determined that Quaker State was not encountering the type of financial difficulties which led to the issuance of additional entitlements in *Commonwealth Oil Refining Co., Inc.*, 5 FEA Par. 83,132 (April 14, 1977). Accordingly, the Quaker State Appeal was denied.

Sun Co., Inc., Dallas, Tex., FXA-1289, FXA-1290, FXA-1291, FXA-1292, FXA-1293, FXA-1294, FXA-1295, FXA-1296, FXA-1297, FXA-1298, FXA-1299, FXA-1300, FXA-1301, FXA-1302, FXA-1303, FXA-1304, FXA-1305, FXA-1306, FXA-1307, FXA-1308, natural gas liquids, natural gas liquid products

The Sun Co., Inc., filed and Appeal from a Decision and Order which the FEA issued to it on April 4, 1977. Under the terms of the April 4 Decision, the FEA granted an extension of the exception relief previously approved which permitted Sun to increase its maximum allowable prices for natural gas liquids and natural gas liquid products calculated pursuant to 10 CFR 212.165 to reflect certain nonproduct cost increases which it incurred at 18 natural gas processing plants which it owns. Sun's request for an extension with respect to four other plants was denied. Sun's Appeal, if granted, would have permitted it to further increase its selling prices based on a recalculation of the per unit increase in non-product costs incurred by 20 of the plants involved in the prior proceeding. In the April 4 Decision the FEA calculated the non-product unit cost increase for each of the plants by comparing Sun's non-product costs on May 15, 1973, with data for the six month period ending December 31, 1976. In its Appeal, Sun contended that the fiscal quarter ending December 31, 1976, should have been utilized for purposes of comparison with May 15, 1973, cost levels instead of the six month period ending on December 31, 1976. In considering the Appeal, the FEA observed that the cases which Sun cited in support of its Appeal did not support the contention that the FEA must use data for only the most recent fiscal quarter in determining the extent of a particular plant's increased non-product costs. In this regard, the FEA found that although the FEA generally uses data for the most recent fiscal quarter in initial requests for exception, this policy does not govern all requests for extension of exception relief previously granted. In particular, the FEA found that in cases where exception relief had been granted for a period of five to six months, as in the Sun case, financial and operating data is available for two additional fiscal quarters and this data should be used in analyzing a subsequent request for an extension of exception relief. Moreover, the FEA noted that the exception relief which was approved was not intended to insure the immediate recovery of all non-product costs incurred by the firm. Accordingly, Sun's Appeal was denied.

Texaco, Inc., Tulsa, Okla., FEA-1221, motor gasoline

Texaco, Inc., filed an Appeal of an Assignment Order which was issued to the LaBrue Oil Co. by FEA Region VI on January 20, 1977. In the Assignment Order, Region VI assigned LaBrue as the base period suppliers of the Lamont Texaco station, a new retail sales outlet in Lamont, Okla. Pursuant to the January 20 Order, Texaco was required to furnish LaBrue with an increased volume of motor gasoline for Lamont Texaco under the upward certification procedure of 10 CFR 211.13(c). The Texaco Appeal, if granted, would result in a rescission of the Assignment Order. In considering the Appeal, the FEA rejected Texaco's claim that it should not have been required to supply LaBrue with motor gasoline for the benefit of Lamont Texaco since it was an unwilling supplier. In this regard, the FEA found that LaBrue rather than Texaco was the actual supplier of Lamont Texaco and was willing to accept the increased supply obligation. Moreover, the FEA found that Texaco failed to demonstrate that its overall supply obligation would be adversely affected to any significant degree by the requirement that it supply LaBrue with the additional volumes of motor gasoline. The FEA also rejected Texaco's contention that the Assignment Order failed to provide it with a satisfactory statement of its legal basis since the order referred to the regulatory provisions which were clearly applicable. However, with respect to Texaco's contention that the order lacked a satisfactory factual basis, the FEA found that the Regional Office had not considered the Lamont Texaco assignment application in light of FEA Ruling 1976-5. Accordingly, the Texaco Appeal was granted in part and the Assignment Order was remanded for further findings.

PETITION FOR SPECIAL REDRESS

V-1 Oil Co., Idaho Falls, Idaho, FSG-0053, FES-0098, propane

V-1 Oil Co. filed a Petition for Special Redress which, if granted, would have resulted in the issuance of an order rescinding a Special Report Order tha FEA Region V issued to the firm on May 5, 1977. V-1 also requested a stay of the provisions of the Special Report Order pending a final determination of its Petition. In considering the V-1 Petition, the FEA noted that section 210.91(d) of the FEA Regulations sets forth criteria governing the review by the Office of Private Grievances and Redress of a Petition in which a firm seeks to rescind a Special Report Order. That Section provides that a preliminary review of the Petition will be made in order to determine whether a reasonable probability exists that the petitioner will be able to satisfy the criteria for relief. If it determines that a Petition might satisfy those critieria, the Petition will be considered on its merits. On the other hand, if the determination is made that the Petition fails to meet this threshold standard, the Petition will be dismissed. See 41 FR 55322 (December 20, 1976). Upon review of the contentions which V-1 advanced in its Petition, the FEA concluded that V-1 had failed to demonstrate a reasonable probability that it could show circumstances so exceptional that an immediate review was warranted to correct substantial errors of law, to prevent substantial injury to legal rights, or to cure a gross abuse of administrative discretion. The V-1 Petition was therefore dismissed and its Application for stay was denied.

SUPPLEMENTAL ORDERS

Ingram Corp., A. Johnson & Co., Inc., Washington, D.C., FEX-0190, motor gasoline

On August 31, 1977, the Federal Energy Adminstration issued a Decision and Order to the Ingram Corporation (Ingram) and A. Johnson and Co., Inc. (Johnson) in which it granted various types of relief which were designed to facilitate the acquisition by Johnson of an interest in a refinery which previously had been operated by Ingram in Wilmington, N.C. (the Wilmington refinery). Ingram Corp.; A. Johnson & Co., Inc., 6 FEA par. ———— (August 31, 1977). With respect to the position of Ingram and Johnson under the FEA Mandatory Oil Import Program, the FEA found that Ingram should be granted a refund of certain import license fees which it paid for crude oil runs to stills at the Wilmington refinery. Subsequently, it came to the attention of the FEA that the method specified in the August 31 Order for making the refunds to Ingram would be unduly burdensome for the Office of Oil Imports, and that the same objective could be achieved in a more efficient manner. Accordingly, the FEA on its own motion modified the provisions of the August 31 Order which specify the manner in which refunds will be made to Ingram.

Little America Refining Co., Evansville, Wyoming, FEX-0192, crude oil

On September 19, 1977, the FEA issued a Proposed Decision and Order to the Little America Refining Company in accordance with new procedures that are applicable to Applications for Exception. In the Proposed Decision and Order, the FEA determined that the projected impact of LARCO's purchase obligations under the Entitlements Program, beginning in the month of September 1977, would prevent the firm from attaining either its historical profit margin or its historical return on invested capital. The FEA therefore concluded that LARCO should be granted exception relief that would reduct by $7,416,392 per month the firm's obligation to purchase entitlements to account for its crude oil receipts during the period July through December 1977. Under the new procedures being applied to the LARCO exception proceeding, the exception relief specified in the Proposed Decision and Order would not become effective until after the July 1977 Entitlement Notice was published by the FEA during the month of September 1977. In view of the tentative determination reached by the FEA in the September 19 Proposed Decision and Order that LARCO's entitlement purchase obligation should be reduced by $7,416,392 commencing with the entitlement notice published in September 1977, the FEA on its own motion determined that in order to prevent an immediate hardship to LARCO, the firm's obligation to purchase entitlements as set forth in the Entitlements Notice which is published in the month of September 1977 should be reduced by $7,416,392 until the conclusion of the pending exception proceeding.

SUMMARY DECISIONS

The FEA Office of Exceptions and Appeals has issued a Decision and Order rescinding a Stay which had been granted to the following firm after a finding was made that the firm had failed to comply with the express conditions of the Stay Order:

Farmers Gas & Oil Co., Ithaca, Mich., FRX-0187

The following firms filed Applications for Stay of Remedial Orders which the FEA issued to the respective firms. In considering the stay requests, the FEA referred to a recent Decision in Rickelson Oil & Gas Co., 6 FEA par. ———— (August 24, 1977), in which it held that a Remedial Order will generally be stayed pending the determination of an Appeal unless it appeared that the public interest required immediate compliance with the Remedial Order. Since the record in these cases did not indicate that the public interest required immediate compliance with the Remedial Orders, the FEA granted the requests for stay pending consideration of the Appeals.

I.U. International Oil & Gas, Inc., Plymouth Meeting, Pa., FRS-1468

James A. Leonard, Austin, Tex., FRS-1476

New York Petroleum Corp., Washington, D.C., FRS-0108

Wilson Oil Co., Wabasha, Minn. FRS-1442

DISMISSALS

The following submission was dismissed following a statement by the applicant indicating that the relief requested was no longer needed:

Etna Oil Co., Washington, D.C., FPI-0127

The following submission was dismissed for failure to correct deficiencies in the firm's filing as required by the FEA Procedural Regulations:

Sabre Refining, Inc., Bakersfield, Calif., FES-0105

The following submission was dismissed on the ground that alternative regulatory procedures existed under which relief might be obtained:

Beatrice Foods Co., Chicago, Ill., FMR-0122

The following submission was dismissed on the grounds that the firm failed to meet the filing requirements of the FEA Procedural Regulations:

Farmers Gas & Oil Co., Ithaca, Mich., FRR-0125

Copies of the full text of these Decisions and Orders are available in the Public Docket Room of the Office of Administrative Review, room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.s.t., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

MELVIN GOLDSTEIN,
Acting Director,
Office of Administrative Review.

NOVEMBER 16, 1977.

[FR Doc. 77-33563 Filed 11-21-77; 8:45 am]

[3128-01]

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF EXCEPTIONS AND APPEALS OF THE FEDERAL ENERGY ADMINISTRATION

Week of September 26 through September 30, 1977

Notice is hereby given that during the week of September 26 through September 30, 1977, the Decisions and Orders summarized below were issued with respect to Appeals and Applications for Exception or other relief filed with the Office of Exceptions and Appeals of the Federal Energy Administration. The following summary also contains a list of submissions which were dismissed by the Office of Exceptions and Appeals and the basis for the dismissal. On October 1, 1977, the Office of Administrative Review of the Department of Energy's Economic Regulatory Administration assumed the responsibilities which had previously been exercised by the FEA Office of Exceptions and Appeals.

APPEALS

Adams Oil Co., Inc., Dillwyn, Va., FRA-1267, Petroleum products

Adams Oil Co., Inc., appealed from a Remedial Order which FEA Region III issued to the firm on April 4, 1977. In the Remedial Order, the FEA determined that Adams had sold gasoline, diesel fuel, kerosene, and No. 2 fuel oil at prices in excess of those permitted under 6 CFR 150.359 and 10 CFR 212.93. In order to remedy the violations cited, Adams was directed to make refunds to the customers which it allegedly overcharged. In its Appeal, Adams contended that the overcharge computations made by the FEA were inaccurate, but that the firm was unable to submit documentation in support of its position because it had been unable to obtain the FEA's workpapers used in computing the overcharges. Upon review of the information contained in the NOPV and the Remedial Order which were issued to Adams, the FEA concluded that Adams was not given sufficient factual information which would have permitted it to verify the accuracy of the FEA's calculations of overcharges and submit a meaningful appeal of the Remedial Order. The FEA therefore remanded the Remedial Order to FEA Region III for further consideration and directed the Regional Administrator to release to Adams all workpapers which set forth the basis for the amount of the alleged overcharges which were found to exist.

C.A.C.I., Arlington, Va., FFA-1453, Freedom of information

C.A.C.I. appealed from a partial denial by the Information Access Officer of a request for information which the firm submitted under the Freedom of Information Act (the Act). In its request for information, C.A.C.I. sought copies of various records in connection with Contract No. CR-06-70084. Pursuant to the provisions of 5 U.S.C. 552(b)(4) the Information Access Officer withheld from disclosure substantial portions of one document which was responsive to C.A.C.I.'s request for information. That document was a technical proposal submitted by Cexec, Inc. (Cexec) in response to FEA Request for Proposal No. 70002. In the Order which was issued to C.A.C.I., the Information Access Officer stated that release of the material involved could cause substantial harm to the competitive position of Cexec. In its Appeal, C.A.C.I. contended that the Information Access Officer's Order failed to state with sufficient particularity the grounds upon which the material at issue was deleted. In considering C.A.C.I.'s Appeal, the FEA determined that the Information Access Officer's Order did not contain any justification for the conclusion that release of the technical proposal could result in substantial harm to Cexec's competitive position. The FEA held that in the absence of a justification of this type an agency could not withhold a document from disclosure under 5 U.S.C. 552(b)(4). The FEA also noted that a party could not be expected to specify the grounds upon which its appeal is brought if it has no knowledge of the basis for the conclusion reached in the disputed Order. As a result of these determinations, the FEA remanded the matter to the Information Access Officer for issuance of a further Order which specifies the nature and extent of the competitive injury that Cexec could incur if the technical proposal were released.

Kern County, Refinery, Inc., Cerritos, Calif., EXA-1211, crude oil

Kern County Refinery, Inc., filed an Appeal from a Decision and Order which the FEA issued to the firm on December 15, 1976. Kern County Refinery, Inc., 4 FEA Par. 83,246 (December 15, 1976). In the December 15 Order, the FEA granted kern's Application for Exception from the provisions of 10 CFR 211.67 (the Old Oil Entitlements Program). Under the terms of that Decision, Kern was relieved of any obligation to purchase entitlements. The Kern Appeal, if granted, would have resulted in an adjustment to the historical level of profitability which was used in determining the level of exception relief granted to Kern. The effect of the Appeal, if granted, would have been to increase the level of profitability which Kern would be permitted to realize while still qualifying for exception relief. In considering the Kern request, the FEA stated that as a general rule it does not permit adjustments to the level of profitability reported by a firm during the seven years used for an historical index in determining whether exception relief from the Entitlements Program is warranted. Specifically, the FEA found that Kern had failed to meet the strict criteria established in previous Decisions for adjustments to the profitability reported by the firm during the seven historical years. Therefore Kern's Appeal was denied.

McClure Oil Co. et al., Oklahoma City, Okla., FRA-1359, refined petroleum products

J. C. and J. H. McClure, d.b.a., McClure Oil Co., et al. (McClure), appealed from a Remedial Order which the Deputy Regional Administrator of (FEA) Region VI issued to the firm on June 2, 1977. The Remedial Order determined that during the period November 1, 1973, through March 31, 1974, McClure sold propane, diesel fuel, and motor gasoline at prices which exceeded the maximum permissible price levels specified in 6 CFR 150.359 and 10 CFR 212.93. In considering McClure's Appeal, the FEA noted that the firm's primary contention was that the FEA failed to provide the firm with sufficient information either during the course of the compliance proceeding which led to the issuance of the Remedial Order or in the Remedial Order itself to enable the firm to understand the nature and basis of the charges against it and to respond to those charges on Appeal. In rejecting this contention, the FEA noted that the Notice of Probable Violation (NOPV) which was issued to McClure on August 18, 1976 contains a set of workpapers which include detailed computations for each covered product of: McClure's May 15, 1973 selling price to each class of purchaser; McClure's weighted average unit cost of product in inventory on May 15, 1973; McClure's increased costs during the audit period; the firm's maximum allowable selling prices; and a comparison between those prices and the prices which McClure actually charged. The FEA determined that the workpapers appear to contain sufficiently detailed material to reveal the methodology which the FEA used in making its calculations and to

identify the data upon which it based these calculations. The FEA noted that McClure had not attempted to challenge the validity of the FEA's calculations in any way. The FEA also found that contrary to McClure's contention, the FEA had stated in both the NOPV And in the workpapers that specific assumptions which it used in making its calculations. The FEA further concluded that the findings in the NOPV with respect to McClure's failure to maintain records in violation of 10 CFR 210.92 were sufficiently detailed and specific to apprise McClure as to what records were lacking. The FEA also determined that the Regional Office had not abused its discretion by denying McClure's request for a conference in connection with the NOPV. Finally, the FEA determined that the Remedial Order itself contained sufficient findings to enable McClure to formulate a meaningful Appeal. On the basis of the foregoing considerations, the FEA denied McClure's Appeal.

National LP-Gas Association; National Committee on Propane Allocation and Price Regulation, Arlington, Va., FEA-1288, propane

The National LP-Gas Association and the National Committee on Propane Allocation and Price Regulation (NLPGA) appealed from a Decision and Order which the FEA Office of Regulatory Programs issued to Ashland Petroleum Co. (Ashland) on April 6, 1977. The April 6 Order assigned Ashland a base period use of propane which the firm may utilize to increase the British thermal unit (Btu) heat value of the synthetic natural gas (SNG) Which it produces at its Buffalo, N.Y. SNG plant. In considering the NLPGA Appeal, the FEA determined that the use of propane for Btu enrichment was an "industrial use" and therefore concluded the Ashland submission had been properly evaluated under the standards for assignment set forth in 10 CFR, Part 211, Subpart D, and Part 205, Subpart C. Based on these considerations, the FEA denied the NLPGA Appeal.

Northern Illinois Gas Co., Chicago, Ill., FEA-1339 natural gas liquids

Northern Illinois Gas Co. (NI-Gas) appealed from a Decision and Order which the FEA Office of Regulatory Programs issued to the firm on April 26, 1977. The April 26 Order modified and extended for an additional six-month period previous FEA Orders under which NI-Gas was assigned a supplier and a base period volume of natural gas liquids and naphtha for use in its Aux Sable, Ill., synthetic natural gas facility. In considering the NI-Gas Appeal, the FEA noted that over the course of the past two years that Office of Regulatory Programs had issued a number of similar Decisions and Orders to NI-Gas and that in its present Appeal NI-Gas had largely reiterated arguments which were advanced in prior proceedings and which were fully considered and rejected by the FEA. The FEA determined that NI—Gas had presented no new evidence or legal authority which would demonstrate that these prior determinations were erroneous. The FEA further noted that the April 26 Order differs from prior Orders issued to NI-Gas only to the extent that the respective volumes and products allocated to NI-Gas for feedstock and for BTU enrichment purposes were adjusted in order to reflect actual volumes and products which NI-Gas uses for enrichment purposes. The FEA concluded that NI-Gas had not shown that this modification was erroneous, and accordingly denied the Appeal.

Twin-Tech Oil Co., Washington, D.C., FXA-1318, natural gas liquids

Twin-Tech Oil Co. (Twin-Tech) filed an Appeal from a Decision and Order which was issued to the firm by the Federal Energy Administration. Twin-Tech Oil Co., 5 FEA Par. 83,126 (March 28, 1977). In that determination, the FEA granted in part an Application for Exception from the provisions of 10 CFR, part 212, subpart K, which Twin-Tech had filed. Specifically, the FEA permitted Twin-Tech to increase the prices which it charges for natural gas liquids and products above maximum permissible levels in order to reflect certain increases in the firm's non-product costs. However, the FEA denied other aspects of the Twin-Tech request which related to the calculation of base prices and the firm's increased costs of natural gas shrinkage. In addition, the FEA dismissed without prejudice Twin-Tech's request for retroactive exception relief.

In its Appeal, Twin-Tech contended that the FEA improperly excluded certain categories of non-product costs from its calculation of the firm's non-product cost increases. Specifically, Twin-Tech argued that it should be permitted to pass through increased interest expenses which are incurred by the Twin City Barge and Towing Co. (Twin City), one of the owners of the Twin-Tech firm. In addition, Twin-Tech contended that it should have been permitted to increase its prices to reflect increased depreciation costs and increased administrative and legal expenses. In considering this portion of the Twin-Tech Appeal, the FEA observed that since Twin City's interest expenses do not arise from the operation of the Twin-Tech gas plant, but arise instead from a change in the ownership status of the plant, the interest expense does not represent the type of operating cost change which justifies exception relief permitting further price increases. Moreover, in accordance with the precedents established in prior cases involving natural gas processors, the FEA determined that Twin-Tech should not be permitted to pass through its increased depreciation costs. Finally, the FEA determined that the prior determination was erroneous in its failure to permit Twin-Tech to pass through certain increases in its administrative and legal expenses which are directly attributable to the operation of its gas plant. Accordingly, this portion of the Twin-Tech Appeal was granted, and the firm was permitted to raise its prices to reflect certain increases in its administrative and legal costs.

In its Appeal, Twin-Tech also contended that the March 28 Decision and Order is erroneous in fact and in law in its findings with respect to natural gas shrinkage. Specifically, Twin-Tech argued that although it has never sold its residue gas and is therefore not entitled to pass through natural gas shrinkage as a matter of law, it should be granted exception relief to permit the firm to pass through an imputed cost of natural gas shrinkage. In considering this aspect of the Twin-Tech Appeal, the FEA observed that the generally applicable regulatory provisions contemplate that a natural gas processor will be permitted to pass through as increased costs of natural gas shrinkage only the actual reduction in sales revenue received from the natural gas because of the reduced gas volume or BTU content of the gas after processing. With respect to Twin-Tech, the FEA determined that since Twin-Tech does not experience any such reduction in sales revenues, the firm should not be permitted to increase its selling prices to reflect increased costs of natural gas shrinkage. Finally, the FEA concluded that Twin-Tech failed to make a showing that the March 28 Order was in any way erroneous in its findings with respect to the firm's base prices, and the firm's request for retroactive exception relief. Accordingly, the Twin-Tech Appeal was granted in part and denied in part.

Villarreal Butane Co., San Benito, Tex., FRA-1234, propane

Villarreal Butane Co., (Villarreal) filed an Appeal from a Remedial Order which the FEA Region VI Office issued to the firm on February 8, 1977. In the Remedial Order the Deputy Regional Administrator of FEA Region VI found that during the period November 1, 1973 through September 30, 1975 Villarreal sold propane at unlawful price levels. In considering the Villarreal Appeal, the FEA determined that the FEA had correctly established the firm's class of purchaser categories and that certain errors alleged to exist in the FEA's calculation of overcharges were either nonexistent or had already been corrected by the FEA in response to Villarreal's response to the Notice of Probable Violation (NOPV). However the FEA found that Villarreal did appear to have established the existence of two computational errors which should be reviewed by the Region VI Office. Finally, the FEA held that in issuing a revised Remedial Order to Villarreal, the FEA Region VI Office should fully consider the level of price reduction through which refunds must be made and should set forth the factors it considered in establishing the appropriate level. Based on these considerations, the Remedial Order was remanded to FEA Region VI.

Western Jobbers, Alliance, San Francisco, Calif., FXA-1266, motor gasoline

The Western Jobbers Alliance, an organization of former Phillips Petroleum Co. branded jobbers, appealed from a Decision and Order which the FEA issued to it on March 9, 1977. Western Jobbers Alliance, 5 FEA Par. 83,100 (March 9, 1977). In the March 9 determination, the FEA denied exception relief from the provisions of the Mandatory Petroleum Price Regulations to the members of the Western Jobbers organization. The Western Jobbers Appeal, if granted, would have resulted in the rescission of the March 9 determination and the issuance of an order requiring the TOSCO Corp., the base period supplier of motor gasoline of the members of Western Jobbers, to place its members into a different class of purchaser. In considering the Western Jobbers Appeal, the FEA found that Western Jobbers had failed to prevent any substantial evidence that the association's members are generally experiencing financial difficulties or that they are experiencing difficulties which result primarily from the prices which they are charged for motor gasoline. The FEA therefore rejected the organiza-

tion's contention that its members as a class have been adversely affected as a result of the FEA approval of exception relief which substituted TOSCO for Phillips as the base period supplier of the members of the association in The Oil Shale Corp., Phillips Petroleum Co., 3 FEA Par. 83,139 (March 23, 1976). The FEA also determined that the fact that the members of Western Jobbers have purchased quantities of motor gasoline in excess of their base period volumes from TOSCO indicates that TOSCO's prices were not inordinately high and uncompetitive, as Western Jobbers contended. The FEA further determined that it was appropriate to compare the price which TOSCO charges the members of Western Jobbers with the rack prices which other independent firms were paying for motor gasoline to determine whether TOSCO's prices were inordinately high, and therefore approved the finding that the prices which TOSCO charges are competitive with the prices charged by major oil companies to the association members. Accordingly, the Western Jobbers Appeal was denied.

REQUEST FOR STAY

Flasher Farmers Union Oil Co., Flasher, N. Dak., FES-4751, refined petroleum products

The Flasher Farmers Union Oil Co. requested that a Consent Order which the firm entered into with the FEA on June 30, 1977, be stayed pending a final determination of an Application for Exception which the firm intends to file. In its stay submission, Flasher indicated that it intends to seek a retroactive exception which would in effect relieve the firm from complying with the Consent Order. In considering the Flasher stay request, the FEA found that in order to resolve an outstanding compliance action concerning past violations of FEA pricing regulations by Flasher, the firm had executed a Consent Order in which it agreed to refund past overcharges to its customers. The FEA determined that under the terms of the Consent Order, Flasher expressly waived any right to further administrative appeal or judicial review of the matter. The FEA further found that Flasher had not demonstrated that any basis exists upon which the agency might exercise its discretion to consider the effect of the Consent Order on Flasher's operations in the context of an exception proceeding. The FEA therefore concluded that the Flasher stay request should be denied.

SUPPLEMENTAL ORDERS

Bassett Oil and Equipment Co., Inc., Bassett, Va., FRX-0194, kerosene, No. 2 fuel oil

On August 3, 1977, the FEA issued a Decision and Order to Bassett Oil and Equipment Co., Inc. (Bassett) which granted in part an Appeal which the firm had filed from a Remedial Order issued to it by the Director of the Compliance Division of FEA Region III. *Bassett Oil & Equipment Co., Inc.*, 6 FEA Par. 80,529 (August 3, 1977). In the August 3 determination the matter was remanded to the Director of the Compliance Division of FEA Region III for further findings of fact concerning the calculation of the overcharges, and the issuance of a revised Remedial Order to Bassett within 45 days. On September 21, 1977, the Director of the Regional Compliance Division notified the Office of Exceptions and Appeals that 60 additional days would be required for the preparation and issuance of a revised Remedial Order. After reviewing the record in this matter, the FEA determined that the August 3 Order should be modified to specify that the revised Remedial Order shall be issued within 105 days of the issuance of the August 3 Order.

Funding Systems Corp., et al., Washington, D.C., FEX-0193, crude oil

Funding Systems Corporation, et al. (Funding) appealed from a Decision and Order issued by the Office of Regulatory Programs of the Federal Energy Administration on June 17, 1977. The June 17 Order determined that Funding is not a "refiner" as that term is defined in 10 CFR 211.62 and accordingly does not qualify to receive entitlements under 10 CFR 211.67. In its Appeal, Funding requested that the FEA vacate the June 17 Order and issue a new Order declaring that Funding is in fact a "refiner" and is therefore eligible to participate in the Entitlements Program. Included in Funding's Appeal Submission was a set of written Interrogatories directed to the FEA. The information and documents which Funding requested in its Interrogatories was related to the assertion made in its Appeal that the FEA applied more stringent standards in evaluating Funding's application for certification of its refinery capacity under Section 211.67(a)(2) than the agency has applied in the past. The material sought consists principally of copies of all previous applications for certification submitted under Section 211.67(a)(2) and the Decisions and Orders issued by the Office of Regulatory Programs in those proceedings. In considering Funding's request for discovery, the FEA noted that it has previously held that a firm appealing an agency Order may obtain discovery through the use of written interrogatories only where a showing is made that: (i) the material involved has previously been determined by the FEA to be exempt from disclosure under the Freedom of Information Act (FOIA); and (ii) access to the material is essential to enable the firm to pursue its appeal effectively. The FEA determined that Funding had not made this type of showing since Funding had not even attempted to obtain the material desired through any of the existing administrative procedures available to it. The FEA noted that in fact the principal items sought in the firm's Interrogatories may well be available under the FOIA. According, the request for discovery was denied.

Whitco, Inc., Dallas, Tex., FEX-0195, motor gasoline

On September 29, 1977, the FEA issued a Proposed Decision and Order to Whitco, Inc. (Whitco) in accordance with new procedures that are applicable to Applications for Exception. Under those procedures, the Proposed Decision and Order could not become final for at least 10 days. Moreover, if any party aggrieved by the proposed Decsion and Order files a Notice of Objection with the FEA, an even greater period could elapse before a final Order on the firm's exception relief could be issued. In the Proposed Decision and Order, the FEA determined that a price disparity continued to exist between the rack prices for motor gasoline established by Sun Co., Inc. (Sun), Whitco's base period supplier and those established by Amtel, Inc., Sun's designated substitute supplier under the provisions of 10 CFR 211.25 and therefore concluded that exception relief previosly granted should be extended for an additional three months. In a decision which the FEA issued on its own motion, the FEA noted that a significant problem was presented because of the period of time which must elapse under the new procedures before an extension of exception relief could be finalized and the necessity of insulating Whitco from the apparent adverse impact which it would experience when its current exception expired. The FEA found that Whitco would incur a more immediate serious hardship or gross inequity than any other firm involved in that proceeding unless the supplier substitution rule is stayed. The FEA also determined that in view of the findings and conclusions contained in the Proposed Decision and Order, there is a very substantial likelihood that Whitco will be successful on the merits of its Application for Exception. The FEA on its own motion therefore stayed the application of Section 211.25 to Whitco pending the issuance of a final Decision and Order in the exception proceeding.

SUMMARY DECISIONS

The following firms filed Applications for Stay of Remedial Orders which the FEA issued to the respective firms. In considering the stay requests, the FEA referred to a recent Decision in *Rickelson Oil and Gas Co.*, 6 FEA Par —— (August 24, 1977) in which it held that a Remedial Order will generally be stayed pending the determination of an Appeal unless it appeared that the public interest required immediate compliance with the Remedial Order. Since the record in these cases did not indicate that the public interest required immediate compliance with the Remedial Orders, the FEA granted the requests for stay pending consideration of the Appeals.

Champlin Petroleum Co., Forth Worth, Tex., FRS-1479
Mountain Fuel Supply Co., Salt Lake City, Utah, FRS-1486
Joe E. Sharber, Wewoka, Okla., FRS-0109
Valley Gas Inc., Fort Yates, N. Dak., FRS-1483

DISMISSALS

The following submissions were dismissed following a statement by the applicant indicating that the relief requested was no longer needed:

George A. Hoffman, Henderson, Ky., FRA-1366
McAlester Fuel Co., Houston, Tex., FEE-4655
Midway Petroleum, Inc., Dundalk, Md., FEE-4731

Copies of the full text of these Decisions and Orders are available in the Public Docket Room of the Office of Administrative Review, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.s.t., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

MELVIN GOLDSTEIN,
Acting Director,
Office of Administrative Review.

NOVEMBER 16, 1977.

[FR Doc. 77-33564 Filed 11-21-77; 8:45 am]

[3128-01]

STRATEGIC PETROLEUM RESERVE

Final Environmental Impact Statement for the Kleer Mine Storage Site

AGENCY: Department of Energy.

ACTION: Notice of Availability of Environmental Impact Statement.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C), the Department of Energy (DOE) has prepared a final environmental impact statement (EIS) on the proposed storage of crude oil at the Kleer Mine site.

DATE: Comments must be received by December 21, 1977.

ADDRESS: Comments to Department of Energy, Executive Secretariat, Room 3317, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

Robert J. Stern, Environmental Impact Division, 12th and Pennsylvania Avenue NW., Room 7121, Washington, D.C. 20461, 202-566-9760.

SUPPLEMENTAL INFORMATION: The Kleer Mine storage site has been proposed as an element of the Strategic Petroleum Reserve. The Reserve (mandated by Part B of Title I, Energy Policy and Conservation Act, 42 U.S.C. 6231-6246) is intended for the storage of crude oil and/or petroleum products for use in the event of a Presidential determination of a severe energy supply interruption or a requirement to meet the obligations of the United States under the International Energy Program.

Single copies of the final Kleer Mines EIS (FES 77-2) may be obtained from the National Energy Information Center, Room 1404, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461. Copies of this EIS will also be available for public review in the DOE Information Access Reading Room, Room 2107, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

DOE shall consider any comments on the final EIS, submitted before the date specified above, before taking any administrative action with regard to site selection or initiation of construction activities at the Kleer Mine site. Comments should be submitted to Box QG, sent to the address provided above, and shall be identified on the outside of the envelope and on the documents submitted with the designation "Kleer Mine Final EIS (FES 77-2)." Fifteen copies should be submitted.

Any information or data, submitted in response to the final Kleer Mine EIS, considered by the person furnishing it to be confidential, must be so identified and submitted in one copy only. The DOE reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

Issued in Washington, D.C., November 16, 1977.

WILLIAM S. HEFFLEFINGER,
Director of Administration.

[FR Doc. 77-33586 Filed 11-21-77; 8:45 am]

[3128-01]

STRATEGIC PETROLEUM RESERVE

Draft Supplement to the Programmatic Final Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Notice of Availability of Draft Supplement to the Programmatic Final Environmental Impact Statement for the Strategic Petroleum Reserve (SPR) Program.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C), the Department of Energy (DOE) has prepared a draft supplement to the programmatic EIS for the SPR program. This supplement presents the environmental impacts associated with the proposed expansion of the Strategic Petroleum Reserve (SPR) program to store one billion barrels of crude oil.

DATE: Comments must be received by January 6, 1978.

ADDRESS: Comments to Department of Energy, Executive Secretariat, Box QH, Room 3317, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461

FOR FURTHER INFORMATION CONTACT:

Robert J. Stern (Environmental Impact Division), 12th and Pennsylvania Avenue, NW., Room 7121, Washington, D.C. 20461, 202-566-9760.

Steven Ferguson (Strategic Petroleum Reserve), 1726 M Street NW., Room 330, Washington, D.C. 20461, 202-634-5500.

SUPPLEMENTAL INFORMATION: The Reserve (mandated by Part B of Title I, Energy Policy and Conservation Act, 42 U.S.C. 6231-6246) will be created for the storage of crude oil and/or petroleum products for use in the event of a Presidential determination of a severe energy supply interruption or a requirement to meet the obligations of the United States under the Internatinal Energy Program.

Single copies of this supplement (FES 76-2) may be obtained from the National Energy Information Center, Room 1404, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461. Copies of this supplement will also be available for public review in the DOE Information Access Reading Room, Room 2107, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to submit written comments with respect to the draft supplement before the date specified above. Comments should be identified on the outside of the envelope and on the document submitted with the designation "Draft Supplement to the Programmatic Final EIS on the Strategic Petroleum Reserve (FES76-2)."

Any information or data, submitted in response to the draft supplement, considered by the person furnishing it to be confidential, must be so identified and submitted in one copy only. The DOE reserves the right to determine the confidential status of this information or data and to treat it according to that determination.

Issued in Washington, D.C., November 16, 1977.

WILLIAM S. HEFFELFINGER,
Director of Administration.

[FR Doc. 77-33660 Filed 11-21-77; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FLR 819-3; (OPP-42051A)]

STATE OF NORTH CAROLINA

Approval of State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

Section 4(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136 et seq.), and the implementing regulations of 40 CFR part 171, require each State desiring to certify applicators to submit a plan to EPA for its certification program. Any State certification program under this section shall be maintained in accordance with the State Plan approved under this section.

On September 21, 1977, notice was published in the FEDERAL REGISTER (42 FR 47583) of the intent of the Regional Administrator, Environmental Protection Agency (EPA) Region IV, to approve the North Carolina State Plan for Certification of Commerical and Private Applicators of Restricted Use Pesticides.

Complete copies of the North Carolina State Plan (except for sample examinations) were made available for public inspection at the following locations: North Carolina Department of Agriculture, Pest Control Division,

Room 364, State Agriculture Building, Raleigh, N.C. 27606; U.S. Environmental Protection Agency, Pesticides Branch, Room 204, 345 Courtland Street NE., Atlanta, Ga. 30308; and the U.S. Environmental Protection Agency, Office of Pesticide Programs, Federal Register Section, Room 401, East Tower, 401 M Street SW., Washington, D.C. 20460.

No comments were received concerning the North Carolina State Plan during the 30 day comment period. Therefore, it has been determined that the North Carolina State Plan will satisfy the requirements of section 4(a)(2) of the amended FIFRA and 40 CFR part 171.

The North Carolina State Plan will remain available for public inspection at the North Carolina Department of Agriculture, Pest Control Division, Room 364, State Agriculture Building, Raleigh, N.C. 27606.

Effective Date. Pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), the Agency finds that there is good cause for providing that the approval granted herein to the North Carolina State Plan shall be effective upon signature of this notice. Accordingly, this approval shall become effective immediately.

Dated: October 25, 1977.

JOHN C. WHITE,
Regional Administrator.

[FR Doc. 77-33641 Filed 11-21-77; 8:45 am]

[6560-01]

[FRL 819-2; (PW13)]

AMERICAN CYANAMID AGRICULTURAL DIVISION

Withdrawal of Pesticide Petition

On April 8, 1976, the Environmental Protection Agency (EPA) gave notice (41 FR 14924) that American Cyanamid Agricultural Division, P.O. Box 400, Princeton, N.J. 08540, had filed a pesticide petition (PP 6F1759) with the Agency. This petition proposed establishment of tolerances for residues of the growth regulator cycocel (2-chloroethyl trimethylammonium chloride) on the raw agricultural commodities sugarcane at the 3.0 parts per million (ppm), in meat, fat, in meat byproducts of cattle, goats, hogs, horses, sheep and poultry at 0.10 ppm and in milk at 0.05 ppm.

The American Cyanamid Agricultural Division has withdrawn this petition without prejudice in accordance with the regulations (40 CFR 180.8) pertaining to section 408 of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 346a(d)).

Dated: November 15, 1977.

DOUGLAS D. CAMPT,
Acting Director,
Registration Division.

[FR Doc. 77-33642 Filed 11-21-77; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 21431-21442; File Nos. 7322-C2-P-70, etc.; FCC 77-692]

ARIZONA MOBILE TELEPHONE CO., ET AL.

Memorandum Opinion and Order Designating Applications for Consolidated Hearing on Stated Issues

Adopted: October 13, 1977.

Released: October 28, 1977.

In re applications of Arizona Mobile Telephone Co., Grand Canyon, Ariz., Docket No. 21431, File No. 7323-C2-P-70; Caribe Mobile Telephone Co., St. Thomas, V.I., Docket No. 21432, File No. 6959-C2-P-70; Colorado Mobile Telephone Co., Grand Junction, Colo., Docket No. 21433, File No. 8598-C2-P-70; Georgia Mobile Telephone Co., Waycross, Ga., Docket No. 21434, File No. 562-C2-P-71; North Carolina Mobile Telephone Co., Rocky Mount, N.C., Docket No. 21435, File No. 564-C2-P-71; Oregon Mobile Telephone Co., Elko, Nev., Docket No. 21436, File No. 1875-C2-P-71; Texas Mobile Telephone Co., Colby, Kans., Docket No. 21437, File No. 563-C2-P-(2)-71; Texas Mobile Telephone Co., Amarillo, Tex., Docket No. 21438, File No. 7324-C2-P-70; Texas Mobile Telephone Co., Pierre, S. Dak., Docket No. 21439, File No. 6957-C2-P-70; Texas Mobile Telephone Co., San Antonio, Tex., Docket No. 21440, File No. 4749-C2-P-70; for construction permits for new air ground stations in the Domestic Public Land Mobile Radio Service; Wisconsin Mobile Telephone Co., Milwaukee, Wis., Docket No. 21441, File No. 1121-C2-P-(3)-71; Mobile Telephone Co., of South Carolina, Greenville, S.C., Docket No. 21442, File No. 2084-C2-P-(3)-70; for construction permits for new land mobile facilities in the Domestic Public Land Mobile Radio Service.

1. On July 6, 1976, the Chief, Common Carrier Bureau, acting pursuant to delegated authority, released an order, 60 FCC 2d 1021, granting the ten above-captioned applications for new air-ground facilities. That order also denied a "Joint Petition for Institution of Special Hearing Proceedings," submitted by six radio common carriers. Three of the joint petitioners and a fourth party have filed timely petitions for reconsideration of the July 6 order.[1]

2. A subsequent order was released by the Chief, Common Carrier Bureau on October 13, 1976, which stayed, pending acton on the petitions for reconsideration, the July 6, 1976 order granting the above-captioned applications. The applicants have filed an application for review of the stay order. These two matters, the petitions for reconsideration and the application for review, are now before us for our consideraton.

3. For reasons set out fully below, by this order we are granting the petitions for reconsideration to the extent that the grants of the air-ground applications and the Wisconsin MTC land mobile application are set aside, and a hearing is ordered to consider issues common to all the referenced applications. In addition, the application of Mobile Telephone Company of South Carolina, Inc. is designated for hearing. Fruthermore, the application for review filed by the applicants is denied.

BACKGROUND

4. The applicants of all 12 of the above-captioned applications, for both air-ground and land mobile facilities, are wholly-owned subsidiaries of the Mobile Telephone Co. (MTC) and its parent company TeleTech Corp. (TeleTech).[2] Mr. Robert Starer is a 62 percent shareholder of TeleTech. In addition, he is the Chief Executive Officer and President of TeleTech, MTC and of each of the applicants listed herein. The July 6, 1976 order considered issues common to all pending applications of subsidiaries of MTC and resolved financial, control and alleged violations of §1.65 of the rules[3] issues in favor of the applicants. Grants were issued to all 10 air-ground applicants and the land mobile applications were to be considered by the Bureau in subsequent orders.[4]

[1] DPRS trading as ZipCall (formerly Electrocom Corp.), Boston, Mass.; All City Telephone Answering Service, Milwaukee, Wis.; Morris Communications, Inc., Greenville, S.C.; and S.M.W. Inc., an applicant for DPLMRS facilities in Boston, Mass.

[2] A list of 18 pending applications, filed by subsidiaries of MTC, is attached as Exhibit A.

[3] Section 1.65 of the Commission's rules states that "each applicant is responsible for the continuing accuracy and completeness of information furnished in a pending application * * *" and requires further that each applicant notify the Commission "whenever there has been a substantial change as to any other matter which may be of decisional significance. * * *"

[4] On July 8, 1976, an order was released granting the above-captioned application of Wisconsin Mobile Telephone Co., and denying a petition to deny filed by All City Telephone Answering Service. The application of Land of Lincoln Mobile Telephone Co., File No. 2244-C2-P-70, Algonquin, Ill., was granted on July 23, 1976. The application of Indiana Mobile Telephone Co., File No. 843-C2-P-71, Indianapolis, Ind., was granted on July 6, 1976. (The grant to Wisconsin MTC was also stayed by the October 13, 1976 Common Carrier Bureau order. That order also canceled the right of both Land of Lin-

5. The Common Carrier Bureau's July 6, 1976 order found that an April 7, 1975 financial proposal of Mobile Telephone Co., plus subsequent documentation, sufficiently demonstrated the availability of the necessary capital to construct and operate the 18 pending applications.[5] The total cash requirements for all applicants is stated to be $468,800.[6] The Bureau found that all financing, to the extent of $500,000, would come from Mr. Robert D. Hedberg, as trustee of certain trusts. The Bureau also found that advances by Mr. Hedberg will be secured by a conventional demand note, guaranteed by the parent MTC and secured by a pledge of equipment purchased, and bearing interest at 2 percent above the prime rate, but not less that 10½ percent. Documentation provided by the applicants convinced the Bureau of Mr. Hedberg's authority to invest assets of the trust fund, the total value of which exceeded $17 million as of December 31, 1975. The Bureau also took note of statements in the April 7, 1975 amendment concerning developments in the financial and corporate structure of TeleTech. The applicants asserted therein that there were no appreciable current liabilities against TeleTech, MTC or any subsidiary. In sum, the Bureau concluded that since Mr. Hedberg was the sole source of financing and because he had sufficient financial resources and had expressed his clear intent and willingness to make the loan, his commitment supported a favorable resolution of the financial issue.

6. In view of the large financial undertaking of Mr. Hedberg, the Bureau's Order also considered whether Mr. Hedberg might exercise de facto control [7] over the applicant companies. The Bureau found that although Mr. Hedberg had been identified as a major stockholder and director of TeleTech, he was not a director, officer or shareholder of any of the applicant companies and that he disavowed any intent to become so involved. Based upon the assurances of Mr. Hedberg in his June 11, 1976 reply to a staff inquiry, the Bureau did not find any indication of any overt effort by Hedberg to influence or control the management decisions of the applicants and thus concluded that no de facto transfer of control has occurred.

7. Finally, the Bureau concluded that a hearing was not warranted on a § 1.65 issue. Although the Bureau recognized that Mobile Telephone Co., had not always informed the Commission of financial developments and organizational changes in the corporate structure of TeleTech and its subsidiaries, the Bureau did not find that any such violations were of such significance to warrant disqualification or that other parties were prejudiced thereby.

PETITIONS FOR RECONSIDERATION

8. The petitions for reconsideration [8] allege that the Bureau erred by relying solely on the Hedberg commitment in finding the applicants financially qualified and by failing to require full disclosure of the financial positions of TeleTech, MTC and the applicants. According to the petitioners, the applicants have not satisfied the requirements of § 21.17(b)(1) of the Rules in that they have not submitted current balance sheets and copies of any financial commitments. With respect to TeleTech and Mobile Telephone Co., they are said to have supplied only self-serving statements concerning their financial status, but should be required to submit balance sheets, profit and loss statements and revenue projections. The inquiry into the financial affairs of TeleTech and MTC is urged for several reasons. Petitioners contend that because these two organizations are operating companies and because MTC is a guarantor of the Hedberg note, knowledge of their respective financial positions is indispensable to a determination of whether the applicants are qualified. The petitioners also argue that if the liabilities greatly exceed the assets of both MTC and TeleTech, then perhaps the funds advanced by Hedberg might be subject to claims by creditors of MTC and TeleTech. Having pierced the corporate veil, petitioners next insist that a full inquiry must be made into the finances of Mr. Starer personally, and of companies he owns either directly or indirectly. In this connection, the petitioners allege that between 1972 and 1976, creditors of Starer and some of his corporations have resorted to legal action on 63 occasions and that as of September 20, 1976, 46 judgments and tax liens, aggregating $204,951.86, remained listed in court records as having been unsatisfied or not released. The petitioners contend that such evidence indicates Mr. Starer is unable or unwilling to meet his legal obligations, demonstrates a lack of financial responsibility, and reflects on his fitness to be a controlling shareholder and principal officer of any Commission licensee. Petitioners also allege that Starer has, in the past, manipulated various corporate entities to serve varying purposes and to insulate himself from personal liability. The petitioners also raise questions about the operations of other Starer-controlled companies, including Minnesota Mobile Telephone Company and Philadelphia Mobile Telephone Company, wherein service to customers was jeopardized and even discontinued because Starer allegedly was delinquent in his payments for local exchange and interconnection services provided by the local wireline telephone companies.

9. The petitioners also quarrel with the Bureau's conclusion that no de facto transfer of control to Mr. Hedberg would occur, alleging that the facts of the case and common business experience dictate that it would be unlikely for Mr. Hedberg, in view of the magnitude of his commitment, to

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coln MTC and Indiana MTC to commence equipment or service tests on their previously authorized facilities.) The captioned application of Mobile Telephone Co. of South Carolina, Inc. is the subject of a petition to deny filed by Morris Communications, Inc., and is still in pending status. Three other applications, Boston Mobile Telephone Co., File No. 5751-C2-P-(5)-69, Michigan Radio Telephone Co., File No. 3475-C2-P-(3)-71, and Washington Mobile Telephone Co., File No. 5547-C2-P-(3)-69, are mutually exclusive with other applications and cannot be granted without a comparative hearing. The final land mobile application, that of Baltimore Mobile Telephone Co., File No. 4744-C2-P-69, is not ripe for our final action due to state certification difficulties.

[5] The financial inquiry was necessitated, in part, because of the magnitude of MTC's initial undertaking. At one point in 1970, 24 applications were on file for new land mobile stations in 24 cities in 16 states. In addition, MTC-controlled companies had on file 61 applications for air-ground stations in 34 States. The initial financial requirements for all 85 applications exceeded $10 million. Since the filing of these applications with the Commission, the TeleTech corporate structure has undergone some reorganization. Shifts in controlling interests have occurred and two wholly-owned subsidiaries, PhysiTech, Inc. and PhysiTech Field Corp., filed petitions under Chapter XI of Federal Bankruptcy Act in U.S. District Court. As a result, several different proposals for financing have been advanced during the course of this proceeding. Thrugh the voluntary dismissal of numerous applications, the original total of 85 applications has been reduced to 18 currently on file. As a result, the corresponding financial requirements have been reduced considerably.

[6] See attached appendix, Exhibit A.

[7] Pursuant to Section 310 of the Communications Act of 1934, as amended, 47 U.S.C. 310, there may be no transfer of control of any construction permit, station license, or rights thereunder, except by application to and appropriate action by the Commission.

[8] Three separate petitions for reconsideration were filed by the parties listed in footnote 1, but all incorporate by reference, or otherwise raise the same essential arguments. The petition of Morris Communications specifically addresses only §§ 1.65 and 21.28(c) and character issues. Section 21.28(c) of the rules states that the "Commission will dismiss an application for failure to prosecute or failure to respond substantially * * * to official correspondence or requests for additional information." Morris merely mentions, but does not elaborate upon, the § 21.28(c) issue and does not demonstrate how the Bureau's conclusion, that the applicants had complied with that provision of the Rules, was in error. Accordingly, that portion of the Morris pleading will be denied and not mentioned further.

leave the management of the business, the success of which depends solely on the funds he is supplying, to others. Finally, petitioners argue that the Bureau's determination to excuse the applicants' non-compliance with the Commission's disclosure requirements of § 1.65 was premature. We are referred to the recent discovery by petitioners of the large number of judgments and tax liens lodged against Starer and companies under his control, which are said to reflect on the financial qualifications of the applicants and the character of Mr. Starer. Moreover, Morris Communications, Inc. (Morris) raises another matter concerning the validity of the state certificate of Mobile Telephone Co., of South Carolina, Inc. (MTC–SC). According to Morris, an order issued on August 7, 1974 by the South Carolina Public Service Commission stated that the certificate previously granted MTC–SC "shall remain valid" but "shall become null and void and shall be revoked" if MTC–SC failed to receive a construction permit from this Commission within 18 months. Morris's contention is that this order was self-executing, that by its terms the MTC–SC certificate was no longer valid after February 7, 1976, and that, in any event, by not informing this Commission of such matters before the South Carolina PSC, which are deemed to be of decisional significance, the applicant has not complied with § 1.65. In view of all the foregoing, the petitioners ask that the July 6 order of the Common Carrier Bureau be set aside, that TeleTech, MTC and the applicants be required to submit full and comprehensive financial information, and that a hearing be ordered to consider financial, transfer of control and § 1.65 issues.

APPLICANTS' OPPOSITION

10. The applicants characterize the petitions for reconsideration as further efforts to block the processing of all applications by MTC affiliated companies. Alleging an abuse of administrative processes, the applicants contend that such conduct is actionable; suggest that the Commission inquire into the motives of the petitioners; and imply that civil action has already been initiated. Procedurally, objections are raised with respect to the petitioners's standing and to the effect that new § 1.65 allegations raised in the petitions are based on facts which could have been ascertained prior to the Bureau's July 6 order, and thus the petitions for reconsideration fail to satisfy the requirement of § 1.106(c) of the rules.

11. Turning to the merits, the applicants contend that an April 7, 1975 amendment, relied upon by the Bureau, discussed in detail the financial situation of TeleTech and Mobile Telephone Company and disclosed all assets and liabilities of the two companies. In addition, the amendment included the Hedberg financial commitment letter. The applicants insist that no inquiry into the personal finances of Mr. Starer is necessary, since no applicant is looking to him for any financial commitment, and he is not personally involved in any way with the financing of any proposed facility. Accordingly, it is argued, Mr. Starer has no obligation under any rule to make public his personal statement, nor has such statement been requested by the Bureau. The petitions for reconsideration contain a list of 11 unsatisfied judgments, totaling $19,046, against Mobile Equipment Company (MEC),[9] but the applicants argue the matter is not significant since MEC is outside their corporate family. Due to filing deadlines, the applicants state that full research into the issue was not possible, although they claim one of the referenced judgments did not even involve MEC, but did involve Mr. Starer, who, it is stated, had long ago paid the amount in full. The applicants also quarrel with the petitioners' discussion of the transfer of control issue. The applicants claim that the risk of failure of the operations is on themselves and Mr. Hedberg, who like any other creditor will look to his security. It is argued that the Commission should not assume the role, as urged by petitioners, of a guarantor of the solvency of every applicant who receives a license. Furthermore, it is stated that Mr. Hedberg has disavowed any intention to intervene in the affairs or otherwise control the activities of the applicant companies. With respect to the § 1.65 issue raised by Morris, the applicants contend that the August 7, 1974 order of the South Carolina PSC was not self-executing, that the MTC–SC certificate did not automatically expire on February 7, 1976, that further proceedings before the South Carolina PSC make this clear, and that since the certificate is currently valid, there has been nothing of "decisional significance" requiring disclosure to this Commission.

APPLICATION FOR REVIEW

12. On October 13, 1976, the Chief, Common Carrier Bureau, pursuant to § 1.102(b)(2) of the rules, released an order which stayed the earlier July 6 order granting the air-ground applications and stayed the July 8, 1976 grant to Wisconsin MTC. Furthermore, pursuant to §§ 21.212(a)(2) and 21.212(b)(2) of the rules, the right to commence equipment or service tests was cancelled for the land mobile stations of Indiana MTC and Land of Lincoln MTC. On November 12, 1976, the applicants filed an Application for Review of the Bureau's stay order and alleged that the Bureau acted in conflict with Section 405 of the Communications Act of 1934, as amended, 47 U.S.C. 405, and § 1.106(j) of the rules.[10] According to the applicants, § 1.106(j) required the Bureau to act on the petitions for reconsideration no later than November 3, 1976, no such order has yet been issued, the October 13, 1976 "Order to Stay Construction" cannot be substituted for or construed to be the action required by § 1.106(j), and in the absence of any action on the petitions for reconsideration, they should be deemed denied. The applicants also allege that the stay order specifically states that it "* * * is taken without prejudice to Commission action on pending Petitions for Reconsideration," and so it explicitly was not ordered in lieu of a decision on the petitions, and cannot be considered to be a decision on the merits. Finally, the applicants suggest that whereas the Commission generally insists on strict adherence to time-for-filing requirements, the Bureau's failure to comply with such procedures in this case would, if upheld, reduce to a nullity the concept of timely action under the legislative and regulatory scheme.

DISCUSSION

APPLICATION FOR REVIEW

13. The petitions for reconsideration and subsequent pleadings raise serious questions as to the integrity of Mr. Starer and his competence to be a licensee of the numerous mobile radio facilities at issue in this proceeding. It is clear that the Bureau's decision to stay the previous grants was triggered by allegations raised in the petitions for reconsideration, since the October 13, 1976, stay order specifically states that it was issued "on the basis of information subsequently brought to (the Bureau's) attention." Such an order could not be issued unless a determination was first made that it was likely the petitioners would prevail on the merits and that the public interest required such action. See *Virginia Petroleum Jobbers Association* v. *FPC*,

[9] The remainder of the judgments and tax liens referred to in paragraph 8, above, were detailed in the petitioners' subsequent "Reply to Opposition of MT&T to Petition for Reconsideration."

[10] The requirements of section 405 of the Communications Act are implemented in § 1.106 of our rules. Section 1.106(j) of the rules states: "The Commission or designated authority may grant the petition for reconsideration in whole or in part or may deny the petition. Its order will contain a concise statement of the reasons for the action taken. Where the petition for reconsideration relates to an instrument of authorization granted without hearing, the Commission or designated authority will take such action within 90 days after the petition is filed."

259 F. 2d 921 (D.C. Cir. 1958). In that case, the U.S. Court of Appeals for the District of Columbia stated that "[I]n litigation involving the administration of regulatory statutes designed to promote the public interest, this factor necessarily becomes crucial. The interests of private litigants must give way to the realization of public purposes." 259 F. 2d at 925. In view of the allegations then before the Bureau and their inherent public interest implications, we believe that the Bureau's stay order was justified and was a proper means of maintaining the status quo pending final action on the petitions for reconsideration.[11] Because the Bureau was contemplating further action, the stay order, by preventing commencement of construction, serves also to protect the $500,000 investment of Mr. Hedberg, pending final disposition of the proceeding. Moreover, we believe that the stay order was a legitimate attempt to satisfy the 90-day requirement of section 405 of the Act.

14. Even if it were held that the stay order did not completely fulfill to the letter the requirements of § 1.106(j), and even if, as a result, a violation of section 405 of the Communications Act was found in that no action was taken within the 90 days specified, "this delay * * * cannot prevent us from adjudicating the basic public interest issue before us." Big Valley Cablevision, Inc., 48 FCC 2d 684, 685 (1974). In that case, delay in action on a petition for reconsideration was due to a large number of CATV applications requiring processing. Here, by issuance of the stay order, more time was made available to study the numerous pleadings, conduct the proper research and write the designation order.[12] Significant questions affecting the public interest will be considered below in our discussion of the petitions for reconsideration. As a result of the allegations contained in those petitions for reconsideration, "* * * there exist(ed) a combination of danger signals that cannot be ignored or bypassed." *Joseph* v. *FCC*, 404 F. 2d 207 (D.C. Cir. 1968). Accordingly, the application for Review is denied.

PETITIONS FOR RECONSIDERATION[13]

STA NDING

15. Two procedural objections to the petitions are advanced by the applicants. First, the applicants have insisted throughout this proceeding that the petitioners lack the requisite standing to protest all the applications at issue. Specifically, it is alleged that only three of the original nine parties to the "Joint Petition for Institution of Special Hearing Proceedings" were parties in interest to any of the 84 specific allegations raised in that petition. No petitioner is said to be a party in interest to any of the air-ground applications. We note that, for reasons of administrative convenience and because common facts and issues are involved, this proceeding has been structured so as to resolve issues common to all the related applicants. While the Bureau's July 6, 1976 order only granted the air-ground applications, the findings and conclusions with respect to the financial, transfer of control and § 1.65 issues were to be incorporated into the records of all other pending land mobile applications. As a result, they would be deemed applicable in subsequent proceedings involving those applications. Since petitioners, existing licensees in areas where some of the applicants proposed to operate or, in the case of S.M.W. Inc., a mutually exclusive applicant with that of Boston MTC, are interested parties, their rights would be adversely affected thereby. Therefore, the four petitioners are considered to possess standing to file the petitions at issue herein.

DEFECTIVE PLEADING

16. The second procedural objection of the applicants is that all of the issues raised by petitioners are based on facts which were known to the petitioners or could have been readily discovered by them prior to the Bureau's July 6 order and, therefore, the petitions for reconsideration should be denied pursuant to § 1.106(c) of the rules.[14] The applicants state that all such judgments and tax liens were recorded before June 18, 1976, and thus petitioners could have presented the information to the Commission's staff at an earlier time. Moreover, since none of the judgments and tax liens listed in the petitions for reconsideration are against TeleTech, MTC, or any of the applicants, they allege these "new facts," even if true, are irrelevant.

1 7. We agree with the applicants to the extent that petitioners were derelict in not calling certain relevant matters to our attention at an earlier time in this proceeding. The court judgment and tax liens all appeared in public records, and some were available for the petitioners' inspection long before the Bureau released its July 6, 1976 order. Ordinarily, we would not excuse the petitioners' lack of due diligence and failure to comply with the literal requirements of § 1.106. However, merely because allegations raised in a petition for reconsideration are not "new facts" within the meaning of Paragraphs (1) and (2) of § 1.106(c), we are not thereby prevented from considering the facts

[11] The application for review argues that the absence of any action on the petitions for reconsideration within the 90-day period, the petitions should be deemed denied, citing *Citizens Committee* v. *FCC*, 436 F. 2d 263 (D.C. Cir. 1970). However, the facts of that case are readily distinguishable. There, the court rejected the appellant's contention that where the Commission's order denying reconsideration was issued beyond the 90-day period, the petition for reconsideration must be taken as granted. The court noted that both parties had requested additional time to file pleadings beyond the expiration of the 90-day period, thereby waiving the 90-day limitation. The applicants here argue that but for that waiver, the petition for reconsideration would have been considered denied had no order been issued within the 90-day period. Applicants' argument is pure speculation. Commission failure to act on a petition for reconsideration within 90 days does not automatically indicate action favorable to or against the petition. The requirement to act on petitions seeking reconsideration of Commission grants of instruments of authorization is, in our view, a means of protecting grantees from adverse decisions on underlying applications long after such applications initially are granted. Clearly, it protects grantees from serious financial losses. In this case, the Bureau's stay order warned the applicants that serious questions about their applications existed. Thus, the stay order acted to negate any possible argument that might justify a finding that a failure to act on the petitions for reconsideration within the statutory period was an implied denial of those petitions.

[12] Both petitioners and the applicants requested, and were granted, extensions of time to file pleadings, and supplemental pleadings were filed as late as October 12, 1976, leaving the staff only three weeks in which to resolve complex issues and prepare necessary documents. In view of allegations concerning the operations of other Starer-operated facilities, the staff found it necessary to peruse the files of other stations which Mr. Starer either has controlled or presently controls in various parts of the country, and thus the research task was made more complex. Compare *Chromcraft Corp.* v. *United States Equal Employment Opportunity Commission*, 465 F. 2d 745 (5th Cir. 1974), where the court upheld the action of an administrative agency which did not result in "unreasonable delay."

[13] Although petitions requesting reconsideration of final action taken pursuant to delegated authority may be acted upon by the designated authority, pursuant to § 1.106(a)(1) of the Commission's rules, this matter has been referred by the Common Carrier Bureau to us for our consideration.

[14] Section 1.106(c) of the rules states:

(c) A petition for reconsideration which relies on facts which have not previously been presented to the Commission * * * will be granted only under the following circumstances:

(1) The facts relied on relate to events which have occurred or circumstances which have changed since the last opportunity to present such matters;

(2) The facts relied on were unknown to petitioner until after his last opportunity to present such matters, and he could not through the exercise of ordinary diligence have learned of the facts in question prior to such opportunity; or

(3) The Commission * * * determines that consideration of the facts relied on is required in the public interest.

where the public interest so requires. The criteria enumerated in Paragraphs (1) and (2) of § 1.106(c) are only two considerations "to be weighed, among others, in making the public interest determination of Paragraph (3)." *Springfield Television Broadcasting Corp.* v. *FCC*, 328 F. 2d 186 at 189 (D.C. Cir. 1964) (emphasis added). We have examined the pleadings herein under the test set forth in The Edgefield-Saluda Radio Company case, 5 FCC 2d 148 (Rev. Bd. 1966), and concluded both that they raise serious material questions of fact concerning the applicants' character qualifications and that the public interest requires that the merits of the allegations be considered.

FINANCIAL QUALIFICATIONS

18. The Common Carrier Bureau considered all the circumstances of the proposed loan arrangement of Mr. Hedberg and concluded that by virtue of his commitment, the applicants have the necessary financial resources to construct and operate the proposed facilities. We believe that, on the basis of all the information in the record, the Bureau was correct in this determination. As indicated in the Appendix, the total resources required for all 18 pending applications is $468,800. Thus, Mr. Hedberg's commitment of $500,000 includes a cushion of $31,200 for unanticipated expenses.[15] There is no dispute as to the financial ability or legal authority of Mr. Hedberg to make his commitment, nor as to the sufficiency of the loan to meet projected expenses. As the Bureau correctly noted, the clear intent and willingness of Mr. Hedberg to loan money to the applicants, where his firm commitment is supported by adequate financial resources, is a sufficient basis for resolving the financial issue. Theodore Granik, 8 FCC 2d 1068 (Rev. Bd. 1967).

19. The petitions for reconsideration allege, however, that the Hedberg loan by itself is an insufficient basis for determining that the applicants are qualified and that a full inquiry into the financial position of the TeleTech corporate structure and Robert Starer is required. The applicants claim in response that they are all relying solely on the Hedberg funds and none are looking to Mr. Starer or any other source for any financing whatsoever. Under the circumstances, although Robert Starer is the principal of the applicants, we do not consider his financial position to be a proper subject for inquiry with respect to the financial issue. Nor do we believe that an investigation into TeleTech is necessary. Section 21.17(a) of the Commission's Rules requires an applicant for DPLMRS facilities to demonstrate the "financial ability to meet the realistic and prudent * * * estimated costs for proposed construction and other initial expenses; and estimated operating expenses for a reasonable period of time." The applicants have made such a showing here and petitioners have provided no compelling reasons to justify the full financial inquiry they seek.

TRANSFER OF CONTROL

20. The Bureau carefully considered this matter, accepted Mr. Hedberg's explanations and found no problem with the transfer of control issue. However, on our own review, we think that particular statements in Mr. Hedberg's June 11, 1976 letter raise problems which warrant further consideration. In that letter, Mr. Hedberg mentions, without elaborating, that he has "participated as a TeleTech director in the formulation of TeleTech policy." We consider this to be a significant factor, since it indicates that Mr. Hedberg is in a position to influence the policy of a corporation, the subsidiaries of which he will be financing and over whom he disclaims any influence. This factor, coupled with his large financial undertaking and its inherent potential for abuse,[16] persuade us to add an issue to determine whether a de facto transfer of control has occurred or is likely to occur.

CHARACTER QUALIFICATIONS

21. We have not considered the numerous judgments and tax liens issued against Robert Starer and his companies to be of decisional importance with respect to the financial qualifications of the applicants involved herein. However, because Mr. Starer is the majority shareholder and principal officer of the multiple applicants in this proceeding, we view those judgments and liens as being significant and relevant to a determination of whether the applicants have the requisite character qualifications to become licensees of this Commission. The petitioners have alleged that on at least 63 occasions between 1972 and 1976, creditors of Starer and some of his companies have resorted to legal action in the courts of Philadelphia County, Pa., and have had judgments rendered in their favor. As of September 20, 1976, 47 judgments and tax liens, totaling more than $204,000, were still listed in court records as not having been satisfied or released. These include: Thirteen judgments against the Starer-owned Mobile Equipment Co., totaling $20,469.10, and two liens, totaling $34,283.86; fourteen judgments and four federal tax liens issued against Starer's Philadelphia MTC, totaling $31,635.03; and thirteen judgments against Robert Starer personally, totaling $121,477.34. Many of these judgments have the creditor listed as "Commonwealth of Pennsylvania" or "Unemployment Compensation Fund." Although we are not aware of the specifics of those transactions, the tax liens indicate that Mr. Starer has not fulfilled certain legal obligations imposed upon him by both the federal and state governments. Mr. Starer has not yet satisfactorily responded to the allegations nor explained what appear to be indications of financial irresponsibility, except to argue that most of the judgments are against companies not related to the applicants and thus are irrelevant to the financial issue. Yet these debts may indicate a recalcitrance on Starer's part to assume his proper financial obligations.

22. Petitioners have provided us with specific information concerning some of the transactions involving creditors of Starer's companies. In two letters, copies of which were forwarded to us, an advertising firm claims it was hired by Robert Starer to handle the advertising and promotion of several of his companies, that Starer "walked away from his debts," and that an unpaid balance of about $16,500 remains, $9,835.04 of which was an obligation of Minnesota Mobile Telephone Co., a licensee formerly controlled by Starer. Furthermore, of those companies said to own the advertising firm money are "Mobile Phone Co., Baltimore-Washington Mobile Phone Co., Atlanta Mobile Phone Co., Indianapolis Mobile Phone Co.," some of which have applications pending before this Commission.

23. Petitioners' supplemental reply pleading discussed an $11,000 judgment rendered in 1971 by the U.S. District Court for the Central District of California against Mobile Telephone Co. in favor of a law partnership which had performed services for MTC. The judgment remains unpaid, according to one of the creditors. The matter is of greater significance when viewed retrospectively in the context of the 1972 applications for transfer of control of Philadelphia MTC and Mobile Telephone Co. of New Jersey from Mobile Telephone Co. to Starer, individually. The judgment creditors

[15] Only two specific alleged liabilities have been brought to our attention. The first is a federal tax lien for $353.78 filed against MTC. The second, discussed in Paragraph 22 below, involves a possibly unsatisfied claim against MTC, dating back several years, of a firm which provided advertising and promotional services. However, we do not consider the amounts of these alleged liabilities to be of great significance with respect to the financial issue in view of the fact that Mr. Hedberg's loan is sufficient to meet some additional costs.

[16] See *Heitmeyer* v. *FCC*, 95 F. 2d 91, 99 (D.C. Cir. 1937): "It is well known that one of the most powerful and effective methods of control of any business * * * is the control of its finances."

filed petitions for reconsideration of the grants of those transfer applications, alleging that the two transferred stations were MTC's most valuable assets, but that transfer of them to Starer would no longer make them available to satisfy the judgment. By letter dated September 11, 1973, the Common Carrier Bureau denied the petitions for reconsideration, finding no evidence that the transfer was intended to defraud the creditors. More importantly, the Bureau specifically relied on the fact that Starer waived immunity from the judgment which excluded him personally from liability, and his offer to honor the judgment led the Bureau to conclude that it was more likely the creditors would receive satisfaction. Apparently, this has not yet happened.

24. Recently, other matters have come to our attention which may reflect on Mr. Starer's competence and responsibility as a licensee. Robert Starer is the sole owner and licensee of Philadelphia Mobile Telephone Co. (PMTC). On June 2, 1976, we received a letter from Taft Broadcasting Co., the lessor of tower antenna space to PMTC, notifying us that PMTC was delinquent in its rental payments, had a substantial unpaid balance due, and, as a result, Taft was about to terminate the lease and remove PMTC's equipment.

25. On August 24, 1976, The Bell Telephone Co., of Pennsylvania (Bell), filed an application for authority to terminate interconnect service provided to PMTC, alleging a nonpayment of bills between November 1975 and July 1976, that PMTC has an unpaid balance of $27,720.93, and that seven checks had been returned because of insufficient funds. Bell described its repeated efforts to obtain payment from PMTC. Confronted with similar circumstances in 1973, Bell had sought then to discontinue service to PMTC, but later withdrew its application. Alleging a contractual dispute and the necessity for maintaining service, Starer and PMTC applied to the U.S. District Court for the Eastern District of Pennsylvania for a temporary retraining order to prevent the disconnection. Such an order was issued on August 23, 1976.[17]

26. That this PMTC-Bell dispute was not an isolated incident is evidenced by the fact that in 1971, local exchange and interconnection services provided by the Northwestern Bell Telephone Co., to the then Starer-controlled Minnesota Mobile Telephone Co., were suspended for approximately 6 weeks for nonpayment of bills totaling $2,966.48. The previous year, Minnesota MTC had asserted in its application for a construction permit that it was holding orders for 181 mobile units from 164 customers. Philadelphia MTC is presently serving approximately 125 two-way mobile and 475 one-way signalling units. Thus, whether or not Starer's two companies had legitimate contractual disputes, as they claimed, with the local Bell affiliates, it is worth noting that in the overall history of Mr. Starer's operations, his stations have on occasion conducted their affairs in such a manner that service to hundreds of customers was jeopardized as a result. The problem becomes more significant when we consider the fact that all the applicants herein state that initially their subscribers will be responsible for acquiring their own mobile units from other sources. Although DPLMRS licensees are not required to furnish their customers with mobile units, Mr. Starer's performance record raises a public interest consideration in that numerous subscribers, who must pay close to $2,000 for such equipment, may find themselves extremely inconvenienced if the Starer-controlled carrier to which they subscribe for mobile radio service experiences the same difficulties described above. Mr. Starer and the TeleTech-MTC corporations are located in Philadelphia. Since problems have developed in their own backyard in the operations of the Philadelphia MTC station, it raises a question as to how Mr. Starer will be able to manage effectively the affairs of facilities scattered across the nation.

27. The foregoing suggests a possible pattern of apparent irresponsibility, carelessness or inability to exercise proper licensee behavior on the part of Robert Starer. In Starer stations of Indiana, 51 FCC 2d 95 (1967), we found that a pattern of questionable past conduct was clearly relevant to a determination of whether such conduct would be likely to occur in the future. Accordingly, we will designate a character qualifications issue to consider whether Mr. Starer has demonstrated such ineptness, that the Commission cannot rely on the applications to fulfill the duties and responsibilities of licensees. See Beamon Advertising, Inc., 1 FCC 2d 28 (Rev. Bd. 1965), and Edward G. Atsinger, III, 29 FCC 2d 443 (Rev. Bd. 1971).

SECTION 1.65 ISSUE

28. The Common Carrier Bureau excused any section 1.65 violation, concluding that there was no evidence of any intent to mislead the Commission, and that no parties had been prejudiced thereby. However, it now seems appropriate to consider whether the applicants violated § 1.65 by failing to report the status of the State certification of Mobile Telephone Co., of South Carolina, as well as the numerous judgments and financial problems of Robert Starer and his companies which may have a bearing on his competence and the applicants' character qualifications. Thus, we are designating an issue to determine whether the applicants have continued to keep the Commission advised of "substantial and significant changes," as required by § 1.65 of the rules.

SERVICE OF PLEADINGS

29. The petitioners allege that certain amendments relied upon by the Bureau were never served upon them as required by the rules. Because all petitioners in this proceeding were and are represented by the same attorney, the applicants claim that it was only necessary that numerous and lengthy amendments be served once on counsel and not that identical documents be served several times for each of the attorney's clients. Furthermore, the applicants insist that counsel for petitioners was served with copies of all documents. Because those pleadings in question indicate that copies were sent to the petitioners' counsel, and because the petitioners have since had the opportunity to raise objections based on such pleadings, we will not consider the matter further.

ABUSE OF PROCESS

30. The applicants content that the petitions for reconsideration constitute further attempts by the petitioners to thwart the expeditious processing of the pending applications. Alleging an abuse of administrative processes, the applicants suggest that legal action is proceeding or will be initiated against the petitioners and their legal counsel. The petitioners contend that, by threatening legal action, the applicants are resorting to intimidation, which reflects adversely on their character qualifications. We recognize the applicants' frustration with the length of this proceeding. But we also note that many valid issues have been raised by the petitioners in the course of this proceeding, as evidenced by the Bureau's orders and our extended discussion. Furthermore, only recently have the applicants submitted information which was considered sufficient to resolve certain issues. For example, the financial issue was only ready for favorable resolution following the recent amendments to the applications containing the viable Hedberg financial proposal. While we might agree that some of the minor allegations raised might not have had a significant bearing on the question as to whether grants of the applications would be in the public interest, conve-

[17] On June 3, 1977, Bell filed similar complaint, alleging that Pennsylvania Radio Telephone Co. (PRTC), a Reading, Pa., station co-owned by Robert Starer, had unpaid bills totaling $3,755.77. On September 22, 1977, we issued an order, stating the Bell may terminate service to PMTC and PRTC if all outstanding bills were not paid within 90 days of the release date of our order.

nience and necessity, we do not find that an abuse of our processes has occurred. Moreover, in view of the serious public interest considerations raised by the petitioners throughout this proceeding, we do not find that their persistence in advancing their claims constitutes an abuse of this Commission's processes. In ATS Mobile Telephone Co., 35 FCC 2d 443 (1972), we warned that appropriate action may follow when parties engage in conduct tending to abuse our processes. Because this proceeding is not yet being terminated but is proceeding into the hearing phase, we take the opportunity to remind both petitioners and applicants alike of the high standard of conduct expected of them by us. See Radio Carrollton, 52 FCC 2d 1187 at 1223 (1974).

OTHER APPLICATIONS

WISCONSIN MOBILE TELEPHONE COMPANY

31. All City Telephone Answering Service has raised several objections in its petition for reconsideration of the July 8, 1976 order granting the application of Wisconsin MTC. All City's first argument, that it was not served with certain amendments, was to some extent considered in Paragraph 29, above. Although All City claims it was not served with a September 24, 1975, amendment which the Bureau relied upon in resolving the need issue, All City was apparently put on notice of that amendment at a later date, and we note that All City has not in its subsequent pleadings challenged the sufficiency of the applicant's need showing. Because the applicant demonstrated substantial unsatisfied demand for service, as the Bureau found, we will not reopen the matter for further inquiry.

MOBILE TELEPHONE COMPANY OF SOUTH CAROLINA

32. Morris Communications filed a separate petition for reconsideration of the July 6 order since issues considered therein were relevant to the application of MTC-SC, against which Morris had filed a petition to deny. That application is still in pending status, but is now ready for further processing, and discussion of the petition to deny is warranted. One allegation, concerning the validity of the state certificate of MTC-SC, was discussed in Paragraph 9 above. We consider such an issue to be appropriate. Moreover, in Paragraph 28 above we stated that the section 1.65 issue will encompass a determination as to whether the applicant failed to notify us of significant developments before the South Carolina Public Service Commission.[18]

33. Morris also alleges misrepresentation in connection with a site availability issue. Initially, the applicant stated it would attach its antenna to a tower used by Southern Bell Telephone & Telegraph Co. for DPLMRS station KIG 295. When Southern Bell claimed no such arrangements had been made, MTC-SC amended its application to indicate it had obtained access to the radio tower of WMUU, owned by Bob Jones University, Inc., and located approximately 100 feet from the Southern Bell tower. Morris insists that a 100-foot change would result in different geographical coordinates, but that the amendment did not specify such a change. According to our records, the coordinates of the two towers differ slightly, by only one second. We note also that MTC-SC initially stated that it would use the Southern Bell tower, but that its application specified the coordinates for the WMUU tower. Although MTC-SC has provided us with letters which indicate that it presently has access to the WMUU tower, it has not satisfactorily responded to Common Carrier Bureau staff inquiries as to whether it had made adequate arrangements for its antenna site prior to the filing of its application. Specifically, MTC has not informed us as to whether or not it had secured antenna space from Southern Bell prior to filing its application. If such arrangements had been made, the question arises as to why improper coordinates were submitted. And if no arrangements had been made, the applicant should explain the basis for its assertion in the application that the Southern Bell tower would be used.

34. The next major issue involves the applicant's need showing. MTC-SC states that it conducted a five-day advertising campaign which generated 100 inquiries, resulting in applications for the proposed service from 44 persons who require 49 mobile units. Although such figures are adequate to support a two-channel grant, MTC-SC has requested three frequencies. We will, therefore, ask for further information to support a grant of the third channel. Other matters raised by Morris do not warrant further inquiry and may be summarily dismissed. An allegation that a grant of the MTC-SC application will lead to destructive market fragmentation lacks the specificity required by *WLVA, Inc.* v. *FCC*, 459 F. 2d 1286 (D.C. Cir. 1970), and Commonwealth Telephone Co., 61 FCC 2d 246 (1976). A complaint alleging that other MTC companies engaged in improper premature advertising was dismissed by us in American Radio Telephone Service, Inc., 20 FCC 2d 963 (1970). Incorporated by reference are allegations made against Washington MTC to the effect that the applicant provided a prospective customer with misleading information as to the rates and other aspects of the proposed service, and that the rate structure had anticompetitive components. We note that the District of Columbia Public Service Commission found no merit to these charges and we do not consider further inquiry to be warranted. Finally, we will dismiss Morris' allegations concerning the feasibility of the MTC-SC technical proposal. We find that the proposed alarm system is satisfactory and that the applicant has made adequate preparations for maintenance and repair in the event of malfunction.

MOTION FOR CONSOLIDATION

35. On November 1, 1976, Lancaster Alarm Co., Inc. tr/a Lancaster Radio Paging Corp. (LRPC) filed a "Motion for Consolidation," asking that an application (File No. 20014-CD-P-77) of the Starer-owned Suburban Mobile Telephone Co. (Suburban) be consolidated for hearing in this proceeding. LRPC alleges that Robert Starer threatened to file and did file the Suburban application for "strike" purposes against a pending application of LRPC (File No. 22575-CD-P-76). Alleging that the strike issue constitutes an abuse of process and reflects on the applicant's character qualifications, LRPC states that consolidation, pursuant to § 1.227(a)(1) of the rules, is warranted. According to LRPC, the Commission could then consider similar issues bearing on character and view the totality of Starer's conduct at once, rather than view isolated incidents in separate proceedings. Starer has denied the allegation, asserting that the Suburban proposal had been under contemplation for some time and that there was no intent to impede the processing of the LRPC application.

36. We will deny the LRPC motion, since we do not believe that these are the proper circumstances for us to exercise the discretion available to us under § 1.227. All the applicants herein are part of the TeleTech-MTC corporate structure, whereas Suburban MTC is owned independently by Robert Starer and Merle Ann Starer. Consequently, issues already discussed in this lengthy proceeding and those remaining to be resolved may not necessarily be relevant to the Suburban MTC application. Moreover, the LRPC application presently lacks a state certificate and is, therefore, not ready for further processing or to be designated for hearing. Although we are denying the "Motion for Consolidation," we agree that a strike application is a seri-

[18] On March 8, 1977, we received a letter from the South Carolina PSC and the copy of a PSC order, issued February 28, 1977, which cancelled the MTC-SC certificate. Morris Communications called the matter to our attention on March 16, but the applicant has not yet advised us of the changed circumstances, as required by § 1.65 of our rules.

ous allegation and may have a significant bearing on an applicant's character qualification. Asheboro Broadcasting Co., 20 FCC 2d 1 (1969); Pass Word Inc., 61 FCC 2d 410 (1976). We will, therefore, designate an issue in this proceeding to consider whether Robert Starer participated in the filing of a strike application and the effect of such conduct on the character qualifications of the applicants. In addition, LRPC, will be permitted to participate as a party with respect to this issue only. The resolution of the issue will be deemed res judicata in any future proceeding involving these two applicants.

CONCLUSION

37. We are hereby reconsidering and setting aside the grants previously issued the ten captioned air-ground applicants and Wisconsin Mobile Telephone Company. A hearing will be held to consider issues common to all affiliates of Mobile-Telephone Co. listed in the appendix. The findings and conclusions of the Administrative Law Judge will be incorporated into the records of the other land mobile applications which are still pending and require further processing (See footnote 4, supra.). The right to commence equipment or service tests for the stations of Indiana Mobile Telephone Co. and Land of Lincoln Mobile Telephone Co. will remain canceled pending the outcome of the hearing and any action which may be deemed appropriate at that time. Finally, the application of Mobile Telephone Co. of South Carolina is designated for hearing on specific issues in addition to those issues common to its affiliated companies.

38. In view of the foregoing: *It is ordered*, That pursuant to sections 405, 309 (d) and (e) of the Communications Act of 1934, as amended, the grants of the ten captioned applications for air-ground stations and the application of Wisconsin Mobile Telephone Co. are hereby set aside and are designated for hearing in a consolidated hearing upon the following issues:

(a) To determine whether Robert D. Hedberg has exercised, now exercises, or is capable of exercising de facto control over the applicant companies contrary to Section 310 of the Communications Act.

(b) To determine whether the management and operations of other licensees and companies owned or controlled by Robert L. Starer has been so irresponsible, careless or inept that the applicants cannot be relied upon to fulfill the responsibilities imposed upon them as licensees of this Commission.

(c) To determine whether Robert Starer participated in the filing of a strike application and, if so, the effect thereof on the applicants' character qualifications.

(d) To determine whether the applicants have continued to keep the Commission advised of all "substantial and significant changes" in information as required by § 1.65 of the Commission's rules.

(e) To determine, in light of the evidence adduced pursuant to the foregoing issues, whether grants of the above-captioned applications would serve the public interest, convenience and necessity.

39. *It is further ordered*, That pursuant to section 309 of the Communications Act, the captioned application of Mobile Telephone Co. of South Carolina is designated for hearing upon the issues listed in Paragraph 38 above and those following:

(a) To determine whether the applicant presently has a valid state certificate issued by the South Carolina Public Service Commission.

(b) To determine the basic need for the proposed service of Mobile Telephone Co. of South Carolina in the Greenville, S.C. area.

EXHIBIT A

APPLICATION

COMPANY	LOCATION	FILE NO.	TYPE APPL	# OF CHAN	EQUIPMENT REQUIREMENTS: Column 1 OWNED & IN CURRENT INVENTORY	EQUIPMENT REQUIREMENTS: Column 2 REQUIRED CAPITAL TO PURCHASE	CASH REQUIREMENTS: Column 3 1ST YR. RQMTS FOR OPRTG EXP	CASH REQUIREMENTS: Column 4 TOTAL CASH NEEDED	Column 5 1ST YR REVENUES
Arizona MTC	Grand Canyon	7323-C2-P-70	AIR	1	-	$ 7,350	$ 4,700	$ 12,050	$ 5,000
Baltimore MTC	Baltimore	4744-C2-P-69	LAND	2	$ 49,700	26,000	8,000	84,000	15,500
Boat MTC	Boston	5761-C2-P-(5)-69	LAND	4	-	38,500	16,800	55,300	15,500
Caribe MTC	St. Thomas, VI	6959-C2-P-70	AIR	1	-	7,350	4,700	12,050	5,000
Colo. MTC	Gr. Junction	5596-C2-P-70	AIR	1	-	7,350	4,700	12,050	5,000
Georgia MTC	Waycross	562-C2-P-71	AIR	1	-	7,350	4,700	12,050	5,000
Indiana MTC	Indianapolis	843-C2-P-(3)-71	LAND	3	37,700	38,000	16,800	54,800	15,500
Land of Lins.	Chicago	2244-C2-P-70	LAND	1	-	14,700	9,300	24,000	15,500
Michigan RTC	Detroit	5475-C2-P-(3)-71	LAND	2	-	31,000	16,800	47,800	15,500
No. Car. MTC	Rocky Mount	564-C2-P-71	AIR	1	-	7,350	4,700	12,050	5,000
Oregon MTC	Elko	1875-C2-P-71	AIR	1	-	7,350	4,700	12,050	5,000
So. Car. MTC	Greenville	2084-C2-P-(3)-70	LAND	3	-	31,000	16,800	47,800	15,500
Texas MTC	Amarillo	7324-C2-P-(2)-71	AIR	1	-	7,350	4,700	12,050	5,000
	Colby	563-C2-P-(2)-71	AIR	1	-	7,350	4,700	12,050	5,000
	Pierre	6967-C2-P-70	AIR	1	-	7,350	4,700	12,050	5,000
	San Antonio	4749-C2-P-70	AIR	1	-	7,350	4,700	12,050	5,000
Washington MTC	Washington, DC	5547-C2-P-(3)-69	LAND	3	80,500	20,000	16,800	36,800	15,500
Wisconsin MTC	Milwaukee	1121-C2-P-(3)-71	LAND	3	-	31,000	16,800	47,000	15,500
					$167,900	$303,700	$165,100	$468,800	$174,000

(c) To determine whether the applicant had reasonable assurance of the availability of an antenna site when the application was filed.

(d) To determine, in light of the evidence adduced pursuant to the foregoing issues, whether a grant of the above-captioned application would serve the public interest, convenience and necessity.

40. *It is further ordered,* That the burden of proof on the issues listed in Paragraphs 38 and 39 is on the respective applicants. The burdens of proceeding with the evidence on the various issues will be assigned by the Administrative Law Judge.

41. *It is further ordered,* That the hearing shall be held at the Commission offices in Washington, D.C., at a time and place and before an Administrative Law Judge, to be specified in a subsequent order.

42. *It is further ordered,* That the Chief, Common Carrier Bureau, DPRS trading as Zip-Call, All City Telephone Answering Service, S.M.W. Inc., and Morris Communications, Inc., are made parties to the proceeding. Lancaster Alarm Co., Inc. tr/a Lancaster Radio Paging Corp. is made a party for the purpose of participating only with respect to the issue specified in Paragraph 38(c).

43. *It is further ordered,* That the applicants and other parties may avail themselves of an opportunity to be heard by filing with the Commission, pursuant to § 1.221(c) of the Commission's rules, within twenty days of the release date hereof, a written notice stating an intention to appear on the date set for the hearing and present evidence on the issues specified in this Memorandum Opinion and Order.

44. *It is further ordered,* That pursuant to §§ 21.212(a)(2) and 21.212(b)(2) of the Commission's rules, the right to commence equipment or service tests for the stations of Land of Lincoln Mobile Telephone Co. and Indiana Mobile Telephone Co. remain canceled pending further action.

45. *It is further ordered,* That the Application for Review filed on November 12, 1976 by the applicants is denied.

46. *It is further ordered,* That the Petition to Deny of Morris Communications, Inc. is granted to the extend indicated above and is denied in all other respects.

47. *It is further ordered,* That the petitions for reconsideration of DPRS trading as Zip-Call, S.M.W. Inc., All City Telephone Answering Service, and Morris Communications, Inc. are granted to the extent indicated above and are denied in all other respects.

48. *It is further ordered,* That the Motion for Consolidation filed by Lancaster Alarm Co., Inc. tr/a Lancaster Radio Paging Corp. is denied.

For the Federal Communications Commission.[19]

WILLIAM J. TRICARICO,
Acting Secretary.

[FR Doc. 77-33479 Filed 11-21-77; 8:45 am]

[6730-01]

FEDERAL MARITIME COMMISSION

[Independent Ocean Freight Forwarder License No. 1918]

EVANS INTERNATIONAL (PETER H. EVANS D.B.A.)

Order of Revocation

By letter dated October 18, 1977, Mr. Peter H. Evans d.b.a. Evans International, 9-11 Maiden Lane, New York, N.Y. 10038 was advised by the Federal Maritime Commission that Independent Ocean Freight Forwarder License No. 1918 would be automatically revoked or suspended unless a valid surety bond was filed with the Commission on or before November 13, 1977.

Section 44(c), Shipping Act, 1916, provides that no independent ocean freight forwarder license shall remain in force unless a valid bond is in effect and on file with the Commission. Rule 510.9 of Federal Maritime Commission General Order 4, further provides that a license will be automatically revoked or suspended for failure of a licensee to maintain a valid bond on file.

Peter H. Evans d.b.a. Evans International has failed to furnish a valid surety bond.

By virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), section 5.01(c) dated August 8, 1977;

It is ordered, That Independent Ocean Freight Forwarder License No. 1918 issued to Peter H. Evans d.b.a. Evans International, be returned to the Commission for cancellation.

It is further ordered, That Independent Ocean Freight Forwarder License No. 1918 be and is hereby revoked effective November 13, 1977.

It is further ordered, That a copy of this Order be published in the FEDERAL REGISTER and served upon Peter H. Evans d.b.a. Evans International.

LEROY F. FULLER,
Director, Bureau of Certification and Licensing.

[FR Doc. 77-33636 Filed 11-21-77; 8:45 pm]

[19] Chairman Wiley not participating; Commissioner Quello concurring in the result.

[6730-01]

[Independent Ocean Freight Forwarder License No. 1157]

P.A. FORWARDING (PEDRO ALICEA D.B.A.)

Order of Revocation

On October 28, 1977, Mr. Charles M. Appel, son-in-law of Pedro Alicea, advised the Commission that Pedro Alicea is deceased and the freight forwarding business of Pedro Alicea has been discontinued. Mr. Appel voluntarily surrendered Pedro Alicea, d.b.a. P. A. Forwarding's Independent Ocean Freight Forwarder License No. 1157 for revocation. The licensee is located at 80 Wall Street, New York, N.Y. 10005.

By virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), 5.01(c), dated August 8, 1977;

It is ordered, That Independent Ocean Freight Forwarder License No. 1157 issued to Pedro Alicea, d.b.a. P. A. Forwarding, be and is hereby revoked effective October 28, 1977.

It is further ordered, That a copy of this Order be published in the FEDERAL REGISTER and served upon P. A. Forwarding.

LEROY F. FULLER,
Director, Bureau of Certification and Licensing.

[FR Doc. 77-33637 Filed 11-21-77; 8:45 am]

[6210-01]

FEDERAL RESERVE SYSTEM

[Reg. C; Docket No. R-0130]

EXEMPTION APPLICATION UNDER HOME MORTGAGE DISCLOSURE ACT OF 1975

New Jersey

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of exemption application.

SUMMARY: United Jerseys Banks, a bank holding company operating six New Jersey-chartered banks, has applied for an exemption from the disclosure requirements of the Federal Home Mortgage Disclosure Act. The exemption request is based upon the claim that New Jersey law provides for substantially similar disclosures.

DATE: Comments regarding the application must be received on or before December 31, 1977.

ADDRESS: Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. All comments should refer to Docket No. R-0130.

FOR FURTHER INFORMATION CONTACT:

Anne J. Geary, Manager, Equal

Credit Opportunity Section, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-3946.

SUPPLEMENTARY INFORMATION: United Jersey Banks, a bank holding company operating six New Jersey chartered banks, has applied to the Board for an exemption from the disclosure requirements of the Home Mortgage Disclosure Act of 1975 (12 U.S.C. 2801-2809), as implemented by Regulation C (12 CFR 203). The application was filed pursuant to Section 306(b) of the Federal act (12 U.S.C. 2805 (b)) and § 203.3(a)(3) and the Supplement to Regulation C (12 CFR 203.3(a)(3)) and is based upon the requirements of the New Jersey Home Mortgage Disclosure Act (N.J.S.A. 17:16F-1 to 17:16F-11) and the implementing regulations of the New Jersey Department of Banking (N.J.A.C. 3:1-9). In its application, United Jersey Banks claims that the provisions of the New Jersey act and departmental regulations contain requirements that are substantially similar to those imposed under the Federal act and that there are adequate provisions for the enforcement of the State law.

If the Board grants an exemption in this case, the exemption would apply, as provided in Regulation C (12 CFR 203(a)(3) and Supplement Section (d)), to all New Jersey chartered depository institutions that are subject to the New Jersey act. While the exemption application is pending before the Board, however, all New Jersey chartered depository institutions that are subject to the Federal act must comply with Regulation C.

Copies of the exemption application are available for public inspection and copying during regular business hours in Room B 1118, at the Board's offices, 20th Street and Constitution Avenue NW., Washington, D.C., and the Federal Reserve Bank of New York, 33 Liberty Street, New York City.

To aid in the Board's consideration of this matter, interested persons are invited to submit written comments to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received no later than December 30, 1977. All submitted materials should include a reference to docket number R-0130. The comments that are received will be made available for public inspection and copying upon request, except as provided in § 261.6(a) of the Board's rules regarding the availability of information (12 CFR 261.6(a)).

By order of the Board of Governors, November 16, 1977.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 77-33570 Filed 11-21-77; 8:45 am]

[4110-86]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control

CHILDHOOD LEAD-BASED PAINT POISONING PREVENTION AD HOC ADVISORY COMMITTEE

Establishment

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. appendix I, the Center for Disease Control (CDC) announces the establishment by the Secretary, Department of Health, Education, and Welfare, on November 15, 1977, of the following advisory committee for a period of 3 months beginning December 1, 1977:

Designation: Childhood Lead-Based Paint Poisoning Prevention Ad Hoc Advisory Committee.

Purpose: The Childhood Lead-Based Paint Poisoning Prevention Ad Hoc Advisory Committee will review the policy statement dated March 1975, "Increased Lead Absorption and Lead Poisoning in Young Children," and make recommendations to the Secretary, HEW, the Assistant Secretary for Health, and the Director, CDC, on updating the statement.

Authority for this Committee will expire March 1, 1978, unless the Secretary formally determines that continuance is in the public interest.

Dated: November 16, 1977.

WILLIAM H. FOEGE,
Director, Center for Disease Control.

[FR Doc. 77-33558 Filed 11-21-77; 8:45 am]

[4110-86]

CHILDHOOD LEAD-BASED PAINT POISONING PREVENTION AD HOC ADVISORY COMMITTEE

Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Center for Disease Control announces the following Committee meeting:

Name: Childhood Lead-Based Paint Poisoning Prevention Ad Hoc Advisory Committee.
Dates: December 8 and 9, 1977.
Place: Classroom 1, Building 1, Center for Disease Control, 1600 Clifton Road NE., Atlanta, Ga. 30333.
Time: 8 a.m.
Type of Meeting: Open.
Contact person: Vernon N. Houk, M.D., Executive Secretary of Committee Environmental Health Services Division, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, Ga. 30333. Phone: 404-633-3311, extension 6747, FTS 236-7747.
Purpose: The Committee is charged with advising and making recommendations to the Secretary, the Assistant Secretary, and the Director, Center for Disease Control, on amendments to the policy statement dated March 1975. "Increased Lead Absorption and Lead Poisoning in Young Children."
Agenda: The Committee will review the policy statement in question and recommend the necessary changes to update the document. Agenda items are subject to change as priorities dictate.

The meeting is open to the public for observation and participation. Anyone wishing to make an oral presentation should notify the contact person listed above as soon as possible before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the presentation. Oral presentations will be scheduled at the discretion of the chairperson and as time permits. Anyone wishing to have a question answered during the meeting by a scheduled speaker should submit the question in writing, along with his or her name and affiliation, through the Executive Secretary to the chairperson. At the discretion of the chairperson and as time permits, appropriate questions will be asked of the speakers.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

Dated: November 16, 1977.

WILLIAM H. FOEGE,
Director, Center for Disease Control.

[FR Doc. 77-33557 Filed 11-21-77; 8:45 am]

[4110-86]

Center for Disease Control

ANNUAL REPORTS

Availability of Filing

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463 (5 U.S.C. Appendix I), Annual Reports for the following Center for Disease Control Committees have been filed with the Library of Congress:

Coal Mine Health Research Advisory Committee.
Safety and Occupational Health Study Section.

Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, and on weekdays between 9 a.m. and 4:30 p.m., at the Department of Health, Education, and Welfare, Department Library, HEW North Building, Room 1436, 330 Independence Avenue SW., Washington, D.C. 20201, telephone 202-245-6791.

Dated: November 10, 1977.

WILLIAM C. WATSON, Jr.,
Acting Director, Center for Disease Control.

[FR Doc. 77-33661 Filed 11-21-77; 8:45 am]

[4110-89]

Office of Education

NATIONAL ADVISORY COUNCIL ON ADULT EDUCATION

Meeting

AGENCY: National Advisory Council on Adult Education.

ACTION: Notice of Meeting.

SUMMARY: This notice sets forth the Schedule and proposed agenda of a forthcoming meeting of the Program Effectiveness and Evaluation Committee of the National Advisory Council on Adult Education. This notice also describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92-463, Section 10(a)(2)).

DATE: December 10, 1977, 9 a.m. to 5 p.m.

ADDRESS: Sahara Hotel, 2535 Las Vegas Boulevard South, Las Vegas, Nev. 89122.

FOR FURTHER INFORMATION CONTACT:

Dr. Gary A. Eyre, Executive Director, National Advisory Council on Adult Education, 425 13th Street NW., Washington, D.C. 20004, 202-376-8892.

SUPPLEMENTARY INFORMATION: The National Advisory Council on Adult Education is established under section 311 of the Adult Education Act (80 Stat. 1216.20 U.S.C. 1201). The Council is directed to:

Advise the Commissioner in the preparation of general regulations and with respect to policy matters arising in the administration of this title, including policies and procedures governing the approval of State plans under section 306 and policies to eliminate duplication, and to effectuate the coordination of programs under this title and other programs offering adult education activities and services.

The Council shall review the administration and effectiveness of programs under this title, make recommendations with respect thereto, and make annual reports to the President of its findings and recommendations (including recommendations for changes in this title and other Federal laws relating to adult education activities and services). The President shall transmit each such report to the Congress together with his comments and recommendations.

The meeting of the Council shall be open to the public.

The proposed agenda includes:

USOE program and financial information
NACAE State survey summary
309 Project impact
Evaluations of programs cooperating with adult education
311(d) Project
Council/committee publication.

Records shall be kept of all Council proceedings, and shall be available for public inspection at the Office of the National Advisory Council on Adult Education, Room 323, Pennsylvania Building, 425 13th Street NW., Washington, D.C. 20004.

Signed at Washington, D.C., on November 16, 1977.

GARY A. EYRE,
Executive Director, National Advisory Council on Adult Education.

[FR Doc. 77-33578 Filed 11-21-77; 8:45 am]

[4110-02]

NATIONAL ADVISORY COUNCIL ON ETHNIC HERITAGE STUDIES

Meeting

AGENCY: National Advisory Council on Ethnic Heritage Studies.

ACTION: Notice.

SUMMARY: This notice sets forth the schedule and proposed agenda on the forthcoming meeting of the National Advisory Council on Ethnic Heritage Studies. It also describes the functions of the Council. Notice of these meetings is required under the Federal Advisory Committee Act (5 U.S.C. Appendix 1.10(a)(2)). This document is intended to notify the general public of their opportunity to attend.

DATES: Meetings December 15, 16, 1977, 9:00 a.m. to 4:30 p.m.

ADDRESS: NASA Building, 600 Independence Avenue SW., Washington, D.C. 20045.

FOR FURTHER INFORMATION CONTACT:

Mr. Edward L. Meador, Acting Chief, Ethnic Heritage Studies Branch, Office of Education, 7th and D Streets SW., ROB No. 3, Room 3919, Washington, D.C. 20202. Telephone 202-245-9691.

SUPPLEMENTARY INFORMATION: The National Advisory Council on Ethnic Heritage Studies was established under section 906(a) of the Elementary and Secondary Education Act of 1965 as added by section 504(a) of the Education Amendments of 1972, Pub. L. 92-318 (20 U.S.C. 900a-4).

The Council is directed to:

(1) Advise the Secretary, the Assistant Secretary for Education, and the Commissioner of Education on the implementation of Title IX of the Elementary and Secondary Education Act of 1965 in order to provide assistance designed to afford students the opportunity to learn about their own cultural heritage and the contributions of the other ethnic groups of the Nation.

(2) Perform specific functions as follows:

(a) Make recommendations to the Commissioner, the Assistant Secretary, and the Secretary regarding the collection of data to facilitate program planning and evaluation; e.g., recommend a survey of needs to determine or modify program priorities, or suggest national or regional reviews of intercultural curriculum and personnel development

(b) Suggest innovations or program changes as the program evolves and develops toward improving ethnic heritage studies.

(c) Suggest promising areas of inquiry to give direction to research; e.g., recommend ethnographic studies as required for substantial intercultural curriculum materials development.

(d) Provide such administrative and legislative proposals as may be appropriate.

(e) Not later than March 31 of each year, submit to the Congress a report of its activities, findings, and recommendations.

The meeting will open to the public beginning at 9:00 a.m. and ending at 4:30 p.m. each day. The meeting will be held at the NASA Building, 600 Independence Avenue SW., Washington, D.C. 20045, Room 5092.

The proposed agenda includes:

(1) Review and approval of minutes of previous meeting.

(2) Subcommittee reports.

(3) Review of recommendations for new legislation.

(4) Review of selected projects.

(5) Review of proposal guidelines for readers.

(6) Public testimony.

Records shall be kept of all Council proceedings and shall be available for public inspection at the Office of the Ethnic Heritage Studies Branch, Office of Education, Room 3919, Regional Office Building No. 3, 7th and D Streets SW., Washington, D.C. 20202.

Signed at Washington, D.C., on November 17, 1977.

EDWARD L. MEADOR,
Acting Chief, Ethnic Heritage Studies Branch.

[FR Doc. 77-33568 Filed 11/21/77; 8:45 am]

[4110-03]

Food and Drug Administration

ADVISORY COMMITTEE

Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested per-

sons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C., app. I)), and FDA regulations (21 CFR, part 14) relating to advisory committees. The following advisory committee meeting is announced:

Committee name	Date, time, and place	Type of meeting and contact person
Vitamin, Mineral and Hematinic Panel.	Dec. 8, 3 p.m., Conference Room I, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md..	Open public hearing/open committee discussion 3 p.m. to 4:30 p.m.; Thomas D. DeCillis, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4960.

General function of the committee. Reviews and evaluates available data concerning the safety and effectiveness of nonprescription drug products.

Agenda—Open public hearing/open committee discussion. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those who desire to make such a presentation should notify the contact person before December 5, 1977, and submit a brief statement of the general nature of the data, information or views they wish to present, the names and addresses of proposed participants, and an indication of the approximate time desired for their presentation.

Open committee discussion. The panel will review data submitted pursuant to the over-the-counter (OTC) review's call for data for this panel (see also 21 CFR 330.10(a)(2)).

The panel will be reviewing, voting upon, and modifying the content of summary minutes and categorization of ingredients and claims.

This meeting will take the form of a telephone conference call between panel members and FDA staff.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this FEDERAL REGISTER notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR, part 14.

Dated: November 15, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 77-33522 filed 11-21-77; 8:45 am]

[4110-03]

OPHTHALMIC DRUGS ADVISORY COMMITTEE

Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announces the renewal of the Ophthalmic Drugs Advisory Committee by the Secretary, Department of Health, Education, and Welfare.

DATE: Authority for this committee will expire on March 20, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

Dated: November 15, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 77-33524 Filed 11-21-77; 8:45 am]

[4110-03]

RADIOLOGICAL DEVICE CLASSIFICATION PANEL

Meeting Cancellation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Radiological Device Classification Panel meeting scheduled for December 9, 1977, is hereby cancelled.

FOR FURTHER INFORMATION CONTACT:

Lillian Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of November 15, 1977 (42 FR 59112), meetings of FDA public advisory committees and other required information in accordance with provisions set forth in section 10 (a) (1) and (2) of the act.

Notice is hereby given that the meeting of the Radiological Device Classification Panel scheduled for December 9, 1977, has been cancelled.

Dated: November 15, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 77-33523 Filed 11-21-77; 8:45 am]

[4110-03]

Food and Drug Administration

[Docket No. 77N-0273]

AMPHETAMINES

Public Hearing

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs announces that to permit sufficient time for all interested persons to submit data, information, or views on the current patterns of medical use and abuse of amphetamines, the administrative record of the public hearing shall remain open for 30 days after the hearing is held.

DATES: The hearing will be held on December 2, 1977; written submissions by January 3, 1978.

ADDRESSES: Written submissions to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857

FOR FURTHER INFORMATION CONTACT:

Ronald Kartzinel, Bureau of Drugs (HFD-120), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4020.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 14, 1977 (42 FR 55374), the Commissioner of Food and Drugs announced that a public hearing will be held on December 2, 1977, to receive information and views from interested persons on the current patterns of medical use and abuse of amphetamines.

The Commissioner has subsequently received requests from three pharmaceutical firms to postpone the scheduled hearing date for 90 days. The requests argue that the announced schedule does not allow interested persons sufficient time to review the data and reports on which FDA has relied. Thus, interested persons will be unable to submit well-documented comments on the merits of the course of action proposed by the Commissioner.

The Commissioner believes that the evidence before him indicating continued abuse of legally manufactured and marketed amphetamines constitutes an apparently significant public health problem. In the interest of public health, he concludes that the development of an administrative record in this matter should not be unduly delayed and has therefore denied the requests to postpone the hearing date.

Because the October 14 notice did not specify otherwise, § 15.25 (21 CFR 15.25) of the procedural regulations provides that the record of the hearing shall remain open for 15 days after the hearing is held for any additional written submissions on the subject matter.

The Commissioner is concerned that all interested persons have sufficient opportunity to participate in this matter. Thus, he has concluded that the record of hearing shall remain open for 30 days after the hearing is held for any interested person to submit written data, information, or views on the information in the October 14, 1977, notice or on any new information that may be presented by participants at the December 2 public hearing.

The administrative record of the hearing in Docket No. 77N-0273 shall remain open until January 3, 1978.

Dated: November 17, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 33674 Filed 11-21-77; 8:45 am]

[4110-03]

[Docket No. 76P-0203]

CAMPBELL SOUP CO.

Concentrated Tomato Juice Deviating From Identity Standards: Extension of a Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces the extension, as requested, of a temporary permit issued to the Campbell Soup Co. to market test concentrated tomato juice prepared from tomato paste and water, and to continue to market test 800 cases of forty-eight 6-ounce cans and 667 cases of twenty-four 12-ounce cans of the test product per month during the extended period. The finished product deviates from the standard of identity for concentrated tomato juice.

EFFECTIVE DATE: This amended permit is effective on November 22, 1977, and shall terminate either on the effective date of an affirmative order ruling on the Campbell Soup Co.'s petition to amend the identity standard for tomato puree or 30 days after a negative order ruling on the petition, whichever the case may be.

FOR FURTHER INFORMATION CONTACT:

Benjamin M. Gutterman, Bureau of Foods (HFF-402), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1231.

SUPPLEMENTARY INFORMATION: The original permit was issued to the Campbell Soup Co., under § 130.17 (21 CFR 130.17) concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of the issuance of the permit was published in the FEDERAL REGISTER of June 4, 1976 (41 FR 22620). This permit covered limited interstate marketing tests of concentrated tomato juice that deviates from the standards of identity prescribed for concentrated tomato juice under § 155.192(b)(2) (21 CFR 155.192(b)(2)) in that the test product is prepared by adding water to tomato paste containing 46 percent tomato soluble solids (21 CFR 155.191) in such quantity that the finished test food will contain 24 percent tomato soluble solids. Upon dilution by the consumer according to label directions, the product will contain tomato soluble solids in an amount equivalent to that found in single strength tomato juice. In addition, ascorbic acid will be added to the concentrated tomato juice in such quantity that the level of the vitamin C in the diluted product is restored to 3.5 milligrams per fluid ounce. All ingredients will be declared on the label by their common or usual name.

The Campbell Soup Co. has also submitted a petition, consistent with the requirements of § 130.17, proposing to amend the standard of identity for tomato puree (21 CFR 155.192) to provide for the preparation of concentrated tomato juice from tomato paste and water and for the addition of ascorbic acid in a quantity so as to restore the level of vitamin C in the product consumed to 3.5 milligrams per fluid ounce. The petition, which is being considered by the Food and Drug Administration, is on file with the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, for review by interested persons.

The Commissioner concludes that it will be in the interest of consumers to extend the time period of the temporary permit and to permit further market testing of the product as requested. Pursuant to § 130.17, all interested persons may participate in the market test under the conditions that apply to the Campbell Soup Co., including the labeling requirements and the amounts to be distributed, 800 cases of forty-eight 6-ounce cans and 667 cases of twenty-four 12-ounce cans per month.

Any interested person who elects to participate in the extended market test shall notify the Commissioner in writing of that fact, the amount to be distributed, and the area of distribution. Along with such notification, he shall submit the labeling under which the food will be distributed.

This permit extension, as issued to the Campbell Soup Co. and such others who participate in accordance with the provisions set out above, expires either on the effective date of an affirmative order ruling on the Campbell Soup Co. petition, or 30 days after a negative order ruling on the petition, whichever the case may be.

Dated: November 16, 1977.

HOWARD R. ROBERTS,
Acting Director,
Bureau of Foods.

[FR Doc. 77-33675 Filed 11-21-1977; 8:45 am]

[1505-01]

[Docket No. 76N-0185; DESI 3158]

CERTAIN ANDROGEN PREPARATIONS

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

Correction

In FR Doc. 77-28771 appearing at page 52487 in the issue for Friday, September 30, 1977, the date "March 28, 1977" which appears in the "DATES" paragraph and also in the first line of the 9th full paragraph in column one of page 52489, should have read "March 29, 1978."

[4110-03]

[Docket No. 77F-0256]

ICI AMERICAS, INC.

Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: ICI Americas, Inc., has filed a petition proposing that the food additive regulations be amended concerning 1,2-benzisothiazolin-3-one, to be used for food-contact applications.

FOR FURTHER IMFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 3B2882) has been filed by ICI Americas, Inc., proposing that § 175.105(c)(5) (21 CFR 175.105(c)(5)) be amended to include in the list of components of adhesives: 1,2-benzisothiazolin-3-one for use as a preservative; and that § 176.170(a)(5) (21 CFR 176.170(a)(5)) be amended to include 1,2-benzisothiazolin-3-one for use as a preservative in paper and paperboard coating compositions.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 16, 1977.

HOWARD R. ROBERTS,
Acting Director,
Bureau of Foods.

[FR Doc. 77-33676 Filed 11-21-77; 8:45 am]

[4110-08]

National Institutes of Health

ADVISORY COMMITTEE TO THE DIRECTOR, NIH

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 15-16, 1977, National Institutes of Health, Building 31, Conference Room 6C. The meeting will take place from 9 a.m. to 9 p.m. on December 15, and from 9 a.m. to 5 p.m. on December 16. The entire meeting will be open to the public.

The purpose of the meeting will be to consider proposed revised Guidelines for recombinant DNA molecule research conducted and supported by the NIH. The proposed Guidelines were published in the FEDERAL REGISTER September 27, 1977, on pages 49596 to 49609. Attendance by the public will be limited to space available.

In addition to current members of the Committee, a number of other scientific and public representatives have been invited to serve on the Committee for this public hearing. In order to ensure careful review, selected witnesses from the following areas will be invited to comment on the Guidelines at the hearing: environmental, commercial, organized labor, and scientific.

Other witnesses who wish to make oral statements concerning the proposed revisions to the Guidelines will be provided reasonable opportunity to do so at appropriate times indicated on the agenda. All witnesses are requested to confine their comments to the proposed revisions. Persons who wish to make oral statements should notify the Executive Secretary of their intention to speak and the Section of the proposed revisions to which they will direct their comments. Travel expenses will be provided for invited witnesses only.

Written comments on the proposed revised Guidelines should be addressed to: Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. The Executive Secretary, Charles R. McCarthy, Ph.D., National Institutes of Health, Building 1, Room 201, Bethesda, Maryland 20014 (301) 496-1480, will furnish rosters of Committee members and guests, and substantive program information.

The tentative agenda for the meeting is as follows:

PROPOSED AGENDA FOR MEETING OF THE ADVISORY COMMITTTEE TO THE DIRECTOR, NIH, DECEMBER 15-16, 1977

THURSDAY, DECEMBER 15

9 a.m.—Opening remarks—Dr. Fredrickson.

DISCUSSION OF SECTIONS OF REVISED DNA GUIDELINES

9:30 a.m.—Introduction to revised guidelines—Dr. Littlefield.

Section I. Physical Containment

Dr. Barkley

10 a.m.—Comments by invited witnesses.
10:30 a.m.—Coffee break.
10:45 a.m.—Comments by other witnesses.

11:30 a.m.—*Section II. Biological Containment*

Dr. Gottesman

11:45 a.m.—Comments by invited witnesses.
12:30 p.m.—Comments by other witnesses.
1 p.m.—Lunch.

2:15 p.m.—*Section III. Experimental guidelines*

Drs. Helinski, Rowe, and Day

2:45 p.m.—Comments by invited witnesses.
3:30 p.m.—Coffee break.
3:45 p.m.—Comments by invited witnesses.
5 p.m.—Dinner.
7:30 p.m.—Comments by other witnesses.
9 p.m.—Adjournment.

FRIDAY, DECEMBER 16, 1977

9 a.m.—Summary and comments—Dr. Fredrickson.

9:15 a.m.—*Section IV. Roles and Responsibilities*

Dr. Walters

9:45 a.m.—Comments by invited witnesses.
10:45 a.m.—Coffee break.
11 a.m.—Comments by other witnesses.
12 a.m.—Lunch.
1:15 p.m.—Committee discussion.
5 p.m.—Adjourn sine die.

Dated: November 15, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer.

[FR Doc. 77-33745 Filed 11-21-77; 8:45 am]

[4110-08]

BOARD OF SCIENTIFIC COUNSELORS, DIVISION OF CANCER BIOLOGY AND DIAGNOSIS

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, DCBD, National Cancer Institute, January 6 and 7, 1978, Building 31, 6th Floor, "C" Wing, Conference Room 7, National Institutes of Health. This meeting will be open to the public on January 6, 1978, from 9 a.m. to 5 p.m. to discuss the scientific research program of the Laboratory of Immunobiology, DCBD. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on January 7, 1978, from 9 a.m. to adjournment, for the review, discussion, and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Alan S. Rabson, Director, Division of Cancer Biology and Diagnosis, National Cancer Institute, Building 31A, Room 3A-03, National Institutes of Health, Bethesda, Md. 20014, telephone 301-496-4345 will furnish summary minutes, rosters of committee members, and substantive program information.

Dated: November 14, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33749 Filed 11-21-77; 8:45 am]

[4110-08]

NATIONAL ADVISORY NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE COUNCIL

Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Advisory Neurological and Communicative Disorders and Stroke Council, National Institutes of Health, January 26, 27, and 28, 1978, at 9 a.m. in Building 31-C, Conference Room 6, Bethesda, Md. 20014. The meeting will be open to the public from 9 a.m. until 1 p.m. on January 26, 1978, to discuss program planning and program accomplishments. Attendance by the public will be limited to space available. In accordance with the provisions set forth in Sections 552b(c)(4), and 552b(c)(6) of Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from 1 p.m. on January 26, 1978, until the conclusion of the meeting that day, and from 9 a.m. until 5 p.m. on January 27 and 28, 1978, for review, discussion and evaluation of individual initial pending and renewal research grant applications and applications for Teacher-Investigatory Awards and Research Career Development Awards. These applications and the discussion could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

The Acting Chief, Office of Scientific and Health Reports, Mr. Robert N. Hinkel, Building 31, Room 8A08, NIH, NINCDS, Bethesda, Maryland, Telephone (301) 496-5751, will furnish summaries of the meeting and rosters of committee members.

Dr. K. Kenneth Hisaoka, Executive Secretary, Federal Building, Room 1016, Bethesda, Md. 20014, telephone 301-496-9248, will furnish substantive program information.

[Catalog of Federal Domestic Assistance Program Nos. 13.851, 13.852, 13.853, 13.854, National Institutes of Health.]

Dated: November 14, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 33752 Filed 11-21-77; 8:45 am]

[4110-08]

NATIONAL ADVISORY NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE COUNCIL PLANNING SUBCOMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Neurological and Communicative Disorders and Stroke Council Planning Subcommittee, January 12, 1978, at 8:30 a.m. in the Connecticut Room, The Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Md. The meeting will be open to the public from 8:30 a.m. to 10:30 a.m. on January 12, 1978, to discuss program planning and program accomplishments. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S. Code and section 10(d) of the Pub. L. 92-463, the meeting will be closed to the public from 10:30 a.m. on January 12, 1978, to adjournment on January 12, 1978. The portion of the meeting being closed involves the review, discussion, and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

The Acting Chief, Office of Scientific and Health Reports, Mr. Robert N. Hinkel, Building 31, Room 8A08, NIH, NINCDS, Bethesda, Md., telephone 301-496-5751, will furnish summaries of the meeting and rosters of committee members.

Dr. O. Malcolm Ray, Executive Secretary of the Committee, Room 1020C, Federal Building, NIH, NINCDS, Bethesda, Md., telehpone 301-496-9234, will provide substantive program information.

(Catalog of Federal Dometic Assistance Program Nos. 13.851, 13.852, 13.853, 13.854, National Institutes of Health.)

Dated: November 14, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33750 Filed 11-21-77; 8:45 am]

[4110-08]

NATIONAL CANCER ADVISORY BOARD SUBCOMMITTEE ON CENTERS

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Cancer Advisory Board's Subcommittee on Centers, National Cancer Institute, December 19 and 20, 1977. On December 19, the meeting will be held in Building 31C, Conference Room 10, National Institutes of Health. On December 20, the meeting will be held in the Landow Building, Room C-418, 7910 Woodmont Avenue, Bethesda, Md. The entire meeting will be open to the public from 9 a.m. to 5 p.m., both days. Attendance by the public will be limited to space available.

Mrs. Marjorie F. Early, Committee Management Officer, National Cancer Institute, Building 31, Room 4B43, National Institutes of Health, Bethesda, Md. 20014, telephone 301-496-5708, will provide summaries of the meeting and rosters of committee members.

Dr. William A. Walter, Executive Secretary, National Cancer Institute, Building 31, Room 10A03, National Institutes of Health, Bethesda, Md. 20014, 301-496-4218 will furnish substantive program information.

Dated: November 17, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33746 Filed 11-21-77; 8:45 am]

[4110-08]

NATIONAL COMMISSION ON DIGESTIVE DISEASES

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given that the National Commission on Digestive Diseases will hold public hearings on January 5 and 6, 1978, from 10 a.m. to 6 p.m., at the following locations: on January 5, in Seattle, Wash. 98109, the Olympic Room in the Northwest Meeting Complex, Seattle Center, 1st North and Republican; and on January 6, in Los Angeles, Calif. 90073, at the Sawtelle Veterans Administration Hospital, Wadsworth Hospital Building No. 500, room 1280, Wilshire and Sawtelle Boulevards. The entire 2 days will be open to the public. Attendance by the public will be limited to space available.

Any member of the public who wishes to appear before the Commission at this time shall file a written statement or detailed summary of his remarks with the Commission before December 22, 1977. Statements or summaries shall be sent to Dr. Thomas P. Vogl, Executive Secretary, National Commission on Digestive Diseases, Room 6C16, the Federal Building, 7550 Wisconsin Avenue, Bethesda, Md. 20014. The time allotted to each participant will be determined by the Commission Chairman based upon the number of individuals who request an opportunity to make presentations.

Messrs. James N. Fordham or Leo E. Treacy, Office of Scientific and Technical Reports, NIAMDD, National Institutes of Health, Building 31, Room 9A04, Bethesda, Md. 20014, telephone 301-496-3583, will provide summaries of the Commission public hearings.

(Catalog of Federal Domestic Assistance Program No. 13.484, National Institutes of Health.)

Dated: November 15, 1977.

SUZANNE FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33748 Filed 11-21-77; 8:45 am]

[4110-08]

NATIONAL HEART, LUNG, AND BLOOD ADVISORY COUNCIL

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Heart, Lung, and Blood Advisory Council, National Heart, Lung, and Blood Institute, December 8-9, 1977, from 9 a.m. to 5 p.m., at the National Institutes of Health, Building 31, Conference Room 10, Bethesda, Md.

This meeting will be open to the public on December 8 from 9 a.m. to 5 p.m. and on December 9 from 9 a.m. to approximately 3 p.m. for the discussion of program policies and issues. Attendance by the public is limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and section 10(d) of Pub. L. 92-463, the meeting of the Council will be closed to the public on December 9 from approximately 3 p.m. to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications.

Mr. York Onnen, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 5A-03, National Institutes of Health, Bethesda, Md. 20014, 301-496-4236, will provide summaries of the meeting and roster of the Council members.

Dr. Jerome G. Green, Director of Extramural Affairs, NHLBI, Westwood Building, Room 7A-17, 301-496-7416, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, 13.838, and 13.839, National Institutes of Health.)

Dated: November 14, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33744 Filed 11-21-77; 8:45 am]

[4110-08]

PERIODONTAL DISEASES ADVISORY COMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Periodontal Diseases Advisory Committee, National Institute of Dental Research, National Institutes of Health, Bethesda, Md., on January 4-5, 1978, in Building 31C, Conference Room 7.

The entire meeting will be open to the public from 9 a.m. to 5 p.m. on January 4, and from 9 a.m., to adjournment on January 5, for the discussion and evaluation of clinical research, the periodontal diseases program and the current methods in diagnosis and treatment of periodontal diseases. Attendance by the public will be limited to space available.

Dr. Paul F. Parakkal, Executive Secretary of the Periodontal Diseases Avisory Committee, National Institute of Dental Research, National Institutes of Health, Westwood Building, Room 519, Bethesda, Md. 20014, phone No. 301-496-7784, will furnish rosters of committee members, a summary of the meeting, and other information pertaining to the meeting.

(Catalog of Federal Domestic Assistance Program No. 13,302, National Institutes of Health.)

Dated: November 15, 1977.

SUZANNA L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33747 Filed 11-21-77; 8:45 am]

[4110-08]

WORKSHOP ON "AMPHOTERICIN B METHYL ESTER IN THE TREATMENT OF SYSTEMIC MYCOTIC INFECTIONS"

Meeting

Notice is hereby given of the workshop on "Amphotericin B Methyl Ester in the Treatment of Systemic Mycotic Infections" sponsored by the Clinical Studies Branch, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, to be held on February 21, 1978, Conference Room 9, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014.

This meeting will be open to the public from 9 a.m. to 5 p.m. to review the current in vitro and in vivo antifungal properties of amphotericin B methyl ester and to evaluate its potential for controlled clinical trials in the treatment of systemic mycotic infections. Attendance by the public will be limited to space available.

Dr. Robert Edelman, Chief, Clinical Studies Branch, Building 31, Room 7A49, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, phone 301-496-5893, will provide additional information.

(Catalog of Federal Domestic Assistance Program No. 13.856, National Institutes of Health.)

Dated: November 11, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 77-33753 Filed 11-21-77; 8:45 am]

[4110-08]

WORKSHOP ON "NEW AND USEFUL METHODS IN VIRAL DIAGNOSIS"

Meeting

Notice is hereby given of the workshop on "New and Useful Methods in Viral Diagnosis" sponsored by the Clinical Studies Branch, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, January 12 and 13, 1978, Conference Room 10, National Institutes of Health, Bethesda, Md. 20014.

This meeting will be open to the public from 8:30 a.m. to 5:15 p.m. on January 12, 1978, and 8:30 a.m. to adjournment on January 13, 1978, to discuss the state of the art of rapid viral diagnosis in clinically important infections, quality control of reagents, and future directions in rapid viral diagnosis. Attendance by the public will be limited to space available.

Martha J. Mattheis, Microbiologist, Clinical Studies Branch, Building 31, Room 7A51, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Md. 20014, phone 301-496-5893, will provide additional information

(Catalog of Federal Domestic Assistance Program No. 13.856, National Institutes of Health.)

Dated: November 10, 1977.

SUZANNE L. FREMEAU,
Committee Management Officer, National Institute of Health.

[FR Doc. 77-33751 Filed 11-21-77; 8:45 am]

[1505-01]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[M 27963]

MONTANA

Opportunity for Public Hearing and Republication of Notice of Proposed Withdrawal

Correction

In FR Doc. 77-27383, appearing at page 47594, in the issue for Wednesday, September 21, 1977, second column, third line under "Beaverhead National Forest" reading "Sec. 10, S½S½S½SSE¼" should read "Sec. 10, S½S½S½SE¹/2."

[4310-84]

Bureau of Land Management

[Wyoming 61533]

WYOMING

Application

NOVEMBER 14, 1977.

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Kansas-Nebraska Natural Gas Co. of Hastings, Nebr., filed an application for a right-of-way to construct a 4½ inch O. D. steel natural gas pipeline for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYO.

T. 36 N., R. 87 W.,
Sec. 13, S½N½.

The pipeline will transport natural gas from a point in the SE¼NE¼ of sec. 13, T. 36 N., R. 78 W., to a point in the SW¼NW¼ of sec. 13, T. 36 N., R. 87 W., Natrona County, Wyoming.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 951 Union Boulevard, Casper, Wyo. 82601.

HAROLD G. STINCHCOMB,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 77-33526 Filed 11-21-77; 8:45 am]

[4310-70]

National Park Service

CAPE COD NATIONAL SEASHORE ADVISORY COMMISSION

Meeting

Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Cape Cod National Seashore Advisory Commission will be held on Friday, December 9, 1977, at 1:30 p.m. at the Headquarters Building, Cape Cod National Seashore, Marconi Station Area, South Wellfleet, Mass.

The Commission was established pursuant to Pub. L. 91-383 to meet and consult with the Secretary of the Interior on general policies and specific matters realting to the development of Cape Cod National Seashore.

The Commission will consider the following matter: Review of Proposed Zoning Standards. There will be subcommittee reports and the superintendent will report on a variety of matters relating to Seashore programs and operations.

The meeting is open to the public. It is expected that 15 persons will be able to attend the session in addition to Commission members. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the official listed below at least seven days prior to the meeting.

Further information concerning this meeting may be obtained from Lawrence C. Hadley, Superintendent, Cape Cod National Seashore, South Wellfleet, Mass. 02663, Telephone 617-349-3785. Minutes of the meeting will be available for public information and copying four weeks after the meeting at the office of the Superintendent, Cape Cod National Seashore, South Wellfleet, Mass.

Dated: November 17, 1977.

ROBERT M. LANDAU,
Assistant for Advisory Boards and Commissions, National Park Service.

[FR Doc. 77-33569 Filed 11-21-77; 8:45 am]

[4310-70]

National Park Service

NATIONAL REGISTER OF HISTORIC PLACES

Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before November 11, 1977. Pursuant to § 60.13(a) of 36 CFR part 60, published in final form on January 9, 1976, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the Keeper of the National Register, National Park Service, U.S. Department of the Interior, Washington, D.C. 20240. Written comments or a request for additional time to prepare comments should be submitted by December 2, 1977.

WILLIAM J. MURTAGH,
Keeper of the National Register.

ALASKA

Sitka Division

Sitka, *Government School*, Katlian Way.

ARIZONA

Coconino County

Flagstaff, *Weatherford Hotel*, 23 N. Leroux St.

Flagstaff vicinity, *Fern Mountain Ranch*, N of Flagstaff.

CALIFORNIA

Inyo County

Little Lake vicinity, *Coso Hot Springs*, NE of Little Lake off U.S. 395.

Los Angeles County

Los Angeles, *Los Angeles Harbor Light Station*, Los Angeles Harbor on San Pedro Breakwater.

Napa County

Yountville, *Veterans Home of California Chapel*, CA 29.

San Diego County

San Diego, *Point Loma Lighthouse*, on Cabrillo National Monument.

Santa Barbara County

Santa Barbara vicinity, *Point Conception Light Station*, W of Santa Barbara off CA 1.

Ventura County

Port Hueneme vicinity, *Anacapa Lighthouse*, SW of Port Hueneme on Anacapa Island.

Ventura, *San Miguel Chapel Site*, 292 E. Thompson Blvd.

GEORGIA

Jefferson County

Louisville, *Old Market-House (Slave Market)*, U.S. 1 and GA 24, HABS.

Rockdale County

Conyers vicinity, *Dial Mill*, NE of Conyers off GA 138.

IDAHO

Ada County

Boise, *South Eighth Street Historic District*, roughly bounded by 8th, 9th, Fulton, Miller, and Broad Sts.

Banock County

Pocatello, *Trinity Episcopal Church*, 248 N. Arthur St.

Bear Lake County

Montpelier, *Montpelier Historic District*, Washington Ave. and 6th St.

Bingham County

Blackfoot, *Nuart Theater*, 195 N. Broadway.

Idaho County

Dixie vicinity, *Moore, Jim, Place*, Salmon River Canyon.

Latah County

Moscow, *McConnell-McGuire Building*, Main and 1st Sts.

Lemhi County

Salmon, *Lemhi County Courthouse*, 1st St. N. and Broadway.
Salmon, *Odd Fellows Hall*, 516 Main St.

Nez Perce County

Lewiston, *Kettenbach, Henry C., House*, 1026 9th Ave.
Lewiston, *St. Stanislaus Catholic Church*, 633 5th Ave.

Owyhee County

Murphy vicinity, *Bernard's Ferry*, N of Murphy off ID 78.

Payette County

Payette, *Chase, David C., House*, 307 9th St. N.
Payette, *Moss, A. B., Building*, 137 N. 8th St.
Payette, *St. James Episcopal Church*, 1st Ave. N. and 10th St.

Twin Falls County

Buhl, *Buhl City Hall*, Broadway and Elm St.

MONTANA

Flathead County

West Glacier vicinity, *Lewis Glacier Hotel*, N of West Glacier on Going-To-The-Sun Rd.

NEW YORK

Jefferson County

Alexandria Bay vicinity, *Boldt, George C., Yacht House*, NW of Alexandria Bay on Wellesley Island.

Sullivan County

Liberty, *Liberty Village Historic District*, N. Main, Academy, and Law Sts.

NORTH CAROLINA

Dare County

Nags Head vicinity, *Bodie Island Light Station*, 10 mi. S. of Nags Head off NC 12.

TENNESSEE

Davison County

Nashville, *Fisk University Historic District*, roughly bounded by 16th and 18th Ave., Hermosa, Herman, and Jefferson Sts.

TEXAS

Houston County

Crockett, *Downes-Aldrich House*, 206 N. 7th St.

Robertson County

Calvert, *Calvert Historic District*, roughly bounded by Main, Garritt, Pin Oak, Maple, and Barton Sts.

UTAH

Davis County

Layton, *Adams, Joseph, House*, 300 N. Adamswood Rd.

Salt Lake County

Salt Lake City, *Converse Hall*, 1840 S. 13th East.
Salt Lake City, *Hotel Utah*, S. Temple and Main St.

Washington County

Washington, *Covington, Robert D., House*, 200 N. 200 East.

VIRGIN ISLANDS

St. John Island

Cruz Bay vicinity, *Mary Point Estate*, NE of Cruz Bay, Maho Bay Quarter.

WISCONSIN

Brown County

Wrightstown, *Mueller-Wright House*, Washington and Mueller Sts.

Dane County

Madison, *Orton Park*, 1100 Spaight St.

Lincoln County

Merrill, *Lincoln County Courthouse*, 1110 E. Main St.

[FR Doc. 77-33239 Filed 11-21-77; 8:45 am]

[4410-01]

JUSTICE DEPARTMENT

Antitrust Division

UNITED STATES v. INCO LIMITED, ET AL.

Proposed Consent Judgment, Stipulation, and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b) through (h), that a proposed consent judgment, stipulation, and competitive impact statement as set out below have been filed with the United States District Court for the Eastern District of Pennsylvania in Civil No. 76-152, *United States of America* v. *Inco Ltd., et al.* The complaint in this case alleged that the acquisition in September 1974, of the stock ownership of ESB Incorporated by American subsidiaries of Inco Ltd., substantially lessened competition between ESB and Inco in the manufacture and sale of industrial batteries and in the research and development of industrial and electric road vehicle batteries in violation of section 7 of the Clayton Act, 15 U.S.C. § 18. The proposed consent judgment requires the defendants to grant unrestricted, nonexclusive, and royalty-free patent and know-how licenses and to sell a manual containing such know-how at a cost not in excess of $1,000.00. The patents and know-how relate to the defendants' recent developments in battery technology. The patent licenses currently include rights to over 200 domestic and foreign patents and patent applications; the know how licenses include rights to all related technical information possessed by the defendants on or before the date of entry of the proposed judgment. The proposed judgment also enjoins the defendants for a period of 10 years from acquiring any battery manufacturer without the United States' or the Court's prior approval. Public comment is invited on or before January 16, 1977. Such comments and responses thereto will be published in the FEDERAL REGISTER and filed with the Court. Comments should be directed to John J. Hughes, Chief, Middle Atlantic Office, Antitrust Division, Department of Justice, 3430 United States Courthouse, Philadelphia, Pa. 19106.

Dated: November 11, 1977.

JOHN H. SHENEFIELD,
Acting Assistant Attorney General, Antitrust Division.

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

United States of America, Plaintiff, v. *Inco Ltd.; Inco United States, Inc.; and ESB Inc.*, Defendants.
Civil Action No. 76-152.
Filed: November 14, 1977.

STIPULATION

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16), and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent, which it may

do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendants and by filing that notice with the Court.

2. In the event plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall not in any manner prejudice any consenting party in this or any other proceeding.

Dated: November 11, 1977.

For the Plaintiff: John H. Shenefield, Acting Assistant Attorney General; William E. Swope, Charles F. B. McAleer, Anthony E. Harris, Elliott H. Moyer, John J. Huges, Raymond D. Cauley, Morton M. Fine, Walter L. Devany, Richard M. Walker, Norma B. Carter, Attorneys, Department of Justice.

For the Defendants: Sullivan & Cromwell, New York, N.Y. and Pepper, Hamilton & Scheetz, Philadelphia, Pa., Attorneys for Inco Ltd.; Inco United States, Inc.; and ESB Inc.

So Ordered: Philadelphia, Pa., Edward R. Becker, United States District Judge.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America, Plaintiff, v. *Inco Ltd.; Inco United States, Inc.;* and *ESB Inc.*, Defendants.

Civil Action No. 76-152.

Filed: November 11, 1977.

FINAL JUDGMENT

Plaintiff, the United States of America, having filed its Amended Complaint herein on April 5, 1976, and defendants Inco Ltd. (formerly known as and sued herein as The International Nickel Co. of Canada, Ltd.), Inco United States, Inc. (formerly known as and sued herein as International Nickel (U.S.), Inc.), and ESB Inc., having appeared and filed their answers to the Amended Complaint denying the substantive allegations thereof, and the parties hereto, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of law or fact and without this Final Judgment constituting any evidence or any admission by any party with respect to any such issue, and the Court having considered the matter and being duly advised,

Now, therefore, before the taking of any testimony and without trial or adjudication of any issue of law or fact herein, and upon consent of the parties hereto, it is hereby

Ordered, adjudged and decreed as follows:

I

This Court has jurisdiction over the subject matter of this action and the parties consenting hereto. The Amended Complaint states claims upon which relief may be granted against the defendants under section 7 of the Clayton Act, as amended (15 U.S.C. § 18).

II

As used in this Final Judgment, the term:

(A) "Person" shall mean any individual, partnership, firm, corporation, association, or other business or legal entity;

(B) "Battery" shall mean any rechargeable or nonrechargeable electrochemical device for providing electrical energy, comprising one or more cells and having all electrochemically reacting mass positioned within the cell at the time of manufacture;

(C) "Battery Component" shall mean any item manufactured for use in a Battery which participates in the electrochemical reaction or the transmission of electrical current derived therefrom, including, but not limited to, any cell, electrode, current-carrying element and electrochemcially reacting mass;

(D) "Battery Manufacturer" shall mean any Person engaged in (i) making Batteries or Battery Components for sale in the United States or (ii) selling in the United States under such Person's trademark, brand-name or label any Batteries or Battery Components made for such Person;

(E) "CMG Inventions" shall mean the "controlled microgeometry method" or process of forming, perforating, and activating metallic foil and constructing Battery electrodes therefrom, and the Battery Components and Batteries which, in whole or in part, incorporate, use or are produced by such method or process;

(F) "CMG Patents" shall mean:

(1) Those patents and patent applications (and patents which are issued upon such applications) listed and described in Appendix A annexed hereto;

(2) Any other United States or foreign patent which has been or may be granted to any defendant or any subsidiary thereof (including, but not limited to, Inco Europe Limited) on any application therefor which was filed or was pending on or before the date of entry of this Final Judgment, or is filed within a period of 3 years from the date of entry of this Final Judgment, and which, in whole or in part, discloses or claims, or the claims of which read upon, (i) any CMG Invention, or (ii) any process, product, article of manufacture, combination, machine, apparatus, or composition of matter designed for use in the manufacture, assembly or use of any CMG Invention;

(3) Those patents and patent applications described above in Paragraph II(F)(2) hereof, but which have been or may be owned or controlled by any defendant in any manner;

(4) Any United States or foreign patent or patent application corresponding to, or a counterpart of, any patent or patent application described above in Paragraphs II(F)(1), (2), and (3) hereof; and

(5) Any continuations, continuations in part, amendments, corrections, divisions, or reissues of any patent or patent applications described above in Paragraphs II(F)(1), (2), (3), and (4) hereof;

(G) "United States" shall mean the United States of America, the District of Columbia, any territory, insular possession or other place under the jurisdiction of the United States of America;

(H) "Know-how" shall mean all written and unwritten technical information which relates to the manufacture, assembly or use of the CMG Inventions, or of any machinery, facility, apparatus, item, or process therefor.

III

The provisions of this Final Judgment applicable to any defendant shall also apply to each of its directors, officers, agents, employees, subsidiaries (including but not limited to Inco Europe Ltd.), successors and assigns and to all Persons in active concert or participation with any of them who receive notice of this Final Judgment by personal service or otherwise.

IV

Each defendant is ordered and directed to:

(A) Grant or cause to be granted to any Person who makes written application therefor, a nonexclusive, unrestricted, irrevocable, and royalty-free license to (i) make, have made, use, or sell in the United States, (ii) make or have made in the United States for use or sale outside the United States, and (iii) make or have made outside the United States for use or sale in the United States, under any, some or all of the CMG Patents for the full term thereof, without limitation or condition, except that the license may provide that the rights granted thereby may not be transferred, by assignment, sub-license, or otherwise (except by operation of the law or in connection with a transfer of the licensee's business or assets to which the license is related).

The licensee shall also be granted and shall enjoy an immunity from suit with respect to any other United States or foreign patent which has been or may be granted to, or owned or controlled in any manner by, any defendant or any subsidiary thereof (including, but not limited to, Inco Europe Ltd.) on any application which was filed or was pending on or before the date of entry of this Final Judgment, or is filed within a period of three years from the date of entry of this Final Judgment, and with respect to any continuations, continuations in part, amendments, corrections, divisions or reissues of any such other patent, to the extent that any process, product, article of manufacture, combination, machine, apparatus or composition of matter disclosed or claimed within any such other patent (or any continuation, continuation in part, amendment, correction, or division thereof) is at any time practiced or produced by the licensee in making, having made, using or selling any invention under a license granted pursuant to this Paragraph IV(A).

Licenses granted pursuant to this Paragraph IV(A) shall provide that the licensee is free to contest the validity and scope of any United States or foreign patent or patent application for which a license or immunity from suit is granted hereunder. An existing licensee, if any, under any of the CMG Patents shall have the right to apply for and receive a license and immunities from suit pursuant to this Final Judgment in substitution for or in addition to its existing license;

(B) Grant or cause to be granted to any Person, who makes written application therefor, a nonexclusive, unrestricted, and royalty-free license of all Know-how possessed, owned, or otherwise controlled by any defendant, in any manner, on or before the date of entry of this Final Judgment, for exploitation of such Know-how in (i) making, having made, using, or selling any item in the United States, (ii) making or having made any item in the United States for use or sale outside the United States, and (iii) making or having made any item outside the United States for use or sale in the United States. Such license shall be granted without limitation or condition, except that the license may provide that the rights granted thereby may not be transferred by assignment, sub-license, or otherwise (except by operation of the law or in connection with a transfer of the licensee's business or assets to which the license is related) and that the licensee may be required to keep confidential the licensed Know-how not otherwise available in the public domain.

Upon payment by the licensee of a sum not in excess of $1,000, all such Know-how shall be furnished promptly in a written manual which shall set forth an accurate and complete description of the methods of manufacture, assembly, and use employed in the production or practice of the CMG Inventions and of any machinery, facility, apparatus, item, or process therefor;

(C) Within thirty (30) days after the entry of this Final Judgment, advise the U.S. Patent and Trademark Office, Washington, D.C., for publication in the Official Gazette of that Office that the lisenses and immunities from suit described in Paragraphs IV (A) and (B) of this Final Judgment are available on the terms set forth in said Paragraphs to any Person, upon written request therefor to any defendant;

(D) Within thirty (30) days after the entry of this Final Judgment, advise by Certified Mail each Battery manufacturer known to defendants and, within ninety (90) days after entry of this Final Judgment, advertise prominently once in the Electric Vehicle News and in The New York Times; in the next two (2) issues of Advanced Battery Technology; and in the next three (3) issues of The Battery Man (The International Journal for Starting, Lighting, Ignition, and Generating Systems) and of The Journal of the Electrochemical Society that:

(1) The licenses and immunities from suit described in Paragraphs IV (A) and (B) of this Final Judgment are available on the terms set forth in said Paragraphs to any Person, upon written request therefor to any defendant; and

(2) The written manual described in Paragraph IV(B) hereof is available to each licensee at a cost not in excess of $1,000.

Within ninety (90) days after the entry of this Final Judgment, a copy of each such letter, each such advertisement, and a copy of the completed manual shall be furnished the plaintiff; and

(E) Within one-hundred twenty (120) days after the entry of this Final Judgment, furnish plaintiff an affidavit as to the fact and manner of its compliance with Paragraphs IV (C) and (D) hereof.

V

Each defendant is enjoined and restrained from:

(A) Acquiring, directly or indirectly, for a period of ten (10) years from the date of entry of this final judgment, an of the business or assets of, or more than one (1) percent of any stock or other financial interest in, any battery manufacturer without either (1) the prior written consent of the plaintiff, or (2) if such consent is not given within thirty (30) days after receipt by plaintiff of a written request therefor and a submission of facts with respect to such proposed acquisition, the prior approval of this Court. The Court's approval shall be granted only after an affirmative showing by such defendant that the effect of such acquisition may not be to substantially lessen competition or to tend to create a monopoly in the manufacture or sale of batteries or battery components (or any submarket thereof) in any section of the country. This injunction shall not be construed to prohibit any of the defendants from acquiring any business or assets of any battery manufacturer where the acquired portion of such business or assets was neither operated nor otherwise employed within either of said battery manufacturer's two most recently completed fiscal years in making Batteries or Battery Components for sale in the United States or in selling in the United States under such Battery Manufacturer's trademark, brand-name or label Batteries or Battery Components made for such Battery Manufacturer; and

(B) Making any disposition (other than by nonrenewal, public dedication or abandonment) of any rights under any United States or foreign patent or of any rights under Know-how which may deprive any of the defendants of the power or authority to grant licenses or immunities from suit or provide written manuals as required in Paragraphs IV (A) and (B) of this Final Judgment, unless the party or parties acquiring such rights from a defendant becomes bound by the provisions of this Final Judgment, other than Paragraph V(A) hereof.

VI

Within ten (10) days of each of the first nine (9) anniversary dates of this Final Judgment, each defendant shall file with the Antitrust Division:

(A) Copies of all requests for licenses and immunities from suit under Paragraph IV (A) and (B) hereof and the disposition of each such request;

(B) Copies of all requests for written manuals under Paragraph IV(B) hereof and the disposition of each such request; and

(C) A listing and description of all CMG Patents in addition to those listed in Appendix A.

VII

(A) For the purpose of determining or securing compliance with this Final Judgment, any duly authorized representative of the Department of Justice shall, upon written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to any defendant made to its principal office, be permitted, subject to any legally recognized privilege:

(1) Access during the office hours of such defendant to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of such defendant relating to any matters contained in this Final Judgment; and

(2) Subject to the reasonable convenience of such defendant and without restraint or interference from it, to interview officers, directors, agents, partners or employees of such defendant, who may have counsel present, regarding any such matters.

(B) A defendant, upon the written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, shall submit such reports in writing with respect to any of the matters contained in this Final Judgment (including copies of any material subject to inspection under Paragraph VII(A)(1) hereof) as may from time to time be requested.

No information obtained by the means provided in this Paragraph VII shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

If at any time information or documents are furnished by a defendant to plaintiff, such defendant represents and identifies in writing the material in any such information or documents of a type described in Rule 26(c)(7) of the Federal Rules of Civil Procedure, and said defendant marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then 10 days notice shall be given by plaintiff to such defendant prior to divulging such material in any legal proceeding (other than a Grand Jury proceeding) to which the defendant is not a party.

VIII

Jurisdiction is retained for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this Final Judgment, for the modification of any of the provisions herein, for the enforcement of compliance herewith, or for the punishment of the violation of any of the provisions contained herein.

IX

Entry of this Final Judgment is in the public interest.

Dated: _____.

_____,

U.S. District Judge.

APPENDIX A

U.S. patent No.	Date patented	Abstract description	Corresponding foreign patent and patent application numbers	
			Country	Numbers
3,579,383	May 18, 1971	Process employing nickel amine complex in activating metal foil for use as an electrode in alkaline storage batteries.	United Kingdom.	1,227,379
			Belgium	736,965
			Canada	910,841
			France	69/24534
			West Germany	1,938,434
			Italy	884,439
			Japan	822,158
			Netherlands	143,736
			Sweden	349,191
			Switzerland	500,596
3,785,867	Jan. 15, 1974	Battery plates composed of stacked, perforated metallic foil elements, with battery active mass between each foil, and a battery utilizing same.	United Kingdom.	1,246,048
			Australia	438,246
			Austria	298,589
			Belgium	749,327
			Canada	936,914
			Denmark	127,829
			France	70/14555
			India	126,204

APPENDIX A—Continued

U.S. patent No.	Date patented	Abstract description	Corresponding foreign patent and patent application numbers	
			Country	Numbers
			Italy	904,223
			Japan	789,196
			Netherlands	148,191
			Norway	134,443
			South Africa	70/2437
			Spain	378,877
			Sweden	353,621
			Switzerland	518,012
			West Germany	*P20 18974.6
3,837,919	Sept. 24, 1974	Process for producing battery active mass suitable for use in nickel cadmium cells or similar cells of batteries.	United Kingdom.	1,398,080
			Australia	469,150
			Austria	317,324
			Belgium	790,585
			Canada	1,005,861
			Denmark	134,375
			France	72/37908
			India	137,150
			Israel	40633
			Italy	969,493
			Luxembourg	66349
			Norway	133,373
			South Africa	72/7370
			Spain	407,966
			Switzerland	561,465
			Eire	*1401/72
			West Germany	*P225,2162.6
			Japan	*106291/72
			Netherlands	*72/14483
			Sweden	*13751/72
			U.S.S.R.	545,272
3,852,112	Dec. 3, 1974	Electrolytic process for activating essentially solid nickel surfaces, e.g., nickel foil, for use as a positive electrode in alkaline storage batteries, using nickel amine complexes.	United Kingdom.	1,240,445
			Belgium	745,283
			Canada	917,598
			France	70/03268
			West Germany	2,004,469
			Italy	897,363
			Netherlands	143,373
			Sweden	361,385
			Switzerland	512,146
			Japan	*8379/70
3,894,885	July 15, 1975	Electrolytic process for activating essentially solid nickel surfaces, e.g., nickel foil, for use as a positive electrode in alkaline storage batteries, using nickel amine complexes.	United Kingdom.	1,240,445
			Belgium	745,283
			Canada	917,598
			France	70/03268
			West Germany	2,004,469
			Italy	897,363
			Netherlands	143,373
			Sweden	361,385
			Switzerland	512,146
			Japan	*8379/70
3,895,961	July 22, 1975	Process for forming iron battery active mass on a cathode (e.g., metallic foil).	United Kingdom.	1,421,338
			Australia	461,756
			Austria	320,770
			Belgium	792,349
			Canada	997,825
			India	136,775

APPENDIX A—Continued

U.S. patent No.	Date patented	Abstract description	Corresponding foreign patent and patent application numbers	
			Country	Numbers
			Israel	40986
			Italy	982,395
			Luxembourg	66697
			South Africa	72/8398
			Spain	409,790
			Sweden	72/15476
			Switzerland	560,974
			Denmark	*6318/72
			Eire	36911
			France	*72/45086
			West Germany	*P226 1997.2
			Japan	*123274/72
			Netherlands	*72/16471
			Norway	*4360/72
			U.S.S.R.	561,528
3,898,098	Aug. 5, 1975	Process for producing electrode structures which are suitable for use as the negative electrode in nickel-iron storage batteries.	United Kingdom.	1,392,188
			Australia	457,245
			Austria	320,046
			Belgium	785,203
			Canada	976,608
			India	136,392
			Israel	39659
			Italy	965,836
			Luxembourg	65540
			Portugal	58020
			South Africa	72/5901
			Spain	404,060
			Sweden	72/08105
			Switzerland	565,456
			Canada	*203,814
			Denmark	*3059/72
			Eire	*771/72
			France	*72/22187
			West Germany	*P222 9977.0
			Japan	*61035/72
			Netherlands	*72/08173
			Norway	135,763
			U.S.S.R.	*1800413/24
3,997,364	Dec. 14, 1976	A process for activation of foil or sheet substrate to render it suitable for electrochemical use.	Belgium	822,136
			Luxembourg	71265
			South Africa	74/6797
			Spain	431,855
			Australia	*74936/74
			Austria	*A9107/74
			Canada	*213,069
			Denmark	*5870/74
			Eire	*2339/74
			France	*74/37145
			West Germany	*P245 3581.7
			Italy	*53953A/74
			Japan	*130071/74
			Netherlands	*74/14723
			Norway	*4036/74
			Sweden	*74/14175-5
			Switzerland	*14985/74
			United Kingdom.	*52658/73

APPENDIX A—Continued

U.S. patent No.	Date patented	Abstract description	Corresponding foreign patent and patent application numbers	
			Country	Numbers
699,055*	June 23, 1976	A process for depositing electrochemically active mass on foil or sheet substance.	Belgium	822,136
			Luxembourg	71265
			South Africa	74/6797
			Spain	431,855
			United Kingdom.	*52658/73
			Australia	*74936/74
			Austria	*A9107/74
			Canada	*213,069
			Denmark	*5870/74
			Eire	*2339/74
			France	*74/37145
			West Germany	P 245 3581.7
			Italy	*53953A/74
			Japan	*130071/74
			Netherlands	*74/14723
			Norway	*4036/74
			Sweden	*74/14175-5
			Switzerland	*14985/74
715,534* (abandoned)	Aug. 18, 1976	Process and apparatus for perforating metal foil by electroetching.	Belgium	845,558
			Luxembourg	75661
			Australia	*17006/76
			Austria	*A6316/76
			Canada	*259,827
789,689* (continuation of 1715,534*).	Apr. 21, 1977	do	Denmark	*3831/76
			Eire	*1887/76
			France	*76/25604
			West Germany	*P 2638115.7
			India	*1537/CAL/76
			Italy	*50999A/76
			Japan	*102155/76
			Netherlands	*76/09393
			Norway	*76/2904
			South Africa	*76/5012
			Spain	*450982
			Sweden	*76/09387-1
			Switzerland	*10793/76
			United Kingdom.	35178/75
747,055*	Dec. 3, 1976	Process for electrodeposition of iron battery active mass.	Canada	*267,245
			United Kingdom.	*50478/75
			Australia	*20269/76
			Austria	*A 9107/76
			Belgium	849,226
			Denmark	*76/5514
			Eire	*2697/76
			France	*76/36785
			West Germany	*P 2655577.1
			India	*2161/CAL/76
			Italy	*52494A/76
			Japan	*147618/76
			Luxembourg	(1)
			Netherlands	*76/13631
			Norway	*76/4158
			South Africa	*76/7110
			Spain	*454048
			Sweden	*76/13783-5
			Switzerland	*15456/76
			U.S.S.R.	*2427155/07
Not now filed in United States		Apparatus for stacking activated foils.	United Kingdom [3].	*29423/76
Do		Apparatus for monitoring battery conditions or testing storage batteries.	United Kingdom [3].	*32287/76

*Represents patent applications.
[1] Represents patents (or patent applications) whose numbers are not yet known.
[2] Filed July 15, 1976; abandoned.
[3] Filed Aug. 3, 1976; abandoned.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America, Plaintiff v. *Inco Ltd, Inco United States, Inc., and ESB Inc.*, Defendants.

Civil No. 76-152.

Filed: November 11, 1977.

COMPETITIVE IMPACT STATEMENT

The United States, pursuant to the requirements of section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

The United States and the defendants have agreed, in a Stipulation, that the proposed Final Judgment may be entered by the court at any time after compliance with the Antitrust Procedures and Penalties Act. Under the provisions of section 2(e) of the Antitrust Procedures and Penalties Act (15 U.S.C. §16(e)), entry of said judgment by the court is conditioned upon its determination that the proposed judgment is in the public interest.

I

NATURE AND PURPOSE OF THE PROCEEDING

On January 19, 1976, the United States initiated a civil antitrust action against Inco Ltd. (then known and sued as The International Nickel Co. of Canada, Ltd.), its wholly-owned American Subsidiary, Inco United States, Inc. (then known and sued as The International Nickel Co., Inc.), and ESB Inc. under section 15 of the Clayton Act (15 U.S.C. § 25) to prevent and restrain the continuing violation by the defendants of section 7 of the Clayton Act (15 U.S.C. § 18). The complaint alleged that the acquisition by Inco Ltd. ("Inco") of substantially all of the stock ownership of ESB Inc. ("ESB") violated section 7 of the Clayton Act by eliminating actual and potential competition in the battery markets described below, and that concentration in those markets may have been preserved and increased by the acquisition. The complaint requested that the merger be declared unlawful and that Inco be required to divest itself of ESB.

II

THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION

ESB, the acquired company, was the largest battery manufacturer in the world. It was engaged in the manufacture and sale of a number of different types of batteries, including industrial batteries. In 1973, ESB had sales of $39 million of industrial batteries—secondary or "storage" batteries with energy characteristics which make them suitable for use in providing electrical power to propel industrial equipment such as forklift trucks and mine locomotives, and for providing stand-by electrical power for electric utility, telephone, lighting and other auxiliary power systems. The complaint alleged that prior to its acquisition by Inco, ESB was the second largest producer of industrial batteries with 27 percent of that market. It also alleged that the manufacture and sale of industrial batteries in the United States is highly concentrated, with four largest industrial battery manufacturers accounting for approximately 83 percent of all such battery sales.

In 1973, over half of ESB's industrial battery sales, or $21 million, were sales of traction batteries, that is, industrial batteries used to provide motive power for forklift trucks and mine locomotives. The complaint alleged that ESB was also the second largest producer of traction batteries in the United States with about 21 percent of all traction battery sales. According to the allegations of the complaint, the manufacture and sale of traction batteries, too, is highly concentrated, the four largest manufacturers accounting for 77 percent of such battery sales.

The complaint also alleges that ESB had expended substantial amounts of money in

researching, developing, and improving industrial batteries as well as all other types of batteries. ESB's research efforts included the development of electric road vehicle batteries—secondary batteries used to produce electrical power to propel over-the-road trucks, vans, and automobiles. While battery powered road vehicles are in the experimental stages of development in the United States, the imposition of various pollution controls and recent increases in the costs of gasoline and oil, inter alia, have led to increased competition in this battery's development.

Inco, the acquiring company, is the world's largest producer of nickel and the largest supplier of primary nickel in the United States. For many years, Inco has also been the nation's principal supplier of nickel to the battery industry. In an attempt to expand the markets for nickel used in batteries, Inco has undertaken extensive research in order to solve certain technical problems related to battery development.

Approximately eight years ago, Inco, in the course of its battery-related research efforts, began to secure a series of patents upon a claimed new battery electrode and a battery constructed using this electrode. This battery electrode—designated by Inco as the "controlled microgeometry" or "CMG" electrode—was composed of thin, perforated sheets of nickel or other metallic substances, and Inco predicted that batteries constructed with the CMG electrode would have an energy output two to three times greater than conventional secondary batteries of the same weight.

Inco did not license its CMG patents or its related technology as it had done in many instances in the past with its other battery related technology. It chose, instead, to commercially exploit the patents and technology itself. To this end, Inco expended a substantial amount of its funds and devoted a considerable amount of its efforts with the intent of developing a CMG battery for manufacture and sale in the United States. Inco had made plans for entry into the industrial battery market in the United States with its CMG battery, particularly the market for tracton batteries; it had constructed facilities to test and ultimately produce its CMG batteries for this purpose.

In short, prior to acquiring ESB, it appeared that Inco had both the desire and available means to enter and compete in the industrial battery and traction battery markets. Moreover, it was also actually engaged in competitive development of electric road vehicle batteries.

In September, 1974, pursuant to a tender offer to shareholders of ESB, Inco acquired ownership and control of virtually all outstanding shares of ESB for cash payments in excess of $225 million.

The complaint alleges that this acquisition had the following effects: (a) that potential competition between Inco and ESB in the manufacture and sale of industrial batteries (and various submarkets) was eliminated; (b) that actual competition between ESB and Inco in the research and development of industrial batteries (and various submarkets) and of electric road vehicle batteries was eliminated; (c) that concentration in the manufacture and sale of industrial batteries (and various submarkets) may have been preserved and increased; and (d) that competition generally in the development, manufacture and sale of industrial batteries (and various submarkets) and in the development of electric road vehicle batteries may have been substantially lessened.

While it appeared at the time of the acquisition of ESB that the CMG battery would provide a near term vehicle for de novo entry into the industrial battery markets, the fact that the battery remains in the research and development stage tends to show that such entry may not have been possible. Nevertheless, it still appears that the advent of the CMG invention presents a significant development in pre-existing battery technology.

III

EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed judgment is an alternative to divestiture relief. It seeks to dissipate the anticompetitive effects of the challenged acquisition by making the patents and technology related to the CMG battery generally available.

The proposed Final Judgment would require the defendants to grant unrestricted, nonexclusive, and royalty-free licenses of their CMG patents and know-how to any applicant for them, and it would also require the defendants to provide a manual containing such know-how to any know-how licensee for a sum not in excess of $1000.00. These grants extend to any applicant's United States operations and, in addition, to its foreign operations to the extent that such foreign operations involve importation to or exportation from the United States.

The patent licenses would include rights to exploit those CMG patents and patent applications on file at the time of the entry of the judgment[1] as well as any CMG patent granted or any CMG patent application filed within a three year period after the entry of the judgment. The proposed judgment also provides that each patent licensee shall be granted and enjoy an immunity from suit for infringement of any other United States or foreign patent of any defendant if the licensee employs such patent in manufacturing, using or selling articles under a CMG patent. This provision prevents any of the defendants from using any of their other patents to inhibit the judgment licensees' exploitation of the licensed patents.

The know-how which would be supplied pursuant to this proposed judgment is that possessed by the defendants on the date of entry of the judgment.

The defendants are further obligated by the proposed Final Judgment to publicize the terms of the availability of the proposed judgment's patent and know-how license, suit immunities, and know-how manuals in the Official Gazette of the United States Patent and Trademark Office and to notify all battery manufacturers known to the defendants, as well as advertise in four prominent battery trade journals and in The New York Times, that such licenses, immunities, and manuals are available.

In addition, the defendants are enjoined for a period of 10 years following entry of the proposed Final Judgment from acquiring the business or assets or a greater than 1-percent stock or other financial interest in any battery manufacturer, unless the United States consents to such acquisition, or in the event it does not consent, without approval of the Court.

[1] Currently these patents and patent applications include the 12 United States and 189 foreign patents and patent applications which are listed in an appendix attached to the proposed judgment.

Finally, the judgment provides methods for determining the defendants' compliance with its terms. Officers, employees, and agents of each defendant may be interviewed by representatives of the Department of Justice regarding the defendants' compliance with the judgment. The United States is given access, upon reasonable notice, to the records of the defendants, to examine these records for possible violations of the judgment. Annual reports are required on certain judgment-related matters, and the United States may require additional reports on any matters contained in the proposed judgment.

IV

ANTICIPATED COMPETITIVE EFFECTS OF THE PROPOSED FINAL JUDGMENT

As noted above, the compulsory CMG patent and know-how licensing relief provided for in the proposed judgment is an alternative to the divestiture relief sought in the complaint. The United States initially sought Inco's divestiture of ESB because it appeared that the CMG battery would soon reach the production stage. Under such conditions, it was believed that divestiture would restore that competition which would have been exerted on the industrial battery markets had Inco carried out its original plans to enter those markets de novo with a CMG battery. The United States also believed that ESB's divestiture would restore actual competition between Inco and ESB in research and development of industrial batteries and electric road vehicle batteries, and that it would at least return concentration in the industrial battery markets to the status quo ante.

The compulsory licensing relief embodied in the proposed judgment is not equivalent to the divestiture relief sought in the complaint. The compulsory licensing relief addresses the circumstances as they now exist and is intended to alleviate the present anticompetitive effects of this acquisition. The fact that the objective possibility of near term de novo entry into the industrial battery markets through the marketing of a CMG battery does not appear as probable as it did at the time we filed our suit suggests that divestiture relief might not be achievable even if the United States were to prevail after a trial on the mertis. However, the compulsory licensing remedy provided in the proposed Final Judgment should lower barriers to entry by others into the industrial battery markets in the near future and in proportion to the potential value of the CMG invention in those markets. The proposed Final Judgment thereby achieves objectives similar to those obtainable through divestiture without incurring the risks attendant to trial on the merits.

Because of the CMG technology's potential advantages over existing battery technologies, the United States believes that a number of persons would be interested in securing the patent and know-how licenses made available by the proposed judgment. While it is difficult to predict how many license applicants there would be under the proposed judgment, the judgment's nonexclusive, unrestricted, and royalty-free licensing terms and its suit immunities encourage the dispersion of the defendants' CMG research to any current or prospective battery manufacturer. This dispersal of the CMG technology, the United States anticipates, would have the following pro-competitive effects: (a) the potential competition which licensees under the proposed judgment

would exert upon the industrial battery markets may equal or surpass that competition which defendant Inco alone would have exerted had it carried out its plans for de novo entry into these markets; (b) incentives would be created for smaller industrial battery manufacturers and firms not presently engaged in industrial battery manufacturing to enter the field, thereby deconcentrating the industrial battery markets, as well as any other battery market in which the CMG technology might be employed; and (c) actual competition in the research and development of, not only industrial and electric road vehicle batteries, but all other types of batteries as well would be enhanced since every applicant would have an opportunity to compete in commercial exploitation of the CMG technology in any battery market.

V

REMEDIES AVAILABLE TO POTENTIAL PRIVATE PLAINTIFFS

Any potential private plaintiff who might have been damaged by the alleged violation will retain the same rights to sue for monetary damages and any other legal and equitable remedies which he would have had were the proposed Final Judgment not entered. This proposed Final Judgment, however, may not be used as prima facie evidence in private litigation pursuant to Section 5(a) of the Clayton Act (15 U.S.C. § 15(a)).

VI

PROCEDURES AVAILABLE FOR THE MODIFICATION OF THE PROPOSED JUDGMENT

The proposed Final Judgment is subject to a Stipulation by and between the United States and the defendants, which provides that the United States may withdraw its consent to the proposed judgment until the Court has found that entry of the proposed judgment is in the public interest. Within the statutory period of sixty (60) days (15 U.S.C. § 16) of the filing of the proposed Final Judgment with the District Court for the Eastern District of Pennsylvania in Philadelphia, Pennsylvania, any person may submit written comments regarding the proposed Final Judgment to:

John J. Hughes, Chief, Middle Atlantic Office, Antitrust Division, U.S. Department of Justice, 3430 U.S. Courthouse, 601 Market Street, Philadelphia, Pa. 19106.

Such comments and the Antitrust Division's responses thereto will be filed with the District Court and published in the FEDERAL REGISTER. The Department of Justice will evaluate such comments and determine, prior to entry of the proposed Final Judgment, whether there is any reason for withdrawal of its consent.

After the entry of the proposed Final Judgment, jurisdiction is retained by the United States District Court for the Eastern District of Pennsylvania, Philadelphia, Pa., to enforce the Final Judgment and to enable the parties to the judgment to apply to the court for construction or modification of any of its provisions.

VII

ALTERNATIVES TO THE PROPOSED JUDGMENT CONSIDERED BY THE UNITED STATES

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits of its claims for an adjudication that the acquisition had violated the antitrust laws and for an order that Inco be required to divest itself of ESB. However, because the CMG battery has not, after some eight years of research and development, reached the commercial production stage, the United States believes it unlikely that divestiture could be achieved after a trial on the merits. The compulsory licensing and other relief embodied in the proposed Final Judgment, by lowering barriers to entry into the industrial battery market, will provide incentives for entry by licensees, exerting significant potential competition from many sources. Moreover, the relief contemplated by the proposed Final Judgment would be implemented more quickly than any divestiture relief obtainable after trial. In light of these factors, the United States believes that the relief which might have been obtained did not warrant the substantial risk, time, and expense normally associated with a full trial on the merits.

VIII

DETERMINATIVE DOCUMENTS

There are no materials or documents which were determinative in formulating the proposed Final Judgment. Consequently, none are being filed by the United States pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16(b)).

Dated: November 11, 1977.

John J. Hughes, Raymond D. Cauley, Morton M. Fine, Walter L. Devany, Richard M. Walker, Norma B. Carter, Anthony E. Harris, Attorneys, Department of Justice, Antitrust Division, Department of Justice, 3430 U.S. Courthouse, Independence Mall West, 601 Market Street, Philadelphia, Pa. 19106.

[FR Doc. 77-33443 Filed 11-21-77; 8:45 am]

[4510-28]

DEPARTMENT OF LABOR

Office of the Secretary

[TA-W-1901]

DARLING FASHIONS

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1901: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 24, 1977 in response to a worker petition received on March 24, 1977 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's and misses' dresses at Darling Fashions, Wilkes-Barre, Pa.

The Notice of Investigation was published in the FEDERAL REGISTER on April 12, 1977 (42 FR 19175). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Darling Fashions, its customers the U.S. Department of Commerce, the International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

Evidence developed during the Department's investigation revealed that Darling Fashions is a contractor for women's and misses' dresses for several manufacturers in the New York City area. None of these manufacturers import women's and misses' dresses or use foreign contractors.

Adjusted sales of Darling Fashions increased 52.2 percent from 1975 to 1976. In December 1976, Darling Fashions lost two major accounts. One of these manufacturers moved from New York to Virginia and placed orders with local area contractors. The other manufacturer changed ownership and the new management switched to other domestic contractors.

Sales of Darling Fashions decreased in the first quarter of 1977 compared to the same period of 1976. Sales increased 16.7 percent from April through July 1976 compared to the same period of 1977 after two new manufacturer accounts were obtained.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the women's and misses' dresses produced at the Wilkes-Barre, Pa. plant of Darling Fashions did not contribute importantly to the total or partial separations and to the sales and production declines at that plant.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33647 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-1904]

BOB ELLEN SPORTSWEAR

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1904: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The invesigation was initiated on March 24, 1977 in response to a worker petition received on March 24, 1977 which was filed by the International Ladies Garment Workers' Union on behalf of workers and former workers producing sportswear at Bob Ellen Sportswear, Wilkes-Barre, Pa. During the course of the investigation it was determined that subteens' and juniors' dresses were produced.

The notice of investigation was published in the FEDERAL REGISTER on April 12, 1977 (42 FR 19175). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bob Ellen Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any other criteria have been met, criterion (4) has not been met.

Evidence developed in the Department's investigation reveals that manufacturers whose contracts accounted for approximately 80 percent of production at Bob Ellen Sportswear in 1976 indicated that although they decreased their contracts with Bob Ellen in 1976 and 1977 they have not switched to foreign contractors nor do they purchase imported dresses. One manufacturer whose contracts accounted for approximately 75 percent of Bob Ellen's production in 1976, indicated that the amount of work it contacted to Bob Ellen had remained relatively constant in 1976 compared to 1975 and then decreased in the first quarter of 1977 compared to the first quarter in 1976. This manufacturer cited a greater than usual post Christmas slump in orders from its retail customers as the primary reason for reducing the amount of work contracted to Bob Ellen and other domestic contractors. However, this manufacturer further stated that its sales have increased in the first half of 1977 compared to the first half of 1976. Another manufacturer whose contracts accounted for approximately five percent of Bob Ellen's production in 1976 indicated that although its sales had increased in 1976 and the first half of 1977 compared to corresponding periods of previous years, it had stopped contracting work to Bob Ellen after Bob Ellen informed them that they were unable to handle any additional work. Work previously contracted to Bob Ellen was transferred to other domestic contractors.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the juniors' and substeens' dresses produced by Bob Ellen Sportswear, Wilkes-Barre, Pa. did not contribute importantly to the decline in sales or production and to the total or partial separations of workers at that firm as required for certification under section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33646 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-2154]

ENGINEERING SYSTEMS, INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2154: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on June 20, 1977, in response to a worker petition received on June 17, 1977, which was filed by three workers on behalf of workers and former workers producing car radios and tape decks at the Brockton, Mass. plant of Engineering Systems, Inc. The Department's investigation revealed that the Brockton plant did not produce tape decks.

The Notice of Investigation was published in the FEDERAL REGISTER on June 28, 1977 (42 FR 32853). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Automatic Radio, Inc., which is the parent firm of Engineering Systems, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all of the above criteria have been met.

Significant total or partial separations. The average number of workers at the plant declined 44.2 percent in 1976 compared to 1975. The plant closed temporarily on June 29, 1976 and reopened September 7, 1976. The plant closed permanently on January 7, 1977, and all workers were permanently laid off.

Sales or production, or both, have declined absolutely. Plant production declined 61.7 percent in quantity in 1976 compared to 1975 and ceased totally when the plant discontinued operations on January 7, 1977.

Increased imports. Imports of automobile radios increased each year

from 1,567,500 units in 1972 to 3,233,800 units in 1974, declined to 3,113,100 units in 1975 and then increased 75.8 percent to 5,473,600 units in 1976. Imports of automobile radios declined from 2,650,100 units in the first half of 1976 to 2,419,000 units in the first half of 1977.

The ratio of imports of car radios to domestic production increased each year from 13.5 percent in 1972 to 50.8 percent in 1975 and continued to increase to 78.5 percent in 1976 before declining from 76.1 percent in the first half of 1976 to 60.8 percent in the first half of 1977.

Contributed importantly. Company imports increased 4.1 percent in value in 1975 compared to 1974 and 192.9 percent in value in 1976 compared to 1975. The parent corporation of Engineering Systems, Automatic Radio, Inc., decided to discontinue domestic production and switch to imports to fulfill their requirements for car radios.

Conclusion. After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the car radios produced at the Brockton, Mass. plant of Engineering Systems, Incorporated, have contributed importantly to the total or partial separation of workers at the plant as required for certification.

In accordance with the provisions of the Act, I make the following certification:

All workers at the Brockton, Mass. plant of Engineering Systems, Inc. who became totally or partially separated from employment on or after June 14, 1976, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33648 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-1879]

FIFI FROCKS

Negative Determination Regarding Eligibility To Apply For Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1879: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 23, 1977, in response to a worker petition received on March 23, 1977, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's dresses at the Hudson, Pa. plant of Fifi Frocks. The investigation revealed that Fifi Frocks also produced women's sportswear.

The Notice of Investigation was published in the FEDERAL REGISTER on April 12, 1977 (42 FR 19176). No public hearing was requested and none was held. (The information upon which the determination was made was obtained principally from officials of Fifi Frocks, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard as to whether any of the other criteria have been met, the investigation has revealed that criterion (4) has not been met.

Fifi Frocks is a contractor that makes clothing for five corporations. None of these firms has done business with foreign clothing contractors nor do they purchase imported garments. All of the firms increased purchases from Fifi Frocks in 1976 compared to 1975. In addition each of these firms had increasing sales in 1976 compared to 1975.

Conclusion. After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the women's dresses and women's sportswear produced at the Hudson, Pa. plant of Fifi Frocks did not contribute importantly to the absolute decline in sales or production or to the total or partial separation of workers of that plant. Therefore, all workers at the Hudson, Pa. plant of Fifi Frocks are denied eligibility to apply for adjustment assistance.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33649 Filed 11-21-77; 8:45 pm]

[4510-28]

[TA-W-1732]

JO-L FASHIONS CORP.

Certification Regarding Eligibility To Apply For Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TAW-1732: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 3, 1977, in response to a worker petition received on March 1, 1977, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats and suits at the San Gabriel, California plant of Jo-L Fashions Corp. During the investigation it was revealed that Jo-L Fashions produces women's coats.

The notice of investigation was published in the FEDERAL REGISTER on March 15, 1977 (42 FR 14185). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jo-L Fashions Corp., its customer, the customers of Jo-L Fashions' manufacturer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, the National Cotton Council of America and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met.

Significant total or partial separations. Average employment at Jo-L Fashions Corp. decreased 6.1 percent in 1975 compared to 1974 and decreased 35.5 percent in 1976 compared to 1975. Employment decreased in every quarter of 1976 compared to the same quarter of 1975.

Jo-L Fashions Corp. was permanently closed on December 13, 1976.

Sales or production, or both, have decreased absolutely. Production at Jo-L Fashions decreased 18.5 percent in quantity in 1975 compared to 1974 and decreased 22.6 percent in 1976 compared to 1975. Production decreased in each quarter of 1976 compared to the same quarter of 1975. Production ceased in December 1976 when the company closed.

Increased imports. Imports of women's, misses', and children's coats and jackets increased from 1,769,000 dozen in 1972 to 1,807,000 dozen in 1973 and then declined to 1,478,000 dozen in 1974 before increasing to 1,517,000 dozen in 1975. In 1976 imports were recorded at 2,252,000 dozen, representing an increase of 48.5 percent compared to 1975. In the first quarter of 1977, imports were recorded at 590,000 dozen, representing an increase of 16.6 percent compared to 506,000 dozen in the first quarter of 1976. The ratio of imports to domestic production declined from 39.3 percent in 1972 to 30.9 percent in 1974 and then increased to 35.4 percent in 1975 and to 52.2 percent in 1976.

Contributed importantly. The sole manufacturer of Jo-L Fashions Corp. decreased orders for women's coats from Jo-L in 1976 compared to 1975. Imports of women's coats by the manufacturer increased 25 percent in the first half of 1977 compared to the first half of 1976. Since imported women's coats are ordered nearly 6 months prior to the time they are delivered, the impact of increased imports by the sole manufacturer of Jo-L Fashions during the first half of 1977 was reflected in reduced orders to its domestic suppliers of women's coats during the second half of 1976.

A survey of the manufacturer's customers indicated that most customers either increased imports of women's coats or increased purchases of foreign-made women's coats from other domestic suppliers. Price and style were the factors that influenced the decision to purchase women's coats from a supplier.

Conclusion. After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's coats produced by Jo-L Fashions Corp. of San Gabriel, Calif. contributed importantly to the total or partial separation or workers and to the decrease in production of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers at the San Gabriel, Calif. plant of Jo-L Fashions Corp. who became totally or partially separated from employment on or after February 14, 1976, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33650 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-1972]

KNAPP KING SIZE CORP.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1972: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on April 11, 1977, in response to a worker petition received on April 7, 1977 which was filed on behalf of workers and former workers producing men's dress shoes at the New Bedford, Mass. plant of the Knapp King Size Corp.

The notice of investigation was published in the FEDERAL REGISTER on April 29, 1977 (42 FR 21872). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Knapp King Size Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all of the above criteria have been met.

Significant Total or Partial Separations.—Average employment of production workers declined 11 percent from 1974 to 1975 and declined 3 percent from 1975 to 1976. Employment declined 5 percent in the first quarter of 1977 compared to the first quarter of 1976. Employment and sales levels do not always have a direct correspondence because different styles of shoes produced at the plant have varied labor demands.

Sales or Production, or Both, Have Decreased Absolutely.—Knapp's sales of men's dress shoes produced at the New Bedford plant increased 2 percent in quantity from 1974 to 1975 and declined 3 percent from 1975 to 1976. Sales quantities declined 17 percent in the first quarter of 1977 compared to the first quarter of 1976.

Increased Imports. Imports of men's dress and casual footwear increased, in absolute terms, from 1972 to 1973, declined from 1973 to 1974, and increased from 1974 to 1975. Imports increased 23.6 percent from 1975 to 1976 and decreased 0.3 percent in the first half of 1977 compared to the first half of 1976. The ratios of imports to domestic product and consumption increased from 58.7 percent and 37.0 percent, respectively, in 1975 to 70.4 percent and 41.3 percent, respectively, in 1976. The ratios of imports to domestic production and consumption increased from 66.0 percent and 39.8 percent, respectively, in the first half of 1976 to 73.9 percent and 42.5 percent, respectively, in the first half of 1977.

Contributed Importantly. Knapp's shoes are marketed primarily through the company's own chain of retail stores located throughout the country. These stores do not sell competing import products. The decline in the Knapp's retail sales of men's dress shoes, produced at the New Bedford plant, can be linked to increased imports in the domestic market in accordance with the recent findings of U.S. International Trade Commission. After considering the various factors affecting the domestic footwear industry, the Commission concluded that certain footwear articles, including men's dress and casual footwear, are being imported into the United States in such increased quantities as to be a substantial cause of serious injury to the domestic industry producing such articles.

In the case of men's dress and casual footwear, the import penetration rate

has been greater than 50 percent for the past five years, culminating in the first half of 1977, when the ratio of imports to domestic production was 73.9 percent.

The downward trend in Knapp's sales of men's dress shoes from 1975 to 1976 and in the first quarter of 1977 compared to the first quarter of 1976 corresponds to the increase in the ratio of imports to domestic production during the same periods, as listed above.

Conclusion. After careful review of the facts obtained in the investigation I conclude that increases of imports like or directly competitive with men's dress shoes produced at the New Bedford, Mass. plant of the Knapp King Size Corp. contributed importantly to the total or partial separation of the workers of the plant. In accordance with the provisions of the Act, I make the following certification:

All workers at the New Bedford, Mass. plant of the Knapp King Size Corp. who became totally or partially separated from employment on or after April 4, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33651 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-1685]

TELEDYNE GURLEY CO.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1685: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 24, 1977, in response to a worker petition received on February 17, 1977, which was filed on behalf of workers and former workers producing surveying instruments. During the investigation it was determined that engineering instruments; hydrological, wind and paper testing instruments; electronic encoders and digital readouts were produced at the Teledyne Gurley Co., Troy, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on March 8, 1977 (42 FR 13093). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Teledyne Gurley Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (2) has not been met.

The evidence developed in the Department's investigation revealed that total sales of Teledyne-Gurley increased 7 percent in 1976 compared to 1975 and increased 7 percent in the first quarter of 1977 compared to 1976. Sales of electronic encoders, digital readouts, engineering instruments, and hydrological, wind, and paper-testing equipment increased in the first quarter of 1977 compared to the first quarter of 1976.

Average employment increased 4 percent in the last three quarters of 1976 compared to the last three quarters of 1975 and remained constant in the first quarter of 1977 compared to the first quarter of 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that sales or production of Teledyne-Gurley, of the Teledyne Gurley Corp., Troy, N.Y., have not declined as required for certification under section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33652 Filed 11-21-77; 8:45 am]

[4510-28]

[TA-W-1441]

U.S. STEEL CORP.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

In FR Document 77-30057, appearing at pages 55310 and 55311 in the FEDERAL REGISTER of October 14, 1977, an incorrect phrase appeared. Accordingly, the following corrections should be made:

Everywhere the words "merchant wire" appeared in the document, they should be corrected to read "carbon steel wire and wire products".

Signed at Washington, D.C., this 14th day of November 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 77-33653 Filed 11-21-77; 8:45 am]

[7510-01]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (77-73)]

ESTABLISHMENT OF ADVISORY COMMITTEES

Determination

Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463) and the Office of Management and Budget Circular No. A-63 Revised, dated March 27, 1974, the NASA Administrator has determined that establishment of the following NASA advisory committees is in each case in the public interest in connection with the performance of duties imposed upon NASA by law:

1. NASA Advisory Council (NAC).
2. NAC Aeronautics Advisory Committee.
3. NAC Aeronautics Advisory Committee, Subcommittee on Aviation Safety Reporting System.
4. NAC Historical Advisory Committee.
5. NAC Life Sciences Advisory Committee.
6. NAC Space and Terrestrial Applications Advisory Committee.
7. NAC Space Science Advisory Committee.
8. NAC Space Systems and Technology Advisory Committee.

The preceding committees will replace the NASA Research and Technology Advisory Council (RTAC), eleven RTAC subgroups, the NASA Space Program Advisory Council (SPAC), three SPAC subgroups, and the NASA Historical Advisory Committee, all of which will be terminated upon establishment of the new units.

Dated: November 16, 1977.

KENNETH R. CHAPMAN,
Acting Associate Administrator for External Relations.

[FR Doc. 77-33576 Filed 11-21-77; 8:45 am]

[7555-01]

NATIONAL SCIENCE FOUNDATION

AD HOC SUBCOMMITTEE ON CEPEX

Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

NAME: Ad Hoc Subcommittee on Controlled Ecosystem Populations Experiment (CEPEX) of the Advisory Committee for Ocean Sciences.

DATE AND TIME: December 15, 1977, 9 a.m.

PLACE: National Science Foundation, 1800 G Street NW., Room 643, Washington, D.C. 20550.

TYPE OF MEETING: Closed.

CONTACT PERSON:

Mr. Feenan D. Jennings, Head, Office for the International Decade of Ocean Exploration, Room 605, National Science Foundation, Washington, D.C. 20550, telephone 202-632-7356.

PURPOSE OF SUBCOMMITTEE: To provide advice and recommendations concerning support for research on CEPEX.

AGENDA: To review and evaluate research proposals as part of the selection process for awards.

REASON FOR CLOSING: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

AUTHORITY TO CLOSE MEETING: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Acting Director, NSF, on February 18, 1977.

Dated: November 17, 1977.

M. REBECCA WINKLER,
Acting Committee Management Officer.

[FR Doc. 77-33654 Filed 11-21-77; 8:45 am]

[7555-01]

ADVISORY COMMITTEE FOR MINORITY PROGRAMS IN SCIENCE EDUCATION

Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting:

NAME: Advisory Committee for Minority Programs in Science Education.

DATE: December 8 and 9, 1977.

TIME: 9 a.m. each day.

PLACE: Room 651, 5225 Wisconsin Avenue NW., Washington, D.C.

TYPE OF MEETING: Open.

CONTACT PERSON:

Mrs. Frances Watts, Staff Assistant, Science Education Directorate, National Science Foundation, Room W-600, Washington, D.C. 20550, telephone 202-282-7930.

SUMMARY MINUTES: May be obtained from the Committee Management Coordination Staff, Division of Personnel and Management, National Science Foundation, Room 248, Washington, D.C. 20550.

PURPOSE OF ADVISORY COMMITTEE: To assist in the evaluation and assessment of activities in the ethnic minority-focused Foundation programs.

AGENDA: Thursday, December 8: Advisory Committee working session; presentation of recommendations and/or ideas developed by the Committee in the working session; Committee working session. Friday, December 9: Presentation of recommendations and/or ideas developed by the Committee.

Dated: November 17, 1977.

M. REBECCA WINKLER,
Acting Committee Management Officer.

[FR Doc. 77-33655 Filed 11-21-77; 8:45 am]

[7555-01]

APPLICATION OF ELECTRONIC DATA PROCESSING IN THE MANAGEMENT OF SYSTEMATIC RESEARCH COLLECTIONS IN HERPETOLOGY

Meeting

The biological research resources program at the National Science Foundation is sponsoring a meeting to be held at the University of Michigan, Ann Arbor, Mich., on December 12-13, 1977.

The meeting involving approximately 18 invited participants is to consider the need for computerizing collection data, costs of capture and storage of data through computerization compared with costs of traditional catalog entry, and the formation of national or regional collection data centers as opposed to local institution-oriented systems.

While this meeting is not considered to be a meeting of an "advisory committee" as defined in section 3 of the Federal Advisory Committee Act (Pub. L. 91-463), the meeting is believed to be of sufficient importance and interest to the general public to be announced in the FEDERAL REGISTER as a meeting open to the public.

The meeting will be chaired by Donald W. Tinkle of the University of Michigan.

Copies of the final report of the meeting will be available through William E. Sievers, Biological Research Resources Program, NSF, Washington, D.C. 20550.

Dated: November 17, 1977.

WILLIAM E. SIEVERS,
Program Director, Biological Research Resources Program.

[FR Doc. 77-33656 Filed 11-21-77; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS; SUBCOMMITTEE ON FLUID/HYDRAULIC DYNAMIC EFFECTS

Meeting; Additional Information

The November 30, 1977, meeting of the ACRS Subcommittee on Fluid/Hydraulic Dynamic Effects, announced in the FEDERAL REGISTER on November 15, page 59136, will be held at the Clift Hotel, 495 Geary Street, San Francisco, Calif. 94102.

All items remain the same as announced in the cited issue of the FEDERAL REGISTER.

Dated: November 17, 1977.

JOHN C. HOYLE,
Advisory Committee Management Officer.

[FR Doc. 77-33552 Filed 11-21-77; 8:45 am]

[7590-01]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS; SUBCOMMITTEE ON REACTOR SAFETY RESEARCH

Meeting

The ACRS Subcommittee on Reactor Safety Research will hold an open meeting on December 7, 1977 in Room 1162, 1717 H St. NW., Washington, D.C. 20555.

In accordance with the procedures outlined in the FEDERAL REGISTER on October 31, 1977, page 56972, oral or written statements may be presented by members of the public, recordings will be permitted only during those

portions of the meeting when a transcript is being kept, and questions may be asked only by members of the subcommittee, its consultants, and staff.

The agenda for subject meeting shall be as follows:

WEDNESDAY, DECEMBER 7, 1977

1 p.m. until the conclusion of business

The Subcommittee will continue preparation of a report on the Reactor Safety Research Program. It may be necessary to organize into working subgroups to prepare those portions of the report dealing with the following areas:

Systems engineering and analysis development.
Metallurgy, materials, and reactor fuel behavior.
Site related safety research.
Advanced reactor safety research.
Safeguards, fuel cycle and environmental research.
Risk assessment research.

Specific arrangements regarding the location and timing of these sessions will be announced during the course of the meeting.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the Designated Federal Employee for this meeting, Mr. Thomas G. McCreless, telephone 202-634-1374 between 8:15 a.m. and 5 p.m., e.s.t.

Dated: November 17, 1977.

JOHN C. HOYLE,
Advisory Committee Management Officer.

[FR Doc. 77-33552 Filed 11-21-77; 8:45 am]

[7590-01]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS; SUBCOMMITTEE ON REGULATORY ACTIVITIES

Meeting

The ACRS Subcommittee on Regulatory Activities will hold an open meeting on December 7, 1977 in Room 1046, 1717 H Street NW., Washington, D.C. 20555.

In accordance with the procedures outlined in the FEDERAL REGISTER on October 31, 1977, page 56972, oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the subcommittee, its consultants, and staff.

The agenda for subject meeting shall be as follows:

WEDNESDAY, DECEMBER 7, 1977

8:45 a.m. until about 12 noon

(A) The Subcommittee will hear presentations from the NRC Staff and will hold discussions with this group pertinent to the following:

(1) Proposed Regulatory Guide 1.XXX, "Linear and Nonlinear Time History Methods of Dynamic Analysis."

(2) Proposed Regulatory Guide 1.XXX, "Nuclear Safety Related Concrete Structures.

(3) Proposed Regulatory Guide 1.XXX, "Containment Isolation Provisions for Fluid Systems."

(4) Regulatory Guide 1.31, Revision 2, "Control of Ferrite Content in Stainless Steel Weld Metal."

(5) Regulatory Guide 1.63, Revision 2, "Electric Penetration Assemblies in Containment Structures for Light Water Cooled Nuclear Power Plants."

(6) Regulatory Guide 1.129, Revision 1, "Maintenance, Testing and Replacement of Large Lead Storage Batteries for Nuclear Power Plants."

12 noon until the conclusion of business

(B) The Subcommittee will hear presentations from the NRC Staff and will hold discussions with this group pertinent to activities which affect the current licensing process or reactor operations, including the following: "Status Report on Guard Pipes," an update on the July 13, 1977 presentation.

Other matters which may be of a predecisional nature relevant to reactor operation or licensing activities may be discussed following this session.

Persons wishing to submit written statements regarding Regulatory Guides 1.31, 1.63, and 1.129 may do so by providing a readily reproducible copy to the subcommittee at the beginning of the meeting. Such comments shall be based upon documents on file and available for public inspection at the NRC Public Document Room, 1717 H Street NW., Washington, D.C. 20555.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the Designated Federal Employee for this meeting, Mr. Gary Quittschreiber telephone 202-634-1374 between 8:15 a.m. and 5 p.m., e.s.t.

Dated: November 17, 1977.

JOHN C. HOYLE,
Advisory Committee Management Officer.

[FR Doc. 77-33553 Filed 11-21-77; 8:45 am]

[7590-01]

[Docket No. 50-247]

CONSOLIDATED EDISON CO. OF NEW YORK, INC.

Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 34 to Facility Operating License No. DPR-26, issued to Consolidated Edison Co. of New York, Inc. (the licensee), which revised Technical Specifications for operation of the Indian Point Nuclear Generating Unit No. 2 (the facility) located in Buchanan, Westchester County, N.Y. The amendment is effective as of its date of issuance.

The amendment revises the Technical Specifications to permit a reduction in the minimum water volume requirements for the Refueling Water Storage Tank (RWST), and adds requirements for RWST low level alarm settings and low level alarm operability.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with the issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment transmitted by letter dated April 6, 1977, (2) Amendment No. 34 to License No. DPR-26, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the White Plains Public Library, 100 Martine Avenue, White Plains, N.Y. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 9th day of November 1977.

For the Nuclear Regulatory Commission.

ROBERT W. REID,
Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 77-33555 Filed 11-21-77; 8:45 am]

[7590-01]

[Docket No. 50-298]

NEBRASKA PUBLIC POWER DISTRICT

Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 40 to Facility Operating License No. DPR-46, issued to Nebraska Public Power District (the licensee), which revised Technical Specifications for operation of the Cooper Nuclear Station located in Nemaha County, Nebr. The amendment is effective as of its date of issuance.

The amendment involves changes to the Environmental Technical Specifications to permit the use of a new radioanalysis system, to reduce the number of required operable Augmented Off-Gas (AOG) system hydrogen monitors, and to permit removing the AOG system from operation for up to 14 days if no hydrogen monitors are operable.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the act and the Commission's rules and regulations in Chapter 10, which are set forth in the license amendment. Prior public notice of this amendment is not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated August 19, 1977, (2) Amendment No. 40 to License No. DPR-46, and (3) the Commission's concurrently issued letter to the licensee which contains the staff's environmental and safety evaluations. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the Auburn Public Library, 118 15th Street, Auburn, Nebr.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 15th day of November 1977.

For the Nuclear Regulatory Commission.

DON K. DAVIS,
Acting Chief, Operating Reactors Branch No. 2, Division of Operating Reactors.

[FR Doc. 77-33556 Filed 11-21-77; 8:45 pm]

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on November 10, 1977 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

ACTION

Action Attitude and Awareness Survey, single time, 2,000 M's & F's over 18 plus 200 college students, Richard Eisinger, 395-3214.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration, questionnaire on impact of ocean pollution research program, single time, marine related groups, Ellett, C. A., 395-6132.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Resources Administration, evaluation of hospital productivity project, single time, sample of non-Federal hospitals in Texas, Human Resources Division, Richard Eisinger, 395-3532.

Office of Education, Strengthening research library resources program, OE-592, annually, Institutions of higher education, major research libraries, Laverne V. Collins, 395-3214.

REVISIONS

DEPARTMENT OF STATE (EXCLUSIVE AID AND ACTION)

Application for immigrant visa and alien registration, FS-510, on occasion, individuals, Ellett, C. A., 395-6132.

RAILROAD RETIREMENT BOARD

Report of former spouse—annuitant, G-476C, on occasion, applicant's for RRA benefits, Caywood, D. P., 395-3443.

DEPARTMENT OF COMMERCE

Bureau of Census, annual demographic survey—March 1978, CPS-1, CPS580, CPS581, CPS630, on occasion, Spanish-American households, Richard Eisinger, 395-3214.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration, evaluation and measurement system—supplemental security income questionnaire, SSA 9750, on occasion, monthly samples of originally adjudicated SSI applications, Caywood, D. P., Human Resources Division, 395-3443.

Social and Rehabilitation Service, Quality control in AFDC, SRS-APA341, 341-A, 341.1, 341.4, on occasion, welfare recipients, Caywood, D. P., 395-3443.

EXTENSIONS

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

Project grant application, NEA-3, on occasion, charitable and educational institutions, Lowry, R. L., 395-3772.

DEPARTMENT OF AGRICULTURE

Statistical reporting service, June acreage survey (planted and harvested by crop), annually, general farms, Ellett, C. A., 395-6132.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc. 77-33697 Filed 11-21-77; 8:45 am]

[3110-01]

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on November 15, 1977 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF ENERGY

Request for Information About Natural Gas Storage Facilities, single-time, major interstate natural gas pipeline companies, C. Louis Kincannon, Lowry, R. L., 395-3211.

OFFICE OF MANAGEMENT AND BUDGET

Federal Legal Representation Quesionnaire, single-time, Government agencies, Caywood, D. P., 395-3443.

ENVIRONMENTAL PROTECTION AGENCY

St. Louis Human Morbidity Study, other (see SF-83), family units, Ellett, C. A., Richard Eisinger, 395-6132.

DEPARTMENT OF AGRICULTURE

Economic Research Service, Land Ownership Survey, single-time, land owners, Ellett, C. A., Office of Federal Statistical Policy and Standards, 393-6132.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control, Cuillain-Barre Syndrome Surveillance, other (see SF-83), neurologists reporting cases of Guillain-Barre Syndrome, Richard Eisinger, 395-3214.

Office of the Secretary:

School System Summary Report, OS-14-77, other (see SF-83), public elementary and secondary school systems, Laverne V. Collins, Office of Federal Statistical Policy and Standards, 395-3214.

Individual School Report, OS-15-77, other (see SF-83), public elementary and secondary schools, Laverne V. Collins, Office of Federal Statistical Policy and Standards, 395-3214.

DEPARTMENT OF LABOR

Employment and Training Administration:

Evaluation of Economic Impact of Job Corps on the Participant, MT—1067A, single-time, Job Corps members, Housing, Veterans and Labor Division, Strasser, A., 395-3532.

Rearranged Work Schedules Study—Part B, MT-281, single-time, employees on rearranged work-weeks, Strasser, A., Office of Federal Statistical Policy and Standards, 395-6132.

DEPARTMENT OF LABOR

Labor Management and Service Administration, Survey of Needs for DPELR Services in the Public Labor Relations Sector, LMSA-41T, single-time, practitioners in labor—management relations, Housing, Veterans and Labor Division, 395-3532.

DEPARTMENT OF TRANSPORTATION

Departmental and other, the Local Rural Road Problem, single-time, businesses and farms, Strasser, A., Office of Federal Statistical Policy and Standards, 395-6132.

REVISIONS

VETERANS ADMINISTRATION

Credit Statement of Prospective Purchaser and Contract of Sale, 26-6705, on occasion, prospective purchaser, Caywood, D. P., 395-3443.

Notice to VA of Veteran or Beneficiary Incarcerated in Penal Institution, VA21-4193, on occasion, penal institutions, Caywood, D. P., 395-3443.

U.S. CIVIL SERVICE COMMISSION

Qualifications Brief for Educators, DM AA 26, on occasion, job applicants, Marsha Traynham, 395-3773.

DEPARTMENT OF AGRICULTURE

Statistical Reporting Service, Farm Production Expenditure Survey, annually, sample of farmers, Ellett, C. A., Office of Federal Statistical Policy and Standards, 395-6132.

DEPARTMENT OF COMMERCE

Bureau of Census, Survey of Housing Starts, Sales and Completions, SOC. 900, SOC. 900.1, SOC. 900A, SOC. 900A.1, monthly, builders of residential construction, Ellett, C. A., Office of Federal Statistical Policy and Standards, 395-6132.

DEPARTMENT OF LABOR

Employment and Training Administration, employment security automated reporting system (ESARS)—ES 2, 09 and other reports, ESARS, on occasion, State Employment Service Offices, Strasser, A., Office of Federal Statistical Policy and Standards, 395-6132.

EXTENSIONS

DEPARTMENT OF AGRICULTURE

Forest Service, Production of Fuelwood, Fence Posts, and Miscellaneous Farm Timber, annually, farm woodland owners, Ellett, C. A., Office of Federal Statistical Policy and Standards, 395-6132.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education, application for Federal assistance—Title IV, Civil Rights Act, OE 296, annually, LEA's, SEA's, Institution of Higher Education, Budget Review Division, 395-4775.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Housing Management, actual modernization cost certificate, HUD 53001, single-time, public housing agencies, Caywood, D. P., 395-3443.

DEPARTMENT OF LABOR

Employment Standards Administration, payroll, WH-347, weekly, contractors, Housing, Veterans and Labor Division, Strasser, A., 395-3532.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration, capital outlay by state highway departments—classified by Federal-aid systems, PR-532A, annually, 50 States, D.C., and Puerto Rico, Strasser, A., Office of Federal Statistical Policy and Standards, 395-6132.

Coast Guard, Application for Number Under Federal Boating Act (boat numbering system—boat owners), CG 3876, on occasion, Boatowners in Alaska, Wash., N.H., and A.S., Strasser, A., 395-6132.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc. 77-33698 Filed 11-21-77; 8:45 am]

[3110-01]

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on November 16, 1977 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF ENERGY

No. 2 Heating Oil Supply/Price Monitoring Report, (schedule A), P112-M-2, monthly, sellers of No. 2 heating oil, Lowry, R. L., 395-3722.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration:

Registration of medical device establishment, FD-2891A, annually, medical device establishments, Richard Eisinger, 395-3214.

An investigation of features of prescription drug advertising using physician perception, single time, physicians in 5 SMSA's, Richard Eisinger, Office of Federal Statistical Policy and Standards, 395-3214.

OFFICE OF HUMAN DEVELOPMENT

National day care home study: caregiver and parent, interview instruments, on occasion, family day care providers, Reese B. F., 395-3211.

REVISIONS

DEPARTMENT OF JUSTICE

Law Enforcement Assistance Administration, Survey of Expenditures and Employment for Civil and Criminal Justice Activities, CJ-6, CJ-23, CJ-6D, annually, county and municipal governments, Laverne V.

Collins, Office of Federal Statistical Policy and Standards, 395-3214.

EXTENSIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development, survey of Head Start handicapped efforts, C5-26-73, annually, Government agencies, Richard Eisinger, 395-3214.

DEPARTMENT OF LABOR

Bureau of Labor Statistics, retail prices—shelter—residential property taxes (CPI), 2921.42, annually, 350 taxing jurisdictions, Strasser, A., Office of Federal Statistical Policy and Standards, 395-6132.

PHILLIP D. LARSEN,
Budget and Management, Officer.

[FR Doc. 77-33699 Filed 11-21-77; 8:45 am]

[8010-01]

SECURITIES AND EXCHANGE COMMISSION

MIDWEST STOCK EXCHANGE, INC.

Application for Unlisted Trading Privileges and of Opportunity for Hearing

NOVEMBER 11, 1977.

In the matter of an application of the Midwest Stock Exchange, Incorporated for unlisted trading privileges in a certain security.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the security of the company as set forth below, which security is listed and registered on one or more other national securities exchanges:

Airco, Inc. (Delaware), Common Stock, $1 par value, File No. 7-5007

Upon receipt of a request, on or before November 27, 1977 from any interested person, the Commission will determine whether the application with respect to the company named shall be set down for hearing. Any such request should state briefly the title of the security in which he is interested, the nature of the interest of the person making the request, and the position he proposes to take at the hearing, if ordered. In addition, any interested person may submit his views or any additional facts bearing on the said application by means of a letter addressed to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549 not later than the date specified. If no one requests a hearing with respect to the particular application, such application will be determined by order of the Commission on the basis of the facts stated therein and other information contained in the official files of the Commission pertaining thereto.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 77-33755 Filed 11-21-77; 8:45 am]

[8010-01]

SECURITIES AND EXCHANGE COMMISSION

PHILADELPHIA STOCK EXCHANGE, INC.

Applications for Unlisted Trading Privileges and of Opportunity for Hearing

NOVEMBER 11, 1977.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the securities of the companies as set forth below, which securities are listed and registered on one or more other national securities exchanges:

Continental Group, Inc. (The), $2.00 Cumulative Convertible Preference Stock, Series A, $1.00 Par Value. File No. 7-5004.
Carborundum Co. (The), Common Stock, $1.50 Par Value. File No. 7-5005.
Airco, Inc. (Delaware), Common stock, $1.00 Par Value. File No. 7-5006.

Upon receipt of a request, on or before November 27, 1977 from any interested person, the Commission will determine whether the applications with respect to the companies named shall be set down for hearing. Any such request should include a brief statement as to the title of the security in which the person is interested, the nature of his interest in making the request, and the position which he proposes to take at the hearing, if ordered. In addition, any interested person may submit his views or any additional facts bearing on the said application by means of a letter addressed to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549 not late than the date specified. If no one requests a hearing with respect to the particular application, such application will be determined by order of the Commission on the basis of the facts stated therein and other information contained in the official files of the Commission pertaining thereto.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 77-33792 Filed 11-21-77; 8:45 am]

[8025-01]

SMALL BUSINESS ADMINISTRATION

[License No. 04/04-0118]

AFFILIATED INVESTMENT FUND, LTD.

Filing of Application for Approval of Conflict of Interest Transaction

Notice is hereby given that Affiliated Investment Fund, Ltd. (Affiliated), 2225 Shurfine Drive, College Park, Ga. 30337, a Federal Licensee under the Small Business Investment Act of 1958, as amended (Act), has filed an application with the Small Business Administration (SBA), pursuant to section 312 of the Act and covered by Section 107.1004 of the SBA Rules and Regulations, governing Small Business Investment Companies (13 CFR 107.1004 (1977)) for approval of conflict of interest transaction falling within the scope of the above section of the Act and Regulations.

Subject to such approval, Affiliated proposes to provide funds to Zack Properties, Inc., for the purpose of remodeling a retail grocery outlet located at 2 Cedar Street, McDonough, Ga. 30253.

The proposed financing is brought within the purview of § 107.1004(b)(1) of the Regulations because Mr. Zack B. Hinton, owner of Zack Properties, Inc., is a member of the Board of Directors of Associated Grocers Co-op, Inc., the sole shareholder of Affiliated, and therefore is considered an Associated of Affiliated as defined by § 107.3 of the Regulations.

Notice is hereby given that any interested person may, not later than December 2, 1977, submit written comments on the proposed transaction to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies).

Dated: November 15, 1977.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 77-33546 Filed 11-21-77; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1399]

ARIZONA

Declaration of Disaster Loan Area

As a result of the President's declaration, I find that Pima, Pinal, and Santa Cruz Counties and adjacent counties within the State of Arizona constitute a disaster area because of damage resulting from severe storms

and flooding beginning about October 6, 1977. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on January 5, 1978, and for economic injury until the close of business on August 4, 1978, at:

Small Business Administration, District Office, 112 North Central Avenue, Phoenix, Ariz. 85004.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 12, 1977.

PATRICIA M. CLOHERTY,
Acting Administrator.

[FR Doc. 77-33549 Filed 11-21-77; 8:45 am]

[8025-01]

[License No. 06/10-0150]

CAPITAL MARKETING CORP.

Filing of Application for Approval of Conflict of Interest Transaction Between Associates

Notice is hereby given, pursuant to section 107.1004 of the Regulations governing small business investment companies (13 CFR 107.104 (1977)), by the Small business Administration (SBA) of a conflict of interest transaction between Capital Marketing Corp. (CMC), 9001 Ambassador Row, Dallas, Tex. 75247, a Federal licensee under the Small Business Investment Act of 1958, as amended (the Act) (15 U.S.C. 661 et seq.), and an associate.

CMC was licensed by SBA on June 24, 1968. There are approximately 415 individual shareholders of CMC with each owning less than 5 percent. Most of these shareholders are members of Affiliated Food Stores, Inc. (Affiliated), a wholesale food cooperative having approximately 675 members. The business address of Affiliated is the same as that of CMC. Affiliated owns a 6.9 percent equity interest in CMC.

CMC proposes to loan Mr. Carlo Angelo approximately $305,300, of which $219,184 represents refinancing of previously approved financing to Mr. Angelo by CMC. Mr. Angelo is a director of CMC, and therefore, an associate, as defined in § 107.3(a) of SBA's rules and regulations.

As such, the proposed financing by CMC would contravene the provisions of § 107.1004(b)(1) of the regulations. Except where a written exemption may be granted by SBA in special instances in furtherance of the purposes of the Act, a licensee shall not, directly or indirectly, provide financing to any of its associates.

Notice is further given that any person may, not later than December 7, 1977, submit to SBA, in writing, comments on this transaction. Any such comments should be addressed to: Associate Administrator for Finance and Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A copy of this notice shall be published by CMC in a newspaper of general circulation in Dallas, Tex.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: November 14, 1977.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 77-33547 Filed 11-21-77; 8:45 pm]

[8025-01]

[Application No. 02/02-5338]

CVC CAPITAL CORP.

Application for License To Operate as a Small Business Investment Company

An application for a license to operate as a small business investment company under the provisions of section 301(d) of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 et seq.), has been filed by CVC Capital Corp. (Applicant), with the Small Business Administration (SBA), pursuant to 13 CFR 107.102 (1977).

The officers, directors, and stockholders of the applicant are as follows:

Joerg G. Klebe, 128 East 62nd Street, New York, N.Y. 10021, President, Director, 50 percent shockholder.

Jeanne K. Drewsen, 300 Central Park West, New York, N.Y. 10024, Secretary, Director.

Ernst A. Teves, Beethoven Strasse 59, 6000 Frankfurt/Main 1, West Germany, Director, 50 percent stockholder.

The applicant, a Delaware corporation, with its principal place of business located at 16 East 63rd Street, New York, N.Y. 10021, will begin operations with $2,005,000 of paid-in capital and paid-in surplus derived from the sale of 1,000 shares of common stock to Mssrs. Klebe and Teves.

The applicant will conduct its activities principally in the State of New York, and in other areas within the United States of America.

Applicant intends to provide assistance to all qualified socially or economically disadvantaged small business concerns in the fields of communication including television broadcasting and production.

As a small business investment company under section 301(d) of the Act, the applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Small Business Investment Act of 1958, as amended from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBA's consideration of the applicant include the general business reputation and character of the proposed management, and the probability of successful operation of the applicant under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act and SBA Rules and Regulations.

Any person may, not later than December 7, 1977, submit to SBA written comments on the proposed applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in New York, N.Y.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: November 14, 1977.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 77-33548 Filed 11-21-77; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1398]

GEORGIA

Declaration of Disaster Loan Area

As a result of the President's declaration, I find that Stephens County and adjacent counties within the State of Georgia, constitute a disaster area because of damage resulting from the collapse of the Kelley Barnes Lake Dam and resultant flooding beginning about November 6, 1977. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on January 6, 1978, and for economic injury until the close of business on August 7, 1978, at:

Small Business Administration, District Office, 1720 Peachtree Road, NW., 6th Floor, Atlanta, Ga. 29201.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 12, 1977.

PATRICIA M. CLOHERTY,
Acting Administrator.

[FR Doc. 77-33550 Filed 11-21-77; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1397]

KENTUCKY

Declaration of Disaster Loan Area

The Miller Hotel located at Public Square in the city of Columbia, in Adair County, Ky., constitutes a disaster area because of damage resulting from a fire which occurred on November 2, 1977. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on January 12, 1978, and for economic injury until the close of business on August 14, 1978, at:

Small Business Administration, District Office, Federal Office Building, Room 188, 600 Federal Place, Louisville, Ky. 40202.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 12, 1977.

PATRICIA M. CLOHERTY,
Acting Administrator.

[FR Doc. 77-33551 Filed 11-21-77; 8:45 am]

[4710-01]

DEPARTMENT OF STATE

[CM-7/133]

STUDY GROUP 1 OF THE U.S. NATIONAL COMMITTEE FOR THE INTERNATIONAL RADIO CONSULTATIVE COMMITTEE (CCIR)

Meeting

The Department of State announces that Study Group 1 of the U.S. National Committee for the International Radio Consultative Committee (CCIR) will meet on December 15, 1977, in Conference Rooms A and B of the Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C., at 9:30 a.m.

Study Group 1 deals with matters relating to efficient use of the radio frequency spectrum and in particular, with problems of frequency sharing, taking into account the attainable characteristics of radio equipment and systems; principles for classifying emissions; and the measurement of emission characteristics and spectrum occupancy. The purpose of the meeting is to establish a program of work on documents for the CCIR Special Preparatory Meeting (SPM) for the 1979 World Administrative Radio Conference. The SPM will convene for four weeks commencing October 23, 1978.

Members fo the general public may attend the meeting and join in the discussions subject to instructions of the Chairman. Admittance of public members will be limited to the seating available.

Dated: November 8, 1977.

GORDON L. HUFFCUTT,
Chairman,
U.S. CCIR National Committee.

FR Doc. 77-33521, Filed 11-21-77; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Notice No. 532]

ASSIGNMENT OF HEARINGS

NOVEMBER 17, 1977.

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 11207 (Sub-No. 387), Deaton, Inc., MC 60014 (Sub-No. 47), Aero Trucking, Inc., MC 66886 (Sub-No. 57), Belger Cartage Service, Inc., MC 73165 (Sub-No. 412), Eagle Motor Lines, Inc., MC 106644 (Sub-No. 242), Superior Trucking Co., Inc., and MC 116915 (Sub-No. 31), Eck Miller Transportation Corp., now assigned December 6, 1977, at Jacksonville, Fla., will be held in Room 100, Voyager Building, 2255 Phyllis Street.

MC 143167, Seyforth Express, Inc., now assigned December 7, 1977, at Jacksonville, Fla., will be held in Room 100, Voyager Building, 2255 Phyllis Street.

MC 109397 (Sub-No. 350), Tri-State Motor Transit Co., now assigned December 8, 1977, at Jacksonville, Fla., will be held in Room 100, Voyager Building, 2255 Phyllis Street.

MC 115162 (Sub-No. 350), Poole Truck Line, Inc., now assigned December 12, 1977, at Jacksonville, Fla., will be held in Room 100, Voyager Building, 2255 Phyllis Street.

MC 115215 (Sub-No. 24), New Truck Lines, Inc., now assigned December 14, 1977, at Jacksonville, Fla., will be held in Room 100, Voyager Building, 2255 Phyllis Street.

MC 96925 (Sub-No. 7), Crown Motor Lines, Inc., now assigned December 12, 1977, at Tallahassee, Fla., will be held in the Florida Public Service Commission, 702 South Duval Street.

MC 13250 (Sub-No. 138), J. H. Rose Truck Line, Inc., now being assigned February 8, 1978 (1 day), for hearing in Jacksonville, Fla., in a hearing room to be later designated.

MC 11207 (Sub-No. 393), Deaton, Inc., MC 60014 (Sub-No. 46), Aero Trucking, Inc., MC 73165 (Sub-No. 405), Eagle Motor Lines, Inc., MC 106398 (Sub-No. 775), National Trailer Convoy, Inc., and MC 118959 (Sub-No. 149), Jerry Lipps, Inc., now being assigned February 9, 1978 (2 days), for hearing in Jacksonville, Fla., in a hearing room to be later designated.

MC 113678 (Sub-No. 667), Curtis, Inc., now assigned February 9, 1978, at Kansas City, Mo., is advanced to January 26, 1978 (2 days), at Kansas City, Mo., in hearing room to be later designated.

MC 123407 (Sub-No. 395), Sawyer Transport, Inc., now being assigned January 23, 1978 (1 day), at Kansas City, Mo., in hearing room to be later designated.

MC 143477, Arcadian Motor Carriers, now being assigned January 30, 1978 (2 days), at Kansas City, Mo., in a hearing room to be later designated.

MC-F-13304, Becker Corp.—Control and Merger—Royal Transportation, Inc., now being assigned February 1, 1978 (3 days), at Kansas City, Mo., in a hearing room to be later designated.

MC 99581 (Sub-No. 4), Horace Simmons, d.b.a. Vaca Valley Bus Lines, now assigned December 5, 1977, ast San Francisco, Calif. is postponed indefinitely.

MC 124078 (Sub-No. 726), Schwerman Trucking Co., now assigned January 25, 1978 at Chicago, Ill. is postponed indefinitely.

MC 140216 (Sub-No. 3), John E. Way, Jr., now assigned December 14, 1977 at Harrisburg, Pa. and will be held in Room 392, Federal Building, 228 Walnut Street.

MC 141776 (Sub-No. 12), Foodtrain Inc. now assigned December 12, 1977 at Philadelphia, Pa. being held at the New U.S. Courthouse, 600 Market Street.

MC 142832 (Sub-No. 1), Spider Wrecker Service, Inc., now being assigned January 11, 1978 (3 days), at Atlanta, Ga., in a hearing room to be later designated.

MC 138157 (Sub-No. 41), Southwest Equipment Rental, Inc., d.b.a. Southwest Motor Freight, now being assigned January 10, 1978, (1 day), at Atlanta, Ga. in a hearing room to be later designated.

MC 94350 (Sub-No. 385), Transit Homes, Inc. now assigned January 11, 1978 at Atlanta, Ga. is postponed indefinitely.

MC 142879, Heely-Brown Trucking Co. now assigned January 10, 1978 at Atlanta, Ga. is canceled and transferred to Modified Procedure.

MC 89684 (Sub-No. 97), Wycoff Co., Inc. now assigned January 23, 1978, at Denver, Colo. is canceled, application dismissed.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 77-33631 Filed 11-21-77; 8:45 am]

[7035-01]

[Notice No. 534]

ASSIGNMENT OF HEARINGS

NOVEMBER 17,1977.

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.

CORRECTION[1]

MC 107107 (Sub-No. 455), Alterman Transport Lines, Inc. now being assigned January 16, 1978 (1 week) at Orlando, Fla. and will be held at the Gold Key Inn, 7100 South Orange Blossom Trail.

H. G. HOMME, Jr.,
Acting Secretary.

[1]This notice corrects the hearing date.

[FR Doc. 77-33632 Filed 11-21-77; 8:45 am]

[7035-01]

[Notice No. 533]

ASSIGNMENT OF HEARINGS

NOVEMBER 16, 1977.

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.

CORRECTION

No. MCC 124211 (Sub-No. 293), Hilt Truck Line, Inc., now assigned December 9, 1977, at Chicago, Ill., is postponed to January 18, 1978 (3 days), at Chicago, Ill., in a hearing room to be later designated.

H. G. HOMME, Jr.
Acting Secretary.

[FR Doc. 77-33633 Filed 11-21-77; 8:45 am]

[7035-01]

FOURTH SECTION APPLICATION(S) FOR RELIEF

NOVEMBER 17, 1977.

An application, as summarized below, has been filed requesting relief from the requirements of section 4 of the Interstate Commerce Act to permit common carriers named or described in the application to maintain higher rates and charges at intermediate points than those sought to be established at more distant points.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1100.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

FSA No. 43464—*Joint Water-Rail Container Rates—Sea-Land Service, Inc.* Filed by Sea-Land Service, Inc., (No. 94), for itself and interested rail carriers. Rates on general commodities, between rail carrier's terminals at Oakland and Los Angeles, Calif., and Barbados, Costa Rica, Curacao, Dominican Republic, El Salvador, Guatemala, Guyana, Haiti, Honduras, Jamaica, Nicaragua, Panama Canal Zone, Republic of Panama, Republic of Panama (Free Zone), and Trinidad.

Grounds for relief—Water competition.

Tariffs—Sea-Land Service, Inc., tariffs Nos. 277, 278, 279, 280, 281, and 282, I.C.C. Nos. 114, 115, 116, 117, 118, and 119, F.M.C. Nos. 153, 154, 155, 156, 158, and 159. Rates are published to become effective on December 15, 1977.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 77-33634 Filed 11-21-77; 8:45 a.m.]

[7035-01]

[AB 43 (Sub-No. 26)]

ILLINOIS CENTRAL GULF RAILROAD COMPANY

Abandonment Near Harwood, La., and Woodville, Miss., in West Feliciana Parish, La. and Wilkinson County, Miss.

NOVEMBER 8, 1977.

The Interstate Commerce Commission hereby gives notice that its section of Energy and Environment has concluded that the proposed abandonment by the Illinois Central Gulf Railway Co. of its line between Woodville, Miss., and Hardwood, La., a distance of 22.45 miles, if approved by the Commission, does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. §§ 4321, et seq., and that preparation of a detailed environmental impact statement will not be required under section 4332(2)(C) of the NEPA.

It was concluded, among other things, that diversion of rail traffic to motor carrier would not result in a significant increase in energy consumption, air pollution, or noise levels. Although it is alleged that increased motor carrier traffic could increase highway maintenance costs, the effect on area highways should not be serious.

Abandonment would adversely affect an industrial development project at Woodville. However, the number of jobs involved is not sufficiently large to be considered significant. There are no other indications of definite developmental projects to be affected. Therefore, abandonment is not expected to have a serious adverse impact on rural and community development.

The right-of-way has recently been determined to be eligible for inclusion in the National Register of Historic Places. Abandonment could open the way for uses of land in the right-of-way which would adversely affect its historic character. Therefore, in accordance with the guidelines for implementation of the National Historic Preservation Act, a status report on the matter has been submitted to the Advisory Council on Historic Preservation to initiate consultation on mitigating possible adverse impacts.

It was determined that the right-of-way is suitable for use for other public purposes. Therefore, the TAS suggests imposition of a condition which would give public agencies 180 days to offer to purchase the right-of-way.

This conclusion is contained in a staff-prepared environmental threshold assessment survey, which is available on request to the Interstate Commerce Commission, Office of Proceedings, Washington, D.C. 20423, telephone 202-275-7011.

Interested persons may comment on this matter by filing their statements in writing with the Interstate Commerce Commission, Washington, D.C. 20423, on or before December 26, 1977.

It should be emphasized that the environmental threshold assessment survey represents an evaluation of the environmental issues in the proceeding and does not purport to resolve the issue of whether the present or future public convenience and necessity permit discontinuance of the line proposed for abandonment. Consequently, comments on the environmental study should be limited to discussion of the presence or absence of environmental impacts and reasonable alternatives.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 77-33635 filed 11-21-77; 8:45 a.m.]

*This notice corrects previous hearing date.

sunshine act meetings

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).

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Securities and Exchange Commission	9

[6335-01]

1

COMMISSION ON CIVIL RIGHTS.

DATE AND TIME: November 23, and 25, 1977 at 11 a.m.

PLACE: Room 800, 1121 Vermont Avenue NW., Washington, D.C.

STATUS: Telephone conference call—closed to the public.

MATTERS TO BE CONSIDERED: Review and discussion of a draft of the Discrimination on the basis of age report.

CONTACT PERSON FOR FURTHER INFORMATION:

Mimi Hartley, Public Affairs Unit, 202-254-6697.

[S-1883-77 Filed 11-18-77; 3:56 pm]

[6740-02]

2

FEDERAL ENERGY REGULATORY COMMISSION.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: (Pub. 11/11/77 42 FR 58830.)

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: November 16, 1977, 10 a.m.; November 17, 1977, 10 a.m.

CHANGE IN THE MEETING: The following items have been added:

Item No., Docket No. and Company

G-26.—Report on the Development and Utilization of Natural Gas Underground Storage.

G-27.—Columbia Gulf Transmission Co. and United Gas Pipe Line Co.

Closed Meeting.—Discussion of pending litigation.

LOIS D. CASHELL,
Acting Secretary.

[S-1880-77 Filed 11-18-77; 9:30 am]

[6720-01]

3

FEDERAL HOME LOAN MORTGAGE CORPORATION

TIME AND DATE: 2:30 p.m., November 22, 1977.

PLACE: 320 First Street, NW., Room 630, Washington, D.C.

STATUS: Open Meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Henry Judy, 202-624-7107.

MATTERS TO BE CONSIDERED: Status Report on FHLMC Move to New FHLBB Building, No. 100, November 18, 1977.

Announcement is being made at the earliest practicable time.

RONALD A. SNIDER,
Assistant Secretary.

[S-1885-77 Filed 11-18-77; 3:56 pm]

[6720-01]

4

FEDERAL HOME LOAN MORTGAGE CORPORATION.

TIME AND DATE: At the conclusion of the open meeting to be held at 2:30 p.m., November 22, 1977.

PLACE: 320 First Street NW., Room 630, Washington, D.C.

STATUS: Closed meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Henry Judy, 202-624-7107.

MATTERS TO BE CONSIDERED:

Consideration of September 1977 Financial Statements and November 1977 Cash Budget.

Consideration of Appointment of Assistant Secretary Capital Adequacy.

Announcement is being made at the earliest practicable time.

No. 99, November 18, 1977.

RONALD A. SNIDER,
Assistant Secretary.

[S-1886-77 Filed 11-18-77; 3:56 pm]

[7020-02]

5

[USITC SE-77-71]

INTERNATIONAL TRADE COMMISSION.

TIME AND DATE: 9:30 a.m., Tuesday, November 29, 1977.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Photo cubes (Inv. 337-TA-30)—vote.
5. Submission to Congress for the FY 1979 budget.
6. Bolts, nuts, and screws of iron or steel (Inv. TA-201-27)—staff briefing.
7. Petitions and complaints (if necessary): (a) Sugar.
8. Motion M-290 by Mr. Hemmendinger to strike testimony in the steel hearings of November 7 and 9, 1977.
9. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-1878-77 Filed 11-18-77; 9:10 am]

[7020-02]

6

[USITC SE-77-70A]

INTERNATIONAL TRADE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: November 21, 1977.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 3 p.m., Tuesday, November 22, 1977.

CHANGES IN THE MEETING:

Additional Agenda Item:

2. High-carbon ferrochromium (Inv. TA-201-28)—reconsideration of the vote and vote on remedy (if necessary).

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-1879-77 Filed 11-18-77; 9:10 am]

[7555-01]

7

NATIONAL SCIENCE BOARD.

TIME AND DATE: 5:30 p.m., November 17, 1977 (open session).

PLACE: Room 540, 1800 G Street NW., Washington, D.C. 20550.

STATUS: As previously announced parts of this meeting were open to the public. Because of scheduling difficulties a continuation of the open session was held.

MATTERS TO BE CONSIDERED:

Portions open to the public.:

Chairman's Report—Continuation of consideration begun in the previously-announced open session, of the NIH Guidelines for the conduct of recombinant DNA research.

CONTACT PERSON FOR MORE INFORMATION:

Vernice Anderson, Executive Secretary, 202-632-5840.

[S-1881-77 Filed 11-18-77; 3:56 pm]

[4910-58]

8

NATIONAL TRANSPORTATION SAFETY BOARD.

TIME AND PLACE: 2:15 p.m., Friday, November 18, 1977, NISB Board Room, 800 Independence Avenue, Washington, D.C. 20594.

STATUS: The first item will be closed to the public; the second will be open. The majority of the Board determined that the business of the Agency required the meeting and that no earlier announcement was possible.

MATTERS TO BE CONSIDERED:

1. Discussion of Office of Management and Budget's Action on FY 1979 Budget.
2. Discussion of On-Going Renovation and Reallocation of Space at Headquarters Offices.

CONTACT PERSON FOR MORE INFORMATION:

Sharon Flemming, 202-755-4930.

[S-1882-77 Filed 11-18-77; 3:56 pm]

[8010-01]

9

SECURITIES AND EXCHANGE COMMISSION.

The following items, previously scheduled for consideration by the Commission on Wednesday, November 16, 1977, at the open meeting for 10 a.m., have been rescheduled for consideration on Thursday, November 17, 1977, as indicated:

Open meeting to be held on Thursday, November 17, 1977, at 11:30 a.m. until 12:15 p.m.:

1. Proposed drafting of a release which would invite public comment and announce public hearings to be held in connection with the possible revision of disclosure requirements as related to small business.
2. Consideration of soliciting public comment on proposed amendments to reporting forms and schedules which would provide simplified registration procedures for small issuers under the Securities Act of 1933.

Open meeting to be held on Thursday, November 17, 1977, at 3 p.m. until 4 p.m.:

1. Proposed publication for comment of amendments to Rule 146, concerning private offering exemptions under the Securities Act of 1933.

Chairman Williams, Commissioners Loomis, Evans, Pollack, and Karmel determined that Commission business required the rescheduling of these items and that no earlier notice thereof was possible.

NOVEMBER 16, 1977.

[S-1884-77 Filed 11-18-77; 3:56 pm]

federal register

TUESDAY, NOVEMBER 22, 1977
PART II



FEDERAL ELECTION COMMISSION

■

FREEDOM OF INFORMATION ACT REGULATIONS

Proposed Rulemaking

[6715-01]

FEDERAL ELECTION COMMISSION

[11 CFR Part 4]

[Notice 1977-54]

FREEDOM OF INFORMATION ACT REGULATIONS

Proposed Rulemaking

AGENCY: Federal Election Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Federal Election Commission publishes for public comment its proposed regulations implementing 5 U.S.C. 552, the Freedom of Information Act.

DATE: Comments on or before February 18, 1978.

ADDRESS: Send comments to: Regulation Section, Office of General Counsel, Federal Election Commission, 1325 K Street NW., Washington, D.C. 20463.

FOR FURTHER INFORMATION CONTACT:

David Fiske, 202-523-4065.

Dated: November 16, 1977.

JOAN D. AIKENS,
Vice Chairman for the Federal Election Commission.

Title 11 CFR is proposed to be amended by adding the following new Part 4:

PART 4—PUBLIC RECORDS AND THE FREEDOM OF INFORMATION ACT

Sec.

4.1 Definitions.
4.2 Policy on disclosure of records.
4.3 Scope.
4.4 Availability of records.
4.5 Categories of exemptions.
4.6 Discretionary release of exempt documents.
4.7 Requests for records.
4.8 Appeal of denial.

AUTHORITY: 5 U.S.C. 552.

§ 4.1 Definitions.

As used in this part: (a) "Commission" means the Federal Election Commission, established by the Federal Election Campaign Act of 1971, as amended.

(b) "Commissioner" means one of the six appointees confirmed by the Senate who is a voting member of the Commission.

(c) "Request" means to seek the release of records under 5 U.S.C. 552.

(d) "Requester" is any person who submits a request to the Commission.

(e) "Act" means the Federal Election Campaign Act of 1971, as amended by the Federal Election Campaign Act Amendments of 1974, and 1976, and unless specifically excluded, includes Chapters 95 and 96 of the Internal Revenue Code of 1954 relating to public financing of Federal elections.

§ 4.2 Policy on disclosure of records.

(a) The Commission will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the rights of persons contracting with the Commission with respect to trade secret and commercial or financial information entitled to confidential treatment, and the need for the Commission to promote free internal policy deliberations and to pursue its official activities without undue disruption.

(b) All Commission records shall be available to the public unless they are specifically exempt under this part.

(c) To carry out this policy, the Commission shall designate a Freedom of Information Act officer.

§ 4.3 Scope.

(a) The regulations in this part implement the provisions of the Freedom of Information Act, 5 U.S.C. 552, with respect to the availability of records for inspection and copying.

(b) The regulations in this part do not govern release of the following records:

(1) Reports of receipts and expenditures, designations of campaign depositories, statements of organizations, candidate designations of campaign committees; and the indexes compiled from the filings herein.

(2) Requests for advisory opinions, written comments submitted thereto and responses issued by the Commission;

(3) With respect to enforcement matters under the provisions of 2 U.S.C. 437g, the results of any conciliation attempt, including any conciliation agreement entered into by the Commission; and any determination by the Commission that no violation of the Act has occurred.

(4) Copies of studies published pursuant to the Commission's duty to serve as a national clearinghouse on election law administration.

(c) Release of the records identified in subsection (b)(1)-(4) above are governed by the provisions of 2 U.S.C. 43 (a)(4) and (a)(5), 437f(c), 437g(a)(6)(C) and 438 (b) and are available to the public from the Office of Public Records located on the first floor at 1325 K Street, NW., Washington, D.C. This office is open Monday through Friday from 9:00 a.m. to 5:00 p.m. except legal holidays.

§ 4.4 Availability of records.

(a) In accordance with 5 U.S.C. 552 (a)(2) and (a)(3) the Commission shall make the following materials available for public inspection and copying:

(1) Statements of policy and interpretation which have been adopted by the Commission;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) General Counsel reports and investigatory materials in enforcement files after the Commission has voted to close a case or to take no further action;

(4) Opinions of Commissioners rendered in enforcement cases after the Commission has voted to close a case or to take no further action.

(5) Letter requests for guidance and responses thereto;

(6) The minutes of Commission meetings;

(7) Material routinely prepared for public distribution, e.g. campaign guidelines, FEC Record, press releases, speeches, notices to candidates and committees.

(8) Proposals submitted in response to a request for proposals formulated pursuant to the Federal Procurement Regulations. 41 CFR 1-1.001 et seq.

(9) Contracts for services and supplies entered into by the Commission.

(10) Statements and certifications (with respect to closing meetings) as required by the Government in the Sunshine Act, 5 U.S.C. 552b.

(b) The Commission shall maintain and make available current indexes and supplements providing identifying information regarding any matter issued, adopted or promulgated after April 15, 1975 as required by 5 U.S.C. 552(a)(2)(C). These indexes and supplements shall be published and made available on at least a quarterly basis for public distribution unless the Commission determines by Notice in the FEDERAL REGISTER that publication would be unnecessary and impracticable. Nevertheless, copies of any index or supplement shall be made available upon request at a cost not to exceed the direct cost of duplication.

(c) The Freedom of Information Act and the provisions of this part apply only to existing records; they do not require the creation of new records.

(d) If documents or files contain both disclosable and nondisclosable information, the nondisclosable information will be deleted and the disclosable information released unless the disclosable portions cannot be reasonably segregated from the other portions in a manner which will allow meaningful information to the disclosed.

§ 4.5 Categories of exemptions.

(a) 5 U.S.C. 552(b) establishes nine categories of matters which are exempt from the mandatory disclosure requirements of 5 U.S.C. 552(a). No requests under 5 U.S.C. 552 shall be denied release unless the record contains, or its disclosure would reveal, matters that are:

(1) Specifically authorized under criteria established by an executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive order;

(2) Related solely to the internal personnel rules and practices of the Commission;

(3) Specifically exempted from disclosure by statute;

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential. Such information includes confidential business information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of income, profits, losses, or ex-

penditures of any person, firm, partnership, corporation, or other organization, if the disclosure is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. These procedures shall be used for submitting business information in confidence:

(i) A request for confidential treatment shall be addressed to the FOIA officer, Federal Election Commission, 1325 K Street, NW., Washington, D.C. 20463, and shall indicate clearly on the envelope that it is a request for confidential treatment.

(ii) With each submission of, or offer to submit, business information which a submitter desires to be treated as confidential under paragraph (a)(4) of this section, the submitter shall provide the following, which may be disclosed to the public: (A) A written description of the nature of the subject information, and a justification for the request for its confidential treatment, and (B) a certification in writing under oath that substantially identical information is not available to the public.

(iii) Approval or denial of requests shall be made only by the FOIA officer or his or her designees. A denial shall be in writing, shall specify the reason therefore, and shall advise the submitter of the right to appeal to the Commission.

(iv) For good cause shown, the Commission may grant an appeal from a denial by the FOIA officer or his or her designee if the appeal is filed within fifteen (15) days after receipt of the denial. An appeal shall be addressed to the Chairman, Federal Election Commission, 1325 K Street, NW., Washington, D.C. 20463 and shall clearly indicate that it is a confidential submission appeal. An appeal will be decided within twenty (20) days after its receipt (excluding Saturdays, Sundays and legal holidays) unless an extension, stated in writing with the reasons therefore, has been provided the person making the appeal.

(v) Any business information submitted in confidence and determined to be entitled to confidential treatment shall be maintained in confidence by the Commission and not disclosed except as required by law. In the event that any business information submitted to the Commission is not entitled to confidential treatment, the submitter will be permitted to withdraw the tender unless it is the subject of a request under the Freedom of Information Act or of judicial discovery proceedings.

(vi) Since enforcement actions under 2 U.S.C. 437g are confidential by statute, the procedures outlined in § 4.5(a)(4)(i) thru (v) are not applicable.

(5) Inter-agency or intra-agency memoranda or letters which would not be available by law to a party in litigation with the Commission.

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personnal privacy.

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel.

(b) Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt.

(c) If a requested record is one of another government agency or deals with subject matter to which a government agency other than the Commission has exclusive or primary responsibility, the request for such a record shall be promptly referred by the Commission to that agency for disposition or guidance as to disposition.

(d) Nothing in this part authorizes withholding of information or limiting the availability of records to the public, except as specifically provided in this part; nor is this part authority to withhold information from Congress.

§ 4.6 Discretionary release of exempt records.

The Commission may, in its discretion, release requested records despite the applicability of the exemptions in § 4.5 (a), if it determines that it is in the public interest and that the rights of third parties would not be prejudiced.

§ 4.7 Requests for records.

(a) A request to inspect or copy Commission public records as described in § 4.3(b) may be made in person or by mail. The Public Records office is open Monday through Friday between the hours of 9 a.m. and 5 p.m. and is located on the first floor, 1325 K Street NW., Washington, D.C. 20463.

(b) Oral or written requests for copies of records not available in the Public Records Office shall be addressed to FOIA Officer, Federal Election Commission, 1325 K Street NW., Washington, D.C. 20463. The request shall reasonably describe the records sought with sufficient specificity with respect to names, dates and subject matter to permit the records to be located. A requestor will be promptly advised if the records cannot be located on the basis of the description given and that further identifying information must be provided before the request can be satisfied.

(c) Records or copies thereof will normally be made available either immediately upon receipt of a request or within ten working days thereafter, or twenty working days in the case of an appeal, unless in unusual circumstances the time is extended. In the latter event, the requestor shall be notified of the reasons for the extension and the date on which a determination is expected to be made, but in no case shall the extended time exceed ten working days. An extension may be made if it is (1) necessary to locate records or transfer them from physically separate facilities; or (2) necessary to search for, collect, and appropriately examine a large quantity of separate and distinct records which are the subject of a single request; or (3) necessary for consultation with another agency which has a substantial interest in the determination of the request, or with two or more components of the Commission which have a substantial subject matter interest therein.

(d) Any person denied access to records by the Commission shall be notified immediately giving reasons therefore, and notified of the right of such person to appeal such adverse determination to the Commission.

(e) Receipt of a request under this part shall be the date on which the FOIA Officer actually receives the request.

§ 4.8 Appeal of denial.

(a) Any person who has been notified pursuant to § 4.6(d) that his/her request for inspection of a record or for a copy has been denied, or who has received no response to a request for a record or copy within ten days (or within such extended period as is permitted under § 4.7(c)) after the request has been received by the Commission, may appeal the adverse determination or the failure to respond by requesting the Commission to direct that the record be made available.

(b) The appeal request shall be in writing, shall clearly and prominently state on the envelope or other cover and at the top of the first page "FOIA Appeal", and shall identify the record in the form in which it was originally requested.

(c) The appeal request should be delivered or addressed to the FOIA Officer, Federal Election Commission, 1325 K Street, NW., Washington, D.C. 20463.

(d) The requester may state facts and cite legal or other authorities as he/she deems appropriate in support of the appeal request.

(e) For good cause shown, the Commission may disclose a record which is subject to one of the exemptions listed in § 4.5.

(f) The Commission will make a determination with respect to any appeal within twenty days (excluding Saturdays, Sundays and legal holidays) after receipt of the appeal (or within such ex-

tended period as is permitted under § 4.7 (c)). If on appeal, the denial of the request for a record or a copy is in whole or in part upheld, the Commission shall advise the requestor of the denial and shall notify him/her of the provisions for judicial review of that determination as set forth in 5 U.S.C. 552(a)(4).

(g) Because of the risk of misunderstanding inherent in oral communications, the Commission will not entertain any appeal from an alleged denial or failure to comply with an oral request. Any person who has orally requested a copy of a record that he/she believes to have been improperly denied should resubmit the request in writing as set forth in § 4.7.

§ 4.9 Fees.

(a) Fees will be charged for copies of records which are furnished a requestor under this part and for time spent in locating and reproducing them in accordance with the fee schedule below:

	Dollar amount
Record search time, 1st ½ hour free; Each additional ½ hour	$2.50
Reproduction of documents, per page	.10
Transcript of tape-recorded matter, per page	3.00

(b) In the event fees for pending requests under this part from the same requestor exceed $25.00, such records will not be searched for or made available, nor copies furnished, unless the requestor first pays or makes acceptable arrangements to pay the total amount due, or if the fee is not precisely ascertainable, the approximate amount due upon the completion of the Commission's search and/or copying. All payments exceeding $5.00 must be in the from of a check or money order made payable to the Treasury of the United States. In the event an advance payment hereunder shall differ from the actual fees due, an appropriate adjustment will be made at the time the copies are delivered or made available or a denial of same is noticed.

(c) The Commission may reduce or waive payment of fees hereunder if such reduction or waiver would be in the public interest.

[FR Doc.77-33584 Filed 11-21-77;8:45 am]

federal register

TUESDAY, NOVEMBER 22, 1977

PART III



DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

■

SURF CLAM AND OCEAN QUAHOG FISHERIES

Emergency Regulations

[3510-12]

Title 50—Wildlife and Fisheries

CHAPTER VI—FISHERY CONSERVATION AND MANAGEMENT, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 652—SURF CLAM AND OCEAN QUAHOG FISHERIES

Emergency Regulations

AGENCY: National Oceanic and Atmospheric Administration.

ACTION: Emergency regulations.

SUMMARY: The National Oceanic and Atmospheric Administration is publishing emergency regulations to implement the Mid-Atlantic Fishery Management Council's Fishery Management Plan for the Surf Clam and Ocean Quahog Fisheries. The regulations include management techniques such as a two-day work week, quotas, and reporting requirements. No foreign fishing is permitted.

EFFECTIVE DATE: 12:01 a.m. November 17, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. William G. Gordon, Regional Director, Northeast Region, National Marine Fisheries Service, 14 Elm Street, Gloucester, Mass. 01930, telephone 617-281-3600.

SUPPLEMENTARY INFORMATION:

Section 305(e) of the Fishery Conservation and Management Act of 1976, 16 U.S.C. 1801 et seq., as amended, (Act) authorizes the Secretary of Commerce (Secretary) to promulgate emergency regulations to implement a fishery management plan when the Secretary determines that an emergency involving any fishery resource exists.

The Acting Deputy Assistant Administrator for Fisheries of the National Oceanic and Atmospheric Administration, acting pursuant to a delegation of authority from the Secretary, authorized the promulgation of emergency regulations for reasons specified below. These regulations will become effective on November 17, 1977, 12:01 a.m. and remain in effect until December 31, 1977, 11:59 p.m. unless terminated earlier by notice in the FEDERAL REGISTER.

The Fishery Management Plan for Surf Clam and Ocean Quahog Fisheries was submitted to the Secretary by the Mid-Atlantic Fishery Management Council. That Council and the National Marine Fisheries Service have provided the Secretary with information which supports a finding by the Secretary that an emergency involving the surf clam and ocean quahog fisheries exists. This information includes the following evidence:

(1) Landings of surf clams to October 1, 1977, were 41 million pounds, 11 million pounds higher than the annual OY recommended in the plan, (and thus far higher than the Council has determined that the stock can stand), and 7 million pounds higher than landings in the same period last year.

(2) The level of present inventories indicates that there is strong market motivation for further fishing during this calendar year.

(3) Prices are twice the levels of January 1976, and this is a strong incentive to fish.

(4) The September 1977 landings were 3.8 million pounds, even though processors restricted landings during the last half of September. This fishing rate, projected through December, would result in landings exceeding the Council's recommended quarterly quota by 5.7 million pounds—almost double the recommended rate of harvest.

If fishing for surf clams were allowed to continue at rates such as those experienced in recent years, serious adverse social and economic effects also would be expected to occur in the industry, as a result of the combination of declining resource abundance and overcapitalization in the fleet.

The Mid-Atlantic Council expressed in the Fishery Management Plan its intention to establish a moratorium on new entries into the surf clam and ocean quahog fisheries. The Secretary intends to implement that provision in permanent regulations which will replace these emergency regulations. The moratorium will be administered through a vessel-permit system. Application forms for vessels in the fisheries are now available from the Regional Director in Gloucester, Mass.

The Secretary recognizes the critical conservation needs of this valuable resource, and finds and determines that an emergency exists which justifies the promulgation of regulations under Section 305(e) of the Act. The Secretary also finds that formal notice of proposed rulemaking is impractical, unnecessary, and contrary to the public interest because of the emergency described above.

Dated this 16th day of November, 1977 at Washington, D.C.

ROBERT W. SCHONING,
Acting Deputy Administrator for Fisheries, National Marine Fisheries Service.

Part 652 is added to read as follows:

Sec.

652.1 Purpose.
652.2 Definitions.
652.3 Foreign fishing.
652.4 Restrictions.
652.5 Penalties.
652.6 Catch quotas.
652.7 Closed area.
652.8 Effort restrictions.
652.9 Vessel permits [Reserved].
652.10 Vessel identification.
652.11 Facilitation of enforcement.
652.12 Reports and records.

AUTHORITY: Sec. 305(e) of the Fishery Conservation and Management Act of 1976, 16 U.S.C. 1801 et seq.

§ 652.1 Purpose.

Regulations of this section apply to domestic fishermen who take surf clams (*Spisula solidissima*) or ocean quahogs (*Arctica islandica*) in that portion of the Atlantic Ocean in which the United States exercises exclusive fishery management authority seaward of the States comprising the Mid-Atlantic, New England, and South Atlantic Fishery Management Councils.

§ 652.2 Definitions.

In addition to the definitions in the Act, and unless the context requires otherwise, the terms used in this Part 652 shall have the following meaning (some definitions in the Act have been repeated here to aid fishermen in understanding the regulations).

(a) *Act*—The Fishery Conservation and Management Act of 1976, Pub. L. 94-265, 16 U.S.C. 1801-1882, as amended.

(b) *Authorized Official.* (1) Any commissioned, warrant, or petty officer of the Coast Guard;

(2) Ay certified Enforcement or Special Agent of the National Marine Fisheries Service;

(3) Any officer designated by the head of any Federal or State agency which has entered into an agreement with the Secretary or the Commandant of the Coast Guard to enforce the provisions of the Act; or

(4) Any Coast Guard personnel accompanying and acting under the direction of any person described in subparagraph (1) of this paragraph.

(c) *Bushel*—A standard unit of measure containing 1.88 cubic feet of clams in the shell.

(d) *Directed Fishery*—A fishery conducted for the purpose of catching that species.

(e) *Fishery Conservation Zone (FCZ)*—The zone contiguous to the territorial sea of the United States, the inner boundary of which is a line coterminous with the seaward boundary of each of the coastal States and the outer boundary of which is a line drawn in such a manner that each point on it is 200 nautical miles from the baseline from which the territorial sea is measured.

(f) *Fishing*—(1) The catching, taking, or harvesting of fish;

(2) The attempted catching, taking, or harvesting of fish;

(3) Any other activity which can reasonably be expected to result in the catching, taking, or harvesting of fish; or

(4) Any operations at sea in support of, or in preparation for, any activity described in subparagraphs (1) through (3).

(5) The term "fishing" does not include any scientific research activity which is conducted by a scientific research vessel.

(g) *Fishing Vessel*—Any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for:

(1) Fishing; or

(2) Aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

(h) *Operator* means any individual, whether designated as the master or not, who is in charge of a fishing vessel.

(i) *Owner* means any person who owns any vessel, or any charterer, whether bareboat, time, or voyage; or any person who acts in the capacity of a charterer, including but not limited to parties to a management agreement, operating agreement, or any similar agreement that bestows control over the destination, function, or operation of the vessel.

(j) *Person* means any individual, corporation, partnership, association, or other entity.

(k) *Regional Director*—The Regional Director, Northeast Region, National Marine Fisheries Service, Federal Building, 14 Elm Street, Gloucester, Mass. 01930. Telephone: 617–281–3600.

(l) *Secretary*—The Secretary of Commerce or a designee.

(m) *Vessel of the United States*—Any vessel documented under the laws of the United States or registered under the laws of any State.

§ 652.3 Foreign fishing.

Fishing for surf clams or ocean quahogs in the Fishery Conservation Zone by any vessel other than a vessel of the United States is prohibited.

§ 652.4 Restrictions.

(a) No person shall catch and retain on board any surf clam or ocean quahog:

(1) During closed seasons; or

(2) In closed areas as specified in these regulations; or

(3) On days of the week on which fishing for that species is not permitted.

(b) (1) Possession of surf clams or ocean quahogs, by any person aboard any fishing vessel engaging in those fisheries, in closed areas or more than 12 hours after a season closure announcement becomes effective pursuant to the provisions of Section 652.6(b) shall be prima facie evidence that such clams or quahogs were taken in violation of the provisions of the Act and these regulations.

(2) Possession of surf clams, by any person aboard any fishing vessel engaging in the surf clam fishery, more than 12 hours after a weekly closure occurs under the provisions of Section 652.8 shall be prima facie evidence that such surf clams were taken in violation of the Act and these regulations.

(c) No person shall possess, have custody of or control of, ship, transport, offer for sale, deliver for sale, sell, purchase, import, export or land, any surf clam, ocean quahog, or part thereof, which was taken in violation of the Act, these regulations, or any other regulations issued under the Act.

(d) No person engaging in the surf clam or ocean quahog fisheries as an owner or operator, or as a dealer, processor or buyer shall unload or cause to be unloaded, sell or buy, any surf clam or ocean quahog whether on land or at sea, without preparing and submitted the documents required by Section 652.12.

(e) No person shall: (1) Refuse to permit an authorized officer to board a fishing vessel subject to such a person's control for purposes of conducting any search, no matter where that vessel may be situated, in connection with the enforcement of the Act, these regulations, or any other regulations issued under the Act.

(2) Forcibly assault, resist, oppose, impede, intimidate, or interfere with any authorized officer in the conduct of any search or inspection described in subparagraph (1) of this paragraph;

(3) Resist a lawful arrest for any act prohibited by these regulations; or

(4) Interfere with, delay or prevent, by any means, the apprehension or arrest of another person, knowing that such other person has commited any act prohibited by these regulations.

§ 652.5 Penalties.

Any person or vessel found to be in violation of these regulations shall be subject to the civil and criminal penalty provisions and forfeiture provisions prescribed in the Act and pertinent regulations.

§ 652.6 Catch quotas.

(a) Catch quotas for the period from November 16, 1977, for 45 days thereafter for the surf clam and ocean quahog fisheries are: 175,000 bushels of surf clams and 375,000 bushels of ocean quahogs.

(b) When the Regional Director determines from logbook reports, processors' reports, survey cruises, or other information that 50 percent of the allowable quota of surf clams or ocean quahogs have been taken, he shall publish in the FEDERAL REGISTER a notice to that effect together with his determination concerning the appropriate action which is necessary. Such action may include a reduction or increase in allowable fishing time per week until further notice, closure at a future time or any other action he deems necessary or desirable in the circumstances. The Regional Director shall send notice of the action, by certified mail, to each surf clam or ocean quahog processor and to each surf clam or ocean quahog vessel owner or operator.

§ 652.7 Closed areas.

(a) It shall be unlawful to fish for surf clams in any designated closed surf clam area.

(b) The Director shall publish notice of any closed area in the FEDERAL REGISTER. The Regional Director shall send notice of the closed area, by certified mail, to each surf clam or ocean quahog processor and to each surf clam or ocean quahog vessel owner or operator.

(c) Areas may be closed to surf clam fishing upon a determination by the Director (based on logbook entries, processors' reports, survey cruises, or other information) that the area contains surf clams of which:

(1) 60 percent or more are smaller than 4½ inches in size; and

(2) Not more than 15 percent are larger than 5½ inches in size. (Sizes shall be measured at the longest dimension of the surf clam.)

§ 652.8 Effort restrictions.

(a) *Surf Clams.* Fishing for surf clams shall be permitted during four days per week, from 12:01 a.m. (0001 hours) Monday to 12 midnight (2400 hours) Thursday, except as adjusted under § 652.6(b). However, no fishing vessel shall engage in fishing for surf clams on more than two days in any week. Each owner or operator of a fishing vessel engaged in the surf clam fishery shall submit in writing, to the Regional Director, on or before December 1, 1977, a list of the two days (among Monday, Tuesday, Wednesday, Thursday) on which that vessel elects to fish for surf clams, and the vessel shall be allowed to fish for surf clams only on the elected days of the week during the effective period of these regulations. Fishing for any part of a day will be counted as one day of fishing. In this paragraph, "fishing" means the actual or attempted catching of fish, but not activities in preparation for fishing, such as traveling to or from the fishing grounds.

(b) *Ocean Quahogs.* Fishing for ocean quahogs shall be permitted seven days per week.

§ 652.9 Vessel permits—[Reserved]

§ 652.10 Vessel identification.

(a) Each fishing vessel 25 feet in length or greater subject to these regulations shall display its official number on the starboard and port side of the deckhouse or hull, and on the appropriate weather deck. Vessels under 25 feet in length do not need to display any number. The official number is that number issued by the U.S. Coast Guard associated with the documentation of the fishing vessel or the official number issued by a State or the U.S. Coast Guard for undocumented vessels.

(b) Such markings shall be at least eighteen (18) inches in height and be legibly painted in a contrasting color.

(c) The person in charge of each vessel shall: (1) Keep the required markings clearly legible and in good repair; and

(2) Insure that no part of the vessel, its rigging or is fishing gear obstructs the view of the markings from an enforcement vessel or aircraft.

(d) In lieu of (a) and (b) above, vessels licensed under New Jersey law may use the appropriate vessel identification markings established by that State.

§ 652.11 Facilitation of Enforcement.

(a) The owner or operator of any vessel subject to the provisions of these regulations shall immediately comply with instructions issued by authorized officers to facilitate boarding and inspection of the vessel for purposes of enforcing the Act and these regulations.

(b) Upon being approached by a Coast Guard cutter or aircraft, or other vessel or aircraft authorized to enforce the Act, the vessel shall be alert for sig-

nals conveying enforcement instructions. The following signals extracted from the International Code of Signals are among those which may be used:

(1) "L" meaning "You should stop your vessel instantly;"

(2) "SQ3" meaning "You should stop or heave to; I am going to board you;" and

(3) "AA AA AA etc." which is the call to an unknown station; to which the signalled vessel should respond by illuminating the vessel identification required by § 652.10(a) above.

(c) A vessel signalled to stop or heave to for boarding shall:

(1) Stop immediately and lay to or maneuver in such a way as to permit the authorized officer and his party to come aboard;

(2) Provide a ladder for the authorized officer and his party;

(3) When necessary to facilitate the boarding, provide a man rope, safety line and illumination for the ladder; and

(4) Take such other actions as necessary to ensure the safety of the authorized officer and his party and to facilitate the boarding.

§ 652.12 Reports and Records.

(a) *Dealers*—(1) All persons who buy surf clams or ocean quahogs from vessels engaged in the surf clam or ocean quahog fishery shall provide to the Regional Director on a weekly basis the following information, on forms to be supplied by the Regional Director:

(i) Dates of purchases;

(ii) Number of bushels purchased, by species;

(iii) Name of the vessel from which surf clams or ocean quahogs are landed or received;

(iv) Price per bushel, by species; and

(v) Mailing address of dealer or processing plant.

(2) All persons purchasing or receiving any surf claims or ocean quahogs at sea for transport to any port of the United States must maintain and furnish records identical to those required under subparagraph (a)(1) of this paragraph.

(b) *Owners and Operators.*—(1) The owner or operator of a vessel landing surf clams or ocean quahogs must maintain an accurate log for each fishing trip, including:

(i) Name of vessel;

(ii) Total amount in bushels of each species taken;

(iii) Date(s) caught;

(iv) Time at sea;

(v) Duration of fishing time;

(vi) Locality fished;

(vii) Crew size;

(viii) Crew share in percent;

(ix) Landing port;

(x) Date sold;

(xi) Price per bushel; and

(xii) Buyer.

(2) The owner or operator shall make the log available for inspection by an authorized official at any time during or after a trip.

(3) The owner or operator shall keep each logbook for one year after the date of the last entry in the log.

(4) The owner or operator shall submit weekly logbook reports to the Regional Director, on forms supplied by the Regional Director.

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federal register

TUESDAY, NOVEMBER 22, 1977

PART IV



DEPARTMENT OF LABOR

Employment and Training Administration

■

STANDARD FOR BENEFIT PAYMENT PROMPTNESS; UNEMPLOYMENT COMPENSATION

Revision of Standard

[4510-30]

DEPARTMENT OF LABOR

Employment and Training Administration

[20 CFR Part 640]

STANDARD FOR BENEFIT PAYMENT PROMPTNESS—UNEMPLOYMENT COMPENSATION

Revision of Standard

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule.

SUMMARY: This is a proposal to revise the Secretary of Labor's Standard for Benefit Payment Promptness. Criteria for promptness in first payments of unemployment benefits are changed so as to increase progressively over the next three years. In addition, enforcement procedures are revised and other changes are made to improve the Standard.

DATES: Comments: All comments on the changes in this proposal must be received on or before December 22, 1977.

PROPOSED EFFECTIVE DATE: Thirty days after publication of the final rule in the FEDERAL REGISTER.

ADDRESSES: Send comments on this proposal to the U.S. Department of Labor, Employment and Training Administration, Room 7000, Patrick Henry Building, 601 D Street, NW., Washington, D.C. 20213.

All comments received will be available for public inspection during normal business hours in Room 7000 at the above address.

FOR FURTHER INFORMATION CONTACT:

Lawrence E. Weatherford, Jr., Administrator, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213, telephone 202-376-7032.

SUPPLEMENTARY INFORMATION: The Social Security Act requires that States' laws must provide for methods of administration which will insure full payment of unemployment compensation when due.

On July 23, 1976, final regulations were published in the FEDERAL REGISTER which established a Benefit Payment Promptness Standard for the Federal-State Unemployment Compensation Program. In that document the Department of Labor undertook to republish the Standard in March 1977, with such revisions as appeared to be supported by studies and experience. Studies were made and a further study is underway. Additional responsibilities of the Department in 1977 have intervened to delay republication of the Standard until now, but the studies completed have been analyzed and on the basis of the analyses and experience a number of changes are proposed to further improve the Standard.

The Department of Labor anticipated that the Standard would result in significant improvements by the States in the promptness of first benefit payments. A majority of the States have shown progressively better performance since publication of the Standard. A comparison of the cumulative averages for the 12 month period ending June 30, 1977, against the States' averages for the 12 month period ending June 30, 1976, shows that 40 States have equalled or improved their performance on intrastate claims and 45 States have equalled or improved their performance on interstate claims.

Some States are not currently meeting the criteria levels of 80 percent of intrastate first payments and 60 percent of interstate first payments issued within 14 days after the end of the first compensable week. The Department has concluded from studies conducted in 17 States that, with the exception of States which do not require a waiting week, the States will be able to attain those criteria levels. It is expected that as States continue to improve their performance, they will be able to meet more stringent promptness criteria.

Although studies of performance by the remaining States are still underway, the Department has sufficient information and experience to proceed with changes to the Standard and has considered the following alternatives:

1. Change the Standard as it applies to States which do not require a waiting period.
2. Establish criteria for subsequent payments.
3. Change the Standard by introducing higher criteria to be achieved over a three year period.
4. Establish graduated criteria.

CRITERIA FOR NON-WAITING WEEK STATES

A non-waiting week State is any State whose law does not require that a noncompensable period of unemployment be served before the payment of benefits commences. The non-waiting week States are:

Alabama	Michigan
Connecticut	Nevada
Delaware	New Hampshire
Georgia	North Carolina
Iowa	Pennsylvania
Kentucky	South Carolina
Maine	Wisconsin
Maryland	

(North Carolina suspended its waiting week requirement through February 15, 1977; South Carolina suspended its waiting week requirement from February 15, 1977, through June 30, 1977; Wisconsin eliminated its waiting week requirement effective January 1977.)

None of the five non-waiting week States included in the 17 States studied by the Department had met either the intrastate or interstate criteria. Further, data for the 12 month period ending June 30, 1977, shows that five non-waiting week States are meeting the intrastate criteria and two non-waiting week States are meeting the interstate criteria. These results tend to support the previous argument of these States that it is inequitable to use the same criteria as the basis for measuring the promptness of benefit payments in both waiting week and non-waiting week States. The Department believes that it is reasonable that non-waiting week States should be allowed 21 days to meet the intrastate and interstate criteria.

CRITERIA FOR SUBSEQUENT PAYMENTS

An analysis of data comparing State performance in processing first payments and subsequent payments did not provide totally conclusive results. It did indicate that States pay a higher percentage of subsequent payments within 14 days of the week ending date than they do first payments. The range in performance varied as much as it does for first payments. The results showed that once the payment process begins, States generally are able to pay subsequent claims promptly.

The information obtained relative to subsequent payment performance therefore supports the same conclusion that was reached after previous studies, i.e., first benefit payment promptness performance correlates with subsequent payment performance so that when first payment promptness is adequate, so is subsequent payment performance.

In addition, current reporting requirements do not include data on subsequent payments. It has been determined that to require such data would be an added reporting burden that would not justify the costs or results.

The Department accordingly concludes that establishment of criteria for subsequent payments is not warranted at this time.

HIGHER CRITERIA AND GRADUATED CRITERIA

The studies completed thus far show that States with the best performance records are able to pay higher percentages of first payments at successive intervals so that 90 percent or better of intrastate first payments and 75 percent or better of interstate first payments are issued by the 35th day after the end of the first compensable week.

The studies show that, if payment delays due to controllable factors had been eliminated, the States in the studies would have issued 95 percent of intrastate first payments and 80 percent of interstate first payments within 14 days after the end of the first compensable week.

There are various factors categorized as uncontrollable delays, e.g., backdating effective date of claim, claimant or employer error, delay in delivery of mail, reversal of a determination, request for transfer of wage records for a combined-wage claim, and agent State delay or error, which make it virtually impossible for States to issue 100 percent of their first payments at a prescribed interval. The effects of other uncontrollable fac-

tors, such as workload variance and turnover in personnel, must also be considered. Theoretically, achievement of 95 percent of intrastate first payments and 80 percent of interstate first payments in 35 days would be equivalent to 100 percent performance as the accomplishment would include instances of uncontrollable delays. Setting the criteria levels at 90 percent for intrastate claims and 75 percent for interstate claims as the ultimate requirement at the 14 day interval are potentially attainable goals.

The Department proposes changes in the Standard which establish higher criteria levels in successive years over a three year period. Thereafter, States would have to meet the highest criteria prescribed by the Standard.

The proposed changes will require States to issue by:

March 31, 1978. 83 percent of intrastate first payments and 65 percent of interstate first payments within 14 days after the end of the first compensable week for waiting week States and 21 days for non-waiting week States; and 90 percent of intrastate first payments and 75 percent of interstate first payments within 35 days after the end of the first compensable week.

March 31, 1979. 87 percent of intrastate and 70 percent of interstate first payments within 14 days and 21 days respectively, for waiting week and nonwaiting week States; and 93 percent of intrastate and 78 percent of interstate first payments within 35 days after the end of the first compensable week.

March 31, 1980. 90 percent of intrastate and 75 percent of interstate first payments within 14 days and 21 days respectively, for waiting week and nonwaiting week States; and 95 percent of intrastate and 80 percent of interstate first payments within 35 days after the end of the first compensable week.

ENFORCEMENT PROCEDURES

The provisions of §§ 640.6 and 640.7 on review of State performance and performance plans of action are revised and new § 640.8 on enforcement is added.

In addition, the Standard previously set a 12 month period ending on June 30 each eyar as the period for measuring States' experience. Beginning in 1978 this period is changed to the 12 months ending on March 31 each year. The change will permit States to prepare any necessary plans of action for improving first payment performance to coincide with the preparation of their annual program and budget plan.

The Department of Labor has determined that this document does not contain a major proposal requiring the preparation of an Economic Impact Statement under Executive Order 11949 and applicable authority.

This document was prepared under the direction of Lawrence E. Weatherford, Jr., Administrator, Unemployment Insurance Service, Emplovment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213. Telephone: 202-376-7032.

Accordingly, Part 640 of Chapter V of Title 20 is proposed to be revised as set out below.

Signed at Washington, D.C., on November 17, 1977.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

PART 640—STANDARD FOR BENEFIT PAYMENT PROMPTNESS—UNEMPLOYMENT COMPENSATION

Sec.

640.1 Purpose and scope.
640.2 Federal law requirements.
640.3 Interpretation of Federal law requirements.
640.4 Standard for conformity.
640.5 Criteria for compliance.
640.6 Review of State compliance.
640.7 Benefit Payment Performance Plans.
640.8 Enforcement of the Standard.
640.9 Information, reports and studies.

AUTHORITY: Sec. 1102, Social Security Act (42 U.S.C. 1302); Secretary's Order No. 4-75, dated April 16, 1975, (40 FR 18515); (5 U.S.C. 553). Interpret and apply secs. 303(a)(1) and 303(b)(2) of the Social Security Act (42 U.S.C. 503(a)(1), 503(b)(2)).

§ 640.1 Purpose and scope.

(a) *Purpose.* Section 303(a)(1) of the Social Security Act requires, for the purposes of Title III of that Act, that a State unemployment compensation law include provision for methods of administration of the law that are reasonably calculated to insure the full payment of unemployment compensation when due to eligible claimants. The Standard in this Part is issued to implement section 303(a)(1) in regard to promptness in the payment of unemployment benefits to eligible claimants.

(b) *Scope.* (1) The Standard in this Part applies to all State laws approved by the Secretary of Labor under the Federal Unemployment Tax Act (section 3304 of the Internal Revenue Code of 1954, 26 U.S.C. 3304), and to the administration of the State laws.

(2) The Standard specified in § 640.4 applies to all claims for unemployment compensation. The criteria for State compliance in § 640.5 apply to first payments of unemployment compensation to eligible claimants following the filing of initial claims and first compensable claims.

§ 640.2 Federal law requirements.

(a) *Conformity.* Section 303(a)(1) of the Social Security Act, 42 U.S.C. 503(a)(1), requires that a State law include provision for:

Such methods of administration * * * as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due.

(b) *Compliance.* Section 303(b)(2) of the Social Security Act, 42 U.S.C. 503(b)(2), provides in part that:

Whenever the Secretary of Labor, after reasonable notice and opportunity for hearing to the State agency charged with the administration of the State law, finds that in the administration of the law there is:

(1) * * *

(2) a failure to comply substantially with any provision specified in subsection (a) of this section;

the Secretary of Labor shall notify such State agency that further payments will not be made to the State until the Secretary of Labor is satisfied that there is no longer any such * * * failure to comply.

Until he is so satisfied, he shall make no further certification to the Secretary of the Treasury with respect to such State * * *.

§ 640.3 Interpretation of Federal law requirements.

(a) *Section 303 (a)(1).* The Secretary interprets section 303(a)(1) of the Social Security Act to require that a State law include provision for such methods of administration as will reasonably insure the full payment of unemployment benefits to eligible claimants with the greatest promptness that is administratively feasible.

(b) *Section 303(b)(2).* The Secretary interprets section 303(b)(2) of the Social Security Act to require that, in the administration of a State law, there shall be substantial compliance with the provision required by section 303(a)(1).

§ 640.4 Standard for conformity.

A State law will satisfy the requirement of section 303(a)(1), if it contains a provision requiring, or which is construed to require, such methods of administration as will reasonably insure the full payment of unemployment benefits to eligible claimants with the greatest promptness that is administratively feasible.

§ 640.5 Criteria for compliance.

The criteria in the schedule below shall apply in determining whether, in the administration of a Stae law, there has been substantial compliance with the provision required by section 303(a)(1) in the issuance of benefit payments to eligible claimants for the first compensable weeks of unemployment in their benefit years:

	Percentage of first payments issued—days following end of first compensable week		
	14 days, waiting week States	21 days, nonwaiting week States [1]	35 days, all States
Intrastate claims			
To be achieved by:			
June 30, 1977	[2] 80	[2] 80	[2] 80
Mar. 31, 1978	65	83	90
Mar. 31, 1979	87	87	93
Mar. 31, 1980 and thereafter.	90	90	95
Interstate claims			
To be achieved by:			
June 30, 1977	[2] 60	[2] 60	[2] 60
Mar. 31, 1978	65	65	75
Mar. 31, 1979	70	70	78
Mar. 31, 1980 and thereafter.	75	75	80

[1] A nonwaiting week State is any State whose law does not require that a non-compensable period of unemployment be served before the payment of benefits commences.

[2] All States.

A State will be deemed to comply substantially, as set out in §§ 640.2(b) and 640.3(b), if its average performance, for the period of review, meets or exceeds the applicable criteria set forth above.

§ 640.6 Review of State compliance.

(a) *Annual reviews.* The administration of each State law shall be reviewed annually for compliance, as set out in §§ 640.2(b) and 640.3(b). Annual reviews shall be for the 12-month period ending on March 31 of each year. An annual review with respect to any State shall be based upon the monthly reports of performance submitted to the Department by the State agency, any special reports of performance submitted to the Department by the State agency, any Benefit Payment Performance Plan applicable to the period being reviewed, any study or analysis of performance relevant to the period being reviewed, and any other audit, study, or analysis as directed by the Department of Labor.

(b) *Periodic review.* The administration of any State law may be reviewed at any other time, when there is reason to believe that there may be failure of compliance as set out in §§ 640.2(b) and 640.3(b). Such a review shall be based upon the same elements as may be required for an annual review.

§ 640.7 Benefit Payment Performance Plans.

(a) *Annual Plan.* An Annual Benefit Payment Performance Plan shall be submitted by a State agency to the Department of Labor when average performance over a 12-month period ending on March 31 of any year does not meet the criteria specified in § 640.5. An Annual Plan shall be submitted by July 31 following the applicable March 31, and shall be a plan for the fiscal year that begins on the succeeding October 1. An Annual Plan shall be subject to continuing appraisal during the period it is in effect, and shall be subject to modification from time to time as may be directed by the Department of Labor after consultation with the State agency.

(b) *Periodic Plan.* A Periodic Benefit Payment Performance Plan shall be submitted by a State agency when directed by the Department of Labor. A Periodic Plan may be in addition to, or a modification of an Annual Plan and may be required even though an Annual Plan covering the same period is not required. A Periodic Plan shall be subject to continuing appraisal during the period it is in effect, and shall be subject to modification from time to time as may be directed by the Department of Labor.

(c) *Content of Plan.* An Annual Plan or Periodic Plan shall set forth such corrective actions, performance and evaluation plans, and other matters as the Department of Labor directs, after consultation with the State agency.

§ 640.8 Enforcement of the Standard.

(a) *Action by the Department of Labor.* When a State agency fails, for an extended period, to meet the Standard set forth in § 640.4 or the criteria specified in § 640.5, or fails to show satisfactory improvement after having submitted a Benefit Payment Performance Plan of Action, the Department of Labor shall pursue the following remedial steps before considering application of the provisions of § 640.2:

(1) Initiate informal discussion with State agency officials pursuant to § 601.5 (b) of this Chapter.

(2) Conduct an evaluation of the State's benefit payment processes and analyze the reasons for the State's failure to meet the Standard.

(3) Recommend specific actions for the State to take to improve its benefit payment performance.

(4) Request the State to submit a plan for complying with the Standard by a prescribed date.

(5) Initiate special reporting requirements for a specified period of time.

(6) Consult with the Governor of the State regarding the consequences of the State's non-compliance with the Standard.

(7) Propose to the Governor of the State and on an agreed upon basis arrange for the use of expert Federal staff to furnish technical assistance to the State agency with respect to its payment operations.

(b) *Action by the Assistant Secretary.* If, after all remedial steps have been exhausted, a State fails to take appropriate action, or otherwise fails to meet the Standard specified in § 640.4, the Assistant Secretary for Employment and Training shall, after taking all factors into consideration, recommend to the Secretary of Labor that appropriate notice be sent to the State agency and that an opportunity for a hearing be extended in accordance with section 303(b) of the Social Security Act.

§ 640.9 Information, reports and studies.

A State shall furnish to the Secretary of Labor such information and reports and make such studies as the Secretary decides are necessary or appropriate to carry out this Part.

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